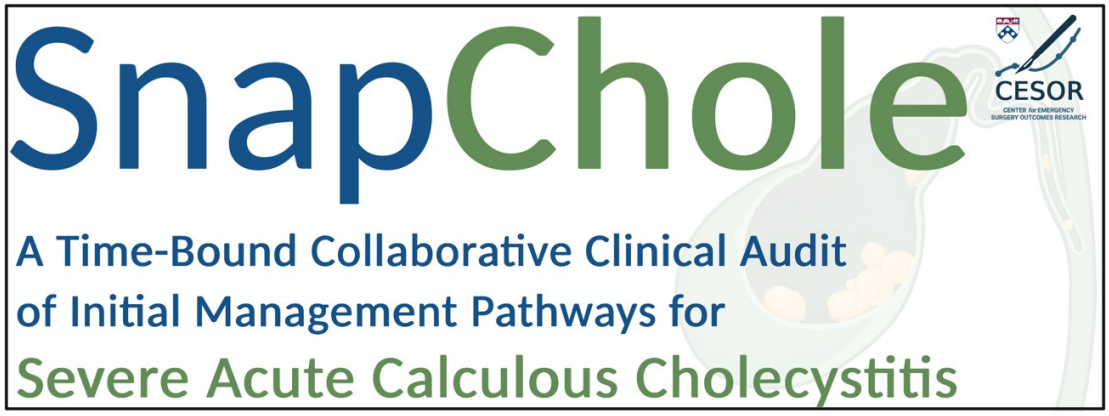
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SnapChole: A Time-Bound Collaborative Clinical Audit of Initial Management Pathways for Moderate and Severe Acute Calculous Cholecystitis

Clinical Audit Specification for Local Clinical Governance Review

2026-09-21

Recruitment schedule revised 6 November 2026

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Summary

SnapChole is a time-bound collaborative clinical audit of routine care for adults with Tokio Guidelines 18 (TG18) Grade II or Grade III acute calculous cholecystitis. It measures initial management pathways, timing of care, escalation, source-control delivery, and routinely recorded outcomes against a pre-specified core set of recognized standards. Care is not allocated, directed or altered by the audit. The purpose is to identify variation from agreed standards, support local quality-improvement action, and enable re-audit. Consecutive eligible cases are identified during one predefined 90-day audit period. Audit information is obtained from routine clinical records and routinely available service data. No study-specific questionnaire, additional clinical procedure, research-only investigation, or direct patient contact is undertaken. The SnapChole audit establishes the denominator of eligible cases, reports Grade II and Grade III disease separately, and returns aggregate findings to participating services for clinical-governance review, quality-improvement planning and, where appropriate, re-audit.

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 audit 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]

