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# GECKO

Resumen protocolo  
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Murcia Junio 2023

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# Global Evaluation of Cholecystectomy Knowledge and Outcomes

# GECKO

*An international prospective cohort study on cholecystectomy*

**Study Protocol v1.0**

**14<sup>th</sup> May 2023**

# Bases de conocimiento. Fundamento del estudio

- Frecuencia de la colecistectomía (laparoscópica)
- Ámbitos:
  - cirugía urgente al ingreso
  - cirugía electiva sin ingresos previos
  - cirugía electiva diferida tras ingresos previos
- El concepto de la “colecistectomía segura” (Gupta)
- Poca evidencia de las variaciones internacionales en la práctica y resultados de la colecistectomía laparoscópica segura.

# Objetivos

## PRIMARIO

definir las variaciones globales en la conformidad con los **estándares**/protocolos (\*) pre, intra y postoperatorios de la colecistectomía laparoscópica (CL)

Un **estudio de cohortes prospectivo internacional, multicéntrico, observacional** promovido por GSC de pacientes consecutivos sometidos a colecistectomía entre el 31 de Julio de 2023 y el 19 de Noviembre de 2023 con sto PO de 30 d y 1 año.

Mini-equipos de hasta **5 colaboradores** en cada centro recogerán prospectivamente los datos en periodos de 14 días.

## SECUNDARIOS

determinar la calidad de la práctica de la CL segura:

- alcanzar la visión de seguridad
- uso IOP de imágenes (CIO)
- uso de opciones de “rescate” (p.e. cole subtotal) cuando la seguridad en riesgo

evaluar los efectos adversos tras CL y su manejo

analizar las tasas de cáncer vesícula incidental

evaluar la variación global de la disponibilidad de la colecistectomía y el entrenamiento para la misma

evaluar globalmente las prácticas sostenibles en la CL



# Estándares

## PREOP

- RX intervencionista 7/24
- Estratificación riesgos (GT...)
- Timing (<48h + < 10 D C.A.)

## INTRAOP

- Visión crítica de seguridad:
  - disección triángulo HC
  - exposición lecho  $\frac{1}{3}$  inf
  - sólo 2 tubos
- Imagen IOP (si precisa)
- Procedimientos de "rescate"
- AB
- Drenajes
- Lesión de vía biliar (0,4 / 0,8%)

## POSTOP:

- reingreso (30d)
- UCI disponible

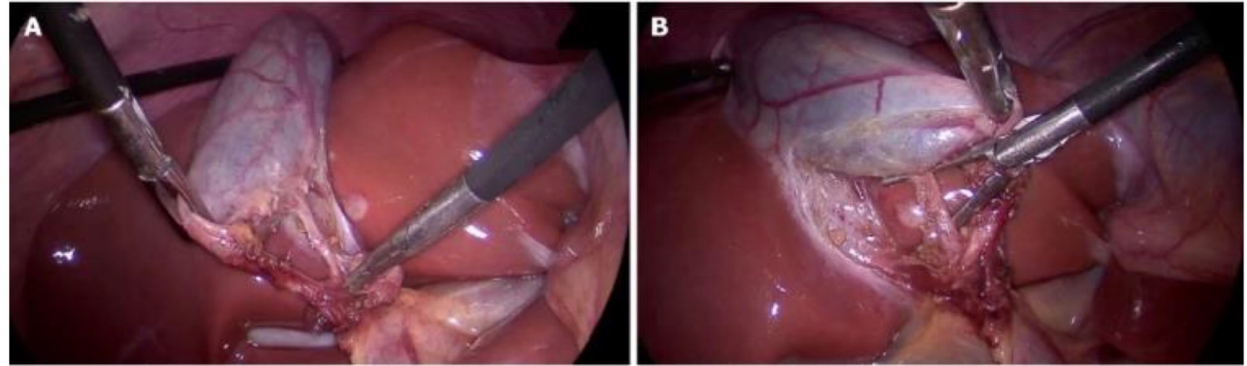


Figure 1: Photographs showing the critical view of safety.

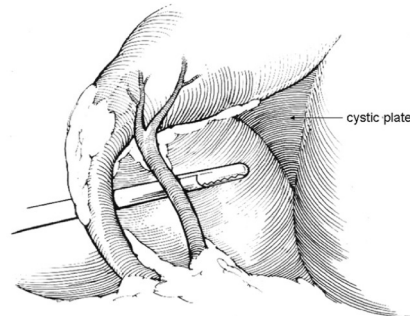


Figure 1. The critical view of safety. The triangle of Calot has been dissected free of fat and fibrous tissue, however, the common bile duct has not been displayed. The base of the gallbladder has been dissected off the cystic plate and the cystic plate can be clearly seen. Two and only 2 structures enter the gallbladder and these can be seen circumferentially.

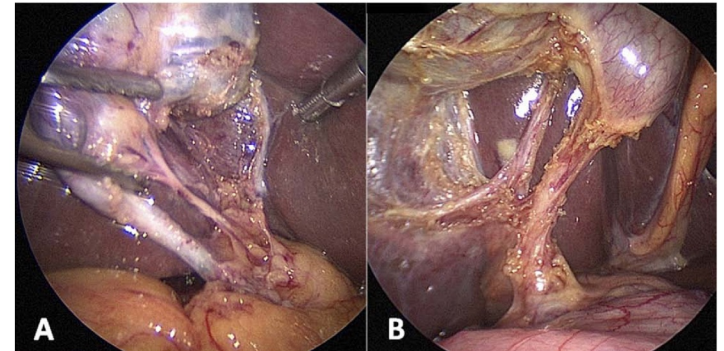


Figure 4. Different appearances of the cystic plate. (A) Critical view of safety (CVS) is seen from in front of the gallbladder as usually shown. The cystic plate is very thin. (B) CVS is seen with the gallbladder reflected to the left so that a posterior view of the triangle of Calot is shown. The cystic plate is thicker and whitish. Both views fulfill criteria for CVS.

