GlobalSurg

NIHR Global Health Research Unit on Global Surgery

Global Evaluation of Cholecystectomy Knowledge and Outcomes

GECKO

An international prospective cohort study on cholecystectomy

Study Protocol v1.1

29th July 2023

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PROJECT TIMELINE

Dates	Description
15th May 2023	Online launch of Gecko protocol
1st Jul 2023	Virtual conference for **GECKO** study launch
00:00 31st Jul – 23:59 13th Aug 2023	Data collection **period 1** (+ 30-day follow-up: ends 12th Sep 2023) (+ one-year follow-up: ends 13th Aug 2024)
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00:00 6th Nov – 23:59 19th Nov 2023	Data collection **period 8** (+ 30-day follow-up: ends 19th Dec 2023) (+ one-year follow-up: ends 19th Nov 2024)
3rd Jan – 5th Mar 2024	Data validation process
6th Mar 2024	Final day submission for 30-day follow-up data
Mid 2024	Results of the short-term outcomes of the **GECKO** study presented
31st Jul – 19th Nov 2024	One-year follow-up period
22nd Dec 2024	REDCap database locked, final day submission for one-year follow-up data
Early 2025	Results of the long-term outcomes of the **GECKO** study presented

STEERING COMMITTEE

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BACKGROUND INFORMATION & RATIONALE

Introduction

Cholecystectomy is amongst the most common surgical operations performed worldwide. Surgical candidates are treated for biliary pathologies, such as biliary cholic, cholecystitis and gallstone pancreatisis [**1,2**]. In patients who are deemed fit for surgery, cholecystectomy can be perfomed under three main settings: (1) emergency setting at index admission; (2) elective setting with no previous admisisons; or (3) delayed setting with one or more previous gallbladder-related admissions [**3**].

The advent of laparoscopy fundementally evolved biliary surgery and quickly became the "gold standard" approach. Recent multicentre collaborative studies [**3,4,5**] have elucidated that the burden imposed on healthcare systems by laparoscopic cholecystectomies is primarily due to patient readmissions and complications arising from the operation, rather than perioperative mortality burden that was more commonly seen in open surgery [**6**]. As a result, national and international societies [**7,8**] have shifted their focus towards creating a culture of safety around this procedure, with the overarching goal of improving patient satisfaction and reducing hospital costs. Gupta et al. [**9**] described safe cholecystectomy as one that is "safe for both the patient (no bile duct/hollow viscus/vascular injury) and for the operating surgeon (no or minimal scope for litigation)". The universal establishment of safe cholecystectomy is a complex process that relies not only on the operation itself, but also on various other factors such as promoting adequate training, improving hospital infrastructure, and enhancing peri-operative patient care.

There remains a paucity of evidence around the variations of safe provision of laparoscopic surgery for gallbladder disease interntionally, including low- and middle-income countries. To bridge this knowledge gap, the **G**lobal **E**valuation of **C**holecystectomy **K**nowledge and **O**utcomes (**GECKO**) study (GlobalSurg 4) will be an international collaborative effort, delivered by the GlobalSurg network [**10**], that will allow contemporaneous data collection on the quality of cholecystectomies using measures covering infrastructure, care processes and outcomes. It will be disseminated via contacts from the National Institute for Health and Care Research (NIHR) Global Surgery unit, leading emergency general surgeons and specialist organisations.

Study Aims

The **primary** aim of this study is to define the global variation in compliance to pre-, intra-, and post-operative audit standards (**see pages 9-10**).

The **secondary** aims of this study are to:

1. To determine the quality of safe provision of cholecystectomy, including the rates of: (i) achieving a critical view of safety; (ii) intraoperative imaging use (e.g., cholangiogram); and (iii) initiating of different bailout procedures (e.g., subtotal cholecystectomy) when safe cholecystectomy is compromised.
2. To assess adverse events following cholecystectomy (e.g., bile duct injury) and their management.
3. To analyse rates and outcomes of unsuspected gallbladder cancer.
4. To evaluate the global variation in the availability of cholecystectomy services and training amongst included hospitals.
5. To assess sustainable practices in laparoscopic cholecystectomy globally.

AUDIT STANDARDS

Pre-operative

1. **Interventional radiology service**: There should be 24-hour access to interventional radiology to support the delivery of an emergency HPB service [**11**].
2. **Risk Stratification**: For patients with acute cholecystitis, surgeons may use the Tokyo Guidelines 18 (TG18) [**8**].
3. **Timing of surgery**: In patients presenting with acute cholecystitis, the optimal timing for cholecystectomy is within 48 hours, and no more than 10 days from symptom appearance [**7**].

Intra-operative

1. **Critical Safety View (CVS)**: The use of the CVS during laparoscopic cholecystectomy (achieving all 3 components – Figure 1) is the recommended approach to correctly identify relevant anatomy and minimize the risk of bile duct injurries [**7,8**]:
    I. **Clearance of the hepatocystic triangle:** The HC triangle should be cleared of all the fibro-fatty and soft areolar tissue.
    II. **Exposure of the lower cystic plate:** The gallbladder should be separated from its liver bed to expose at least the lower third of the cystic plate.
    III. **Only two tubular structures should be seen entering the gallbladder:** the cystic duct and the cystic artery.

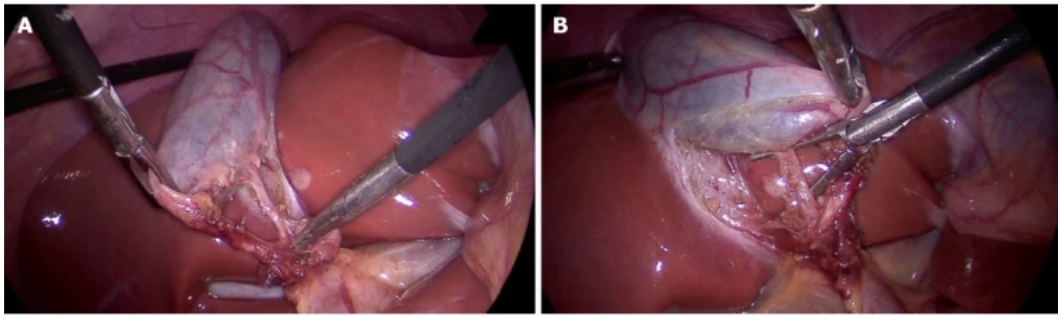

Figure 1: Photographs showing the critical view of safety.

2. **Intraoperative imaging**: in patients with uncertainty of biliary anatomy or suspision of bile duct injury, intraoperative imaging (e.g. cholangiogram, laparoscopic ultrasound and incisionless cholangiography with fluorescence) may help delineate relevant anatomy, detect bile duct stones, and decrease the risk of bile duct injury [**7,8,12**].
3. **Bailout Procedures**: When CVS cannot be achieved and the biliary anatomy cannot be clearly defined by other methods (e.g. imaging) during laparoscopic cholecystectomy, surgeons should

consider a bailout procedure (e.g. subtotal cholecystectomy or total cholecystectomy by the fundus-first (top down) approach) [**7**].

4. **Antibiotic use**: Antibiotics are not required in low risk patients undergoing laparoscopic cholecystectomy, but may reduce the incidence of wound infection in high risk patients (age > 60 years, the presence of diabetes, acute colic within 30 days of operation, jaundice, acute cholecystitis, or cholangitis) [**12**].
5. **Use of drains**: drains are not needed after elective laparoscopic cholecystectomy and their use may increase complication rates; however, they may be useful in complicated cases particularly if choledochotomy is performed [**12**].
6. **Bile Duct Injury (BDI)**:
    a. If major BDI occur, outcomes are improved by early recognition and immediate referral to experienced hepatobiliary specialists for further treatment before any repair is attempted by the primary surgeon, unless the primary surgeon has significant experience in biliary reconstruction [**7,8,12**].
    b. If considering all types of BDIs, rates are 0.4% and 0.8% for elective and emergency settings, respectively [**7**].
    c. It is recommend knowing Strasberg's classification, which remains the most commonly used classification for BDIs [**7**].

Post-operative

1. **30-day readmission**: rate should be <10% [**11**].
2. **Critical care**: There should be access to critical care beds (both level 2 and level 3) with on-site renal support [**11**].

OVERVIEW OF STUDY DESIGN

GECKO is a prospective, international, multicentre, observational cohort study delivered by GlobalSurg Collaborative. This will be on consecutive patients undergoing cholecystectomy, between 31st July 2023 to 19th November 2023, with follow-up at 30-day and one-year postoperatively. Mini-teams of up to five collaborators (**see page 17**) per 14-day data collection period will prospectively collect data at each participating centre.

GLOBALSURG COLLABORATIVE

GlobalSurg (http://globalsurg.org/) is a collaboration between practising surgeons from around the world, performing research in surgery to foster local, national and international research networks. The collaborative model used has previously been described elsewhere [**13**] and has already facilitated three multicentre, international, prospective cohort studies including a total of 46,186 patients undergoing emergency and elective abdominal surgery [**14-16**]. The NIHR Unit on Global Surgery was established in 2017 and is a consortium between the Universities of Birmingham, Edinburgh and Warwick, together with international partners. The unit's objective is to advance the education of medical students and doctors in surgical science, clinical research and audit methods by promoting participation in collaborative clinical research and audit studies.

STUDY SETTING

The study is open to any hospital worldwide that performs emergency and/or elective cholecystectomy. An eligible hospital must collect consecutive patients undergoing cholecystectomy during the specified study period, following appropriate registration of the study according to local hospital regulations.

