UNIVERSITY of MARYLAND BALTIMORE

Date: Wednesday, May 20, 2026 10:59:08 AM Print Close

HP-00118992 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
POCOBI

2 * Full Title:
Postoperative Cystography for Operative Bladder Injuries

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

HP-00118992

Research Team Information_V2

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Tyler Holliday

CITI Training: ID00019579

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Eric Ley

CITI Training: ID00019705

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	Shailvi Gupta	no	no	Research Team Member	no	ID00019529

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

HP-00118992 Resources_V2

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
Dr. Holliday will be responsible for study design, overseeing site coordination, and data analysis, approximately 10 hours monthly.

2 * Describe the facilities where research procedures are conducted:
All research activities will be conducted at the University of Maryland Baltimore's Shock Trauma Center, University of Maryland Medical Center, and University of Maryland Capital Region Medical Center.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
Not applicable. There will be no consequences to the subjects, as this is an observational study and their care will not be altered as a result.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Regular communication via email, phone or video-conferencing between the study coordinator and the research personnel will be use to ensure that all personnel are up to date with the procedures and protocol. The research team will meet regularly to evaluate progress, ensure protocols are being followed, and that duties are being performed appropriately. All persons assisting with the protocol are familiar with the appropriate analytical tools. Each person has completed CITI training and are familiar with the processes for use and security of the data.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- (●) **Multi-Site**
- ( ) Single Site

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

( ) Yes (●) **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

( ) Yes (●) **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Reliance or Authorization Agreement (IAA), UMB Local Context Questionnaire [Form HRP 801], UMB Communication and Responsibilities Plan [WORKSHEET HRP 830], local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon execution of all required regulatory approvals.

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

(●) **Yes** ( ) No

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

( ) Yes (●) **No**

6 * Institution(s) where the research activities will be performed:

- [ ] University of Maryland, Baltimore
- [ ] University of Maryland, Upper Chesapeake Kaufman Cancer Center
- [ ] VAMHCS
- [ ] UMB School of Medicine
- [ ] Marlene and Stewart Greenebaum Cancer Center
- [ ] University Physicians Inc.
- [x] **Shock Trauma Center**
- [ ] General Clinical Research Center (GCRC)
- [ ] Maryland Psychiatric Research Center (MPRC)
- [ ] Johns Hopkins
- [ ] International Sites
- [ ] UMB Dental Clinics
- [ ] Center for Vaccine Development
- [ ] Community Mental Health Centers
- [ ] Private Practice in the State of Maryland
- [ ] Institute of Human Virology (IHV) Clinical Research Unit
- [ ] Joslin Center
- [ ] UMB Student Classrooms
- [ ] National Institute of Drug Abuse (NIDA)
- [ ] National Study Center for Trauma and EMS
- [ ] Univ of MD Cardiology Physicians at Westminster
- [ ] Nursing Homes in Maryland
- [ ] University of Maryland Biotechnology Institute
- [ ] Maryland Department of Health

- [ ] Maryland Proton Treatment Center
- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [x] **Other Sites**
- [x] **University of Maryland Medical System (Select below)**

* UMMS Sites:

- [ ] University of Maryland Medical Center
- [ ] UMMC Midtown Campus (formerly Maryland General Hospital)
- [ ] UM St. Joseph Medical Center
- [ ] UM Baltimore Washington Medical Center
- [x] **UM Capitol Region Health**
- [ ] UM Charles Regional Medical Center
- [ ] UM Shore Medical Center at Easton
- [ ] UM Shore Medical Center at Chestertown
- [ ] UM Shore Medical Center at Dorchester
- [ ] UM Shore Emergency Center at Queenstown
- [ ] UM Shore Regional Health
- [ ] University of Maryland Rehabilitation & Orthopaedic Institute (formerly Kernan Hospital)
- [ ] UM Upper Chesapeake Health
- [ ] UM Upper Chesapeake Medical Center
- [ ] UM Harford Memorial Hospital
- [ ] University of Maryland Community Medical Group

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

UM Coordinating Center

You indicated that UM is the Coordinating Center for this multi-site study.

2.1 *Describe the processes to ensure communication among sites.
Things to consider including in the communication plan:

- all sites have the most current version of the protocol, consent document, etc.
- all required approvals have been obtained at each site (including approval by the site's IRB of record).
- all modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
- all engaged participating sites will safeguard data as required by local information security policies.
- all local site investigators conduct the study appropriately.
- all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

The study coordinator and the principal investigator will be available via email, phone, or web-conferencing to answer all questions from participating sites. When a site signs up to participate in the study, the study coordinator will send the most recent protocol, the approved University of Maryland IRB and any additional required documentation. Participating centers will not be provided access to REDCap until they have received IRB approval at their institution and a DUA has been executed.

2.2 *Describe the method for communicating to engaged participating sites including:

- reportable new information.
- problems.
- interim results.
- the closure of a study.

Communication with participating sites will be done via email or phone by the study coordinator with the contact person designated by each site.

ID: VIEW4DF737D4C2800
Name: v2_UM Coordinating Center

Other Sites Where Research Activities Will Be Conducted

You selected "Other Sites," "Private Practice," "Community Mental Health Centers," and/or "Nursing Homes in Maryland" as a site where research will be conducted.

3.1 * Specify the name of the site(s):
Once IRB approval obtained, recruitment for other sites will be undertaken at that time via EAST website. A modification will be submitted on CICERO upon the identification of the other research location(s).

3.2 * Contact Person(s) for Other Site:
To be determined.

3.3 * Phone (if no phone available, input "none"):
None

3.4 * Email Address (if no email available, input "none"):
None

ID: VIEW4DF8712DB5800
Name: v2_Other Sites Where Research Activities Will Be Conducted

Funding Information

1 * Indicate who is funding the study:

- [ ] Federal
- [ ] Industry
- [x] **Department / Division / Internal**
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [ ] Participant Compensation
- [ ] Procedures
- [ ] Other

3 Please discuss any additional information regarding funding below:

ID: VIEW4DF85DF452400
Name: v2_Funding Information

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

HP-00118992

Risk Level_V2

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

HP-00118992 Exempt Categories_Fed

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

☐
i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Category 3: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

☐
i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

☑
i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Category 6: Taste and food quality evaluation and consumer acceptance studies:

☐
i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

☐ **The research does not qualify as Exempt.**

ID: VIEW8D50FF499486A05
Name: v2_Exempt Categories

Exempt Category 4

You indicated on the "Exempt Categories" page that this study qualifies as Exempt under Category 4.

1 * Will the identifiable private information or identifiable biospecimens be secondary in nature?
● **Yes** ○ No

1.1 * Provide justification for the response selected above:
This is a prospective chart review and patients data including some identifiers will be accessed/collected. The data will be de-identified but not until after the data has been accessed and/or collected. Given the observational nature of this study, the data being obtained from existing medical records or lab results is being collected for standard/routine clinical purposes.

2 * Will the identifiable private information or identifiable biospecimens are publicly available?
○ Yes ● **No**

3 * Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
○ Yes ● **No**

4 * The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, for the purposes of "health care operations", "research", or "public health activities and purposes".
● **Yes** ○ No

4.1 * Please clarify which of the above purposes the research falls under and provide justification:
This study involves the collection and analysis of medical records data to investigate if earlier follow up imaging leads to shorter duration of urinary catheterization and reduced incidence of catheter associated urinary tract infections. The findings aim to contribute to generalizable knowledge by improving understanding of traumatic bladder injury management.

5 * The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
○ Yes ● **No**

ID: VIEW8D50FF499486B26
Name: v2_Exempt Category 4

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Traumatic bladder injuries are uncommon but carry significant morbidity if not properly managed. Current national trauma and urology guidelines provide broad recommendations regarding surgical management, yet practice patterns vary considerably with respect to follow-up imaging and urinary catheter duration. Intraperitoneal injuries are universally managed with surgical repair followed by urinary catheterization for an ill-defined period. Extraperitoneal injuries, depending on associated injuries and specific injury characteristics, may be managed surgically or nonoperatively, with the latter often requiring prolonged catheterization. In both injury types, follow-up imaging is frequently obtained before catheter removal to confirm healing.

High-quality evidence-based guidance regarding the optimal duration of catheterization and the necessity or timing of follow-up imaging is lacking. This variability contributes to potentially unnecessary imaging and prolonged catheter use, both of which have been associated with higher rates of catheter-associated urinary tract infection (CAUTI).