# PROJECT TIMELINE

Dates	Description
15 <sup>th</sup> May 2023	Online launch of Gecko protocol
1 <sup>st</sup> Jul 2023	Virtual conference for GECKO study launch
00:00 31 <sup>st</sup> Jul – 23:59 13 <sup>th</sup> Aug 2023	Data collection <b>period 1</b> (+ 30-day follow-up: ends 12 <sup>th</sup> Sep 2023) (+ one-year follow-up: ends 13 <sup>th</sup> Aug 2024)
00:00 14 <sup>th</sup> Aug – 23:59 27 <sup>th</sup> Aug 2023	Data collection <b>period 2</b> (+ 30-day follow-up: ends 26 <sup>th</sup> Sep 2023) (+ one-year follow-up: ends 27 <sup>th</sup> Aug 2024)
00:00 28 <sup>th</sup> Aug – 23:59 10 <sup>th</sup> Sept 2023	Data collection <b>period 3</b> (+ 30-day follow-up: ends 10 <sup>th</sup> Oct 2023) (+ one-year follow-up: ends 10 <sup>th</sup> Sept 2024)
00:00 11 <sup>th</sup> Sept – 23:59 24 <sup>th</sup> Sept 2023	Data collection <b>period 4</b> (+ 30-day follow-up: ends 24 <sup>th</sup> Oct 2023) (+ one-year follow-up: ends 24 <sup>th</sup> Sept 2024)
00:00 25 <sup>th</sup> Sept - 23:59 8 <sup>th</sup> Oct 2023	Data collection <b>period 5</b> (+ 30-day follow-up: ends 7 <sup>th</sup> Nov 2023) (+ one-year follow-up: ends 8 <sup>th</sup> Oct 2024)
00:00 9 <sup>th</sup> Oct – 23:59 22 <sup>nd</sup> Oct 2023	Data collection <b>period 6</b> (+ 30-day follow-up: ends 21 <sup>st</sup> Nov 2023) (+ one-year follow-up: ends 22 <sup>nd</sup> Oct 2024)
00:00 23 <sup>rd</sup> Oct – 23:59 5 <sup>th</sup> Nov 2023	Data collection <b>period 7</b> (+ 30-day follow-up: ends 5 <sup>th</sup> Dec 2023) (+ one-year follow-up: ends 5 <sup>th</sup> Nov 2024)
00:00 6 <sup>th</sup> Nov – 23:59 19 <sup>th</sup> Nov 2023	Data collection <b>period 8</b> (+ 30-day follow-up: ends 19 <sup>th</sup> Dec 2023) (+ one-year follow-up: ends 19 <sup>th</sup> Nov 2024)
3 <sup>rd</sup> Jan – 5 <sup>th</sup> Mar 2024	Data validation process
6 <sup>th</sup> Mar 2024	Final day submission for 30-day follow-up data
Mid 2024	Results of the short-term outcomes of the GECKO study presented
31 <sup>st</sup> Jul – 19 <sup>th</sup> Nov 2024	One-year follow-up period
22 <sup>nd</sup> 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



GlobalSurg & The NIHR Global Health Research Unit on Global Surgery

- registro del estudio en el centro (CEIC)
- registro consecutivo
- en el periodo especificado
- > 90% de los datos completos (o exclusión del estudio)
- no hay número mínimo de pacientes por centro
- **1 Hospital Lead, 1 mini team (5 personas) y 1 auditor de datos independiente (tarea autores)**

# Registro del centro local

El estudio se registrará en cada centro

- como “auditoría” o “evaluación del servicio” (si es posible)
- como estudio de investigación (requiere aprobación del comité de ética correspondiente)

Insistir, al registrarlo en:

- carácter internacional del estudio
- sobre práctica asistencial real
- sin cambios en el protocolo asistencial habitual
- almacenamiento datos
  - seguro en REDCap
  - nunca antes de aprobación comité de ética de investigación local
  - sin datos que permitan identificar al paciente

## AUTORÍA:

Se asegura la autoría de todos los colaboradores (s/ National Research Collaborative Authorship guidelines) que cumplan los requisitos:

- autorización local del estudio
- completar encuesta del centro local
- registro correcto de datos de al menos 1 paciente en el tiempo pre-elegido
  - completo (> 95% de los datos / registro)
  - verificación > 90%
  - en el periodo especificado

## La autoría se divide (y reconoce) en los siguientes roles:

- grupo de redacción del artículo
- comité científico del proyecto
- comité asesor externo
- análisis estadístico
- líderes nacionales
- staff/especialistas de supervisión
- **líderes de centro (hospital)**
- **colaboradores locales (mini team)**
- **validadores de datos independientes**

# Población a estudio

Pacientes consecutivos atendidos durante el periodo de estudio pre-especificado que son sometidos a colecistectomía con intervención índice (objetivo).

## CRITERIOS DE INCLUSIÓN

- **Edad**  $\geq$  18 años
- Procedimiento: **colecistectomía (ppal)**
- **Cualquier acceso:** abierto, lap o robótico (y conversiones)
- **Cualquier urgencia:** electivas, diferidas y de urgencia.