Included centres should ensure data collection is >90% complete. Centres with >10% missing data, when including all data points, will be excluded from the final analysis and removed from the authorship. There is no minimum number of patients per centre, as long as all eligible patients treated during the study period are included.

STUDY POPULATION

Summary

The study population includes consecutive patients, admitted to hospital within the pre-specified data collection periods, undergoing cholecystectomy as the index operation.

Inclusion Criteria

- **Age**: All adult patients (greater than or including 18 years of age).
- **Procedure**: Primary cholecystectomy, where this is the main procedure planned.
- **Approach**: Open, laparoscopic (standard and single-port), and robotic. Gasless laparoscopic and robotic approaches are inluded. Laparoscopic and robot converted cases are also eligible.
- **Urgency**: Elective, delayed and emergency procedures.

Exclusion Criteria

- **Procedure**: Patients having a cholecystectomy as a part of another surgical procedure; for example, Whipple's procedure, bariatric, anti-reflux, or transplant operations, should be excluded.
- **Indication**: Patients with Mirizzi syndrome should be excluded.
- **Return to theatre**: Each patient should only be entered into the study once. Any patient returning to theatre and requiring a cholecystectomy for whatever indication, should not be included.
- **Known gallbladder malignancy**: when the diagnosis of gallbladder cancer is established pre-operatively, the patient should be excluded. However, if gallbladder cancer is found unexpectedly during or after cholecystectomy (i.e. on histology), the patient should be included.

STUDY PROCEDURES

Site Survey

In order to describe local processes and resources, each site will be asked to complete an online site survey questionnaire to delineate the variation of cholecystectomy services and training amongst included hospitals (**Appendix C**).

> *Completion of the short site survey can be done by a supervising consultant (preferred) or a hospital lead trainee that is familiar with the cholecystectomy practices at your site. Completion of the site survey is necessary before the site is granted access to the online **GECKO**: Data Collection form.*

Data Collection

Collaborators will collect data on consecutive eligible patient undergoing cholecystectomy within the pre-specified data collection periods (**Table 1; page 15**). Data collectors should use a combination of the **GECKO** Case Report Form (**Appendix A**) alongside the Data Dictionary (**Appendix B**) to successfully record required data on all eligible patients. Collaborators will create clear mechanisms appropriate to their institution to identify and include all eligible patients, involving daily review of operating logbooks, multidisciplinary team meeting, admission and handover lists. Local arrangements may include daily review of the patient and notes focused on included data points.

Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application (**see pages 20-21**), hosted and managed by the University of Edinburgh, United Kingdom. No patient identifiable data will be uploaded or stored on the REDCap database.

Strategies to identify consecutive eligible patients could include:

- *Daily review of elective theatre lists.*
- *Daily review of handover sheets/emergency admission and ward lists.*
- *Daily review of theatre logbooks (both elective and emergency).*

Follow-up Period

Centres will undertake patient follow-up at two timepoints:

1. **30-day follow-up**: should be performed for all recruited patients. Each patient will be followed-up for 30 days starting on the day of surgery (day 0).

2. **One-year follow-up**: due to the nature of the study, aiming to assess bile duct injury and unsuspected gallbladder cancers, we aim to collect one-year follow-up data on all recruited patients. Each patient will be followed-up for one year starting on the day of surgery (day 0). Patients are excluded from one-year follow-up if they had died within 30 days of index surgery, as there would be no additional data to collect from these patients since the 30-day follow-up that had already been completed previously. Additional collaborators can be recruited to to aid one-year follow-up data collection once the follow-up period begins (31st Jul 2024).

Local arrangements forsuccessful 30-day and one-year follow-up may include: reviewing patient notes, reviewing patient status in outpatient clinics or via telephone interview at 30 days (if this is normal practice) and checking for readmission through handover lists. Follow-up should be performed in line with current routine practices of each hospital. No additional telephone, in-person or questionnaire-based follow-up is required. Source data may be acquired from hospital in-patient notes, clinical electronic systems, or outpatient letters.

Key to successful 1-year follow-up:

1. *Ensure you keep a list of all patient ID and corresponding RedCap ID in a safe, secure computer to allow follow-up of these patients. This will be in the form of an encrypted spreadsheet held securely on the local hospital computer network by a member of the data collection team (a hospital lead, supervising consultant/attending, or audit officer).*
2. *Where it is anticipated that a hospital lead will rotate to another hospital, then the supervising consultant should facilitate the secure storage of patient ID and corresponding RedCap ID.*
3. *Ensure the audit office / local governing bodies are clear this will be a follow-up study.*
4. *In high-volume centres where achieving high data completeness may be burdensome, involvement additional team members to provide support can be permitted.*

Table 1: Data collection periods

Dates	Description
00:00 31st July – 23:59 13th Aug 2023	Start of data collection **period 1** (+ 30-day follow-up: ends 12th Sep 2023) (+ one-year follow-up: ends 13th Aug 2024)
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QUALITY ASSURANCE

Project Design

To ensure high data quality, this protocol was written with guidance from an expert cross-speciality advisory group and published online. Protocol translations into multiple common languages will be performed to ease collaborator understanding.

Patient and Public Involvement

The relevance of these research topics was discussed with patients who have had gallstone disease. All these topics were thought to be important and relevant to patients. We will involve patient liaison throughout the study and will produce patient facing materials after analysing the data.

Training

Countries with multiple sites will be assigned a national lead, who will be responsible for coordinating multiple teams across sites to ensure duplication of data does not occur. **GECKO** national leads are encouraged to hold any local meetings with collaborating teams to ensure they are up to date on the protocol as well as to feedback any local issues or questions raised to the central management team.

Data Validation

The present collaborative methodology has been widely validated across multiple data sets, both nationally in the UK and Ireland, and internationally, demonstrating high levels of case ascertainment, typically greater than 90% and data accuracy greater than 95% [**16**]. Therefore, validation of the data is very important to this cohort study.

Validation by primary data collection teams:

- Follow-up methodology at patient level: all hospitals will self-report the methods used to determine 30-day outcomes.
- Patient identification methodology: all hospitals will self-report the methods used to identify patients who fulfil the inclusion criteria.

Validation by independent teams:

- Case ascertainment: hospital records will be reviewed to identify patients fulfilling the inclusion criteria within a 2-week data collection period and comparing this to the actual number of cases submitted. This will be performed by individuals not involved in collecting the primary data. By comparing samples, a quantitative estimate of case ascertainment will be produced by the central data team.
- Data accuracy: a subset of collected variables will be validated by individuals who are independent of the primary data collection process. Following the "case ascertainment" stage, validators will be asked to provide data for a subset of variables, two patient variables, two operation variables, and two outcome measures.

Project Team Structure

Each registered centre must have a supervising consultant/attending to ensure adequate data quality. In the case that the hospital lead is a registrar/resident then they must recruit a consultant/attending to superise the study. The hospital lead should also ensure that they recruit independent data validators (registrars/residents or consultants/attendings) to perform the data validation outlined in the section above.

For data collection, the hospital lead should recruit a "mini-team" of up to five local collaborators for each data collection period (**Table 1; page 15**). Medical students, doctors (non registrars/residents or consultants/attendings) and nurses can act as local collaborators and their participation is encouraged. The same "mini-team" can cover different time periods at each hospital if they wish to. Each team should include at least one qualified doctor to provide additional local support for participating medical students or nurses. Additional collaborators can be recruited to to aid one-year follow-up data collection once the follow-up period begins (31st Jul 2024). A detailed specification of each role can be found below (see **pages 23-24**).

STATISTICAL CONSIDERATIONS

Primary Outcome Measure

The primary endpoint of this study is the compliance to pre-, intra-, and post-operative audit standards (see pages 9-10).

Secondary Outcome Measures

The secondary endpoints include:

- Rates of achieving a critical view of safety.
- Rates of different bailout procedures initiated when safe cholecystectomy is compromised.
- 30-day and one-year rates of textbook outcomes [**2**] for cholecystectomy, which covers: postoperative complications (Clavien-Dindo classification), intraoperative complications (including bile duct and vascular injuries), length of stay, readmission, mortality, and postoperative imaging or intervention.
- Unsuspected gallbladder cancer rates and their 30-day and one-year outcome rates, which includes: (1) complication rates (Clavien-Dindo classification); (2) time-to-recurrence rates (time from surgery to recurrence); and (2) revisional surgery rates (liver resection, bile duct resection and/or lymph node dissection).
- A description of the global variation in the availability of cholecystectomy services, training and sustainable practice.

Control of Bias and Confounding

Data will be collected on audit standards and confounding factors for risk-adjusted analyses. These include age, sex, body mass index, American Society of Anaesthesiologists (ASA) grade, and relevant comorbidities. Variables including operative urgency, operative contamination, and operative approach will also be collected. Without appropriately adjusting for risk factors, it is likely that any findings would be biased and unable to be appropriately analysed on an internnational scale. A full list of required data fields is available in **Appendix B**, and on the REDCap database.

Data Analysis & Sample Size

Variation across different international health settings will be tested using the human development index (HDI) countries [**17**] a composite statistic of life expectancy, education and income indices published by the United Nations. Initially, data will be reported using descriptive analyses. Comparisons between groups will be undertaken using appropriate parametric and non-parametric analyses. Multilevel logistic regression multivariate models will be constructed to account for case mix, with population stratification by hospital and country as random effects.

