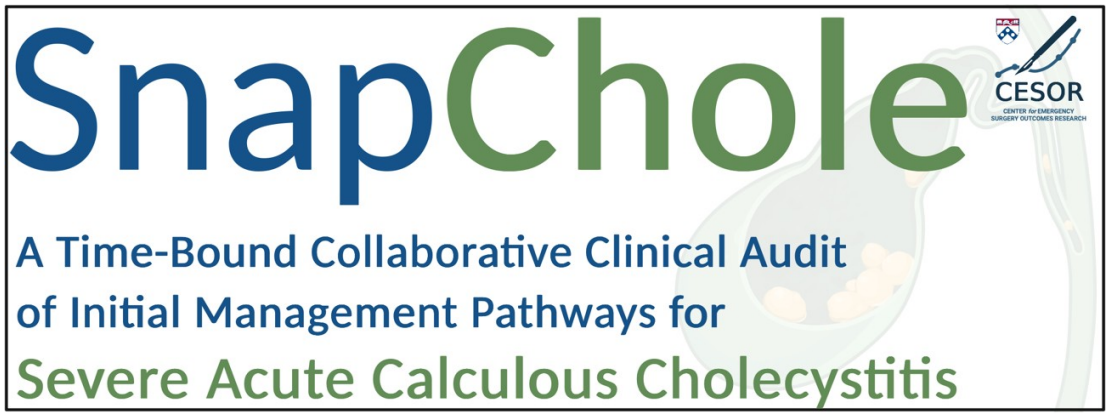
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SnapChole: A Time-Bound Collaborative Clinical Audit of Initial Management Pathways for Moderate and Severe Acute Calculous Cholecystitis

Patient-Reported Outcomes Protocol
IRB Submission

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Recruitment schedule revised 6 November 2026

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Summary

SnapChole is a prospective, international observational study of adults with Tokyo Guidelines 2018 (TG18) Grade II or Grade III acute calculous cholecystitis. This protocol describes its optional patient-reported outcomes component, using the published Gastrointestinal Quality of Life Index (GIQLI) at baseline and 90 days. Questionnaires involve direct patient contact and voluntary consent, separately from routine clinical-record collection under the requested consent and HIPAA authorization waivers. Treatment remains entirely at the discretion of the clinical team. Penn will enroll patients and serve as the coordinating and data-analysis center. Patient-reported outcomes will be analyzed descriptively or associationally; they will not constitute causal comparisons between treatment strategies.

Background and Rationale

Acute calculous cholecystitis is a common emergency general surgical condition requiring timely decisions about initial management and source control. The Tokyo Guidelines 2018 (TG18) classify acute cholecystitis into three grades: Grade I, or mild disease; Grade II, or moderate disease, defined by features such as marked local inflammation, prolonged symptoms, a palpable right-upper-quadrant mass or substantially elevated white-cell count; and Grade III, or severe disease, defined by dysfunction of at least one organ system, including the cardiovascular, neurological, respiratory, renal, hepatic or haematological systems.[1] This study focuses on Grade II and Grade III disease because these patients may have greater inflammatory burden, local complications or organ dysfunction, and management decisions may consequently depend on physiological reserve, operative risk, disease characteristics, local expertise and available resources, Figure 1. TG18 and World Society of Emergency Surgery guidance provide the relevant framework for diagnosis, severity assessment and management.[2–4]