The long-term goal of this research is to establish evidence-based guidelines for the management of traumatic bladder injuries that optimize healing while minimizing complications and healthcare resource use. The objective of this proposal is to define the role of follow-up imaging in both surgically and nonoperatively managed bladder injuries and to determine the ideal urinary catheter duration. Our central hypothesis is that early (≤7 days) follow-up imaging after surgical repair will not increase radiologic finding of postoperative leak and allow for shorter catheterization, thereby reducing CAUTIs.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

Hypothesis: Early postoperative cystography will result in shorter urinary catheterization and fewer CAUTIs.

Specific Aims:
1. Evaluate differences in postoperative urinary leak incidence, catheter duration, and CAUTI between patients undergoing early (≤7 days) and late (>7 days) or no postoperative imaging following bladder repairs overall and by bladder injury location (intraperitoneal versus extraperitoneal versus combined).
2. Evaluate differences in urinary leak incidence, catheter duration, CAUTI, pelvic hardware infections, and interval cystography between operative and nonoperative management of isolated extraperitoneal bladder injuries.
3. Determine the association between intraoperative leak testing and pelvic drain placement with postoperative drain creatinine testing with postoperative leaks.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

The study design will be a prospective observational trial. No randomization or control subjects will be used.

All patients who are admitted with full-thickness intraperitoneal and/or extraperitoneal bladder injuries will be prospectively identified, reviewed, and data entered into REDCap. Data collection will include patient demographics, mechanism of injury, overall and bladder specific injury severity, other abdominal and pelvic injuries, management strategy, length of stay, leaks, infections, urinary catheter duration, and reinterventions.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

High-quality evidence-based guidance regarding the optimal duration of catheterization and the necessity or timing of follow-up imaging is lacking. This variability contributes to potentially unnecessary imaging and prolonged catheter use, both of which have been associated with higher rates of CAUTI.

Our hypothesis is supported by institutional observations where early postoperative cystography had similar rates of urinary leak to late postoperative cystography (3.5% (1/29) vs 8.6% (6/70), p=0.67) and significantly shorter duration of urinary catheterization (7.0 ± 4.0 days vs 14.0 ± 7.0 days, p=0.0001) and lower rates of CAUTI (6.9% (2/29) vs 30% (21/70), p=0.017).

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Trauma literature generally supports the use of urinary catheter drainage for 10 to 14 days following operative and nonoperative management of intraperitoneal and/or extraperitoneal bladder injuries with or without follow up cystography. One prospective study demonstrated no urinary leak by cystogram (mean 8.6 days, range 5-13 days) following 69 simple bladder repairs. As such, current EAST recommendations are based on a handful of studies (<10) with small patient populations (<130 patients) without a comparative assessment of early (<7 days) versus late (>7 days) removal of urinary catheter following injury/repair.

Our study will be the first prospective multicenter study to compare the effect of early (≤7 days) and late (>7 days) or no postoperative imaging following bladder repairs on postoperative outcomes (postoperative urinary leak, urinary catheter duration, CAUTI). This study will provide us with a better understanding of optimal urinary catheter duration and postoperative cystography utilization.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Trauma literature generally supports the use of urinary catheter drainage for 10 to 14 days following operative and nonoperative management of intraperitoneal and/or extraperitoneal bladder injuries with or without follow up cystography. One prospective study demonstrated no urinary leak by cystogram (mean 8.6 days, range 5-13 days) following 69 simple bladder repairs. As such, current EAST recommendations are based on a handful of studies (<10) with small patient populations (<130 patients) without a comparative assessment of early (<7 days) versus late (>7 days) removal of urinary catheter following injury/repair.

1. Yeung LL, McDonald AA, Como JJ, Robinson B, Knight J, Person MA, et al. Management of blunt force bladder injuries: A practice management guideline from the Eastern Association for the Surgery of Trauma. Journal of Trauma and Acute Care Surgery. 2019 Feb 1;86(2):326-36.
2. Morey AF, Brandes S, Dugi DD, Armstrong JH, Breyer BN, Broghammer JA, et al. Urotrauma: AUA guideline. The Journal of urology. 2014 Aug;192(2):327-35.
3. Kitrey ND, Campos-Juanatey P, Hallscheidt P, Mayer P, Serafetinidis E, Waterloos M. EAU Guidelines on Urological Trauma 2025. European Association of Urology Guidelines. 2025.
4. American College of Surgeons (ACS). Best Practices Guidelines: Management of Genitourinary Injuries [Internet]. 2025 [cited 2026 Jan 5]. Available from: https://www.facs.org/media/ya5hcu0s/genitourinary_guidelines.pdf
5. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, Strobe Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. International journal of surgery. 2014 Dec 1;12(12):1495-9.
6. Wilson DJ, Melin I, Shah N, O'Connor RC, Carver T. Investigating the timing of catheter removal after traumatic bladder injury: a single-institution 12-year experience. Trauma Surgery & Acute Care Open. 2025 Feb 19;10(1).
7. Corriere JN, Sandler CM. Management of the ruptured bladder: seven years of experience with 111 cases. Journal of Trauma and Acute Care Surgery. 1986 Sep 1;26(9):830-3.
8. Inaba K, Okoye OT, Browder T, Best C, Branco BC, Teixeira PG, et al. Prospective evaluation of the utility of routine postoperative cystogram after traumatic bladder injury. Journal of Trauma and Acute Care Surgery. 2013 Dec 1;75(6):1019-23.
9. Inaba K, McKenney M, Munera F, De Moya M, Lopez PP, Schulman CI, et al. Cystogram follow-up in the management of traumatic bladder disruption. Journal of Trauma and Acute Care Surgery. 2006 Jan 1;60(1):23-8.
10. Barnard J, Overholt T, Hajiran A, Crigger C, Jessop M, Knight J, et al. Traumatic bladder ruptures: a ten-year review at a level 1 trauma center. Advances in urology. 2019;2019(1):2614586.
11. Anderson RE, Keihani S, Moses RA, Nocera AP, Selph JP, Castillejo Becerra CM, et al. Current management of extraperitoneal bladder injuries: results from the multi-institutional genito-urinary trauma study (MiGUTS). The Journal of urology. 2020 Sep;204(3):538-44.
12. Urry RJ, Clarke DL, Bruce JL, Laing GL. The incidence, spectrum and outcomes of traumatic bladder injuries within the Pietermaritzburg Metropolitan Trauma Service. Injury. 2016 May 1;47(5):1057-63.
13. Johnsen NV, Dmochowski RR, Guillamondegui OD. Clinical utility of routine follow-up cystography in the management of traumatic bladder ruptures. Urology. 2018 Mar 1;113:230-4.
14. Lepor H, Nieder AM, Fraiman MC. Early removal of urinary catheter after radical retropubic prostatectomy is both feasible and desirable. Urology. 2001 Sep 1;58(3):425-9.
15. Safdar N, Codispoti N, Purvis S, Knobloch MJ. Patient perspectives on indwelling urinary catheter use in the hospital. American journal of infection control. 2016 Mar 1;44(3):e23-4.
16. Byars VH, Byerly SE, Dong CT, Lenart EK, Evans CR, Kerwin AJ, et al. Management of Extraperitoneal Bladder Injuries in Patients With Pelvic Fractures. The American Surgeon™. 2024 Aug;90(8):2061-5.
17. Tan LB, Chiang CP, Huang CH, Chou YH, Wang CJ. Surgical treatment of the ruptured bladder: 22 years reviewed. Journal of the Formosan Medical Association = Taiwan yi zhi. 1990 Nov 1;89(11):986-91.
18. Johnsen NV, Young JB, Reynolds WS, Kaufman MR, Milam DF, Guillamondegui OD, et al. Evaluating the role of operative repair of extraperitoneal bladder rupture following blunt pelvic trauma. The Journal of Urology. 2016 Mar;195(3):661-5.

2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

HP-00118992 Study Procedures_V2

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:
Given the prospective observational nature of this study, all procedures are performed per usual care of the patient. Data abstraction or review of medical records are being performed for research purposes only. The data points will include variables related to the diagnosis and management of traumatic bladder injuries. To reaffirm that when it comes to HIPAA-protected PHI, only the information checked off in the "Protected Health Information (PHI)" section of CICERO will be collected.

2 * Describe all procedures already being performed solely for standard of care, including diagnostic or treatment purposes (if not applicable to the study, enter "N/A")":
N/A

3 * Describe the duration of an individual participant's participation in the study:
N/A

4 * Describe the amount of time it will take to complete the entire study:
5 years

5 * Describe any additional participant requirements:
None

ID: VIEW4E0280585B400
Name: v2_Study Procedures

HP-00118992

Sample Size and Data Analysis_V2

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

We anticipate collaboration with 20-30 Level I and II trauma centers. Based our institutional trauma registries, each site is expected to enroll 5-15 eligible patients annually over a 3-year recruitment period, yielding a target sample size of 750 patients.