Further prespecified subgroup analyses will be made by operative approach (open, laparoscopic and converted), and operative urgency (elective, emergency and delayed surgery). Audit standards (**see pages 9-10**) and site survey (**Appendix C**) will guide exploratory analysis into the global variation in the provision of cholecystectomy and available resources. However, it is acknowledged that some audit standards are designed for high-income settings and therefore their attainment will not be considered mandatory or a potential definitive measure of quality in global cholecystectomy.

Identification of hospital or surgeon-specific performance will not be reported. Following analysis, results will be fed back to participants at the centre level, but no other centres will be identifiable.

Based on previous GlobalSurg studies [**14-16**], **GECKO** is anticipated to include around 500 centres globally. With consideration to recent figures provided by previous collaborative studies [**3,5**] on cholecystectomy, a sample of approximately 15000 patients is anticipated. The recent multi-society practice guidelines on prevention of bile duct injury [**8**] advised that a study adequately powered to detect and report on bile duct injury would require at least 9000 patients.

DATA GOVERNANCE

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application [**18**]. REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing safe anonymised data storage on the REDCap database. The service is managed by the Global Surgery REDCap system hosted by the University of Edinburgh, United Kingdom. The security of the study database system is governed by the policies of the University of Edinburgh. These include best practices such as network firewalls, system and security monitoring and two factor authentication. RECap access privileges will be managed and maintained by the NIHR Unit on Global Surgery to ensure that users can only access data relevant to their site. That is, data from one site cannot be viewed by data collectors from a different site, local data will only be accessible to local collaborators and the data analysis team. Collaborator access will be limited to their site only. Personnel handling data collection are professional medical students and health staff (consultants and doctors on site). **There is no new data collected directly from patients; data from routine practice will be collected.** A named consultant or attending will ensure data completeness and accuracy, and data collection will be completed by a team of local surgical trainees or medical students working at that hospital.

We have created a data dictionary (**Appendix B**) prior to the start of data collection which includes only fields that would be necessary to analysis. Collaborators can either enter data directly onto REDCap or use paper case report forms (**Appendix A**), although the former is encouraged. Collaborators are required to leave any papers with personal information in a designated safe storage space (a locked room or cabinet) while not using them.

Patient-identifiable information items will be minimised to age and sex. No identifiable information is essential for the specified purpose of this study. However, sex and age will be used to identify the overall demographics of the study population and an essential pre-requisite to meaningful analysis of our data. These data points present negligible risks of inadvertent patient identification.

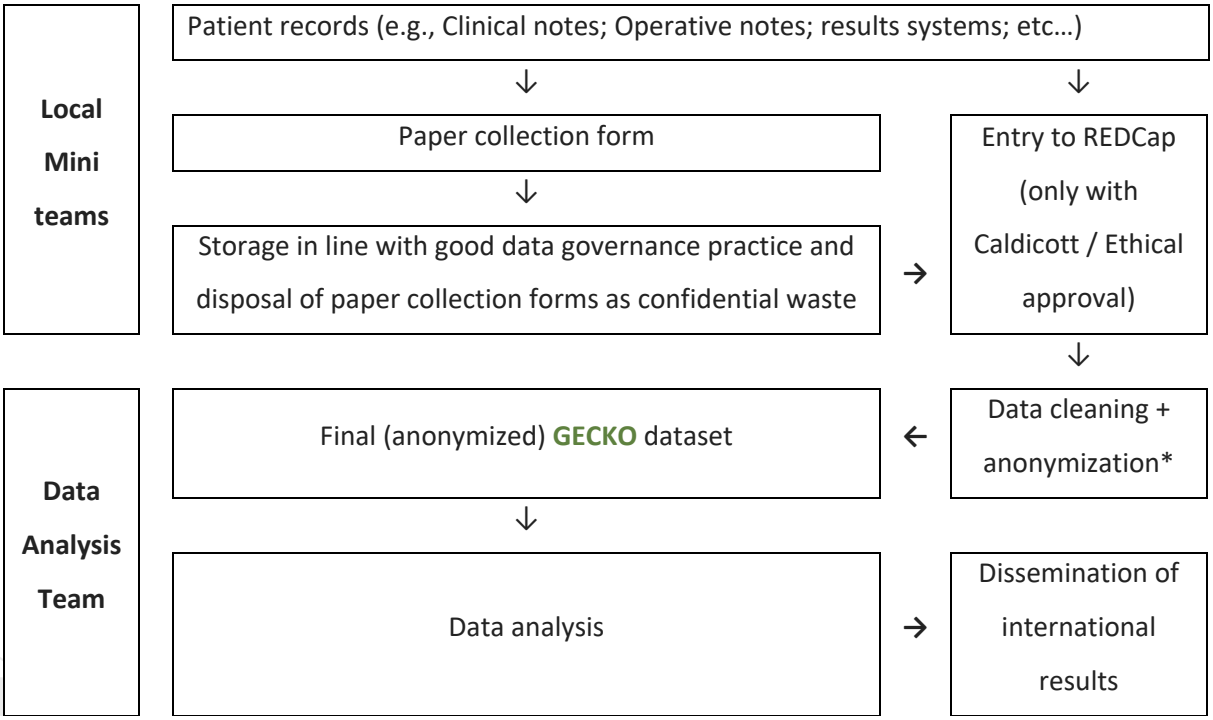
Collaborators will be given individual, unique, secure login details with a password to the REDCap project server before the start of the project. Passwords are stored as an encrypted one-way hash of the password. Users are auto logged out after 30 mins of no activity. Access will be revoked once data collection and follow-up is complete. All transmission and storage of web-based information by this online system is encrypted and was designed to be compliant with HIPAA-Security Guidelines [**18**]. Any

patient identifiable information stored by collaborators will not be available for data-analysis and are automatically stripped. Logins will only be issued on confirmation of local study registration, and no patient data can be uploaded or stored on the REDCap database until this is fulfilled. All data must be handled in accordance with local data governance policies and paper copies of any data should be destroyed as confidential waste. All data will be anonymized at the point of analysis, with identifiable data collected (gender and age) only used to provide a summary of the demographics of the cohort studied. There will be no data published at the level of the patient, surgeon, or hospital, preventing patients from being identified. The anonymization process includes:

1. The full dataset will be evaluated against the eligibility criteria, and any ineligible procedures excluded.
2. The REDCap record ID will be stripped from the dataset (the only linkage between any locally stored lists of patient records).

Hospital related variables: separate variables will be collected via an online questionnaire describing each hospital's local policies, facilities, and procedures. This will be distributed to the hospital lead at the start of the study.

The data flow is summarised in the diagram below:



*Performed on secure University of Edinburgh servers as described

LOCAL PROJECT REGISTRATION

In all centres, if the option is available, this project may be registered as clinical audit or service evaluation. Alternatively, it may be necessary to obtain formal ethical approval. It is the responsibility of the local hospital lead at each site to ensure that the study is registered appropriately, according to local regulations. When registering **GECKO** as a clinical audit you can emphasis that:

- **GECKO** is an international audit, and all data collected will measure current practice.
- No changes to normal patient pathways/treatment will be made.
- All **GECKO** data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap database.

All data should be handled in accordance with national and local data governance policies. For instance, collaborators in the UK should seek their trust's Caldicott Guardian's permission to submit data to the REDCap system. **No data should be uploaded to REDCap prior to written approval from the Caldicott Guardian or ethical board**. No patient identifiable information should be uploaded or stored on the REDCap database without explicit permission from the trust's Caldicott Guardian. In other countries, no data should be uploaded to REDcap without local governance authorisation.

AUTHORSHIP

All authors will be credited in accordance with National Research Collaborative Authorship guidelines, and research outputs from **GECKO** will be listed under a single corporate authorship of GlobalSurg Collaborative, NIHR Global Surgery Unit [**16,19,20**].

Requirements for authorship on **GECKO** outputs include:

- Successful in obtaining all relevant local approvals for conduct of the **GECKO** study.
- Have completed the site survey.
- Successful data collection of at least one eligible patient per period for each site.
- Individual sites must also ensure:
    - A complete data set (>95% data points entered per record).
    - High case ascertainment (>90%, **see pages 16-17**).
    - All data has been uploaded by the specified database closure deadline.

All collaborators will be listed as PubMed-citable collaborators in accordance with the roles defined below (so long as the minimum requirements for authorship are met):

- **Writing Group:** A group of medical students, doctors and external advisory board members responsible for the overall scientific content, data analysis, and preparation of research manuscripts.
- **Steering Committee**: A core group of medical students and doctors who have overall responsibility for protocol design, project co-ordination, and data handling.
- **External Advisory Group:** A panel of international, cross-disciplinary field experts who are able to ensure contextual and scientific relevance of the protocol design, data fields and data interpretation.
- **Statistical Analysis**: A small team of dedicated statisticians who take overall responsibility for the statistical analysis plan and quality assurance of data analysis.

- **National Leads:** A network of surgeons established with previous Global Surgery studies who are responsible for the national coordination of the study, acting as a link between mini-teams, hospital leads, and the steering committee.

- **Supervising Specialist Consultant** (if the hospital lead is not a consultant)**:** if the hospital lead is not a consultant/attending, a supervising specialised consultant will be recruited by the hospital lead. The responsibilities of this role are to ensure that local guidelines are adhered to by all members of the mini-team and to ensure that any incidental findings made during the course of the data collection process are communicated to the treating gallbladder surgeon according to local hospital policy.