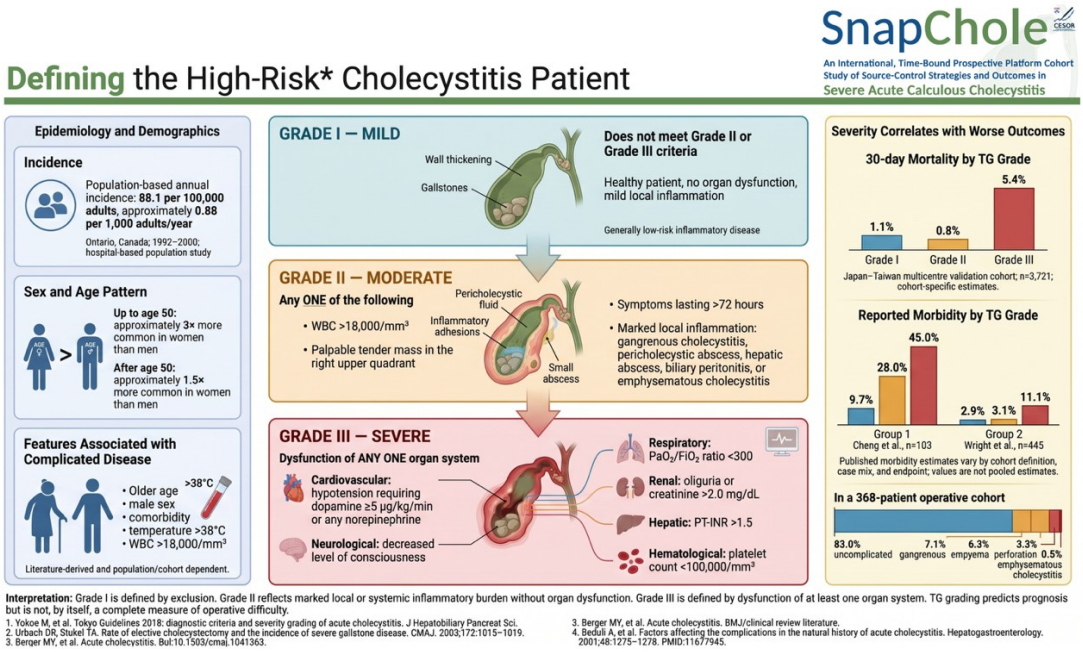


Figure 1. Tokyo Guidelines 2018 severity classification and clinical context. SnapChole includes Grade II and Grade III acute calculous cholecystitis; Grade I is shown for context.[1]

Initial management may comprise cholecystectomy-first, percutaneous cholecystostomy or drainage-first, or antimicrobial-only management. Although guidance supports early laparoscopic cholecystectomy for many patients, the appropriate approach may differ according to TG18 grade, comorbidity, physiological reserve, local expertise and the available operative or interventional-radiology capacity. [2,4,5,6]

The only available randomized control trial compared early cholecystectomy with percutaneous drainage in high-risk patients with acute cholecystitis, showed a significant advantage in terms of reduction of complications after laparoscopic cholecystectomy. The trial was interrupted after the interim analysis due to the net benefit of laparoscopic cholecystectomy and the potential negative effects of the percutaneous drainage. [7]

Despite existing guidance, care remains heterogeneous across healthcare systems. In the European Society for Trauma and Emergency Surgery snapshot audit of complicated biliary disease, only 45% of patients underwent index-admission cholecystectomy, while centres with a dedicated acute-care surgery model reported higher rates than centres using a traditional on-call structure.[8] Other analyses have similarly demonstrated variation associated with patient factors, hospital resources and organizational models. [9,10]

Additionally, the use of non-surgical options like percutaneous cholecystostomy is burdened by high heterogeneity in patients' selection, timing of drainage, and post-drainage management. [11,12]

Variation in treatment pathways provides the context for assessing recovery from the patient perspective. The descriptive audit will characterize routine care; this optional questionnaire component will describe gastrointestinal symptoms and health-related quality of life during recovery. Participation will not assign treatment or recommend a preferred management pathway.

This document specifies the patient-reported outcomes component. Sites may contribute to the routine-care cohort without undertaking questionnaires. Questionnaire collection requires the applicable local ethics and consent arrangements before recruitment.