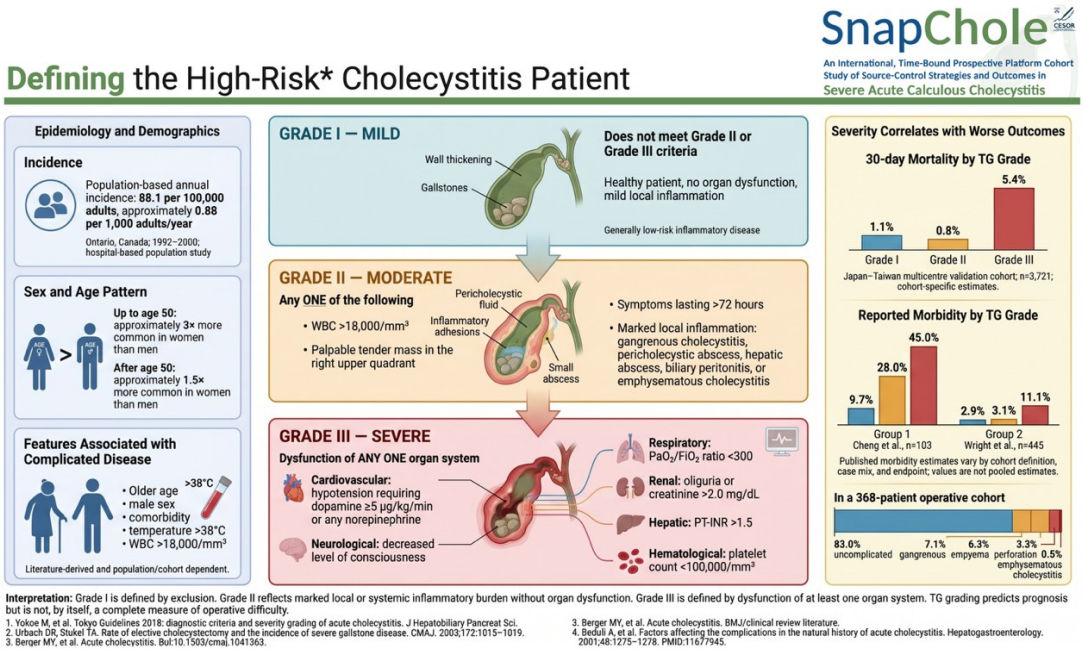


Figure 1. The visual provide a graphical summary of the Tokyo Guidelines definitions of cholecystitis grades alongside with epidemiologic, demographic and outcome-related insights, providing a comprehensive view of the factor impacting the surgical decision-making .

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]

This variation provides the rationale for a collaborative clinical audit. SnapChole will assess whether routine care for TG18 Grade II and Grade III acute calculous cholecystitis meets pre-specified standards for diagnosis, initial management, timing, source-control delivery and escalation. The audit will record the clinical and service context in which management decisions are made, report Grade II and Grade III cases separately, and return aggregate findings to participating services to support local quality-improvement action and re-audit. SnapChole will not assign treatment or recommend a preferred pathway.

The SnapChole project articulates in different, separate, but integrable working packages. The audit constitutes the first one, as reported in Figure 2.

