

Appendix B – Data Dictionary

Section A Pre-operative data

1. **Patient age:** Years (Whole years at the time of operation)
 - a. [If "Patient age" less than or equal to 17]
Age in months in addition to age in years (whole months between 0 and 11 in addition to age in years above)
2. **Patient sex at birth:** Male / Female
3. **ASA grade:** I / II / III / IV / V (Appendix C for definitions)
4. **Clinical Frailty Score:** 1 to 9 (For definitions see Appendix C)
5. **Co-Morbidities** - (Select all that apply)

Myocardial Infarction (MI) / Other ischaemic heart disease / Congestive Heart Failure (CHF) / Peripheral Arterial Disease (PAD) / 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) / T1DM / T2DM / Solid Tumour / Chronic Kidney Disease (CKD) / Other(s)

 - a. If "T2DM": Diet-Controlled / Medication (non-insulin) controlled / Insulin-controlled
 - b. If "Solid Tumour": Localised / Metastatic
 - c. If "Solid Tumour": Please specify type
 - d. If "Liver Disease": Mild / Moderate or Severe
 - e. If "Chronic Kidney Disease (CKD)": Stage I / II / IIIa / IIIb / IV / V
 - f. If "Other(s)": Please specify

Definitions:

Other ischaemic heart disease: Angina pectoris, requirement for percutaneous coronary intervention, requirement for coronary artery bypass grafting

Peripheral arterial disease: Diagnosis of arterial insufficiency, intermittent claudication, requirement for vascular or endovascular intervention in the absence of trauma.

eGFR for CKD stages: I $\geq$ 90; II = 60-90; IIIa = 45-59; IIIb = 30-44; IV = 15-29; V <15

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.

6. **Prior intraperitoneal abdominopelvic surgery**

Open Any open procedure where peritoneum is opened including laparoscopic and robotic cases in which conversion to open is required.

Laparoscopic Any intraperitoneal procedure using one or more port sites where procedure was not converted to open. Incision for specimen extraction or extracorporeal anastomosis not considered conversion and should be recorded as laparoscopic. Extraperitoneal hernia approaches should not be considered in this category.

Robotic Any intraperitoneal procedure using any robotic platform where procedure was not converted to open. Incision for specimen extraction or extracorporeal anastomosis not considered conversion and should be recorded as robotic.

None

- a. If Yes Above Umbilicus / All below umbilicus

Considered above umbilicus if any incision is performed above the umbilicus or surgery is performed on organs typically lying above or partly the umbilicus (gallbladder, stomach, diaphragm, pancreas, liver, kidneys, spleen, adrenals, aorta, duodenum, jejunum, hepatic flexure, transverse colon or splenic flexure).

7. **Weight** Please enter value in kilograms. Set to 0 if unknown and not possible to estimate from historical patient records.
8. **Height** Please enter value in centimetres. Set to 0 if unknown and not possible to estimate from historical patient records.
9. **BMI** (calculated field)
10. **Number of acute admissions in past 12 months with biliary symptoms**
Please record total number of admissions with acute symptoms in any hospital within the 12 months prior to the operation date. Please do not include the admission for the operation in which BDI occurred.
11. **History of acute cholecystitis or cholangitis?** Y/N Any history of either cholecystitis or cholangitis at any time irrespective of whether hospital admission was required.

12. Pre-operative Imaging? Any pre-operative imaging undertaken at any time prior to the operation in which BDI occurred. This can be in any hospital.

- a. USS Y/N
- b. CT Y/N
- c. MRCP Y/N
- d. EUS Y/N
- e. ERCP Y/N
- f. Hepatobiliary Iminodiacetic Acid (HIDA) Y/N

13. Imaging Findings

- a. Gallstones Y/N
- b. Thick-walled GB Y/N/Specific measurement
 - i. Measurement (if provided) Where differing imaging modalities provide different values please use the thicker of the two measurements
- c. Pericholecystic fluid Y/N
- d. Dilated CBD Y/N/Specific measurement
 - i. Measurement (if provided) Where differing imaging modalities provide different values please use the larger of the two measurements
- e. CBD stones Y/N/Sludge only

14. Indication for Surgery:

Cholecystitis (Tokyo I, II or III) / Biliary Colic / Pancreatitis / GB polyp / CBD Stones / Other (please specify)

Please see Appendix C for definitions of the Tokyo criteria.