Patient-Reported Outcome Measures (PROMs)

This component evaluates recovery following TG18 Grade II or Grade III acute calculous cholecystitis. The overall study's primary clinical outcome, days alive and out of hospital through 90 days (DAOH90), combines survival and hospital utilization.[13] GIQLI complements this measure by describing symptoms and health-related quality of life.[14]

GIQLI is a validated 36-item instrument assessing gastrointestinal symptoms, physical, emotional and social functioning, and treatment effects. Scores range from 0 to 144, with higher scores indicating better health-related quality of life.[16] Its gastrointestinal focus and use in patients undergoing cholecystectomy for acute cholecystitis support its selection.[17]

The published GIQLI will be administered without modification at baseline and 90 days, retaining its original wording, response options, recall period and scoring instructions. No study-developed questionnaire items will be added. The validated instrument is described and cited here in accordance with Penn IRB guidance; its full item text is not reproduced.[18]

Methods

Study Design and Setting

SnapChole uses prospective, consecutive enrollment during a predefined 90-day period, following snapshot methodology.[15] There is no randomization, study-assigned treatment or alteration to clinical care. At Penn, patients will be enrolled at the Hospital of the University of Pennsylvania (primary site), Penn Presbyterian Medical Center and Pennsylvania Hospital, with an administrative enrollment ceiling of 90 patients across these hospitals. Routine clinical information will be abstracted from medical records under the requested waivers; the optional GIQLI component involves patient contact and separate voluntary consent.

Phase	Timeline	Major Activities
Protocol and approvals	Before enrollment	Finalize GIQLI administration, consent, HIPAA arrangements and local approvals
Site activation	Before enrollment	Train staff; confirm validated language versions and secure data capture
Enrollment and baseline	90-day site window	Consecutive screening; voluntary consent; baseline GIQLI when clinically able
Follow-up	90 days	GIQLI by secure survey or telephone; document response and vital status
Data reconciliation	After follow-up	Local pairing, completeness checks and approved aggregate reporting
Analysis and dissemination	After checks	Descriptive recovery summaries and reporting of missingness

Table 1. Planned implementation of the patient-reported outcomes component, subject to local approvals and site activation.

Each participating center will use one predefined 90-day enrollment window within the planned March–August 2027 recruitment period, with 90-day follow-up extending into November 2027. Local enrollment will begin only after required approvals and activation; dates may be revised for multicenter logistics.

Study Population

Adults aged 18 years or older presenting with suspected acute calculous cholecystitis are eligible if a definitive diagnosis is established prospectively using the Tokyo Guidelines 2018 (TG18) diagnostic criteria, comprising compatible local signs, systemic signs of inflammation and characteristic imaging findings.[1] Eligible cases must meet TG18 Grade II or Grade III severity criteria at index presentation or during the early index episode, before the initial management pathway is recorded.

TG18 Grade II acute cholecystitis is defined by at least one of the following: elevated white-cell count above 18,000/mm^3, a palpable tender right-upper-quadrant mass, symptom duration exceeding 72 hours, or marked local inflammation. Grade III acute cholecystitis is defined by organ dysfunction involving the cardiovascular, neurological, respiratory, renal, hepatic or hematological system.[1] TG18 grade will be recorded separately for every included case using the earliest qualifying clinical, laboratory and imaging data.

Cases are excluded if they have TG18 Grade I disease only, acalculous cholecystitis, isolated choledocholithiasis or cholangitis without cholecystitis, primary gallstone pancreatitis, or elective admission for chronic biliary symptoms. These exclusions are consistent with the TG18 disease definitions and the boundaries of this study. [1,2] Clinical outcomes will be reported separately for

Grade II and Grade III disease. Combined moderate-to-severe results may be presented descriptively but will not replace grade-specific reporting.

Case Identification

Consecutive eligible cases will be identified through routine clinical systems and recorded in a local screening log. Patients may join the routine-record cohort independently of questionnaire participation. GIQLI will be offered only when patients can provide informed consent and respond for themselves; declining or being unable to complete questionnaires will not exclude an otherwise eligible patient from the routine-record cohort. No proxy GIQLI responses will be collected. Identifiers and linkage keys will remain in secure local records separate from the research dataset.

Management Pathway Classification and Timing

The first documented management decision by the attending surgeon or surgical team will define the observed initial pathway: cholecystectomy-first, percutaneous cholecystostomy-first or antimicrobial-only management. Endoscopic gallbladder drainage, where used, will be recorded separately. These categories describe clinician-selected care and are not assigned by the study. PROM reporting will retain the initial pathway while recording subsequent treatment transitions.