Sample size calculations were based on preliminary institutional data comparing early (≤7 days) versus late (>7 days) follow-up imaging after traumatic bladder injury. In our pilot cohort (n=99), early cystography was associated with lower CAUTI rates (6.9% [2/29] vs 30.0% [21/70], p=0.017; absolute difference 23.1%), shorter urinary catheter duration (7.0 ± 4.0 vs 14.0 ± 7.0 days, p=0.0001; absolute difference 7.0 days), and no increase in urinary leak rates (3.5% [1/29] vs 8.6% [6/70], p=0.67; absolute difference 5.1%).

Using a two-sided α = 0.05 and 80% power, detecting the observed CAUTI difference requires 49 patients per group (total n=98) under equal allocation. For catheter duration, 17 patients per group (total n=34) are needed under equal allocation. Urinary leak requires a substantially larger sample size of 368 patients per group (total n=736) to detect the observed difference.

Early postoperative cystography following surgical repaired occurred in approximately 25% of our institutional case with traumatic bladder injuries grade of 2 or higher. Assuming a 1:3 weight, we would need to enroll 136 patients and 44 patients to detect the observed differences for CAUTI and catheter duration. Taken to extreme where only 10% of patients would undergo early postoperative cystography, we would need to enroll 290 patients and 90 patients to detect the observed differences for CAUTI and catheter duration, respectively.

To ensure adequate power for the outcomes (CAUTI and catheter) while accommodating potential attrition and variability in practice across sites, we plan to enroll a minimum of 400 patients across participating trauma centers.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

The primary objective is to compare the rate of postoperative urinary leak between patients undergoing early (≤7 days) versus delayed (>7 days) postoperative cystography following traumatic bladder repair. The primary analysis will be a comparison of proportions using chi-square or Fisher's exact test, directly addressing the study hypothesis.

All analyses will be performed using SAS (v9.4 or later). Categorical variables will be summarized as frequencies and percentages; continuous variables as means with standard deviations or medians with interquartile ranges, as appropriate. Comparisons of continuous variables will be conducted using two-tailed t-tests or Mann-Whitney U tests. A two-sided p-value <0.05 will be considered statistically significant.

Multivariable regression will be used to evaluate the independent association between imaging timing and outcomes. Covariates of interest, informed by preliminary data, include injury mechanism, multiple bladder injuries/repairs, associated bowel injury, intraoperative leak testing, pelvic hemorrhage control, and AAST Grade V bladder injury. Variables with clinical relevance or p <0.20 on univariable analysis will be included, with exclusion of collinear variables.

To account for clustering by center, mixed-effects models with center as a random effect will be used. Mixed-effects logistic regression will be applied for dichotomous outcomes (urinary leak, CAUTI), and mixed-effects linear regression for continuous outcomes (catheter duration). Sensitivity analyses using robust standard errors clustered at the center level will be performed.

Secondary outcomes (catheter duration and CAUTI) will be analyzed using the same framework.

Patients with missing primary outcome data will be excluded from the primary analysis. Sensitivity analyses will assess missingness patterns, and multiple imputation (chained equations) will be performed for covariates and secondary outcomes, with results compared to complete-case analyses.

This approach aligns the primary comparison with the study objective while appropriately adjusting for confounding and center-level variation.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

Individual results will not be shared with the subjects or with others. A manuscript based on the study results will be submitted for publication in a peer-reviewed medical journal.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

HP-00118992 Participant Selection_V2

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
150

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
100

Worldwide - the number being enrolled total at all sites (including local enrollment):
750

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [x] **12 to 17 (Adolescents)**
- [x] **18 to 88 years (Adult)**
- [x] **89 years and older**

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

○ Yes ● **No**

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

HP-00118992 Vulnerable Populations_V2

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [x] **Children (Minors)**
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [ ] None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

HP-00118992

Vulnerable Populations Children_V2

Vulnerable Populations - Children

You indicated that children are included in this study.

1 * Describe how you will prevent undue influence:

This a prospective observational study so treatment is routine care per surgeon or institutional practice. Subject participation will not have influenced their treatment or clinical course

1.1

* Choose the risk level(s) that to your research:

- (●) **45 CFR 46.404/21 CFR 50.51 - The research presents no greater than minimal risk to the children.**
- ( ) 45 CFR 46.405/21 CFR 50.52 – The research presents greater than minimal risk but presents the prospect of direct benefit to the individual participants.
- ( ) 45 CFR 46.406/21 CFR 50.53 - The research presents greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. ***Please note that Institutional Official approval is also required.***
- ( ) 45 CFR 46.407/21 CFR 50.54 – Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. ***Please note that Institutional Official approval is also required.***

Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.

1.2 * Provide justification for the risk level selected above:

The only risks are the presence of identifying data elements that are included on the data sets. All data sets are maintained in REDCap are used only by the persons directly involved with the project. All personal identifiers are removed prior to any release of data, reports or analysis. All data elements considered sensitive by the data owners are also removed from any analysis released.

ID: VIEW4E207F69EE800
Name: v2_Vulnerable Populations - Children

HP-00118992 Eligibility_V2

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

○ Yes ● No

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date

There are no items to display

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Confirmed full-thickness bladder injury (grade ≥2) by cystography or intraoperative findings from a traumatic mechanism
View	2	Initial evaluation and/or definitive surgical management at study institution

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Age <14 years
View	2	Death during admission or any body region AIS score 6
View	3	Concomitant urethral, ureteral injury, or suprapubic catheterization
View	4	Lost to follow-up prior to urinary catheter removal or postoperative/interval imaging
View	5	Neurogenic bladder
View	6	Iatrogenic bladder injuries
View	7	End-stage renal disease

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00118992 v4-29-2026-1777480678102(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

HP-00118992 Recruitment_V2

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
Data will be collected from medical records/chart review in the institution's electronic medical record on all subjects. Charts will be identified by tracking bladder injuries. There will be no interactions between patients and the study staff, as this is an observational study only.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):
N/A

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00118992

Advertising_V2

Advertising

1 * Will you be using advertisements to recruit potential participants?

○ Yes ● No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

HP-00118992 Research Related Risk_V2

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

The only risks are the presence of identifying data elements that are included on the data sets. All data sets are used only by the persons directly involved with the project. All personal identifiers are removed prior to any release of data, reports or analysis. All data elements considered sensitive by the data owners are also removed from any analysis released.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
No benefits will by gained by any particular individual. The goal is to provide timely and topical research and analysis that can be used to improve clinical outcomes of trauma patients.

2 * Describe the importance of the knowledge expected to result from the study:
The evaluation and analysis that can be conducted through the use of these datasets will help guide and direct efforts to reduce the number of complications that occur each year.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
There are no anticipated risks to any individual in the analysis of these datasets. The potential benefits, as listed above, greatly outweigh any risks.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
There are no alternatives. Subjects are not recruited.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
N/A

2 * Describe procedures for orderly termination:
N/A

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
N/A

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
N/A

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
N/A

3 * Describe potential environmental stressors that may be associated with the research:
N/A

4 * Will this study have a site based in the European Union?
○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?
○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

HP-00118992 Confidentiality of Data_V2

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

Research data is obtained in electronic format and is maintained on password protected computers (on encrypted laptops, no paper files will be collected). Firewalls have been established by the University of Maryland School of Medicine to protect the computer systems from unauthorized access. Computers and electronic media are kept in locked rooms and file cabinets as appropriate. Collected data will
eventually be entered into REDCap to create a database. This is a secure database platform that will be deidentified. There will be no way to link deidentified data back to patients.

3 * How will such data be secured?

Privacy will be protected by removing all sensitive and identifiable pieces of information prior to the release of any data, reports, or analysis. Data will be protected through the use of firewalls, password protection, locked offices and cabinets and only accessed by investigators via passwords sent in separate secure emails.

4 * Who will have access to research data?

Only the research staff directly involved with the linkage and analysis of the databases will have access to identifiers.

5 * Will study data or test results be recorded in the participant's medical records?

( ) Yes (●) **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)***

( ) Yes (●) **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?

( ) Yes (●) **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date
There are no items to display		

8 * Discuss any other potential confidentiality issues related to this study:

N/A

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

HP-00118992

Monitoring Plan Selection_V2

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ○ Data Safety Monitoring by a Committee
- ○ Data Safety Monitoring by an Individual
- ● **There is no data safety monitoring plan in place**

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

No Monitoring Plan

You indicated that there is no data safety monitoring plan in place for the study.