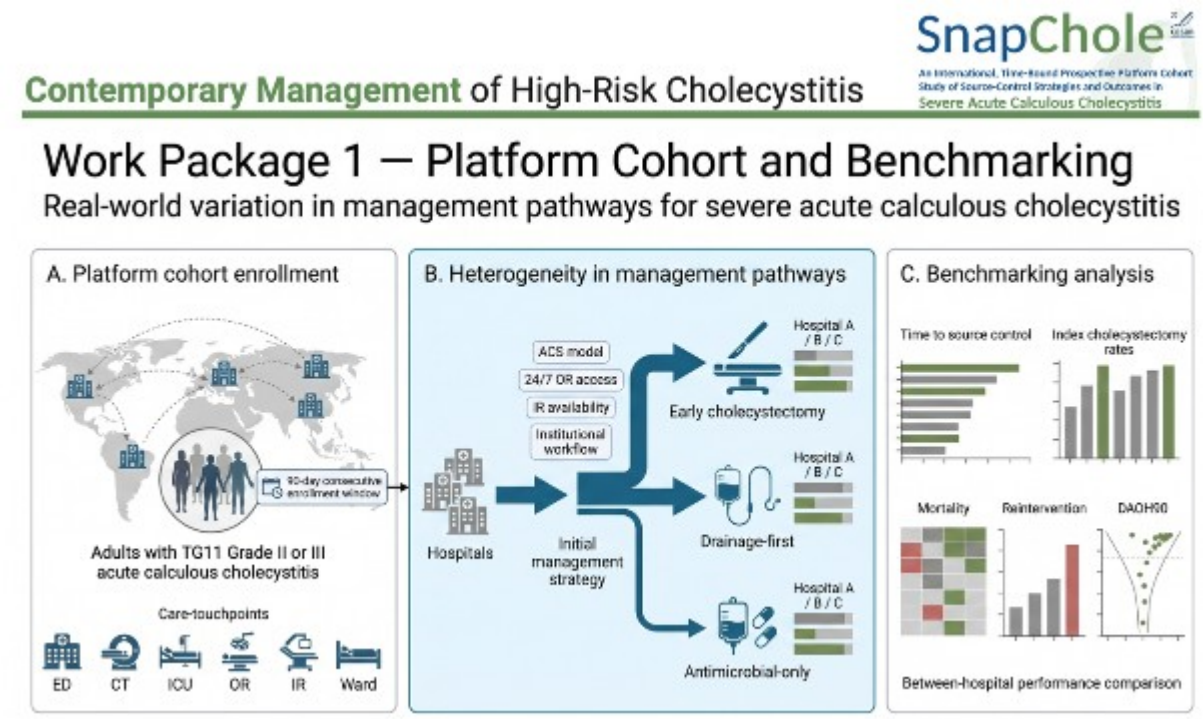


Figure 2. The Audit infrastructure is reported in this visual, from the cohort enrollment to the different available treatment options, ending with the benchmarks that will be used to measure the quality of care compared to available literature standards.

This work package establishes the denominator population and provides a comprehensive description of patient characteristics, management pathways, timing of care, and outcomes under routine clinical conditions. Consecutive prospective enrollment within a time-bound accrual window captures real-world practice with high fidelity while limiting selection and temporal biases associated with retrospective data. Its primary function is to characterize international variation in practice and outcomes using consistent definitions and transparent benchmarking methods.

Prior multicenter audits have demonstrated substantial heterogeneity in the use and timing of cholecystectomy for acute cholecystitis, with system-level factors such as dedicated acute care surgery services associated with higher rates of index-admission operative management [8] Additional observational studies have shown that hospital resources, operating room access, and institutional organization influence both treatment selection and outcomes.[9] Benchmarking analyses within this work package will quantify variation across centers in the proportion of patients assigned to each strategy, timing of achieved source control, and short-term outcomes. Their purpose is to define the empirical landscape of severe acute calculous cholecystitis, identify system-level constraints associated with pathway availability and timing.

Methods

Audit Design and Setting

SnapChole is a time-bound, multicentre collaborative clinical audit of routine care for adults with TG18 Grade II or Grade III acute calculous cholecystitis. The audit involves no randomisation, treatment allocation, protocol-mandated intervention, or alteration to clinical decision-making, and will follow the snapshot methodology [13]. All diagnostic and therapeutic decisions remain with the clinical team. Each participating service will identify consecutive eligible cases during one predefined 90-day audit period. Audit data will be abstracted from routine clinical records using a standardised audit form. No study-specific questionnaire, additional clinical procedure, research-only investigation, or direct patient contact will be undertaken.

Study Timeline

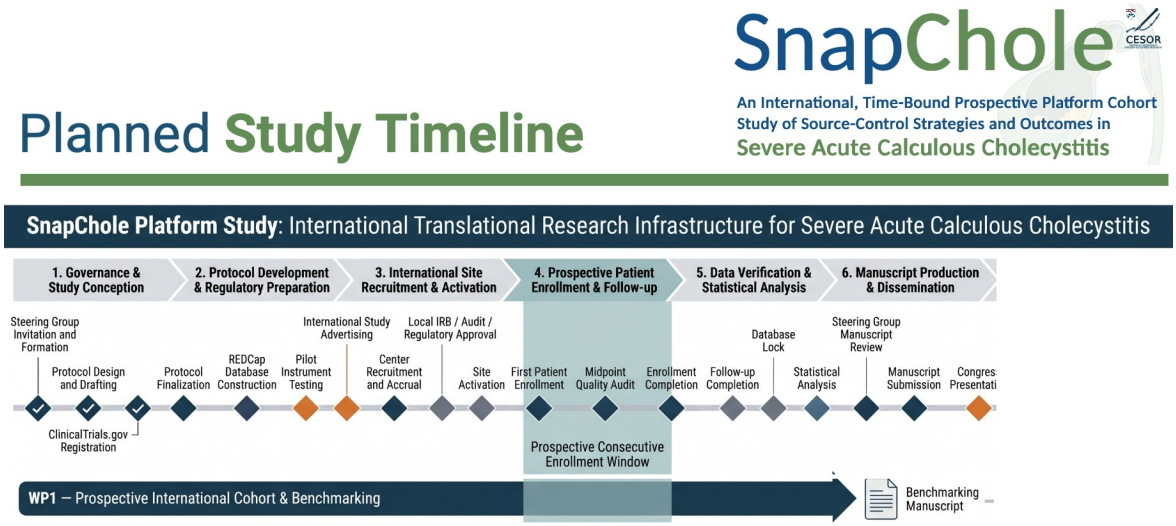


Figure 3. The research infrastructure of the audit is reported, identifying different steps from governance and study description to study dissemination.