- **Hospital Leads**: Single lead point of contact for data collection at each site. Usually this is a consultant or attending, but can be a specialist registrar/resident. The Hospital Lead will have the overall responsibility for site governance registration and coordination of the local team. Only one person can fill this role. The supervising consultant(s) will have to oversee validity (as defined above) by ensuring a complete, accurate dataset is returned. Units which fail to submit data, or withdraws participation, will be excluded from the authorship list. If substantially incomplete data is submitted the writing committee may decide to exclude that unit from further analysis

- **Local Collaborators:** A team of up to 5 people responsible for data collection per specialty group over the defined data collection period. In any centre, the team should ideally be formed of a heterogeneous group with different levels of clinical training. Each collaborating team should participate in the creation of the local system, registering the audit, identifying patients, collecting data, and completing follow-up. Additional collaborators can be recruited to to aid one-year follow-up data collection once the follow-up period begins (31st Jul 2024).

- **Independent data validators:** A resgistrar/resident or a consultant/attending not involved with data collection whose role is to ensure adequate data ascertainment and data collection accuracy (**see pages 16-17**). The validator will be assigned to a 2-week data collection period at their local centre to validate. Data validation will occur following completion of data collection (including follow-up). After completing validation, the validator will send a summary of how many records were reviewed and error rates to the study management group.

APPENDIX A: CASE REPORT FORM (CRF)

GECKO Case Report Form (CRF)

Use with Appendix B (Data Dictionary) to help data collection.

REDCap unique ID	
Data collection period	

Section 1: Pre-operative data fields

Age		**Sex**	◻ M ◻ F	**ASA**	◻ I ◻ II ◻ III ◻ IV ◻ V	**BMI**	_ _
Frailty	◻ 1 ◻ 2 ◻ 3 ◻ 4 ◻ 5 ◻ 6 ◻ 7 ◻ 8 ◻ 9						

Comorbidities (Tick all that apply)	◻ MI ◻ CHF ◻ PVD ◻ CVA/TIA ◻ Dementia ◻ COPD ◻ CTD ◻ PUD ◻ Hemiplegia ◻ Leukaemia ◻ Lymphoma ◻ HIV/AIDS ◻ Hypertension ◻ IBD	**History of acute cholecystitis or cholangitis**	◻ Yes ◻ No
	Diabetes mellitus: ◻ Diet-controlled ◻ Non-insulin ◻ Insulin controlled		
	Solid tumour: ◻ Localised ◻ Metastatic		
	Liver disease: ◻ Mild ◻ Moderate to Severe	**Number of admissions with biliary symptoms in previous 12 months prior to surgery**	_ _
	CKD: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IV ◻ V		
	◻ None of the Above		
Preoperative imaging (Tick all that apply)	**USS**: ◻ Yes ◻ No - not available ◻ No - not indicated ◻ No - patient declined ◻ Unknown **CT**: ◻ Yes ◻ No: not available ◻ No: not indicated ◻ No: patient declined ◻ Unknown **MRCP**: ◻ Yes ◻ No: not available ◻ No: not indicated ◻ No: patient declined ◻ Unknown **ERCP**: ◻ Yes ◻ No: not available ◻ No: not indicated ◻ No: patient declined ◻ Unknown **EUS**: ◻ Yes ◻ No: not available ◻ No: not indicated ◻ No: patient declined ◻ Unknown **HIDA**: ◻ Yes ◻ No: not available ◻ No: not indicated ◻ No: patient declined ◻ Unknown		
Imaging findings	◻ Gallstones ◻ Thick-walled gallbladder ◻ Pericholecystic fluid ◻ CBD stones ◻ Dilated CBD (**Diameter**: _ _ . _ mm (1dp))		
Days between	**First symptom onset and admission**: _ _ _ **Diagnosis and decision to operate**: _ _ _ **Decision to operate and surgery**: _ _ _	**Urgency of surgery**	◻ Elective ◻ Delayed ◻ Emergency (**patient was on elective waiting list?** ◻ Yes ◻ No)
Indication for surgery	◻ Acute calculous cholecystitis (**Tokyo grade**: ◻ I ◻ II ◻ III; **Was Tokyo grade documented in notes**: ◻ Yes ◻ No) ◻ Biliary colic ◻ Acalculous cholecystitis ◻ Chronic cholecystitis ◻ CBD stone ◻ Polyp ◻ Dyskinesia ◻ Gallstone pancreatitis (**Atlanta criteria**: ◻ Mild ◻ Mod ◻ Severe; **Was Atlanta criteria documented in notes**: ◻ Yes ◻ No)		

Section 2: Intraoperative data fields

Mode of anaesthesia (Tick all that apply)	◻ Local (**Route**: ◻ Subcutaneous ◻ Intraperitoneal) ◻ Regional (**Route**: ◻ spine-related ◻ regional nerve block) ◻ Sedation ◻ General inhaled (**Type**: ◻ sevoflurane ◻ halothane ◻ desflurane ◻ N2O ◻ isoflurane) ◻ Total Intravenous Volatile Anaesthetic	**Intraoperative antibiotics**	◻ Yes - Prophylactic ◻ Yes – Intra-op spillage ◻ Yes – cholecystitis ◻ No
Primary operator	◻ Consultant or attending (**Specialty**: ◻ General ◻ OG ◻ HPB ◻ Colorectal ◻ Breast ◻ Vascular ◻ Other:) ◻ Surgical trainee (**Grade**: ◻ Senior ◻ Junior; **Training operation?** ◻ Yes ◻ No; **Consultant present?** ◻ Yes ◻ No) ◻ Non-surgeon **Number of cholecystectomies performed by primary surgeon prior to this procedure**: ◻ 0-50 ◻ 51-100 ◻ 101-200 ◻ >200		
Operative approach	◻ Open (**Why?** ◻ No laparoscopy ◻ Surgeon not trained in laparoscopy ◻ Laparoscopy broken ◻ Previous surgeries ◻ Disease severity) ◻ Open conversion (**Why?** ◻ Suboptimal view ◻ Adhesions ◻ Unable to safely dissect CVS ◻ Suspected BDI ◻ Pneumoperitoneum not tolerated ◻ Bleeding ◻ Bowel injury ◻ Equipment failure ◻ Suspected or actual cholecystoduodenal or cholecystocolonic fistula ◻ Laparoscopic (**Type**: ◻ Standard ◻ SILS; **Gasless?** ◻ Yes ◻ No; **Reusable equipment**: ◻ Yes ◻ No) ◻ Robotic (**Type**: ◻ Standard ◻ SILS; **Gasless?** ◻ Yes ◻ No; **Reusable equipment**: ◻ Yes ◻ No)		

Intraoperative difficulty (Nassar) – for minimally invasive technique	◻ I ◻ II ◻ III ◻ IV ◻ V	**CVS obtained successfully? – for minimally invasive technique**	◻ Yes ◻ No **If No, which criteria was met?** (Tick all that apply) ◻ Clearance of the hepatocystic triangle ◻ Exposure of the lower cystic plate ◻ Only two structures are attached to the gallbladder ◻ None of the above	**Was there a time-out to verify CVS?**	◻ Yes ◻ No

Operation performed	◻ Total cholecystectomy (**Type**: ◻ Standard ◻ Fundus-first approach) ◻ Subtotal cholecystectomy (**Type**: ◻ Reconstituting ◻ Fenestrated) ◻ Not performed (◻ Diagnostic laparoscopy ◻ Cholecystostomy)	**Abdominal drain**	◻ Yes ◻ No	**Anatomical biliary variant**	◻ Yes ◻ No
Intraoperative CBD assessment (Tick all that apply)	◻ Intraoperative cholangiogram ◻ Incisionless fluorescent cholangiography ◻ Laparoscopic US ◻ Intraoperative ERCP **Decision**: ◻ Selective ◻ Routine; **If selective, indication:** ◻ Raised LFT ◻ BDI concern ◻ Pre-op imaging suggests CBD stone **Findings**: ◻ Stone ◻ No stone; **If stone, management**: ◻ Flushing with saline and smooth muscle relaxant ◻ Fogarty catheter trawl ◻ Basket retrieval ◻ Choledocholescope ◻ No intraoperative treatment attempted				
CBD exploration	◻ Yes (**Type**: ◻ Trancystic ◻ Choledochotomy; **If Choledochotomy, closure**: ◻ Primary closure ◻ T-tube) ◻ No	**Operative contamination**	◻ Clean ◻ Clean-Contaminated ◻ Contaminated ◻ Dirty		
Intraoperative complications – *excluding BDI* (see section 4)	◻ Bile spilt ◻ Stones Spilt ◻ Bleeding ◻ Major vascular injury ◻ Bowel injury	**Reusable gowns**	◻ Yes (◻ All staff ◻ some staff) ◻ No	**Reusable drapes**	◻ Yes ◻ No

Section 3: 30-day outcomes

Highest 30-day Clavien-Dindo (CD)	◻ 0 ◻ I ◻ II ◻ IIIa (**Radiological drainage?** ◻ Yes ◻ No) ◻ IIIb (**Re-operation?** ◻ Yes ◻ No) ◻ IVa ◻ IVb ◻ V (**Postop day of death**: _ _)	**Unplanned critical care admission**	◻ Yes (**Length of stay**: _ _) ◻ No	**Unplanned Re-imaging**	◻ Yes (**Type**: ◻ USS ◻ CT ◻ MRI ◻ ERCP) ◻ No
30-day postoperative Complications (Tick all that apply)	◻ Surgical site infection (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Pulmonary complications (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Bile leak (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Bleeding (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Intra-abdominal collection (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Acute pancreatitis (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V)				
Length of stay	_ _ **days**	**Unplanned 30-day Readmission**	◻ Yes (**Length of stay**: _ _) ◻ No		