1 * Provide the rationale for why a data safety monitoring plan is not necessary for this study:
We will monitor for breaches in confidentiality and will report any breaches found through an RNI application through CICERO.

ID: VIEW4E1B07B5A2400
Name: v2_No Monitoring Plan

HP-00118992 Research Related Costs_V2

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- (●) **No**
- ( ) Yes

1.1 If Yes, check all that apply:

- [ ] Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)
- [ ] Investigational or Study Device
- [ ] Investigational or Study Drug
- [ ] Investigational Procedure(s)

1.2 If No, who is responsible for payment?
There will be no research related costs.

2 * Who is responsible for the uncovered research-related costs?

- [ ] Participant
- [ ] Sponsor
- [ ] UM
- [ ] Other
- [x] **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

◯ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

◯ Yes ● **No**

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HP-00118992

HIPAA_V2

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● **Yes** ○ No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

HP-00118992 Protected Health Information_V2

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [ ] Address (if more specific than Zip Code)
- [x] **Dates**
- [x] **Ages over age 89**
- [ ] Telephone numbers
- [ ] Fax numbers
- [ ] Email addresses
- [ ] Social Security numbers
- [x] **Medical record numbers**
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?

If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).

Name and MRN are necessary to access the patient charts for data review. Ages over 89 are required as our study population includes all trauma patients who suffer traumatic full-thickness bladder injuries. Dates will be required to assess specific time intervals being investigated as a part of the study. Once the chart is accessed, the data will be recorded on a de-identified data collection tool.

3 * What is the source(s) of the PHI?

The patient's medical record

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).

The data collected for this study will not be re-used in another study or for any other purpose that has not been approved.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [ ] Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")*
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

HP-00118992

Waiver - Alteration of Authorization_V2

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
The research data being collected is from standard of care. No additional information is being collected as part of research. Therefore, this study does not increase the privacy risk to participants.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
All databases used in this project are maintained on password protected computers. All files are encrypted and access is provided only to the project staff.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
Research data collected by the PI and research staff will be kept confidential and used for research purposes only. All hardcopy data will be stored in a designated locked office and stored in secured, locked storage files at the University of Maryland Baltimore and University of Maryland Medical Center. Electronic data will be stored in a password protected computer. Only designated members of the research team will have access to the study materials and data storage equipment. Identifiers such as name, MRN, dates, and ages over 89 will be destroyed following data collection.

4 * Why could the research not practicably be done without access to and use of this PHI?
The evaluation of data requires the linkage of data sets. To complete these linkages, data elements that are identified as PHI are invaluable.

5 * Why could the research not practicably be done without the waiver or alteration?
The research cannot be done without the use of names and MRNs to locate the patient's online medical record and collect data. The amount of time it would take to contact the participants or their family members for HIPAA authorization would be prohibitive. Since this is an observational study only, with no alteration in the patient's care and minimal potential harm, the burden of contacting the patients or their families would far outweigh the minimal potential risks involved in participating in the study. Additionally, the likelihood of high loss to follow-up due to unknown contact information availability or many participants may be deceased, unreachable, or otherwise difficult to locate, etc. would be burdensome to investigators and far outweigh the minimal potential risks involved in participating in the study.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
○ Yes ● **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [x] **Not applicable (study may qualify as exempt)**
- [ ] Request to Waive Consent/Parental Permission (Consent is not being obtained)
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [ ] Request to Waive Documentation of Consent (Verbal/Oral Consent)
- [ ] Written Consent Form
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:
N/A

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

○ Yes ● **No**

4 * Describe who will obtain Informed Consent:
N/A

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A

6 * Describe the setting for consent:
N/A

7 * Describe the provisions for assessing participant understanding:
N/A

8 * Describe the consideration for ongoing consent:
N/A

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

HP-00118992 Children (Assent)_V2

Children (Assent)

You indicated that children are included in this study.

1 * From whom will assent be obtained?

- ○ All children
- ● **None of the children**
- ○ Some children

1.1 If assent will be obtained from some children, describe which children will not be asked for assent and why:

2 * How will assent be documented? (*Answer "N/A" if assent will not be obtained from any of the children*)

N/A

ID: VIEW4E1B2E37C1C00
Name: v2_Children (Assent)

Waiver of Assent

1 * Why is a waiver of child assent being requested?

A waiver of assent is justified based upon the following:

- (●) **1. The research involves no more than minimal risk to subjects**
  2. The waiver will not adversely affect the rights and welfare of the subjects
  3. The research could not practicably be carried out without the waiver; and
  4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- ( ) The capability of these children is so limited that they cannot reasonably be consulted (taking into account the ages, maturity, and psychological state of the children involved)
- ( ) The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research

2 * Provide a justification/explanation for the choice above:

The amount of time it would take to contact the participants or their family members for HIPAA authorization would be prohibitive. Since this is an observational study only, with no alteration in the patient's care and minimal potential harm, the burden of contacting the patients or their families would far outweigh the minimal potential risks involved in participating in the study. Additionally, the likelihood of high loss to follow-up due to unknown contact information availability or many participants may be deceased, unreachable, or otherwise difficult to locate, etc. would be burdensome to investigators and far outweigh the minimal potential risks involved in participating in the study.

ID: VIEW4E1B2E3AC3800
Name: v2_Waiver of Assent

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
No Consent Forms Uploaded		

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
There are no items to display		

2 Upload any HIPAA authorization forms here:

There are no items to display

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Surgery

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Please answer the following question to determine whether review by the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) is required:

* Does this protocol involve oncology patients and/or oncology data in any capacity? This includes, but is not limited to, the inclusion of cancer patients, as well as research related to prevention, treatment, or diagnosis of oncological diseases. ○ Yes ● **No**

If Yes, or if you have any questions regarding Cancer Center review, please contact the UMGCCC Regulatory Office at UMGCCCRegulatory@umm.edu.

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● **No**

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● **No**

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

HP-00118992

Summary of Required Reviews_V2

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Surgery	Complete
SOM Program in Trauma	Complete
Peds Specialty Review	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

HP-00118992 Additional Documents_V2

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Surgery	Complete
SOM Program in Trauma	Complete
Peds Specialty Review	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
Shailvi Gupta

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Faculty surgeon who currently conducts research at UMB.

University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Email: hrpo@umaryland.edu

EXEMPT DETERMINATION

The IRB and the HRPO, as part of the Office of Accountability and Compliance is committed to excellence and customer service. Please take a moment to tell us how we are doing: HRPO/IRB/OAC Customer Feedback Survey

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Date: May 18, 2026

To: Tyler Holliday
RE: HP-00118992
Protocol Version and ID #:
Type of Submission: Initial Review
Type of IRB Review: Exempt

Determination Date: 5/18/2026

This is to certify that University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has reviewed the above referenced protocol entitled, "Postoperative Cystography for Operative Bladder Injuries."

Your protocol has been determined to be exempt under 45 CFR 46.104(d) from IRB review based on the following category(ies):
Category (4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available; OR
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR
- The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

The IRB made the following determinations regarding this submission:
- Subpart D Determination for research involving children: 45 CFR 46.404/21CFR 50.51.
- A waiver of HIPAA authorization for release of the PHI identified in the CICERO application has been reviewed and approved for this research study.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study.
Research activity involving veterans or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@umaryland.edu.

Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY
DATA COLLECTION TOOL

Multicenter Study: POCOBI: Postoperative Cystography for Operative Bladder Injuries

Enrolling Center: _____
Enrolling Co-investigator: _____

Demographics / Injury Variables:

Age (years):_____ Sex (M/F):_____ BMI (kg/m^2):_____

Comorbidities (check all that apply):

___Diabetes	___Cirrhosis	___HIV/immunosuppression
___Tobacco use	___Chronic kidney disease	___Congestive heart failure
___Recurrent UTIs	___Prior urologic surgery	___Anticoagulation/antiplatelet use
___Baseline catheter dependence	___Neurogenic bladder	___End stage renal disease

Mechanism of injury:

Blunt (circle one): Yes / No
Type of blunt mechanism (check all that apply):

___Motor vehicle collision	___Motorcycle collision	___Recreational vehicle collision
___Pedestrian struck	___Fall	___Crush
___Assault	___Other:_____	

Penetrating (circle one): Yes / No
Type of penetrating mechanism (check all that apply):

___Gunshot	___Shotgun	___Blast fragmentation
___Knife	___Impalement	___Iatrogenic
___Other:_____		

Injury severity:

ISS:_____ Admission GCS:_____ Discharge GCS:_____

AIS Head:_____	AIS Face:_____	AIS Neck:_____	AIS Thorax:_____
AIS Abdomen / Pelvis:_____	AIS Extremities:_____	AIS Spine:_____	AIS Skin:_____