## CRITERIOS DE EXCLUSIÓN:

- **Procedimiento:** pacientes en lo que la colecistectomía se realiza como parte de otro procedimiento principal (cirugía obesidad, DPC, anti-reflujo, trasplante...)
- **Indicación:** excluidos sdr Mirizzi
- **Reintervenciones:** los pacientes se incluyen sólo una vez: no se incluirán los pacientes en los que se realice la colecistectomía como reintervención.
- **Neoplasia** vesicular conocida (sí se admiten las “incidentales” en AP def)

# Procedimientos durante el estudio

**ENCUESTA AL CENTRO:** [requisito antes de acceso a base de datos]

- se completará un cuestionario online del centro (se valoran los servicios disponibles, entrenamiento, número de procedimientos/año, etc) [staff o residente jefe]
- se especifica el mini-team (hasta 5 colaboradores) y el validador independiente de datos

sin entrevistas presenciales o telefónicas extra

**RECOPIACIÓN DE DATOS:**

- ptes consecutivos, periodo pre-especificado [¡identificar c/ día!]
  - programación
  - sesiones (urgencias)
  - registros
- Doc. recogida de datos + diccionario (\*)
- REDCap (U Edinburgo)

mantener listado seguro con NHC e ID RedCAP

**TIEMPOS:**

- Sto de 30 días (100%)
  - visitas / HCE
  - reingresos
  - entrevista telefónica (s/p)
- Sto anual [colaboradores adicionales]
  - visitas / HCE
  - reingresos
  - entrevista telefónica (s/p)



# 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: <ul style="list-style-type: none"> <li>What is the approximate total number performed each year? (Number)</li> <li>Do you have dedicated theatres for these services? Yes (Everyday / Once a week / Once every 2 week / More than once every 2 weeks) / No</li> </ul>
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

**Table 1: Data collection periods**

Dates	Description
00:00 31 <sup>st</sup> July – 23:59 13 <sup>th</sup> Aug 2023	Start of data collection <b>period 1</b> (+ 30-day follow-up: ends 12 <sup>th</sup> Sep 2023) (+ one-year follow-up: ends 13 <sup>th</sup> Aug 2024)
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00:00 11 <sup>th</sup> Sept – 23:59 24 <sup>th</sup> Sept 2023	Start of data collection <b>period 4</b> (+ 30-day follow-up: ends 24 <sup>th</sup> Oct 2023) (+ one-year follow-up: ends 24 <sup>th</sup> Sept 2024)
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00:00 6 <sup>th</sup> Nov – 23:59 19 <sup>th</sup> Nov 2023	Start of data collection <b>period 8</b> (+ 30-day follow-up: ends 19 <sup>th</sup> Dec 2023) (+ one-year follow-up: ends 19 <sup>th</sup> Nov 2024)

staff supervisor datos  
(líder del estudio en el hospital)

mini-equipo (5) colaboradores:

- estudiantes
- médicos (Rs, staff)
- enfermeras

[periodos de asignación s/ convenga]  
[pueden añadirse colaboradores para el sto anual]