Section 4: BDI data fields						
BDI identified at 30-day follow-up of index cholecystectomy	◻ Yes (if yes, please fill in the rest of the data points below) ◻ No (**Was BDI identified at one-year of index cholecystectomy**: ◻ Yes ◻ No (if yes, please fill in the rest of the data points below)					
Presentation of BDI	◻ Intraoperatively ◻ Controlled bile leak from abdominal drain ◻ Abdominal pain due to uncontrolled bile leak ◻ Obstructive jaundice or cholangitis ◻ Intra-abdominal abscess or biloma			**Days from index cholecystectomy to diagnosis (0 = intraoperatively)**	_ _	
BDI grade (Strasberg)	◻ A ◻ B ◻ C ◻ D ◻ E1 ◻ E2 ◻ E3 ◻ E4 ◻ E5	**Concomitant vascular injury**	◻ Yes (◻ Right hepatic artery ◻ Common hepatic artery ◻ Main portal vein ◻ Right portal vein) ◻ No			
Imaging modality to investigate and confirm BDI	◻ OTC ◻ USS ◻ MRCP ◻ CT ◻ ERCP ◻ PTC ◻ Nuclear medicine scan ◻ Tubogram ◻ None			**Discussion with specialist HPB centre**	◻ Yes (**Days from injury to referral**: _ _ ; **Transferred?** ◻ Yes ◻ No) ◻ No ◻ Not required - Injury occurred at specialist HPB centre	
Management of BDI (Tick all that apply)	◻ ERCP alone (**Days after index cholecystectomy**: _ _) ◻ ERCP and stent (**Days after index cholecystectomy**: _ _) ◻ PTC (**Days after index cholecystectomy**: _ _) ◻ Washout only (**Days after index cholecystectomy**: _ _) ◻ Surgical repair (**Days after index cholecystectomy**: _ _)					
Specialty of surgeon performing BDI repair	◻ HPB surgeon ◻ UGI surgeon ◻ General surgeon	**Method of repair**	◻ Roux-en-Y Hepaticojejunostomy ◻ CBD repair without T-tube ◻ CBD repair with T-tube ◻ CBD end to end anastomosis ◻ Hepaticoduodenostomy	**Vascular repair**	◻ Yes ◻ No	If BDI surgical repair
One-year complications (Tick all that apply)	◻ Stricture formation (**Days from repair to complication**: _ _) ◻ Cholangitis (**Days from repair to complication**: _ _) Anastomotic leakage (**Days from repair to complication**: _ _) ◻ Intra-abdominal abscess or biloma (**Days from repair to complication**: _ _) ◻ Re-repair (**Days from repair to complication**: _ _)					If BDI surgical repair
Section 5: Histology data fields						
Postoperative histology	◻ Not sent for examination ◻ Sent for examination (**Indication**: ◻ Routine ◻ Selective; **Days from index cholecystectomy to histology result**: _ _ ; **Result**: ◻ Benign ◻ Malignant (if malignant, please fill in the rest of the data points below)					
Staging investigations after index cholecystectomy	◻ CT thorax abdomen pelvis (**Days from histology result to staging**: _ _) ◻ MRI liver (**Days from histology result to staging**: _ _) ◻ PET-CT (**Days from histology result to staging**: _ _) ◻ Staging laparoscopy (**Days from histology result to staging**: _ _)					
TNM grade (AJCC 8th edition)	**T category**: ◻ Tis ◻ T1a (lamina propria) ◻ T1b (muscularis) ◻ T2a (peritoneal side) ◻ T2b (hepatic side) ◻ T3 ◻ T4 **N category**: ◻ N0 ◻ N1 (1-3 nodes) ◻ N2 (>3 nodes) **M category**: ◻ M0 ◻ M1					
Discussed at MDT	◻ Yes ◻ No	**Adjuvant treatment**	◻ Chemotherapy ◻ Radiotherapy ◻ None			
Revisional surgery	◻ Yes ◻ No – not required ◻ No – unresectable tumour					
Type of revisional surgery (Tick all that apply)	◻ Liver resection (**Extent**: ◻ Liver bed ◻ 1 segment ◻ 2 segments ◻ ≥3 segments) ◻ Bile duct resection ◻ Lymph node dissection			**Days from histology result to revisional surgery**	_ _	If revisional surgery
Pathology results	**Resection margin status**: ◻ R0 ◻ R1 ◻ R2 **Lymphovascular invasion**: ◻ Yes ◻ No **Perineural invasion**: ◻ Yes ◻ No					If revisional surgery
Recurrence on imaging at one year	◻ Yes (**Days from surgery to recurrence**: _ _) ◻ No					
Section 6: One-year outcomes						
Highest one-year Clavien-Dindo (CD)	◻ 0 ◻ I ◻ II ◻ IIIa (**Radiological drainage?** ◻ Yes ◻ No) ◻ IIIb (**Re-operation?** ◻ Yes ◻ No) ◻ IVa ◻ IVb ◻ V (**Postop day of death**: _ _)			**Total number of readmissions**	_ _	
One-year complications (Tick all that apply)	◻ Surgical site infection (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Pulmonary complications (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Bile leak (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Biliary stricture (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Bleeding (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Intra-abdominal collection (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V) ◻ Acute pancreatitis (**CD Grade**: ◻ I ◻ II ◻ IIIa ◻ IIIb ◻ IVa ◻ IVb ◻ V)					

APPENDIX B: DATA DICTIONARY

Pre-operative Data Fields	Required data (definition / comment)
1. **Patient age**	**Years** (Whole years at the time of operation)
2. **Patient sex at birth**	**Male** / **Female**
3. **ASA grade**	**I / II / III / IV / V** (**Appendix D** for definitions)
4. **Body Mass Index (BMI in kg/m²)**	**Underweight BMI Below 18.5 / Normal weight BMI 18.5-24.9 / Pre-obesity BMI 25.0-29.9 / Obesity class I BMI 30.0-34.9 / Obesity class II BMI 35.0-39.9 / Obesity class III BMI 40+**
5. **Clinical Frailty Scale**	**1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9** (**Appendix D** for definitions)
6. **Comorbidities** (Select all that apply)	**Myocardial Infraction (MI) / Congestive Heart Failure (CHF) / Peripheral Vascular Disease (PVD)** **Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) / Dementia /** **Chronic Obstructive Pulmonary Disease (COPD) / Connective Tissue Disease (CTD)** **Peptic Ulcer Disease (PUD) / Hemiplegia / Leukaemia / Lymphoma /** **Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS) /** **Hypertension / Inflammatory Bowel Disease (IBD) /** **Diabetes Mellitus** (Type 1 or Type 2). If yes: Diet-Controlled / Medication (non-insulin) controlled / Insulin-controlled **Solid Tumour.** If yes: Localised / Metastatic **Liver Disease.** If yes: Mild / Moderate to Severe **Chronic Kidney Disease (CKD).** If yes: Stage I / II / IIIa / IIIb / IV / V **None of the Above** Definitions: • eGFR for CKD stages: I≥ 90; II = 60-90; IIIa = 45-59; IIIb = 30-44; IV = 15-29; V <15 • Definitions for Liver Disease: Mild defined as chronic hepatitis or cirrhosis without portal hypertension; Moderate defined as cirrhosis and portal hypertension but no variceal bleeding history; Severe defined as cirrhosis and portal hypertension with variceal bleeding history.
7. **History of acute cholecystitis or cholangitis**	**Yes / No**
8. **Number of admissions with biliary symptoms in previous 12 months prior to surgery**	**Number of admissions excluding the current one**
9. **Preoperative imaging** (Select all that apply)	**Yes / Unknown / No** (Not available / Not indicated / Patient declined) for each of the following: **USS / CT / ERCP / MRCP / Endoscopic Ultrasound (EUS) / Hepatobiliary IminoDiacetic Acid (HIDA)**
10. **Preoperative imaging findings***	*Only for USS / CT / MRCP, what are the findings (tick all that apply): **Gallstones** **Thick-walled Gallbladder** (≥3mm or reported as thick walled) **Pericholecystic fluid** **CBD stones** **Dilated CBD.** If yes: CBD diameter (record in mm, to one decimal)
11. **Days between first biliary symptom onset and admission**	**Number of days** (Whole number, day 0 is same day of first symptom onset)