Pathway Transitions and Escalation

Escalation from antimicrobials to drainage or surgery, subsequent cholecystectomy after drainage, and repeat or rescue interventions will be recorded as components of routine care. Research REDCap records will contain elapsed intervals relative to the initial treatment-selection decision (time zero), rather than calendar dates or clock times. Age will be recorded only in prespecified bands. Identifiable source records needed to derive these measures will remain separate from the research dataset.

Questionnaire Administration

Baseline and 90-Day Assessments

Baseline GIQLI will be collected during the index admission, at the bedside when the patient is clinically able to consent and respond. Care will not be delayed to obtain a questionnaire. Timing relative to time zero and treatment initiation will be recorded; an assessment obtained after treatment begins will not be represented as a pretreatment measure. The 90-day assessment will be offered by secure Penn REDCap survey or telephone, with staff recording the patient's own responses. Published scoring instructions will be followed, including handling of incomplete questionnaires.

Validated language versions will be used where available. Qualified interpretation, including MARTTI at Penn, may support the consent discussion and communication; ad hoc interpretation of questionnaire items will not be treated as a validated GIQLI translation. The same validated language version will be used at both assessments where possible, and language and administration mode will be recorded. Patients may decline any question or stop participation without affecting their care.

PROM Data Analysis and Data Flow

GIQLI scores at each assessment and within-patient changes among paired respondents will be summarized overall, by TG18 grade and by observed initial management pathway. Analyses will be descriptive or associational, without causal treatment-effect interpretation. Ninety-day scores describe surviving respondents; death before follow-up will be reported separately and will not be assigned a GIQLI score or treated as ordinary questionnaire nonresponse. This differs from the separate DAOH90 outcome, for which death is assigned zero.

Data Quality Assurance and Missing Data Handling

Sites will report the numbers eligible, invited, consenting, assessed at each time point and providing paired assessments, together with completeness and available reasons for nonresponse. Baseline and follow-up responses will be paired locally. External sites will transmit only approved, deidentified aggregate PROM summaries, including scores and paired changes by assessment time and initial pathway. Penn patient-level responses will be stored in Penn REDCap, with identifiers, contact details and linkage keys held separately in access-restricted local records. Penn will receive and analyze external summaries; no individual Penn participant-level data or PHI will be disclosed outside the Penn Medicine covered entity. Differential response and loss to follow-up will be acknowledged as limitations.

Ethics, Consent and Confidentiality

The prospective questionnaire component requires its own ethics and consent arrangements and is not justified solely by a local clinical-audit designation. At Penn, voluntary consent will use the participant information sheet and recruitment/follow-up script, with a requested waiver of documentation of consent. Routine clinical-record access is covered by separate requests for waiver of consent and HIPAA authorization. A waiver of consent documentation does not itself waive HIPAA authorization; authorization or an IRB-approved waiver applicable to the linked questionnaire component must be in place before collection. No approval or exemption is assumed until formally determined by the IRB. Recruitment and follow-up will comply with applicable Penn patient-contact restrictions.

Governance, Contributions and Dissemination

Governance

Each participating site will appoint a local investigator responsible for approvals, staff training, consent, secure data handling and data quality. Penn will act as the coordinating and data-analysis center. Sites will retain identifiers and linkage keys locally and will share only approved aggregate PROM summaries with Penn. Coordinating staff will review completeness and consistency using agreed reporting templates. The questionnaire component may proceed only at sites with the necessary approvals; participation in the routine-record cohort does not require participation in PROM collection.

Contributions

Contributions to study design, recruitment, data collection, validation, analysis and reporting will be acknowledged according to actual contributions. Authorship will follow the study's authorship policy. Any expansion beyond the approved PROM data flow or descriptive/associational analysis will require the applicable ethics and governance review before implementation.

Dissemination

Findings will be reported in aggregate, with suppression of potentially identifying small cells and no ranking of services. Reports will describe symptoms, quality of life, paired change and assessment completeness, while making clear the effects of survival and response selection. They will not present these descriptive PROM comparisons as causal treatment effects. No individual Penn participant-level data, identifiers or linkage keys will be shared outside the Penn Medicine covered entity.

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