# APPENDIX A: CASE REPORT FORM (CRF)

## GECKO Case Report Form (CRF)

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

Age		Sex	M	F	ASA	I	II	III	IV	V	BMI	...	(1dp)	Frailty	0	1	2	3	4	5	6	7	8	9	
Comorbidities (Tick all that apply)		MI <input type="checkbox"/> CHF <input type="checkbox"/> PVD <input type="checkbox"/> CVA/TIA <input type="checkbox"/> Dementia <input type="checkbox"/> COPD <input type="checkbox"/> CTD <input type="checkbox"/> PUD <input type="checkbox"/> Hemiplegia <input type="checkbox"/> Leukaemia <input type="checkbox"/> Lymphoma <input type="checkbox"/> AIDS <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Controlled <input type="checkbox"/> Uncontrolled <input type="checkbox"/> End-organ damage <input type="checkbox"/> Liver disease <input type="checkbox"/> Diet related <input type="checkbox"/> Severe <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> None <input type="checkbox"/> CKD <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> Solid tumour <input type="checkbox"/> Localised <input type="checkbox"/> Metastatic <input type="checkbox"/> None of the Above <input type="checkbox"/>												History of prior attacks of cholecystitis or cholangitis <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>		Number of admissions with biliary symptoms in previous 12 months prior to surgery <input type="checkbox"/> --									
Preoperative imaging (Tick all that apply)		USS: <input type="checkbox"/> Yes <input type="checkbox"/> No: not available <input type="checkbox"/> No: not indicated <input type="checkbox"/> No: patient declined <input type="checkbox"/> Unknown <input type="checkbox"/> CT: <input type="checkbox"/> Yes <input type="checkbox"/> No: not available <input type="checkbox"/> No: not indicated <input type="checkbox"/> No: patient declined <input type="checkbox"/> Unknown <input type="checkbox"/> MRCP: <input type="checkbox"/> Yes <input type="checkbox"/> No: not available <input type="checkbox"/> No: not indicated <input type="checkbox"/> No: patient declined <input type="checkbox"/> Unknown <input type="checkbox"/> ERCP: <input type="checkbox"/> Yes <input type="checkbox"/> No: not available <input type="checkbox"/> No: not indicated <input type="checkbox"/> No: patient declined <input type="checkbox"/> Unknown <input type="checkbox"/> EUS: <input type="checkbox"/> Yes <input type="checkbox"/> No: not available <input type="checkbox"/> No: not indicated <input type="checkbox"/> No: patient declined <input type="checkbox"/> Unknown <input type="checkbox"/> HIDA: <input type="checkbox"/> Yes <input type="checkbox"/> No: not available <input type="checkbox"/> No: not indicated <input type="checkbox"/> No: patient declined <input type="checkbox"/> Unknown <input type="checkbox"/>																							
Imaging findings		<input type="checkbox"/> Gallstones <input type="checkbox"/> Thick-walled gallbladder <input type="checkbox"/> Pericholecystic fluid <input type="checkbox"/> CBD stones <input type="checkbox"/> Dilated CBD (Diameter: ... mm (1dp))																							
Days between		First symptom onset and diagnosis: ...		Diagnosis and decision to operate: ...		Urgency of surgery <input type="checkbox"/> Elective <input type="checkbox"/> Delayed <input type="checkbox"/> Emergency (patient was on elective waiting list?) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>		Decision to operate and surgery: ...																	
Indication for surgery		<input type="checkbox"/> Acute calculous cholecystitis (Tokyo grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III; Was Tokyo grade documented in notes: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> Biliary colic <input type="checkbox"/> Acalculous cholecystitis <input type="checkbox"/> Chronic cholecystitis <input type="checkbox"/> CBD stone <input type="checkbox"/> Poly <input type="checkbox"/> Dyskinesia <input type="checkbox"/> <input type="checkbox"/> Gallstone pancreatitis (Atlanta criteria: <input type="checkbox"/> Mild <input type="checkbox"/> Mod <input type="checkbox"/> Severe; Was Atlanta criteria documented in notes: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																							
Section 2: Intraoperative data fields																									
Mode of anaesthesia (Tick all that apply)		<input type="checkbox"/> Local (Route: <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Intraperitoneal <input type="checkbox"/> <input type="checkbox"/> Regional (Route: <input type="checkbox"/> spine-related <input type="checkbox"/> regional nerve block <input type="checkbox"/> <input type="checkbox"/> General inhaled (Type: <input type="checkbox"/> sevoflurane <input type="checkbox"/> halothane <input type="checkbox"/> desflurane <input type="checkbox"/> N2O <input type="checkbox"/> Isoflurane) <input type="checkbox"/> <input type="checkbox"/> Total Intravenous Volatile Anaesthetic <input type="checkbox"/>												Intraoperative antibiotics <input type="checkbox"/> Yes - Prophylactic <input type="checkbox"/> Yes - Intra-op spillage <input type="checkbox"/> Yes - cholecystitis <input type="checkbox"/> No <input type="checkbox"/>											
Primary operator		<input type="checkbox"/> Consultant or attending (Specialty: <input type="checkbox"/> General <input type="checkbox"/> OG <input type="checkbox"/> HPB <input type="checkbox"/> Colorectal <input type="checkbox"/> Breast <input type="checkbox"/> Vascular <input type="checkbox"/> Other <input type="checkbox"/> <input type="checkbox"/> Surgical trainee (Grade: <input type="checkbox"/> Senior <input type="checkbox"/> Junior; Training operation? <input type="checkbox"/> Yes <input type="checkbox"/> No; Consultant present? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> Non-surgeon <input type="checkbox"/>																							
Operative approach		Number of laparoscopies performed by primary surgeon prior to this procedure: 0-50 <input type="checkbox"/> 51-100 <input type="checkbox"/> 101-200 <input type="checkbox"/> >200 <input type="checkbox"/> <input type="checkbox"/> Open (Why? <input type="checkbox"/> No laparoscopy <input type="checkbox"/> Surgeon not trained in laparoscopy <input type="checkbox"/> Laparoscopy broken <input type="checkbox"/> Previous surgeries <input type="checkbox"/> Disease severity) <input type="checkbox"/> <input type="checkbox"/> Laparoscopic (Type: <input type="checkbox"/> Standard <input type="checkbox"/> SILS; Converted to open? <input type="checkbox"/> Yes <input type="checkbox"/> No; Gases? <input type="checkbox"/> Yes <input type="checkbox"/> No; Reusable equipment: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> Robotic (Type: <input type="checkbox"/> Standard <input type="checkbox"/> SILS; Converted to open? <input type="checkbox"/> Yes <input type="checkbox"/> No; Gases? <input type="checkbox"/> Yes <input type="checkbox"/> No; Reusable equipment: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																							
Intraoperative difficulty (Nassar)		<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/>		CVS obtained successfully? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>		If No, which criteria was met? <input type="checkbox"/> Clearance of the hepatocystic triangle <input type="checkbox"/> <input type="checkbox"/> Exposure of the lower cystic plate <input type="checkbox"/> <input type="checkbox"/> Only two structures are attached to the gallbladder <input type="checkbox"/>		Was there a time-out to verify CVS? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																	
Operation performed		<input type="checkbox"/> Total cholecystectomy (Type: <input type="checkbox"/> Standard <input type="checkbox"/> Fundus-first approach) <input type="checkbox"/> <input type="checkbox"/> Subtotal cholecystectomy (Type: <input type="checkbox"/> Reconstituting <input type="checkbox"/> Fenestrated) <input type="checkbox"/> <input type="checkbox"/> Not performed ( <input type="checkbox"/> Diagnostic laparoscopy <input type="checkbox"/> Cholecystectomy) <input type="checkbox"/> <input type="checkbox"/> Intraoperative cholangiogram <input type="checkbox"/> Incisionless fluorescent cholangiography <input type="checkbox"/> Laparoscopy US <input type="checkbox"/>																							
Intraoperative CBD assessment (Tick all that apply)		Decision: <input type="checkbox"/> Selective <input type="checkbox"/> Routine; If selective, Indication: <input type="checkbox"/> Raised LFT <input type="checkbox"/> BDI concern <input type="checkbox"/> Pre-op imaging suggests CBD stone <input type="checkbox"/> Findings: <input type="checkbox"/> Stone <input type="checkbox"/> No stone; If stone, management: <input type="checkbox"/> Flushing with saline and smooth muscle relaxant <input type="checkbox"/> Fogarty catheter trawl <input type="checkbox"/> <input type="checkbox"/> Basket retrieval <input type="checkbox"/> Choledochoscopy <input type="checkbox"/> No intraoperative treatment attempted <input type="checkbox"/>																							
CBD exploration		<input type="checkbox"/> Yes (Type: <input type="checkbox"/> Transcystic <input type="checkbox"/> Choledochotomy; If Choledochotomy, closure: <input type="checkbox"/> Primary closure <input type="checkbox"/> T-tube) <input type="checkbox"/> <input type="checkbox"/> No <input type="checkbox"/>		Operative contamination <input type="checkbox"/> Clean <input type="checkbox"/> Clean-Contaminated <input type="checkbox"/> Contaminated <input type="checkbox"/> Dirty <input type="checkbox"/>																					
Intraoperative complications - excluding BDI (see section 4)		<input type="checkbox"/> Bile spill <input type="checkbox"/> Stones Spilt <input type="checkbox"/> Bleeding <input type="checkbox"/> <input type="checkbox"/> Major vascular injury <input type="checkbox"/> Bowel injury <input type="checkbox"/>		Reusable gowns <input type="checkbox"/> Yes <input type="checkbox"/> (All staff <input type="checkbox"/> some staff) <input type="checkbox"/> No <input type="checkbox"/>		Reusable drapes <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																			
Section 3: 30-day outcomes																									
Highest 30-day Clavien-Dindo (CD)		<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/>		Critical care admission <input type="checkbox"/> Yes <input type="checkbox"/> (Length of stay: ...) <input type="checkbox"/> No <input type="checkbox"/>		Re-imaging (Type: <input type="checkbox"/> USS <input type="checkbox"/> CT <input type="checkbox"/> MRI <input type="checkbox"/> ERCP) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																			
30-day postoperative Complications (Tick all that apply)		<input type="checkbox"/> Surgical site infection (CD Grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IVa <input type="checkbox"/> IVb <input type="checkbox"/> V) <input type="checkbox"/> <input type="checkbox"/> Pulmonary complications (CD Grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IVa <input type="checkbox"/> IVb <input type="checkbox"/> V) <input type="checkbox"/> <input type="checkbox"/> Bile leak (CD Grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IVa <input type="checkbox"/> IVb <input type="checkbox"/> V) <input type="checkbox"/> <input type="checkbox"/> Bleeding (CD Grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IVa <input type="checkbox"/> IVb <input type="checkbox"/> V) <input type="checkbox"/> <input type="checkbox"/> Intra-abdominal collection (CD Grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IVa <input type="checkbox"/> IVb <input type="checkbox"/> V) <input type="checkbox"/> <input type="checkbox"/> Acute pancreatitis (CD Grade: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IVa <input type="checkbox"/> IVb <input type="checkbox"/> V) <input type="checkbox"/>																							
Length of stay		<input type="checkbox"/> Same day discharge <input type="checkbox"/> <input type="checkbox"/> Admitted (Number of days inpatient: ...) <input type="checkbox"/>		30-day Readmission <input type="checkbox"/> Yes (Length of stay: ...) <input type="checkbox"/> No <input type="checkbox"/>																					