Diagnostic Variables:

Hematuria (select one):
___Gross ___Microscopic ___None

Diagnostic modality (select one):
___Cystogram ___Imaging without dedicated cystography ___Intraoperative finding (no imaging)
Type of cystogram, if performed (select one):
___Plain radiography (X-ray) ___Fluoroscopy ___Computed tomography

Bladder Injury Characteristics:

AAST grade (1-5):_____
Advanced one grade for multiple lesions up to grade 3 (circle one): Yes / No

Size of largest injury (cm):_____ Number of injuries:_____

Bladder injury location(s) (select one):
___Intraperitoneal ___Extraperitoneal ___Combined

Bladder injury morphology (select one):
___Linear ___Spiculated ___Unknown ___Other:_____

Bone fragment or foreign body within the bladder wall (circle one): Yes / No

Concomitant internal fixation of pelvis performed (circle one): Yes / No

Management Variables:

Management strategy (circle one): Nonoperative / Operative

Nonoperative Management:
(Please complete the following only if nonoperative management was the intended strategy)

Reason(s) to pursue nonoperative management (check all that apply):

___No intraperitoneal injury suspected ___Single extraperitoneal injury ___Simple extraperitoneal injury
___Small extraperitoneal injury ___Delayed diagnosis ___High operative risk
___Surgeon preference ___Patient preference ___Institutional protocol
___Other:_____

Operative Management:
(Please complete the following only if operative management was the intended strategy)

Reason(s) to pursue operative management (check all that apply):

___Suspected intraperitoneal injury ___Abdominal/pelvic exploration ___Penetrating mechanism
___Reduce orthopedic complications ___Reduce urologic complications ___Multiple bladder injuries
___Suspected vaginal injury ___Suspected rectal injury ___Suspected ureter injury
___Bone fragments in bladder wall ___Foreign body in bladder wall ___Bladder neck injury
___Surgeon preference ___Patient preference ___Institutional protocol
___Other:_____

Time from injury to initial bladder operation (hours):_____

All full-thickness bladder injuries repaired (circle one): Yes / No
If "No", which injuries were not repaired (check all that apply):
___Extraperitoneal ___Intraperitoneal
Reason(s) for not repairing all full-thickness injuries (check all that apply):
___Difficult/unable to access ___Adjacent to ureteral/urethral office ___Small size (cm):_____
___Tissue not amendable to repair ___Damage control operation ___Extraperitoneal
___Other:_____

Surgical team performing bladder repair (select one):
___Trauma ___Urology ___Orthopedic ___Other:_____

Operative approach (select one):
___Laparotomy ___Laparoscopy ___Pelvic incision ___Other:_____

Primary suture repair technique (select one):
___Simple running ___Running locking ___Simple interrupted

Number of repair layers (select one):
___Single-layer ___Double-layer ___Triple layer

Intraperitoneal cystotomy created to repair extraperitoneal injury (circle one): Yes / No

Omental flap reinforcement (circle one): Yes / No

Intraoperative leak evaluation post-repair (circle one): Yes / No
Leak test agent (select one):
___Methylene blue ___Saline ___Air ___Other:_____
Intraoperative leak present after initial repair (circle one): Yes / No
Additional repair performed (circle one): Yes / No
Intraoperative leak present at conclusion of repair (circle one): Yes / No

Pelvic drain placement (circle one): Yes / No

Drain creatinine obtained (circle one): Yes / No
If "Yes", postoperative day of drain creatinine testing:_____
Drain creatinine:_____ Serum creatinine of same day:_____ Drain-to-serum creatinine ratio:_____
If repeated, postoperative day of drain creatinine testing:_____
Drain creatinine:_____ Serum creatinine of same day:_____ Drain-to-serum creatinine ratio:_____
If repeated, postoperative day of drain creatinine testing:_____
Drain creatinine:_____ Serum creatinine of same day:_____ Drain-to-serum creatinine ratio:_____

High volume drain output concerning for urinary leak (circle one): Yes / No
If "Yes", number of days with high volume drain output:_____
Surgeon/care team definition threshold for high volume drain output (mL/day):_____

Ureteral stent placement (circle one): Yes / No

Suprapubic catheter placement (circle one): Yes / No

Associated Injuries/Interventions:

Associated injuries (check all that apply):

___Urethra ___Ureter ___Renal
___Vagina (full thickness) ___Rectal (full thickness) ___Other bowel (full thickness)
___Pelvic fracture ___Pelvic hematoma
___Intracranial hemorrhage ___Paraplegia/quadriplegia

Associated interventions (check all that apply):

___Urethral repair ___Ureteral repair ___Renal repair / nephrectomy
___Vaginal repair ___Rectal repair ___Bowel resection
___Diverting ostomy ___Pelvic external fixation ___Pelvic internal fixation
___Pelvic packing ___Pelvic embolization ___Surgical ligation of internal iliac artery

Extended antibiotic prophylaxis (circle one): Yes / No

Follow-Up / Postoperative Cystography:

Primary management team (select one):
___Trauma ___Urology ___Orthopedic ___Medicine ___Other:_____

Bladder injury management team (select one):
___Trauma ___Urology ___Orthopedic ___Medicine ___Other:_____

Follow-up / postoperative cystography (circle one): Yes / No
If "Yes",
Time to follow-up cystogram after admission (days):_____
If bladder repair performed, postoperative day of initial follow-up cystogram:_____
Type of cystogram, if performed (select one):
___Plain radiography (X-ray) ___Fluoroscopy ___Computed tomography

Rationale for timing or omission of cystography (check all that apply):

___Simple repair ___Complex repair ___Nonoperative management
___Single injury ___Multiple injuries ___Penetrating mechanism
___Small (<2 cm) injury ___Large (>2 cm) injury ___Blunt mechanism
___Post-repair intraoperative leak ___High drain-to-serum creatinine ratio ___High pelvic drain output
___Spiculated injury morphology ___Bladder neck involvement ___Repair or tissue concerns
___Concomitant rectal / vaginal injury ___Concomitant ureter / urethra injury ___Orthopedic hardware
___Persistent gross hematuria ___Low urine output ___Urinary catheter malfunction
___Surgeon preference ___Patient preference ___Institutional protocol
___Other:_____

Follow-up / postoperative cystography plan altered due to drain findings (circle one): Yes / No
If "Yes", reason to pursue follow-up cystography (check all that apply):
___High volume drain output ___High drain-to-serum creatinine ratio ___Other:_____
Follow-up / postoperative cystogram pursued when not previously planned (circle one): Yes / No
If "No", how did drain findings affect cystography timing (select one):
___Earlier cystogram ___Later cystogram ___No change

Initial follow-up / postoperative cystography outpatient (circle one): Yes / No

Urinary leak present on initial follow-up / postoperative cystogram (circle one): Yes / No
If "yes",
Total number of follow-up / postoperative cystograms until resolution of urinary leak:_____
Time to urinary leak resolution after admission (days):_____
If bladder repair performed, postoperative day confirming urinary leak resolution:_____

Subsequent follow-up cystography revealed a urinary leak not previously identified (circle one): Yes / No
If "yes",
Type of initial follow-up / postoperative cystogram (select one):
___Plain radiography (X-ray) ___Fluoroscopy ___Computed tomography
Type of cystogram that identified new urinary leak (select one):
___Plain radiography (X-ray) ___Fluoroscopy ___Computed tomography

Lost to follow-up prior to prior to resolution of urinary leak (circle one): Yes / No

Urinary Catheter Data:

Total urinary catheter duration (days):_____
Postoperative urinary catheter duration (days):_____

Urinary catheter removed within 24 hours of cystogram with urinary leak resolution (circle one): Yes / No
If "No",
Reason to delay urinary catheter removal (check all that apply):
___Critical illness ___Urinary retention ___Planned surgeries
___Surgeon preference ___Patient preference ___Institutional policy
___Unknown ___Other:_____

Outpatient urinary catheter removal (circle one): Yes / No

Outcome Data:

Hospital Length of Stay (days):_____
Critical Care Length of Stay (days):_____
Ventilator days:_____

Complications:

Bladder operation required for persistent / postoperative urinary leak (circle one): Yes / No

Catheter-associated urinary tract infection (circle one): Yes / No
CAUTI organism(s):_____
Time to CAUTI (days):_____

Bacteremia (circle one): Yes / No
Bacteremia organism(s):_____
Time to bacteremia (days):_____