Phase	Timeline	Major Activities
Audit Standards and Governance	2026	Finalise standards, audit form, local classification materials and information-governance requirements
Site Onboarding	2026–2027	Local audit registration, service onboarding and staff briefing
Audit Period	2027	Consecutive case identification during 90-day audit periods
Data Reconciliation	2027	Local denominator reconciliation and completeness review
Service Feedback	2027	Confidential audit reports and quality-improvement action planning
Re-audit	Local	Repeat measurement where indicated by local governance

Table 1. Practical steps integrated with a year-based timeline are shown in the table. The end of 2026 will be used to finalize the study infrastructure and launch the project. The latter will happen entirely in the year 2027.

Registered centers will enroll consecutive patients during any 3 months period in a 6-month time window from March 2027 to August 2027, allowing the last follow up window to end in November 2027.

Audit 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 haematological 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 audit. [1,2] All audit standards and 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

Eligible cases will be identified through routine clinical systems, including emergency-department presentations, acute surgical admissions, radiology reports, operating-room schedules and interventional-radiology records. Consecutive case identification is required to preserve the audit denominator. Each participating service will maintain a local audit log documenting eligible cases, inclusion status and reasons for exclusion or non-inclusion. Patient identifiers and local linkage information will remain within the participating service.

Management Pathway Classification and Timing

The first documented attending surgeon-level management plan after confirmation of TG18 Grade II or Grade III acute calculous cholecystitis will be recorded, together with the relevant clinical context and availability of operative, interventional-radiology and endoscopic services. Initial management pathways will be classified as cholecystectomy-first, percutaneous cholecystostomy or drainage-first, or antimicrobial-only management. These categories describe care as delivered and do not represent treatments assigned by the audit. The audit will assess whether the documented pathway and timing meet the applicable pre-specified standard for the patient's TG18 grade and clinical context.

Pathway Transitions and Escalation

Subsequent transitions will be recorded as components of routine care, including escalation from antimicrobial-only management to drainage or surgery, conversion from drainage-first management to cholecystectomy, repeat or rescue intervention, and delayed definitive surgery. These events will be assessed against applicable audit standards and will not be treated as deviations from an assigned treatment strategy. Timing measures will be calculated from routinely recorded clinical time points and will include time to diagnostic confirmation, time to the initial management plan, time to initiation and completion of source control, and time to escalation or reintervention. Exact date-time fields will be used where routinely available and necessary to assess an audit standard; otherwise, pre-specified categorical intervals will be used.

Audit Measures and Outcomes for Work Package 1

The primary audit measures will be the proportions of eligible cases meeting each pre-specified standard for diagnosis, initial management, timing, source-control delivery and escalation.

Secondary audit measures will include the documented initial management pathway, time to source control, escalation, repeat intervention, index and total hospital length of stay, in-hospital mortality and readmission where routinely available without additional patient contact.

When available through existing routine records or administrative data sources, the following outcomes at 90-day will be measured: Days Alive and Out of Hospital (DAOH90), Mortality, Readmission, Reintervention.

Days Alive and Out of Hospital Integrates survival and healthcare utilization and has been validated as a meaningful measure of recovery after acute illness. [14]

Failure of source control will be defined as persistent or recurrent infection requiring escalation of intervention. [15]

Audit Variables and Data Collection

The audit will collect only the minimum variables necessary to determine eligibility, assess compliance with the pre-specified standards and describe relevant service context. These may include age category, TG18 grade, frailty or comorbidity measures, organ dysfunction, physiological and laboratory severity, imaging findings, symptom duration, initial management pathway, timing, escalation and routinely recorded outcomes. Variables will not be collected solely to enable comparative analyses of management pathways. Any additional local variables must be documented before data collection and approved through the relevant local audit and information-governance process. Data will be recorded using a standardized audit form with predefined variable definitions, range of checks and validation rules. Site audit staff will be responsible for data accuracy and completeness. Patient-level records and any local linkage logs will remain under the control of the participating service.