12. Days between diagnosis and decision to operate	**Number of days** (Whole number, day 0 is same day of diagnosis) Guide for decision to operate day: • For elective cases this should be the day the patient was seen in the outpatient clinic. • For delayed cases this is the day the patient was LAST discharged from hospital with biliary disease. • For emergency cases this should be the day the decision was made to perform an acute cholecystectomy in that emergency admission. If the patient was previously on an elective waiting list for surgery, please still use the date it was decided to perform the operation as an emergency.
13. Days between decision to operate and surgery performed	**Number of days** (Whole number, day 0 is same day as surgery)
14. Urgency of surgery (**Appendix D** for definitions)	**Elective** **Delayed** **Emergency**. If yes: Was the patient already on the elective waiting list for surgery? (Yes / No)
15. Indication for surgery **(Appendix D** for definitions)	**Acute calculous cholecystitis.** If yes: Tokyo grade: I / II / III (Was the Tokyo grade documented in patient notes: Yes / No) **Biliary colic** **Acalculous cholecystitis** **Chronic calculous cholecystitis** **Common Bile Duct (CBD) stone** **Gallbladder polyp** **Dyskinesia** **Gallstone pancreatitis.** If yes: Atlanta criteria: mild / moderate / severe (Was the Atlanta criteria documented in patient notes: Yes / No)
Intra-operative Data Fields	**Required data** (definition / comment)
1. Mode of Anaesthesia* (Select all that apply)	**Local** (subcutaneous / intraperitoneal) **Regional** (spine-related / regional nerve block) **Sedation** (e.g., midazolam) **General Inhaled** (sevoflurane / halothane / desflurane / Nitric Oxide (N2O) / isoflurane) **Total Intravenous Volatile Anaesthetic (TIVA)** *This refers to the anaesthetic used during the operation and NOT as induction agents
2. Intraoperative antibiotics*	**Yes** (Prophylactic / Intraoperative spillage / Cholecystitis) **/ No** *Defined as administration of antibiotics at least 30 minutes prior to skin incision to end of operation
3. Primary operator	**Consultant or attending** **Senior trainee** (i.e., senior registrar or resident with >4 years surgical training/residency) **Junior trainee** (i.e., junior registrar or resident with ≤ 4 years surgical training/residency) **Non-surgeon** (e.g., medical practitioner or nurse) If Consultant: What specialty? (General / Oesophago-gastric (OG) / HPB / Colorectal / Breast / Vascular / Other) If Trainee: Was this a training operation? (Yes / No). Was a consultant present? (Yes / No) If any: Number of cholecystectomies performed prior to this procedure: 0-50 / 51-100 / 101-200 / >200
4. Operative approach	**Open / Open conversion / Laparoscopic** (Standard / Single Incision Laparoscopic Surgery (SILS)) / **Robotic** (Standard / SILS) 1) If open, why: No laparoscopic equipment / Surgeon not trained in laparoscopy / Laparoscopy equipment broken / Multiple previous surgery / Disease severity. 2) If open conversion, why: Suboptimal view / Adhesions / Not able to safely dissect CVS / Suspected bile duct injury / Patient unable to tolerate pneumoperitoneum / Bleeding / Bowel injury / Laparoscopic or robotic equipment failure / Suspected or actual cholecystoduodenal or cholecystocolonic fistula. 3) If laparoscopic or robotic: was this gasless (Yes / No), were reusable equipment used? (Yes / No).
5. Intra-operative difficulty score – this is for minimally invasive surgery	**I / II / III / IV / V** (Nassar Grade: **Appendix D** for definitions)
6. Was the Critical View of Safety (CVS) obtained (all three) – this is for minimally invasive surgery	**Yes / No** If no, which criteria was met: 1) Clearing fat and fibrous tissue from the hepatocystic triangle.

	2) The lower third of the gallbladder being cleared from the cystic plate. 3) Only two structures are attached to the gallbladder.
7. Was there a time-out to verify CVS	**Yes / No** Defined as a momentary pause that what one is seeing is likely the correct anatomy
8. Operation performed	**Standard total cholecystectomy** **Total cholecystectomy by the fundus-first (top down) approach** **Subtotal cholecystectomy** (reconstituting / fenestrated) **Not performed** (diagnostic laparoscopy / cholecystostomy) Definitions of subtotal cholecystectomy: • Fenestrated: does not occlude the gallbladder but may suture the cystic duct internally • Reconstituting: closes off the lower end of the gallbladder, creating a remnant gallbladder
9. Abdominal drain insertion	**Yes / No**
10. Anatomical Biliary variant	**Yes / No**
11. Intraoperative CBD Assessment	**Intraoperative cholangiogram (IOC) / Incisionless fluorescent cholangiography/ Laparoscopic ultrasound / Intraoperative ERCP** If yes to any of the above: • Decision: Selective / Routine. If selective, state Indication: Raised liver function test / Concern of a bile duct injury / pre-operative imaging suggestive of CBD stone • Findings: Stone / No stone. If stone, tick all that apply for management: Flushing with saline and smooth muscle relaxant / Fogarty catheter trawl / Basket retrieval / Choledocholescope / No intraoperative treatment attempted
12. Common Bile Duct exploration	**Yes** (Trancystic / Choledochotomy) **/ No** If Choledochotomy then select closure: Primary closure / T-tube
13. Operative contamination	**Clean** (Gastrointestinal (GI) and genitourinary (GU) tract not entered) **Clean-Contaminated** (GI or GU tracts entered but no gross contamination) **Contaminated** (GI or GU tracts entered with gross spillage or major break in sterile technique) **Dirty** (There is already contamination prior to operation, e.g., faeces or bile).
14. Intraoperative complications - excluding bile duct injury (BDI) (Select all that apply)	**Bile spilt / Stones Spilt / Bleeding / Major vascular injury / Bowel injury**
15. Were reusable gowns used in this procedure?	**Yes** (All scrubbed staff/ some scrubbed staff) **/ No**
16. Were reusable drapes used in this procedure?	**Yes / No**
30-day Outcomes	**Required data** (definition / comment)
1. Highest 30-day Clavien-Dindo (CD) Grade	**0 / I / II / IIIa / IIIb / IVa / IVb / V** (**Appendix D** for definitions) If CD IIIa: Radiological drainage (yes / No) If CD IIIb: Re-laparoscopy (yes / No) If CD V (death): please indicate time from index cholecystectomy to death: number of days (whole number, 0 = same day)
2. Unplanned critical care admission - where critical care admission was not part of pre-operative plan	**Yes / No** If yes, please indicate length of stay in critical care: number of days (whole number)
3. Unplanned Re-imaging - where imaging in post-operative period (e.g.,	**Yes / No** If yes then tick all that apply: USS / CT / MRI / ERCP

CT, MRCP) was not part of pre-operative plan	
4. 30-day postoperative complications (Select <u>all</u> that apply)	**Surgical site infection** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Postoperative pulmonary complications** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Bile leak** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Bleeding** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Intra-abdominal collection** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Acute pancreatitis** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) *<u>For all of the above</u>, please indicate the Clavien-Dindo grade associated with that complication
5. Length of stay	**Whole number of days** (Where discharge < 23 hours, enter 0. If the patient has not been discharged prior to the end of 30-day follow-up, enter '31')
6. Unplanned readmission within 30 days	**Yes** (Length of stay) **/ No**
Bile Duct Injury (BDI) data fields	**Required data** (definition / comment)
1. BDI identified within 30-days of index cholecystectomy	**Yes / No** <u>If yes</u>: please fill in the rest of the data points below. <u>If No</u>: **Was BDI identified within one-year of index cholecystectomy**: Yes / No (if yes, then please fill in the rest of the data points below)
2. Presentation of BDI	**Intraoperatively / Controlled bile leak from surgically placed abdominal drain / Abdominal pain due to uncontrolled bile leak / Obstructive jaundice or cholangitis / Intra-abdominal abscess or biloma**
3. Days from index cholecystectomy to diagnosis	**Number of days** (0 = intraoperatively)
4. Bile duct injury grade	**A / B / C / D / E1 / E2 / E3 / E4 / E5** (Strasberg Injury Grade: **Appendix D** for definition)
5. Concomitant vascular injury	**Yes** (Right hepatic artery / Common hepatic artery / Main portal vein / Right portal vein) **/ No**
6. Imaging modality to investigate and confirm BDI	**On-table cholangiography (OTC) / USS / MRCP / CT / ERCP / Percutaneous transhepatic cholangiography (PTC) / Nuclear medicine scan (e.g. Functional liver scan) / Tubogram / None**
7. Discussion with a specialist HPB centre	**Yes / No / Not required** (Injury occurred at specialist HPB centre) <u>If yes</u>: • Transferred to specialist HPB centre: Yes / No • Time from injury to referral: number of days (whole number)
8. Management of Bile duct injury (Select <u>all</u> that apply)	**Non-surgery** (ERCP only / ERCP and stent / PTC) **/ Surgery** (washout only / repair) <u>If any of the above</u>: • **Time after index cholecystectomy**: number of days (Whole number, day of index cholecystectomy = day 0) <u>If surgical repair</u>: • **Specialty of surgeon performing Bile duct injury repair**: HPB surgeon / UGI surgeon / General surgeon • **Method of repair**: Roux-en-Y Hepaticojejunostomy / CBD repair without T-tube / CBD repair with T-tube / CBD end to end anastomosis / Hepaticoduodenostomy • **Vascular repair**: Yes / No • **One-year complications**: Stricture formation / Cholangitis / anastomotic leakage / intra-abdominal abscess or biloma / re-repair. <u>If yes to any</u>, time from repair to complication: number of days (Whole number, day of repair = day 0)