Surgical site infection (circle one): Yes / No
If "Yes", location of surgical site infection (check all that apply):
___Superficial ___Deep ___Pelvic hardware
Surgical site infection organism:_____
Time to surgical site infection (days):_____
Surgical site infection management (check all that apply):
___Incisional drainage ___Operative drainage ___Radiologic drainage
___Pelvic hardware removal ___Antibiotics ___Other:_____

Bladder spasm (circle one): Yes / No

Persistent gross hematuria (circle one): Yes / No

Urinary retention requiring catheter reinsertion (circle one): Yes / No

Mortality (circle one): Yes / No
Time to death after admission (days):_____

Discharge disposition (select one):
___Home ___Rehabilitation ___Skilled nursing ___LTACH ___Morgue
___Other:_____

Thirty-day readmission for complication (circle one): Yes / No
Type of complication requiring readmission (check all that apply):
___Surgical site infection ___Urinary complication ___Orthopedic complication
___Other:_____

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EAST MULTICENTER STUDY
DATA DICTIONARY

POCOBI: Postoperative Cystography for Operative Bladder Injuries Study – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
Enrollment	
Enrolling Center	Participating institution enrolling the patient into the study
Enrolling Co-investigator	Name of the site investigator or study personnel entering the data
Demographics / Injury Variables	
Age (years)	Age of the patient at time of admission in completed years
Sex (M/F)	Biological sex of the patient, options: Male / Female
BMI (kg/m2)	Body mass index documented upon admission
Comorbidities	
Diabetes	History of diabetes mellitus requiring medical management
Cirrhosis	Documented history of liver cirrhosis
HIV/immunosuppression	HIV infection or chronic immunosuppressive medication/condition
Tobacco use	Current or recent tobacco/nicotine use documented in medical record
Chronic kidney disease	Pre-existing chronic kidney disease prior to admission - Estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m² for ≥ 3 months
Congestive heart failure	History of clinically diagnosed heart failure - HFrEF: LVEF ≤40% - HFmrEF: 41–49% - HFpEF: ≥50% with evidence of elevated filling pressures/diastolic dysfunction
Recurrent UTIs	Recurrent urinary tract infections documented prior to injury
Prior urologic surgery	Prior operative urologic intervention before traumatic event

Anticoagulation/antiplatelet use	Use of anticoagulant or antiplatelet medication at time of injury
Baseline catheter dependence	Chronic indwelling urinary catheter or intermittent straight catheter use prior to injury
Neurogenic bladder	History of neurogenic bladder dysfunction
End stage renal disease	ESRD requiring dialysis or equivalent renal replacement therapy
Mechanism of injury	
Blunt injury	Select “Yes” if blunt trauma mechanism contributed to bladder injury
Motor vehicle collision	Occupant involved in motor vehicle crash
Motorcycle collision	Motorcycle-related collision or crash
Recreational vehicle collision	ATV, snowmobile, bicycle, or similar recreational vehicle collision
Pedestrian struck	Pedestrian struck by motor vehicle or moving object
Fall	Injury resulting from fall from standing or elevated height
Crush	Crush mechanism injury
Assault	Non-penetrating assault mechanism
Other blunt mechanism	Any blunt mechanism not otherwise specified, use free-text entry
Penetrating injury	Select “Yes” if penetrating trauma mechanism contributed to injury
Gunshot wound	Refers to handgun/rifle/single-projectile injuries
Shotgun	Refers to pellet-based firearm injury from a shotgun
Blast fragmentation	Penetrating injury secondary to blast fragments/shrapnel
Knife	Stab wound from knife
Impalement	Injury caused by impalement object
Iatrogenic	Unintentional injury caused by a medical or surgical intervention, instrument, or procedure
Other penetrating mechanism	Any penetrating mechanism not otherwise specified, use free-text entry
Injury severity	
ISS	Injury Severity Score documented during admission
Admission GCS	Glasgow Coma Scale score at admission
Discharge GCS	Glasgow Coma Scale score at discharge
AIS Head	Abbreviated Injury Scale score for head injuries

AIS Face	Abbreviated Injury Scale score for facial injuries
AIS Neck	Abbreviated Injury Scale score for neck injuries
AIS Thorax	Abbreviated Injury Scale score for thoracic injuries
AIS Abdomen / Pelvis	Abbreviated Injury Scale score for abdominal and pelvic injuries
AIS Spine	Abbreviated Injury Scale score for spinal injuries
AIS Extremities	Abbreviated Injury Scale score for extremity injuries
AIS Skin	Abbreviated Injury Scale score for skin/soft tissue injuries.

Diagnostic Variables

Gross hematuria	Visible blood in the urine that can be seen without microscopy
Microscopic hematuria	Red blood cells in the urine that are not visible grossly but are detected on microscopic urinalysis, ≥3 red blood cells per high-power field
No hematuria	No visible blood in the urine and no significant red blood cells detected on urinalysis/microscopy, <3 red blood cells per high-power field
Diagnostic modality	Primary modality used to identify bladder injury, options: Cystogram, Imaging without dedicated cystography, or Intraoperative diagnosis without imaging
Cystogram	A diagnostic imaging procedure in which contrast is instilled into the bladder, typically through a urinary catheter, to evaluate bladder integrity and identify urinary extravasation or structural abnormalities
Imaging without dedicated cystography	Cross-sectional or radiographic imaging performed without retrograde bladder contrast instillation specifically intended to evaluate bladder integrity
Intraoperative diagnosis without imaging	Identification of injury during operative exploration without the use of preoperative or postoperative radiographic imaging specifically confirming the diagnosis
Plain radiography cystogram	Conventional X-ray cystogram
Fluoroscopy cystogram	Dynamic fluoroscopic cystography
Computed tomography cystogram	Computed tomography cystography

Bladder Injury Characteristics

AAST grade	American Association for the Surgery of Trauma bladder injury grade, options: - Grade 1: Bladder contusion, intramural hematoma, or partial-thickness bladder laceration without full-thickness disruption. - Grade 2: Extraperitoneal bladder wall laceration less than 2 cm in size

	- Grade 3: Extraperitoneal bladder wall laceration ≥2 cm or intraperitoneal bladder wall laceration <2 cm - Grade 4: Intraperitoneal bladder wall laceration ≥2 cm - Grade 5: Intraperitoneal or extraperitoneal bladder wall laceration extending into the bladder neck or ureteral orifice (trigone) * Multiple bladder injuries may increase the grade by one level (up to Grade 3 in the original scale)
Advanced one grade for multiple lesions up to grade 3	Select “Yes” if multiple lesions resulted in grade advancement (up to grade 3) according to AAST criteria
Size of largest injury (cm)	Largest documented bladder injury dimension in centimeters as determine at surgical exploration or maximal linear dimension of the contrast extravasation defect measured on adequately distended bladder cystography
Number of injuries	Total number of full-thickness bladder injuries identified
Intraperitoneal injury	Injury involving intraperitoneal bladder surface
Extraperitoneal injury	Injury involving extraperitoneal bladder surface
Combined injury	Combined intra- and extraperitoneal bladder injury
Linear morphology	Linear bladder laceration morphology
Spiculated morphology	Stellate, irregular, or spiculated bladder injury morphology
Other morphology	Other bladder injury morphology not otherwise described, use free-text entry
Bone fragment or foreign body within the bladder wall	Select “Yes” if pelvic fracture bone fragment or retained foreign body involving or protruding into the bladder wall or lumen
Concomitant internal fixation of pelvis performed	Select “Yes” if operative internal fixation of the pelvis performed during the same hospitalization as bladder injury management
Management Variables	
Management strategy	Primary intended management approach, options: Nonoperative or Operative
Reason(s) to pursue nonoperative management	The primary clinical rationale(s) for selecting conservative treatment without surgical intervention
No intraperitoneal injury suspected	Nonoperative management selected due to lack of suspected intraperitoneal injury
Single extraperitoneal injury	Single isolated extraperitoneal injury favored nonoperative management
Simple extraperitoneal injury	Injury considered uncomplicated extraperitoneal injury * Complicating features: - Bladder neck injury - Trigonal or ureteral orifice involvement - Concomitant rectal or vaginal injury