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





# 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	Male / Female
3. ASA grade	I / II / III / IV / V (Appendix D for definitions)
4. Body Mass Index (BMI)	kg/m <sup>2</sup> (record to one decimal places)
5. Clinical Frailty Scale	1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 (Appendix D for definitions)
6. Comorbidities (Select all that apply)	<p>Myocardial Infarction (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 / Acquired Immunodeficiency Syndrome (AIDS) / Diabetes Mellitus (Type 1 or Type 2). <i>If yes:</i> Diet-Controlled / Uncomplicated / End-Organ Damage / Solid Tumour. <i>If yes:</i> Localised / Metastatic / Liver Disease. <i>If yes:</i> Mild / Moderate / Severe / Chronic Kidney Disease (CKD). <i>If yes:</i> Stage I / II / IIIa / IIIb / IV / V / None of the Above</p> <p><b>Definitions:</b></p> <ul style="list-style-type: none"> <li>eGFR for CKD stages: I ≥ 90; II = 60-90; IIIa = 45-59; IIIb = 30-44; IV = 15-29; V &lt;15</li> <li>Definitions for Diabetes Mellitus: Uncomplicated is defined as medically managed and no end-organ damage.</li> <li>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.</li> </ul>
7. History of prior attacks 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*	<p>*Only for USS / CT / MRCP, what are the findings (tick all that apply):</p> <p>Gallstones Thick-walled Gallbladder (≥23mm or reported as thick walled) Pericholecystic fluid CBD stones Dilated CBD. <i>If yes:</i> CBD diameter (record in mm, to one decimal)</p>
11. Days between first biliary symptom onset and diagnosis	Number of days (Whole number, day 0 is same day of first symptom onset)
12. Days between diagnosis and decision to operate	<p>Number of days (Whole number, day 0 is same day of diagnosis)</p> <p>Guide for decision to operate day:</p>

