GECKO Case Report Form (CRF)

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

Section 1: Pre-operative data fields

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>M</th>
<th>F</th>
<th>ASA</th>
<th>I</th>
<th>II</th>
<th>IV</th>
<th>V</th>
<th>BMI</th>
<th>Frailty</th>
<th>History of acute cholecystitis or cholangitis</th>
<th>Number of admissions with biliary symptoms in previous 12 months prior to surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>M</td>
<td>3</td>
<td>7</td>
<td>8.5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>25</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Comorbidities (Tick all that apply)

- MI
- CHF
- PVD
- CVA
- HIV/AIDS
- CD

- Hemiplegia
- Leukaemia
- Lymphoma
- Infection
- CD

- Diabetes mellitus
- Diet-controlled Non-insulin
- Insulin controlled

- Solitary
- Localised
- Metastatic

- Liver disease
- Mild
- Moderate to Severe

- CKD
- I
- II
- IIIb
- IV
- V

Imaging findings

- First symptom onset and admission:
- Diagnosis and decision to operate:
- Operative approach
- Operation

Preoperative imaging (Tick all that apply)

- USS: Yes
- No: not available
- Not indicated
- Patient declined
- Unknown

- CT: Yes
- No: not available
- Not indicated
- Patient declined
- Unknown

- MRI: Yes
- No: not available
- Not indicated
- Patient declined
- Unknown

- ERCP: Yes
- No: not available
- Not indicated
- Patient declined
- Unknown

- EUS: Yes
- No: not available
- Not indicated
- Patient declined
- Unknown

- HIDA: Yes
- No: not available
- Not indicated
- Patient declined
- Unknown

- Gallstones
- Thick-walled gallbladder
- Pericholecystic fluid
- CBD stones
- Dilated CBD
- Diameter (Data Dictionary) to help data collection.

Number of admission with biliary symptoms in previous 12 months prior to surgery

- Yes
- No

Days between

- First symptom onset and admission:
- Diagnosis and decision to operate:
- Urgency of surgery
- Emergency (patient was on elective waiting list?)
- Yes
- No

Indication for surgery

- Acute calculous cholecystitis (Tokyo grade I II III)
- Gallstone pancreatitis (Atlanta criteria: Mild Mod Severe)
- Not performed

Mode of anaesthesia (Tick all that apply)

- Local (Route): Subcutaneous
- Intrapleural
- Regional (Route): Spinal
- Peripheral (route: regional nerve block)
- Sedation
- General inhaled

Primary operator

- Consultant
- Senior staff
- Junior
- Training officer
- Unknown

Operative approach

- Open (Why)?
- Laparoscopy
- Surgeon not trained in laparoscopy
- Laparoscopy broken
- Previous surgeries
- Disease severity
- Patient's wishes
- NOS

Operative difficulty (Nassar) - for minimally invasive technique

- CVS obtained successfully
- Only two structures are attached to the gallbladder
- None of the above

Intraoperative cholangiogram - Inconclusionary

- Incisionless fluoroscopically
- Laparoscopic
- USS
- HRCT
- ERCP

Operation performed

- Total cholecystectomy
- Subtotal cholecystectomy
- Not performed

Abdominal drain

Was there a time-out to verify CVS?

- Yes
- No

Anatomical biliary variant

- Yes
- No

Intraoperative CBD assessment (Tick all that apply)

- 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 trolley
- Basket retrieval
- Cholecystectomy
- No intraoperative treatment attempted

CBD exploration

- Yes (Type: Trancystic Cholecystectomy)
- Yes (Type: Cholecystolithotomy: T-Tube)
- No

Operative contamination

- Clean
- Clean-Contaminated
- Contaminated
- Dirty

Intraoperative complications - excluding BDI (see section 4)