	- Bone fragments or foreign body protruding into the bladder - Associated pelvic hardware requiring fixation
Small extraperitoneal injury	Small (<2 cm) extraperitoneal injury favored catheter drainage
Delayed diagnosis	Delayed recognition influenced nonoperative approach
High operative risk	Medical or physiologic risk favored avoidance of surgery
Surgeon preference	Surgeon preference contributed to nonoperative strategy
Patient preference	Patient preference contributed to nonoperative strategy
Institutional protocol	Institutional pathway or protocol guided nonoperative strategy
Other nonoperative rationale	Free-text rationale for nonoperative management
Reason(s) to pursue operative management	The primary clinical rationale(s) for selecting surgical intervention
Suspected intraperitoneal injury	Operative intervention pursued due to concern for intraperitoneal injury
Abdominal/pelvic exploration	Bladder repair performed during planned abdominal or pelvic exploration
Penetrating mechanism	Penetrating mechanism contributed to operative decision-making
Reduce orthopedic complications	Repair pursued to reduce risk of orthopedic hardware or pelvic complications
Reduce urologic complications	Repair pursued to reduce urinary/urologic complications
Multiple bladder injuries	Multiple injuries contributed to operative management
Suspected vaginal injury	Concern for associated full-thickness vaginal injury contributed to operative management
Suspected rectal injury	Concern for associated full-thickness rectal injury contributed to operative management
Suspected ureter injury	Concern for associated ureter injury contributed to operative management
Bone fragments in bladder wall	Presence of pelvic fracture fragments protruding into bladder wall
Foreign body in bladder wall	Presence of retained foreign material involving bladder wall
Bladder neck injury	Concern for bladder neck involvement contributed to repair
Surgeon preference	Surgeon preference contributed to operative strategy
Patient preference	Patient preference contributed to operative strategy
Institutional protocol	Institutional pathway or protocol guided operative strategy
Other operative rationale	Free-text explanation for operative management

Time from injury to initial bladder operation (hours)	Time interval from injury occurrence to initial bladder operation in hours
All full-thickness bladder injuries repaired	Select “Yes” if all identified full-thickness injuries underwent repair
Injuries not repaired	Identify bladder injury location(s) not repaired
Difficult/unable to access	Injury not repaired due to inability or difficulty accessing defect
Adjacent to ureteral/urethral orifice	Injury not repaired because of proximity to ureteral or urethral orifice
Small size	Injury considered too small to require repair. Record size if available
Tissue not amenable to repair	Tissue quality precluded safe repair
Damage control operation	Damage control principles limited definitive repair
Surgical team performing bladder repair	Primary surgical service responsible for bladder repair, options: Trauma, Urology, Orthopedic, or Other: Free-text explanation for surgical team
Operative approach	Primary operative exposure used for bladder repair
Laparotomy	A surgical incision through the abdominal wall performed to gain access to the abdominal cavity during an open operative procedure
Laparoscopy	A minimally invasive surgical technique in which a camera and specialized instruments are inserted through small abdominal incisions to visualize or operate within the abdominal cavity
Pelvic incision	Surgical incision performed to access the pelvis for operative reduction and internal or external fixation of pelvic fractures
Other operative approach	Free-text explanation of operative approach
Primary suture repair technique	Dominant repair suture technique used for bladder repair
Simple running	Continuous single-layer running suture technique without locking
Running locking	A continuous locking suture pattern using sequential locked throws along the length of the repair
Simple interrupted	Suture technique in which individual stitches are placed and tied separately across a wound or repair site
Number of repair layers	Number of closure layers used during repair
Single-layer	One suture layer
Double-layer	Two suture layers
Triple-layer	Three suture layers
Intraperitoneal cystotomy created	Select “Yes” if intentional intraperitoneal cystotomy performed to

to repair extraperitoneal injury	facilitate extraperitoneal repair,
Omental flap reinforcement	Select “Yes” if omental tissue used to reinforce bladder repair
Intraoperative leak evaluation post-repair	Select “Yes” if any intraoperative urinary leak test performed after repair completion
Leak test agent	Primary agent used during intraoperative leak test, options: Methylene blue, Saline, Air, or Other: Free-text description of agent
Intraoperative leak present after initial repair	Evidence of urinary leak after first repair attempt
Additional repair performed	Additional suturing or repair after positive urinary leak evaluation
Intraoperative leak present at conclusion of repair	Urinary leak present at end of operation despite repair attempts
Pelvic drain placement	Placement of pelvic drain at operation conclusion
Drain creatinine obtained	Drain fluid creatinine testing performed postoperatively
Postoperative day of drain creatinine testing	Postoperative day drain creatinine sample obtained
Drain creatinine	Drain fluid creatinine concentration
Serum creatinine of same day	Serum creatinine obtained same day as drain sample
Drain-to-serum creatinine ratio	Calculated ratio of drain creatinine divided by serum creatinine
High volume drain output concerning for urinary leak	Clinical concern for urinary leak based on drain output volume
Number of days with high volume drain output	Consecutive postoperative days with elevated drain output
Surgeon/care team threshold for high drain output	Threshold in mL/day considered clinically concerning by treating team
Ureteral stent placement	Ureteral stent placed during operation or hospitalization
Suprapubic catheter placement	Suprapubic urinary catheter placed during operation or hospitalization
Associated Injuries/Interventions	
Urethral injury	Associated urethral injury identified
Ureter injury	Associated ureteral injury identified
Renal injury	Associated kidney injury identified
Vaginal injury	Full-thickness vaginal injury identified
Rectal injury	Full-thickness rectal injury identified

Other bowel injury	Full-thickness bowel injury other than rectum identified
Pelvic fracture	Pelvic ring fracture documented
Pelvic hematoma	Pelvic hematoma documented radiographically or intraoperatively
Intracranial hemorrhage	Associated intracranial bleeding injury
Paraplegia/quadriplegia	Spinal cord injury resulting in paralysis
Urethral repair	Operative urethral repair performed
Ureteral repair	Operative ureteral repair performed
Renal repair/nephrectomy	Kidney repair or nephrectomy performed
Vaginal repair	Operative vaginal repair performed
Rectal repair	Operative rectal repair performed
Bowel resection	Operative bowel resection performed
Diverting ostomy	Creation of fecal diversion ostomy
Pelvic external fixation	External fixation applied for pelvic stabilization
Pelvic internal fixation	Internal orthopedic fixation performed
Pelvic packing	Pelvic packing performed for hemorrhage control
Pelvic embolization	Angiographic embolization performed for pelvic bleeding
Surgical ligation of internal iliac artery	Operative ligation of internal iliac artery performed
Extended antibiotic prophylaxis	Antibiotics prophylaxis beyond perioperative period (>24 hours)

Follow-Up / Postoperative Cystography

Primary management team	Service primarily directing overall inpatient care, options: Trauma, Urology, Orthopedic, Medicine, or Other: Free-text description of care team
Bladder injury management team	Service primarily directing bladder injury management, options: Trauma, Urology, Orthopedic, Medicine, or Other: Free-text description of care team
Follow-up/postoperative cystography	Any follow-up cystogram obtained after diagnosis or repair
Time to follow-up cystogram after admission (days)	Days from admission to first follow-up cystogram
Postoperative day of initial follow-up cystogram	Postoperative day first cystogram obtained after repair
Type of cystogram	Imaging modality used for follow-up cystography

Plain radiography cystogram	Conventional X-ray cystogram
Fluoroscopy cystogram	Dynamic fluoroscopic cystography
Computed tomography cystogram	Computed tomography cystography
Rationale for timing or omission of cystography	Factors influencing the decision to perform, delay, expedite, or omit follow-up/postoperative cystography after traumatic bladder injury diagnosis or repair, multiple selections permitted
Simple repair	Cystography timing influenced by uncomplicated repair as determined by bladder repair surgeon; for example, a linear repair of the bladder dome
Complex repair	Cystography timing influenced by complex repair as determined by bladder repair surgeon; for example a stellate bladder injury that requires significant bladder mobilization to access the injury
Nonoperative management	Cystography timing influenced by nonoperative management strategy
Single injury	Single injury influenced imaging timing
Multiple injuries	Multiple injuries influenced imaging timing
Penetrating mechanism	Penetrating trauma influenced imaging timing
Small (<2 cm) injury	Small (<2 cm) injury size influenced imaging timing
Large (>2 cm) injury	Large (>2 cm) injury size influenced imaging timing
Blunt mechanism	Blunt trauma influenced imaging timing
Post-repair intraoperative leak	Intraoperative urinary leak present after initial or final bladder repair influenced imaging timing
High drain-to-serum creatinine ratio	Elevated drain-to-serum creatinine ratio influenced imaging timing
High pelvic drain output	Elevated pelvic drain output influenced imaging timing
Spiculated injury morphology	Stellate, irregular, or spiculated bladder injury morphology influenced imaging timing
Bladder neck involvement	Bladder neck injury influenced imaging timing
Repair or tissue concerns	Concerns regarding repair integrity or tissue quality influenced imaging timing
Concomitant rectal/vaginal injury	Associated rectal or vaginal injury influenced imaging timing
Concomitant ureter/urethra injury	Associated ureteral or urethral injury influenced imaging timing
Orthopedic hardware	Presence of orthopedic hardware influenced imaging timing
Persistent gross hematuria	Ongoing gross hematuria influenced imaging timing
Low urine output	Reduced urine output influenced imaging timing