	Stricture definition: defined as a clinically relevant stricture leading to either jaundice, significant alterations of the liver function tests, cirrhosis or reoccurring cholangitis requiring radiological/surgical intervention or a liver failure related death
Histology data fields	**Required data** (definition / comment)
1. Postoperative histology	**Not sent for examination / Sent for examination** If sent for examination, please complete: • Indication: Routine / Selective • Time from index cholecystectomy to histology result: Number of days (whole number) • Result: Benign / Malignant If Malignant, please complete the rest of the data points below
2. Staging investigations after index cholecystectomy (select all that apply)	**CT thorax abdomen pelvis / MRI liver / PET-CT / Staging laparoscopy** For any of the above, please indicate time from histology result to staging investigation: number of days (whole number)
3. TNM grade (AJCC 8th edition) (Appendix D for definition)	**T category**: Tis / T1a (lamina propria) / T1b (muscularis) / T2a (peritoneal side) / T2b (hepatic side) / T3 / T4 **N category**: N0 / N1 (1-3 nodes) / N2 (>3 nodes) **M category**: M0 / M1
4. Discussed at MDT	Yes / No
5. Adjuvant treatment	No / Chemotherapy / Radiotherapy
6. Revisional surgery completed	Yes / No (not required) / No (unresectable tumour) • If yes, type of surgery (select all that apply): Liver resection (liver bed / one segment / two segments/ ≥ 3 segments) / bile duct resection / lymph node dissection • If yes, time from histology result to revisional surgery: Number of days (whole number)
7. Pathology results if revisional surgery	Resection margin status: R0 / R1 / R2 Lymphovascular invasion: Yes / No Perineural invasion: Yes / No Resection margin definition: R0 = microscopically negative for residual tumor; R1 = microscopically margins still demonstrate the presence of tumor; R2 = macroscopically-visible disease remains post-surgery.
8. Recurrence on imaging at one year	Yes / No If yes, time from surgery to recurrence: number of days (whole number)
One-year Outcomes	**Required data** (definition / comment)
1. Highest one-year Clavien-Dindo (CD) Grade	**0 / I / II / IIIa / IIIb / IVa / IVb / V** If CD IIIa: Radiological drainage (yes / No) If CD IV: Re-laparoscopy (yes / No) If CD V (death): please indicate time from index cholecystectomy to death: number of days (whole number)
2. Readmissions	**Total number of readmissions**

3. One-year complications (Select <u>all</u> that apply)	**Surgical site infection** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Postoperative pulmonary complications** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Bile leak** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Biliary stricture** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Bleeding** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Intra-abdominal collection** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) **Acute pancreatitis** (CD Grade* 0 / I / II / IIIa / IIIb / IVa / IVb / V) *<u>For all of the above</u>, please indicate the Clavien-Dindo grade associated with that complication

APPENDIX C: SITE SURVEY

Hospital-level services	
What is your hospital type?	Tertiary / District (Rural) / District (Non-rural)
How is your hospital funded?	Public / Private / Mixed
Total number of inpatient beds	(Number)
Do you have Level 2 (HDU) or Level 3 (ITU) facilities?	Yes (Number of beds) / No
Do you have a specialised HPB team at your centre	Yes / No If yes: (i) Are there on-call services from them: Every day 24 hour / Everyday, daytime 0800 - 1700 / Weekdays, 24 hour / Weekdays, daytime 0800 - 1700 (ii) Do they have a dedicated pathway for management of bile duct injury: Yes / No If no, are there on-call surgeons specialised in HPB: Within the same city / In other city / In the region / None
Do you have access to minimally invasive surgical equipment?	Yes (Laparoscopic / Robotic) / No If yes, do you routinely take intraoperative images? Yes (Video / Photo) / No
Cholecystectomy services	
What is the approximate total number of cholecystectomies performed each year?	(Number)
What is the number of consultants/ attending surgeons who perform cholecystectomies each year?	(Number)
Which specialist consultants/ attending surgeons perform cholecystectomies each year? (select all that apply)	General / Upper GI / HPB / Colorectal / Breast / Other
What type of services for cholecystectomy services do you provide? (select all that apply)	Elective / Emergency If emergency: • What is the approximate total number performed each year? (Number) • Do you have dedicated theatres for these services? Yes (Everyday / Once a week / Once every 2 week / More than once every 2 weeks) / No
Where does cholecystectomy get performed on your site? (select all that apply)	Day unit / Elective theatre / Emergency theatre
Have you got access to intraoperative cholangiogram?	Yes - routinely / Yes - selectively / No if yes - selectively or no: What is the supply for these? Good supply / Limited supply / None
Number of consultants / attendings who perform laparoscopic cholecystectomy	(Number)
Do you routinely follow-up after cholecystostomy?	Yes - routinely / Yes - selectively / No

Diagnostic / treatment around gallbladders	
Types of diagnostic imaging available (select all that apply)	Ultrasound (On-site / Off-site) / Computer Tomography (On-site / Off-site) / MRCP (On-site / Off-site) / EUS (On-site / Off-site) / HIDA (On-site / Off-site)
Does your hospital have access to cholecystostomy for gallbladder drainage?	Yes / No If yes, are there on-call services from them: Every day 24 hour / Everyday, daytime 0800 - 1700 / Weekdays, 24 hour / Weekdays, daytime 0800 - 1700 If no, are there on-call surgeons specialised in HPB: Within the same city / In other city / In the region / None
Is there a dedicated ERCP list?	Yes (Everyday / Once a week / Once every 2 week / More than once every 2 weeks) / No
Which of the following services do you have?	Intraoperative cholangiogram / Laparoscopic ultrasound / ICG For each: Routine use / Selective use with good supply / Selective use with limited supply
Do you send gallbladders for histological examination after surgery?	Yes - routinely / Yes - selectively / Not sent for histology / No access to histology
Training in cholecystectomy	
Are there trainees in the department who perform gallbladder surgery?	Yes / No If yes: (i) How many? (Number) (ii) What is their grade? Post-training fellow / Trainee / Non-trainees or doctors
Are there facilities for simulations training for cholecystectomies?	Yes (Local hospital / Regional / National) / No If yes to either, what are the types of simulation training: Box trainer / IT simulation model / Animal model
Are there specific structured educational programmes or coaching for bile duct injury training?	Yes (Local hospital / Regional / National) / No
Green surgery for laparoscopic cholecystectomy	
Are reusable laparoscopic ports used?	Yes (Always / Sometimes) / No / Not available
Are reusable surgical instruments used?	Yes / No / Not available
Are reusable drapes used?	Yes (Always / Sometimes) / No / Not available
Are reusable gowns used?	Yes (Always / Sometimes) / No / Not available
Are reusable scrub caps provided by your hospital?	Yes – routinely / Yes - if requested / No / Not available
Are single-use instruments recycled?	Yes / No / Not available
Are "clean" paper and plastic waste recycled?	Yes / No
Is general anaesthesia given through IV rather than anaesthetic gases for environmental reasons?	Yes – routinely / Yes – occasionally / No / Not available

APPENDIX D: STUDY DEFINITIONS

American Society of Anaesthegiologists (ASA) Classification

ASA Classification [**21**]	Definition	Example
I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents
IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction

Clinical Frailty Scale

Clinical frailty scale [**22**] (nine components):

1. **Very Fit**: People who are robust, active, energetic, and motivated.
2. **Well**: People who have no severe disease symptoms but are less fit than category 1. They exercise or are very active occasionally, e.g., seasonally.
3. **Managing Well**: People whose medical problems are well-controlled but are not regularly active beyond routine walking.
4. **Living With Very Mild Frailty**: While not dependent on others for daily help, symptoms often limit activities. A common complaint is being "slowed-up" and being tired during the day.
5. **Living with Mild Frailty:** These people usually have more evident slowing and need help in higher-order instrumental activities of daily living (IADLs) such as finance, transportation, heavy housework, and medication management. Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation, and housekeeping.
6. **Living With Moderate Frailty**: People need help with all outside activities and housekeeping. Inside often have problems with stairs, need help with bathing, and may need minimal assistance with dressing.
7. **Living With Severe Frailty**: Completely dependent for cognitive and physical personal care. However, they seem stable and not at high risk of dying (within six months).
8. **Living with Very Severe Frailty**: Completely dependent for personal care and approaching end of life. Typically, they could not recover even from minor illnesses.
9. **Terminally Ill**: Approaching the end of life. This category applies to people with a life expectancy of under six months who are not otherwise living with severe frailty.

Indication for Surgery

Indication	Definition
Biliary colic	The presence of colicky right upper quadrant pain associated with gallstones or sludge on an USS, but no signs of acute cholecystitis [**23**]
Acute calculous cholecystitis	Clinical (right upper quadrant pain, with or without fever, WCC > 11 × 10^9/l) OR ultrasound evidence (thick walled gallbladder (≥ 3mm), OR USS tenderness over the gallbladder, the presence of gallstones) [**23,24**]
Acute acalculous cholecystitis	Clinical OR ultrasound evidence (thick walled gallbladder and/or pericholecystitis, USS tenderness over the gallbladder) in the absence of gallstones [**23**]
Chronic calculous cholecystitis	Previous clinical or ultrasound evidence (thick walled gallbladder and/or pericholecystitis, OR USS tenderness over the gallbladder OR the presence of gallstones) of cholecystitis [**23**]
Common bile duct stone	Common bile duct stones, as confirmed by before or at the time of surgery
Gallbladder polyp	Hyperechoic lesions on USS imaging which have no acoustic shadow and do not move with positional changes, with no overt features of malignancy [**25**]
Dyskinesia	Biliary like abdominal pain, occurring in a normal appearing gallbladder with a functional HIDA scan showing an abnormal gallbladder ejection fraction of less than 40% [**26,27**]

Tokyo Guidelines 2018 for Grading of Acute Cholecystitis

Tokyo guidelines 2018 grading [**24**] are listed below:

- **Grade I (mild)**: No organ dysfunction and mild inflammatory changes in the gallbladder.
- **Grade II (moderate)**:
    - Elevated WBC count (>18,000/mm3)
    - Palpable tender mass in the right upper abdominal quadrant
    - Duration of complaints >72 hours
    - Marked local inflammation (gangrenous cholecystitis, pericholecystic abscess, hepatic abscess, biliary peritonitis, emphysematous cholecystitis)
- **Grade III (severe)**:
    - Cardiovascular dysfunction: hypotension requiring treatment with dopamine ≥5 µg/kg per min, or any dose of norepinephrine
    - Neurological dysfunction: decreased level of consciousness
    - Respiratory dysfunction: PaO2/FiO2 ratio <300
    - Renal dysfunction: oliguria, creatinine >2.0 mg/dl
    - Hepatic dysfunction: PT-INR >1.5
    - Hematological dysfunction: platelet count <100,000/mm3

Revised Atlanta Criteria for Acute Pancreatitis

Atlanta Criteria [**28**] is listed below:

- **Mild**: No organ failure. No local complications (e.g., necrosis or collection). No systemic complications.
- **Moderate**: Transient organ failure (<48 hours) OR Local/systemic complications
- **Severe**: Persistent organ failure

Urgency of Surgery

The urgency of index cholecystectomy is defined as [**3**]:

- Elective: planned elective admission for cholecystectomy via a routine surgical waiting list from the outpatient department only. Patients on an elective waiting list treated as an emergency should be classed as 'acute' cases.
- Delayed: all other planned cholecystectomies; for example, patients who have had one or more acute admissions with biliary symptoms, but then discharged for a planned procedure on an elective operating list.
- Emergency: emergency admission with biliary disease through the Emergency Department or primary care, and cholecystectomy performed during that emergency admission.