	<ul style="list-style-type: none"> <li>For elective cases this should be the day the patient was seen in the outpatient clinic.</li> <li>For delayed cases this is the day the patient was LAST discharged from hospital with biliary disease.</li> <li>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.</li> </ul>
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)	<p>Elective Delayed Emergency. <i>If yes:</i> Was the patient already on the elective waiting list for surgery? (Yes / No)</p>
15. Indication for surgery (Appendix D for definitions)	<p>Biliary colic Acute calculous cholecystitis. <i>If yes:</i> Tokyo grade: I / II / III (Was the Tokyo grade documented in patient notes: Yes / No) Acalculous cholecystitis Chronic calculous cholecystitis Gallstone pancreatitis. <i>If yes:</i> Atlanta criteria: mild / moderate / severe (Was the Atlanta criteria documented in patient notes: Yes / No) Common Bile Duct (CBD) stone Gallbladder polyp Dyskinesia</p>
Intra-operative Data Fields	Required data (definition / comment)
1. Mode of Anaesthesia* (Select all that apply)	<p>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</p>
2. Intraoperative antibiotics*	<p>Yes (Prophylactic / Intraoperative spillage / Cholecystitis) / No *Defined as administration of antibiotics at least 1 hour prior to skin incision to end of operation</p>
3. Primary operator	<p>Consultant or attending Senior trainee (i.e., senior registrar or resident) Junior trainee (i.e., junior registrar or resident) Non-surgeon (e.g., medical practitioner or nurse)</p> <p><i>If Consultant:</i> What specialty? (General / Oesophago-gastric (OG) / HPB / Colorectal / Breast / Vascular / Other) <i>If Trainee:</i> Was this a training operation? (Yes / No). Was a consultant present? (Yes / No) <i>If any:</i> Number of cholecystectomies performed prior to this procedure: 0-50 / 51-100 / 101-200 / &gt;200</p>
4. Operative approach	<p>Open / Laparoscopic (Standard / Single Incision Laparoscopic Surgery (SILS)) / Robotic (Standard / SILS)</p> <p>1) <i>If open, why:</i> No laparoscopic equipment / Surgeon not trained in laparoscopy / Laparoscopy equipment broken / Multiple previous surgery / Disease severity.</p> <p>2) <i>If laparoscopic or robotic:</i> converted to open (Yes / No), was this gasless (Yes / No), were reusable equipment used? (Yes / Some / No).</p> <p>3) <i>If converted to open, why:</i> 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.</p>
5. Intra-operative difficulty score	I / II / III / IV / V (Nassar Grade: Appendix D for definitions)
6. Was the Critical View of Safety (CVS) obtained (all three)	<p>Yes / No <i>If no, which criteria was met:</i></p> <ol style="list-style-type: none"> <li>Clearing fat and fibrous tissue from the hepatocystic triangle.</li> <li>The lower third of the gallbladder being cleared from the cystic plate.</li> <li>Only two structures are attached to the gallbladder.</li> </ol>

	<ul style="list-style-type: none"> <li>For elective cases this should be the day the patient was seen in the outpatient clinic.</li> <li>For delayed cases this is the day the patient was LAST discharged from hospital with biliary disease.</li> <li>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.</li> </ul>
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. <u>If yes:</u> Was the patient already on the elective waiting list for surgery? (Yes / No)
15. Indication for surgery (Appendix D for definitions)	Biliary colic Acute calculous cholecystitis. <u>If yes:</u> Tokyo grade: I / II / III (Was the Tokyo grade documented in patient notes: Yes / No) Acalculous cholecystitis Chronic calculous cholecystitis Gallstone pancreatitis. <u>If yes:</u> Atlanta criteria: mild / moderate / severe (Was the Atlanta criteria documented in patient notes: Yes / No) Common Bile Duct (CBD) stone Gallbladder polyp Dyskinesia
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 1 hour prior to skin incision to end of operation
3. Primary operator	Consultant or attending Senior trainee (i.e., senior registrar or resident) Junior trainee (i.e., junior registrar or resident) Non-surgeon (e.g., medical practitioner or nurse)  <u>If Consultant:</u> What specialty? (General / Oesophago-gastric (OG) / HPB / Colorectal / Breast / Vascular / Other) <u>If Trainee:</u> Was this a training operation? (Yes / No). Was a consultant present? (Yes / No) <u>If any:</u> Number of cholecystectomies performed prior to this procedure: 0-50 / 51-100 / 101-200 / >200
4. Operative approach	Open / Laparoscopic (Standard / Single Incision Laparoscopic Surgery (SILS)) / Robotic (Standard / SILS) 1) <u>If open, why:</u> No laparoscopic equipment / Surgeon not trained in laparoscopy / Laparoscopic equipment broken / Multiple previous surgery / Disease severity. 2) <u>If laparoscopic or robotic:</u> converted to open (Yes / No), was this gasless (Yes / No), were reusable equipment used? (Yes / Some / No). 3) <u>If converted to open, why:</u> 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.
5. Intra-operative difficulty score	I / II / III / IV / V (Nassar Grade: Appendix D for definitions)
6. Was the Critical View of Safety (CVS) obtained (all three)	Yes / No <u>If no, which criteria was met:</u> 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.

	Intra-abdominal collection (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V) Acute pancreatitis (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V) *For all of the above, please indicate the Clavien-Dindo grade associated with that complication
5. Length of stay	Same day discharge Admitted (If admitted, please indicate number of days inpatient, considering day of surgery as day 0 to day of discharge. If the patient has not been discharged prior to the end of 30-day follow-up, enter '31').
6. 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	None / On-table cholangiography (OTC) / USS / MRCP / CT / ERCP / Percutaneous transhepatic cholangiography (PTC) / Nuclear medicine scan / Functional liver scan / Tubogram
7. Discussion with a specialist HPB centre	Yes / No / Not required (Injury occurred at specialist HPB centre)  <u>If yes:</u> <ul style="list-style-type: none"> <li>Transferred to specialist HPB centre: Yes / No</li> <li>Time from injury to referral: number of days (whole number)</li> </ul>
8. Management of Bile duct injury (Select all that apply)	Non-surgery (ERCP only / ERCP and stent / PTC) / Surgery (washout only / repair)  <u>If any of the above:</u> <ul style="list-style-type: none"> <li>Time after index cholecystectomy: number of days (Whole number, day of index cholecystectomy = day 0)</li> </ul> <u>If surgical repair:</u> <ul style="list-style-type: none"> <li>Specialty of surgeon performing Bile duct injury repair: HPB surgeon / UGI surgeon / General surgeon</li> <li>Method of repair: Roux-en-Y Hepaticojejunostomy / CBD repair without T-tube / CBD repair with T-tube / CBD end to end anastomosis / Hepaticoduodenostomy</li> <li>Vascular repair: Yes / No</li> <li>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)</li> </ul> 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  <u>If sent for examination,</u> please complete:

	<ul style="list-style-type: none"> <li>• Indication: Routine / Selective</li> <li>• Time from index cholecystectomy to histology result: Number of days (whole number)</li> <li>• Result: Benign / Malignant</li> </ul> <p>If <b>Malignant</b>, please complete the rest of the data points below</p>
2. <b>Staging modality</b> (select <u>all</u> that apply)	<p><b>CT thorax abdomen pelvis / MRI liver / PET-CT / Staging laparoscopy</b></p> <p>For any of the above, please indicate time from histology to staging: number of days (whole number)</p>
3. <b>TNM grade (AJCC 8<sup>th</sup> edition)</b> (Appendix D for definition)	<p><b>T category:</b> Tis / T1a (lamina propria) / T1b (muscularis) / T2a (peritoneal side) / T2b (hepatic side) / T3 / T4</p> <p><b>N category:</b> N0 / N1 (1-3 nodes) / N2 (&gt;3 nodes)</p> <p><b>M category:</b> M0 / M1</p>
4. <b>Discussed at MDT</b>	Yes / No
5. <b>Adjuvant treatment</b>	No / Chemotherapy / Radiotherapy
6. <b>Revisional surgery completed</b>	<p>Yes / No (not required) / No (unresectable tumour)</p> <ul style="list-style-type: none"> <li>• If <u>yes</u>, type of surgery (select all that apply): Liver resection (liver bed / one segment / two segments/ ≥ 3 segments) / bile duct resection / lymph node dissection</li> <li>• If <u>yes</u>, time from histology result to revisional surgery: Number of days (whole number)</li> </ul>
7. <b>Pathology results if revisional surgery</b>	<p>Resection margin status: R0 / R1 / R2</p> <p>Lymphovascular invasion: Yes / No</p> <p>Perineural invasion: Yes / No</p> <p><u>Resection margin definition:</u> R0 = microscopically negative for residual tumor; R1 = microscopically margins still demonstrate the presence of tumor; R2 = macroscopically-visible disease remains post-surgery.</p>
8. <b>Recurrence on imaging at one year</b>	<p>Yes / No</p> <p>If <u>yes</u>, time from revisional surgery to recurrence: number of days (whole number)</p>
<b>One-year Outcomes</b>	<b>Required data</b> (definition / comment)
1. <b>Highest one-year Clavien-Dindo (CD) Grade</b>	<p><b>0 / I / II / IIIa / IIIb / IVa / IVb / V</b></p> <p>If CD IIIa: Radiological drainage (yes / No)</p> <p>If CD IV: Re-laparoscopy (yes / No)</p> <p>If CD V (death): please indicate time from index cholecystectomy to death: number of days (whole number)</p>
2. <b>Readmissions</b>	<b>Total number of readmissions</b>
3. <b>One-year complications</b> (Select <u>all</u> that apply)	<p><b>Surgical site infection</b> (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V)</p> <p><b>Postoperative pulmonary complications</b> (CD Grade I / II / IIIa / IIIb / IVa / IVb / V)</p> <p><b>Bile leak</b> (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V)</p> <p><b>Biliary stricture</b> (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V)</p> <p><b>Bleeding</b> (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V)</p> <p><b>Intra-abdominal collection</b> (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V)</p> <p><b>Acute pancreatitis</b> (CD Grade* I / II / IIIa / IIIb / IVa / IVb / V)</p> <p>*For all of the above, please indicate the Clavien-Dindo grade associated with that complication</p>

## APPENDIX D: STUDY DEFINITIONS

### American Society of Anaesthesiologists (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):

- Very Fit:** People who are robust, active, energetic, and motivated.
- 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.
- Managing Well:** People whose medical problems are well-controlled but are not regularly active beyond routine walking.
- 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.
- 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.
- 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.
- 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).
- Living with Very Severe Frailty:** Completely dependent for personal care and approaching end of life. Typically, they could not recover even from minor illnesses.
- 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
<b>Biliary colic</b>	The presence of colicky right upper quadrant pain associated with gallstones or sludge on an USS, but no signs of acute cholecystitis [23]
<b>Acute calculous cholecystitis</b>	Clinical (right upper quadrant pain, with or without fever, WCC > 11 × 10 <sup>9</sup> /l) OR ultrasound evidence (thick walled gallbladder (≥ 3mm), OR USS tenderness over the gallbladder, the presence of gallstones) [23,24]
<b>Acute acalculous cholecystitis</b>	Clinical OR ultrasound evidence (thick walled gallbladder and/or pericholecystitis, USS tenderness over the gallbladder) in the absence of gallstones [23]
<b>Chronic calculous cholecystitis</b>	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]
<b>Common bile duct stone</b>	Common bile duct stones, as confirmed by before or at the time of surgery
<b>Gallbladder polyp</b>	Hyperechoic lesions on USS imaging which have no acoustic shadow and do not move with positional changes, with no overt features of malignancy [25]
<b>Dyskinesia</b>	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/mm<sup>3</sup>)
  - 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: PaO<sub>2</sub>/FiO<sub>2</sub> ratio <300
  - Renal dysfunction: oliguria, creatinine >2.0 mg/dl
  - Hepatic dysfunction: PT-INR >1.5
  - Hematological dysfunction: platelet count <100,000/mm<sup>3</sup>