Urinary catheter malfunction	Urinary catheter malfunction influenced imaging timing
Other cystography rationale	Free-text rationale for timing or omission of cystography
Follow-up cystography plan altered due to drain findings	Select “Yes” if initial cystography strategy changed due to drain output or creatinine findings
High volume drain output	Drain output volume specifically prompted change in cystography strategy
High drain-to-serum creatinine ratio	Elevated drain-to-serum creatinine ratio specifically prompted change in cystography strategy
Follow-up cystogram pursued when not previously planned	Select “Yes” if cystogram newly ordered despite no prior plan for imaging
Earlier cystogram	Drain findings resulted in earlier imaging than initially intended
Later cystogram	Drain findings resulted in delayed imaging
No change	Drain findings did not alter planned imaging timing
Initial follow-up/postoperative cystography outpatient	Select “Yes” if first follow-up/postoperative cystogram obtained after hospital discharge
Urinary leak present on initial follow-up/postoperative cystogram	Select “Yes” if contrast extravasation from urinary bladder present on first follow-up/postoperative cystography study
Total number of follow-up/ postoperative cystograms until resolution of urinary leak	Number of follow-up/postoperative imaging studies required until urinary leak resolution documented
Time to urinary leak resolution after admission	Days from admission until imaging-confirmed urinary leak resolution
Postoperative day confirming leak resolution	Postoperative day confirming absence of urinary leak on imaging
Subsequent cystography revealed new urinary leak	Select “Yes” if later imaging identified urinary leak not previously recognized on prior follow-up/postoperative imaging
Type of initial follow-up/postoperative cystogram	Modality used during initial negative cystogram
Type of cystogram identifying new urinary leak	Imaging modality identifying delayed urinary leak
Lost to follow-up prior to urinary leak resolution	Select “Yes” if patient did not complete follow-up before documented urinary leak resolution
Urinary Catheter Data	
Total urinary catheter duration	Total duration of urinary catheterization in days
Postoperative urinary catheter duration	Days of urinary catheterization following operative repair

Urinary catheter removed within 24 hours of urinary leak resolution cystogram	Select “Yes” if urinary catheter removal occurred within 24 hours after cystogram confirming no urinary leak
Critical illness	Delay in catheter removal due to ongoing critical illness
Urinary retention	Delay in catheter removal due to urinary retention concerns
Planned surgeries	Additional planned operations/interventions delayed catheter removal
Surgeon preference	Surgeon practice pattern delayed catheter removal
Patient preference	Patient desired delayed catheter removal
Institutional policy	Institutional practice pattern delayed catheter removal
Unknown	Reason for delayed removal unclear or undocumented
Outpatient urinary catheter removal	Select “Yes” if urinary catheter removed after discharge from hospital
Outcome Data	
Hospital length of stay	Total consecutive inpatient days during index hospitalization
Critical care length of stay	Total ICU days during index hospitalization
Ventilator days	Total days requiring invasive mechanical ventilation during index hospitalization
Complications	An unintended adverse event, condition, or outcome occurring during or after bladder injury management
Bladder operation for persistent/ postoperative urinary leak	Select “Yes” if bladder operation required due to persistent urinary leak
Catheter-associated urinary tract infection	Select “Yes” if catheter-associated urinary tract infection diagnosed during hospitalization (not present upon admission) or follow-up, Centers for Disease Control and Prevention / National Healthcare Safety Network criteria (patient must meet 1, 2, **and** 3 below): 1. Indwelling urinary catheter - Present for >2 consecutive days - Present on the date of event or removed the day prior 2. At least one sign or symptom, including: - Fever (>38.0°C) - Suprapubic tenderness - Costovertebral angle pain or tenderness - Urinary urgency - Urinary frequency - Dysuria 3. Positive urine culture - No more than two organisms identified - At least one bacterium with ≥100,000 CFU/mL
CAUTI organism(s)	Organism identified from urine culture associated with CAUTI

Time to CAUTI	Days from admission until CAUTI diagnosis
Bacteremia	Select “Yes” if positive blood culture with clinically significant organism, Centers for Disease Control and Prevention / National Healthcare Safety Network criteria (patient must meet 1 **or** 2 below): 1. Presence of either one positive blood culture growing a recognized bacterial pathogen not attributable to another infection source 2. Two or more positive blood cultures growing common skin contaminants in the setting of clinical signs of infection, such as fever, chills, or hypotension.
Bacteremia organism	Organism isolated from blood culture
Time to bacteremia	Days from admission until bacteremia diagnosis
Surgical site infection	Select “Yes” if surgical site infection involving operative incision or repair site
Superficial surgical site infection	Infection occurring within 30 days of an NHSN-defined operative procedure involving only the skin or subcutaneous tissue of the incision and meeting CDC/NHSN criteria, (patient must meet **one** of the following): 1. Purulent drainage from the superficial incision 2. Identification of an organism from an aseptically obtained specimen of the superficial incision or subcutaneous tissue using culture or non–culture-based microbiologic testing performed for clinical diagnosis or treatment (excluding active surveillance testing) 3. Deliberate opening, re-access, or aspiration of the superficial incision by a surgeon, physician, or physician designee with initiation or continuation of antibiotic or antifungal therapy on or within two calendar days of the procedure for a duration of two or more calendar days, in the presence of at least one sign or symptom such as new or worsening localized pain or tenderness, localized swelling, erythema, or warmth 4. Diagnosis of a superficial incisional SSI by a surgeon, physician, or physician designee
Deep incisional surgical site infection	Infection occurring within 90 days of an NHSN-defined operative procedure involving the deep soft tissues (fascia and muscle layers) of the incision and meeting CDC/NHSN criteria, (patient must meet **one** of the following): 1. Purulent drainage from the deep incision 2. Identification of an organism from the deep soft tissues of the incision using culture or non–culture-based microbiologic testing performed for clinical diagnosis or treatment (excluding active surveillance testing) 3. Deliberate opening, re-access, or aspiration of the deep incision by a surgeon, physician, or physician designee, or spontaneous dehiscence, with initiation or continuation of antibiotic or antifungal therapy on or within two calendar days of the event for a duration of two or more calendar days, in the presence of fever (>38°C) or new or worsening localized pain or tenderness 4. Evidence of infection involving the deep incision, such as an abscess, identified on gross anatomic examination, histopathologic evaluation, or imaging
Pelvic hardware infection	Infection involving pelvic orthopedic hardware, criteria (patient must meet 1 **or** 2 below):

	1. Infection involving surgically implanted pelvic hardware identified by purulent drainage, evidence of abscess/infection on imaging or reoperation, or diagnosis by the treating surgeon consistent with CDC/NHSN surgical site infection criteria 2. Culture-confirmed infection involving deep soft tissues (fascial or muscular layers) in proximity to surgically implanted pelvic fixation hardware, with organism(s) identified from operative or percutaneous specimens obtained for clinical diagnosis or treatment
Surgical site infection organism	Organism isolated from SSI culture
Time to surgical site infection	Days from index operation until SSI diagnosis
Bedside drainage	Bedside drainage procedure performed for SSI
Operative drainage	Operative drainage/debridement performed for SSI
Radiologic drainage	Image-guided drainage procedure performed for SSI
Pelvic hardware removal	Removal of pelvic orthopedic hardware due to infection
Antibiotics	SSI treated with antibiotic therapy
Other SSI management	Additional management strategy for SSI, use free-text entry
Bladder spasm	Select “Yes” if symptomatic bladder spasms documented
Persistent gross hematuria	Select “Yes” if ongoing gross hematuria beyond expected hospital/postoperative course
Urinary retention requiring catheter reinsertion	Select “Yes” if urinary retention necessitating catheter reinsertion after removal
Mortality	Select “Yes” if death during index hospitalization
Time to death after admission	Days from admission until death
Home	Discharge to home environment
Rehabilitation	Discharge to inpatient rehabilitation facility
Skilled nursing	Discharge to skilled nursing facility
LTACH	Discharge to long-term acute care hospital
Morgue	Patient expired prior to discharge
Other disposition	Alternative discharge location not otherwise specified, use free-text entry
Thirty-day readmission for complication	Select “Yes” if readmission within 30 days related to complication of bladder injury or treatment
Surgical site infection readmission	Readmission related to SSI
Urinary complication readmission	Readmission related to urinary complication

Orthopedic complication readmission	Readmission related to orthopedic complication
Other complication requiring readmission	Other complication leading to readmission, use free-text entry