Each participating service will submit only anonymous aggregate audit data, including pre-specified numerators, denominators, and summary outcomes. Names, contact details, dates of birth, NHS or other unique identifiers, coded patient-level records and linkage keys will not be transferred to the coordinating centre. Each site will determine the applicable lawful basis, confidentiality arrangement, retention period and information-governance approvals for local audit activity. Cross-border sharing of aggregate data will only were approved by the relevant institutional data protection and information-governance authorities. A site requiring patient-level data transfer will require separate classification and governance review before proceeding under this audit specification.

Audit Data Analysis

The primary analysis will report counts and proportions of eligible cases meeting each audit standard, overall and by participating service. Results will be reported separately for TG18 Grade II and Grade III disease. Continuous timing and outcome measures will be summarised using appropriate descriptive statistics. Pathway frequencies, timing measures, source-control delivery, escalation and routinely available outcomes will be described by service and TG18 grade. Combined moderate-to-severe results may be reported descriptively where appropriate, but grade-specific results will remain in primary.

Service-Level Audit Feedback

Each participating service will receive a confidential summary of its audit results, including denominators, compliance with each standard and relevant descriptive outcome. Any collaborative report will use anonymous aggregate data, suppress small cells, and avoid ranking services or

presenting comparative treatment-effect estimates. The primary purpose of reporting is to support local clinical-governance review, quality-improvement action, and, where appropriate, re-audit.

Data Quality Assurance and Missing Data Handling

Data completeness will be assessed for eligibility, TG18 severity, initial management pathway, timing, and each primary audit standard. Missing fields and denominator exclusions will be reported by service. Sites may correct source data discrepancies through their ordinary audit-validation processes before local reporting. Data-quality findings will be used to improve the reliability of local audit results and future re-audit.

Audit Governance and Ethical Considerations

SnapChole involves no alteration to patient care, additional patient procedures, study-specific questionnaires, research-only investigations or direct patient contact. Each participating service will obtain written local confirmation of its clinical-audit or service-evaluation of classification and information-governance requirements before data collection begins. Each service will determine whether patient notification, opt-out, consent or another confidentiality arrangement is required under applicable law and institutional policy.

Governance, Contributions and Dissemination

Governance

SnapChole will operate under a collaborative clinical-audit governance model. Each participating service will appoint a local audit lead responsible for local classification, approvals, case identification, data accuracy, completeness and review of findings. A coordinating audit group will maintain the common audit standards, data dictionary, audit form and aggregate reporting template. Data integrity will be supported through consecutive case ascertainment, standardised data collection, predefined validation rules and local denominator reconciliation. Each service will retain responsibility for its patient-level records and any local linkage information. The coordinating audit group will receive only anonymous aggregate data and will not direct clinical care or adjudicate treatment decisions. Audit data will be reviewed for completeness, internal consistency and adherence to the agreed data definitions. Services with incomplete or unreliable audit data may be excluded from the relevant aggregate report. Any exclusion will be documented and communicated to the affected service. Each participating service will determine and document the applicable clinical-audit, information-governance and data-protection requirements before data collection begins. Cross-border sharing will be limited to approved anonymous aggregate data.

Contributions

Contributions to audit-standard development, local audit leadership, case ascertainment, data validation, analysis, clinical-governance review, quality-improvement planning and reporting will be acknowledged according to actual contributions. Any future publication proposing conclusions beyond the audit population, comparative treatment-effect estimates or patient-level analysis will require separate classification and governance review before preparation or submission.

Dissemination

Each participating service will receive a confidential summary of its audit findings for local clinical-governance review, quality-improvement planning and, where appropriate, re-audit. A collaborative aggregate report may be prepared using anonymous service-level data, with suppression of small cells and no ranking of services. External dissemination, where appropriate, will describe audit findings and improvement opportunities without presenting the results as comparative treatment-effect estimates. Patient-level data, linkage keys and directly identifiable information will not be shared under this audit specification.

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