Nassar Grade of Operative Difficulty

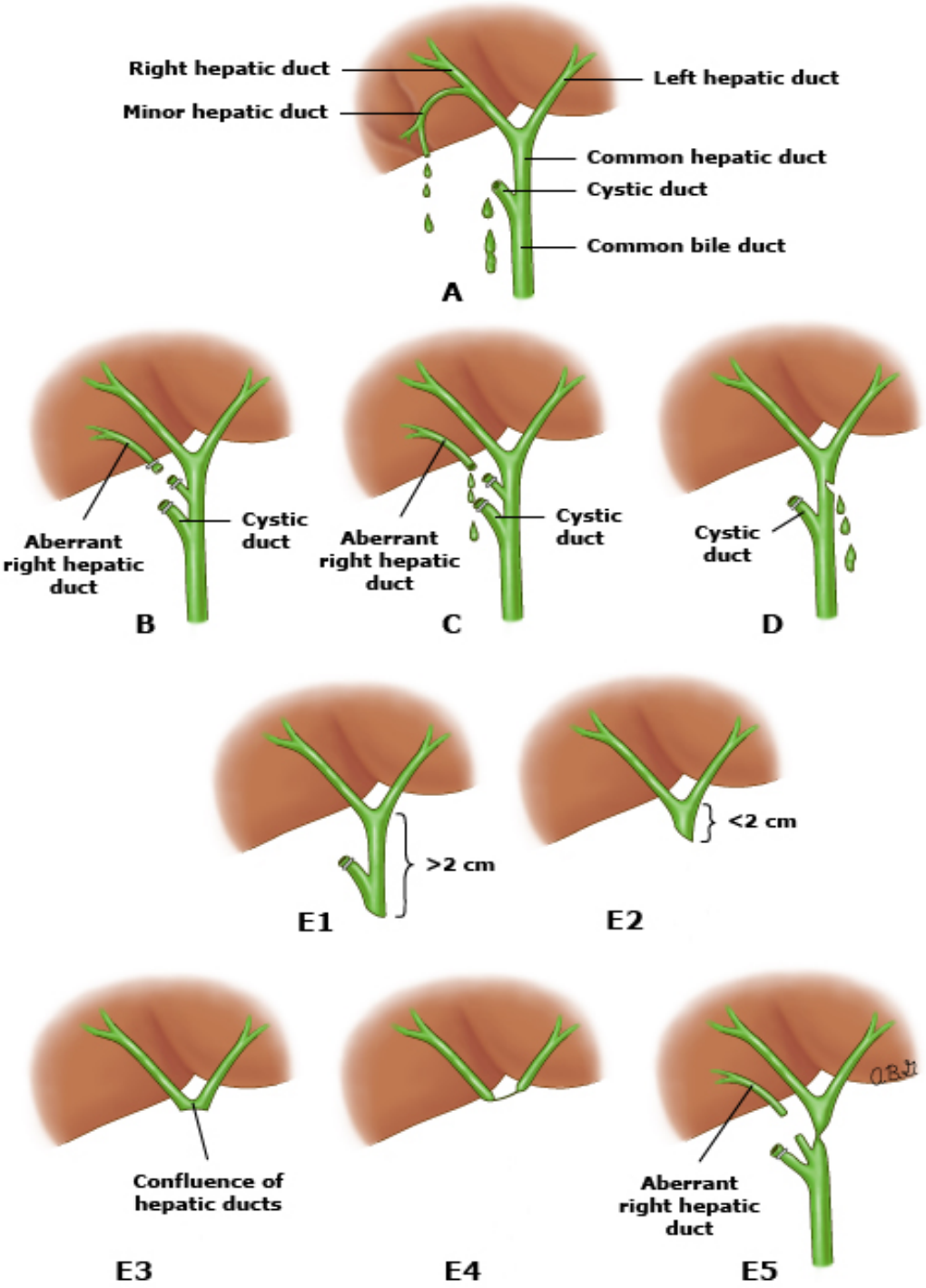
Grade [**29**]	Gallbladder	Cystic pedicle	Adhesions
I	Floppy, non-adherent	Clear, thin	Simple, up to neck and Hartmann's pouch
II	• Mucocele • Packed with stones	Fat-laden	Simple, up to the body
III	• Deep fossa • Acute cholecystitis • Contracted, fibrous Hartmann's pouch adherent to CBD or with stone impaction	• Abnormal anatomy • Cystic duct short, dilated or obscured	• Dense, up to the fundus • Involving hepatic flexure or duodenum
IV	• Completely obscured • Empyema/gangrene • Mass	Impossible to clarify	Dense, fibrous, wrapping the gallbladder. Duodenum or hepatic flexure is difficult to separate
V	As in grade IV with presence of Mirizzi Syndrome type 2 or higher, cholecysto-cutaneous, cholecysto-duodenal or cholecysto-colic fistula		

Clavien-Dindo Classification System

Grade [**30**]	Definition (examples listed in italics)
I	Any deviation from the normal postoperative course without the need for pharmacological (other than "allowed therapeutic regimens"), surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics. ***Examples**: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.*
II	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. ***Examples**: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.*
IIIa	Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA). ***Examples**: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures.*
IIIb	Requiring surgical, endoscopic or radiological intervention, under GA. ***Examples**: Return to theatre for any reason.*
IVa	Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA). ***Examples**: Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke*
IVb	Life-threatening complications requiring critical care management with multi-organ dysfunction.
V	Death

Definition of Complications

Complication	Definition
Surgical site infection	Purulent drainage from the incision; OR At least two of: pain or tenderness; localised swelling; redness; heat; fever; AND the incision is opened deliberately to manage infection, or the clinician diagnoses a surgical site infection; OR Wound organisms AND pus cells from aspirate/ swab.
Pulmonary complications [**31**]	Atelectasis OR pneumonia OR pulmonary aspiration OR acute respiratory distress syndrome
Bile leak	**Grade A**: bile leak which requires little or no change in the patient's management; resolves with conservative management within 1 week. **Grade B:** bile leak or collection which requires additional diagnostic or interventional procedures, such as ERCP or re-laparoscopy or Grade A bile leak which lasts more than 1 week. **Grade C:** Bile leak or collection which requires re-laparotomy.
Intra-abdominal abscess/collection	A clinical diagnosis of intra-abdominal collection (fever or abdominal pain or wound infection with dehiscence of any layer below fat/Scarpa's fascia) with operative or radiological evidence of a collection.
Acute pancreatitis [**28**]	Diagnosed using the revised Atlanta guidelines which state the diagnosis of acute pancreatitis requires two of the following three features: • Abdominal pain consistent with acute pancreatitis (acute onset of a persistent, severe, epigastric pain often radiating to the back) • Serum lipase activity (or amylase activity) at least three times greater than the upper limit of normal • Characteristic findings of acute pancreatitis on contrast-enhanced computed tomography.
Common bile duct injury [**32-34**]	Any injury to the main biliary tree will be classified using the Strasberg Classification System (see figure below): A – leak from cystic duct or small duct in liver bed B – occlusion of an aberrant right hepatic duct C – leak from an aberrant right hepatic duct D – lateral injury to the common hepatic or bile duct (<50% of circumference) E1 – transection or stricture of common hepatic or common bile duct >2cm from the hilum. E2 - transection or stricture of common hepatic duct <2cm from the hilum. E3 – Transection of the common hepatic duct at the level of the bifurcation without loss of contact between left and right hepatic duct. E4 – Transection of the common hepatic duct at the level of the bifurcation with loss of communication between the left and right hepatic duct. E5 – injury of a right segmental duct combined with an E3 or E4 injury.



Strasberg Classification System

American Joint Committee on Cancer (AJCC) 8th Edition TNM Stage

Category [**35**]	Definition
T category	
Tis	Carcinoma in-situ
T1a	Limited to the lamina propria
T1b	Invades the muscle layer
T2a	Invades the perimuscular connective tissue on the peritoneal side
T2b	Invades the perimuscular connective tissue on the hepatic side
T3	Perforates the serosa and/or directly invades the liver and/or other adjacent organs or structures (stomach, duodenum, colon, pancreas, omentum, or extrahepatic bile ducts)
T4	Invades the main portal vein or hepatic artery or two or more extrahepatic organs or structures
N category	
N0	No regional metastasis
N1	Metastasis in 1-3 regional lymph nodes
N2	Metastasis in >3 regional lymph nodes
M category	
M0	No distant metastasis
M1	Distant metastasis

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