## 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

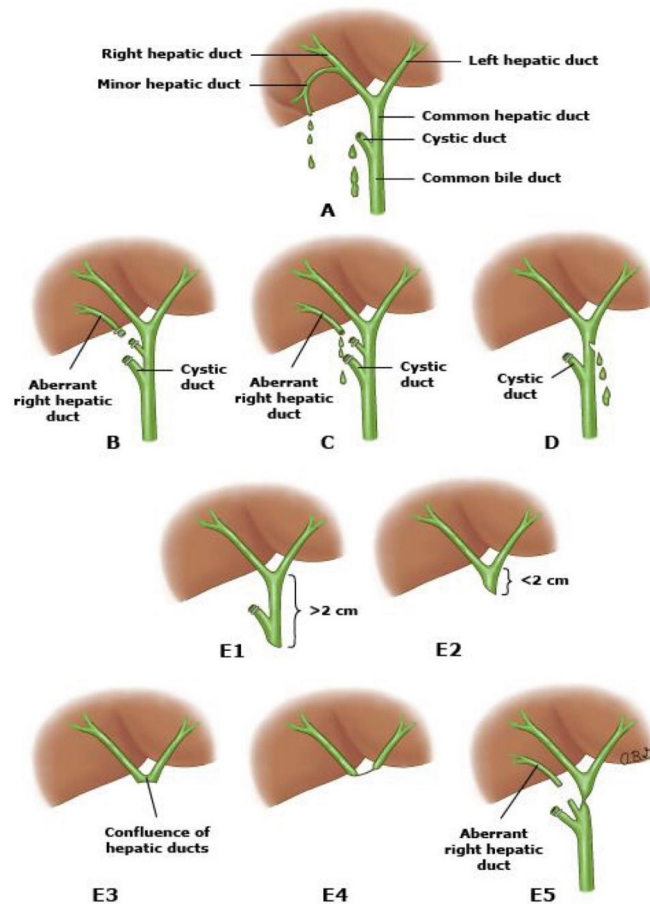
Grade [29]	Gallbladder	Cystic pedicle	Adhesions
I	Floppy, non-adherent	Clear, thin	Simple, up to neck and Hartmann's pouch
II	<ul style="list-style-type: none"> <li>• Mucocoele</li> <li>• Packed with stones</li> </ul>	Fat-laden	Simple, up to the body
III	<ul style="list-style-type: none"> <li>• Deep fossa</li> <li>• Acute cholecystitis</li> <li>• Contracted, fibrous Hartmann's pouch adherent to CBD or with stone impaction</li> </ul>	<ul style="list-style-type: none"> <li>• Abnormal anatomy</li> <li>• Cystic duct short, dilated or obscured</li> </ul>	<ul style="list-style-type: none"> <li>• Dense, up to the fundus</li> <li>• Involving hepatic flexure or duodenum</li> </ul>
IV	<ul style="list-style-type: none"> <li>• Completely obscured</li> <li>• Empyema/gangrene</li> <li>• Mass</li> </ul>	Impossible to clarify	Dense, fibrous, wrapping the gallbladder. Duodenum or hepatic flexure is difficult to separate

## Clavien-Dindo Classification System

Grade [30]	Definition (examples listed in italics)
I	<p>Any deviation from the normal postoperative course without the need for pharmacological (other than "allowed therapeutic regimens"), surgical, endoscopic or radiological intervention.</p> <p>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.</p> <p><b>Examples:</b> <i>Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.</i></p>
II	<p>Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.</p> <p><b>Examples:</b> <i>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.</i></p>
IIIa	<p>Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA).</p> <p><b>Examples:</b> <i>Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures.</i></p>
IIIb	<p>Requiring surgical, endoscopic or radiological intervention, under GA.</p> <p><b>Examples:</b> <i>Return to theatre for any reason.</i></p>
IVa	<p>Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA).</p> <p><b>Examples:</b> <i>Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke</i></p>
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	<b>Grade A:</b> bile leak which requires little or no change in the patient's management; resolves with conservative management within 1 week. <b>Grade B:</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. <b>Grade C:</b> 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: <ul style="list-style-type: none"> <li>Abdominal pain consistent with acute pancreatitis (acute onset of a persistent, severe, epigastric pain often radiating to the back)</li> <li>Serum lipase activity (or amylase activity) at least three times greater than the upper limit of normal</li> <li>Characteristic findings of acute pancreatitis on contrast-enhanced computed tomography.</li> </ul>
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

# Plan de trabajo. Cronograma

1. Completar **registro local del estudio**
  - a. CEIC
  - b. Global Surg
2. Elegir **equipo** (actual y anual)
3. Difundir y estudiar **protocolo**.
4. Resolver dudas (***national lead***)
5. Decidir **periodo** recolección datos (inclusión de pacientes).
6. Definir "**plan B**" en caso de imposibilidad de un colaborador.
7. Establecer una **hoja maestra de registro** con NHC e id REDcap
8. Comunicar al **servicio**



Global Evaluation of Cholecystectomy

Knowledge and Outcomes

# GECKO

*An international prospective cohort study on cholecystectomy*

Study Protocol v1.0

14<sup>th</sup> May 2023