- Bile spill
- Stones Spill
- Bleeding
- Major vascular injury
- Bowel injury

Reusables

- Gowns
- Yes (All staff same staff)
- No

- Drapes
- Yes
- No

Section 3: 30-day outcomes

- Highest 30-day Clavien-Dindo (CD)
- 0 I II III IV V

- 30-day postoperative Complications (Tick all that apply)
- Surgical site infection (CD Grade: 0 I II III IV V)
- Pulmonary complications (CD Grade: 0 I II III IV V)
- Bile leak (CD Grade: 0 I II III IV V)
- Bleeding (CD Grade: 0 I II III IV V)
- Acute pancreatitis (CD Grade: 0 I II III IV V)

- Length of stay
- Unplanned 30-day Readmission
- Yes
- No

Redcap unique ID

Data collection period

Days between

- First symptom onset and admission:
- Diagnosis and decision to operate:
- Urgency of surgery
## 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  
| Abdominal pain due to uncontrolled bile leak  
| Obstructive jaundice or cholangitis  
| Intra-abdominal abscess or biloma |  □ Yes (□ Right hepatic artery □ Common hepatic artery □ Main portal vein □ Right portal vein)  
| Days from index cholecystectomy to diagnosis  
| (□ = intraoperatively) |  -- |
| BDI grade (Strasberg) |  □ A □ B □ C □ D  
| □ E1 □ E2 □ E3  
| □ E4 □ E5 |  □ Yes |
| Imaging modality to investigate and confirm BDI |  □ OTC □ USS □ MRCP □ CT □ ERCP □ PTC  
| Nuclear medicine scan □ Tubogram  
| None |  Discussion with specialist HPB centre |
| (Days from injury to referral: _ _ ; Transferred? □ Yes □ No) |  □ Yes  
| 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: _ _ ) |  □ Yes |
| Speciality 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  
| □ Hepatico-duodenostomy |  □ No |
| Vascular repair |  □ Yes  
| □ No |
| 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: _ _ ) |  □ Yes |
| Postoperative histology |  □ Not 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: _ _ ) |  □ Yes |
| TNM grade (AJCC 8th edition) |  □ Tis □ T1a (lamina propria) □ T1b (musculaira) □ T2a (peritoneal side) □ T2b (hepatic side) □ T3 □ T4  
| N category: □ N0 □ N1 (1-3 nodes) □ N2 (>3 nodes)  
| M category: □ M0 □ M1 |  □ Yes |
| Discussed at MDT |  □ Yes □ No |
| Adjuvant treatment |  □ Yes |
| Chemotherapy □ Radiotherapy □ None |
| Revisonal surgery |  □ Yes  
| □ No - not required  
| □ No - unresectable tumour |
| Type of revisonal 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 |
| Recurrence on imaging at one year |  □ Yes (Days from surgery to recurrence: _ _ )  
| □ No |
| Section 5: Histology data fields |
| Section 6: One-year outcomes |

### 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 □ IIb □ IVa □ IVb □ V)  
| □ Pulmonary complications (CD Grade: □ I □ II □ IIIa □ IIb □ IVa □ IVb □ V)  
| □ Bile leak (CD Grade: □ I □ II □ IIIa □ IIb □ IVa □ IVb □ V)  
| □ Biliary stricture (CD Grade: □ I □ II □ IIIa □ IIb □ IVa □ IVb □ V)  
| □ Bleeding (CD Grade: □ I □ II □ IIIa □ IIb □ IVa □ IVb □ V)  
| □ Intra-abdominal collection (CD Grade: □ I □ II □ IIIa □ IIb □ IVa □ IVb □ V)  
| □ Acute pancreatitis (CD Grade: □ I □ II □ IIIa □ IIb □ IVa □ IVb □ V) |  □ Yes |
| Adjuvant treatment |  □ Yes |
| Chemotherapy □ Radiotherapy □ None |
| Revisonal surgery |  □ Yes  
| □ No - not required  
| □ No - unresectable tumour |
| Type of revisonal 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 |
| Recurrence on imaging at one year |  □ Yes (Days from surgery to recurrence: _ _ )  
| □ No |