15. Days between decision to operate and surgery performed: Number of days. Day 0 is same day as surgery. 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.

16. Pre-operative blood tests:

- a. Bilirubin
- b. Alkaline phosphatase
- c. Gamma glutamyl transferase

Please enter 0 for any result which was not known prior to surgery. For all cases, please use the most recent result available even if this is several weeks or months earlier for elective cases.

17. Prior Biliary Procedures

- a. Cholecystostomy Y/N (include any percutaneous drainage whether performed for cholecystitis or abscess regardless of the radiological method used for insertion)
- b. Subtotal cholecystectomy Y/N (any case in which a subtotal cholecystectomy was previously documented or any case in which further resection of the gallbladder or cystic duct stump has been undertaken regardless of whether the earlier procedure was listed as subtotal or total cholecystectomy)
- c. Endoscopic sphincterotomy Y/N
- d. Common bile duct stenting Y/N
- e. Other procedure Y/N (Please specify)

18. Use of pre-operative weight loss injections

None / Tirzepatide (Mounjaro) / Semaglutide (Wegovy/Ozempic) / Other (please specify) / Unknown

Please include any use whether this was prescribed by a doctor, obtained through an online pharmacist or taken without prescription (e.g. supplied relative). Tick all that apply. Please include any use within previous 12 months.

Section B Operative Details

19. Urgency of surgery (Appendix C for definitions)

- a. Emergency / Delayed / Elective
- b. If Emergency, was patient on elective WL Y/N

20. Date of initial operation

Date on which primary operation, during which BDI sustained, commenced.

21. Type of Hospital – DGH / Teaching / Private / Treatment Centre

Type of hospital in which the bile duct injury occurred regardless of where subsequently managed

22. Operating Surgeon – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other

Consultant Senior doctor on UK or Republic of Ireland Specialist Register

Post-CCT Fellow (Fellow who has completed UK / ROI training or equivalent and holds a valid Certificate of Completion of Training)

Specialist registrar (trainee in general surgery with a national training number)

Trust Grade (Locally appointed trust doctor, not on a formal training program, also including Fellows without a Certificate of Completion of Training from UK / ROI level)

23. **Most senior surgeon in theatre** – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other

24. **Most senior Surgeon Specialty** – HPB / UGI / Colorectal / Vascular / Endocrine / Breast / Emergency / Transplant

List the specialty of the consultant present in theatre. Where no consultant was present list the specialty of the most senior operating surgeon.

25. **Setting** – Elective Day case / Elective main theatre / Emergency / Semi-Elective

26. **Operative approach** – Open / Laparoscopic / Robotic / Laparoscopic converted to open / Robotic converted to open.

- a. If relevant, reason for open conversion – Adhesions / Unable to show Critical View of Safety / Bowel injury / Bleeding / Suspected BDI / Other (Please specify)

27. **Critical view of safety**

- a. Description in operation note of “critical view of safety” or similar term – Yes-explicitly stated / No-operation note states such a view not possible / Not documented.
- b. Is there a description of only two structures clearly seen to be connected to the gallbladder. Y/N
- c. Is there a description of the lower one third of the gallbladder being separated from the liver to expose the cystic plate.
- d. Is there a description of the hepatocystic triangle being completely cleared of all adipose and fibrous tissue.
- e. Photographs available from initial operation Y/N
 - i. If Y, are these consistent with all three elements of “critical view of safety” prior to application of clips or division of cystic artery and cystic duct? Y/N
- f. Is there a description of a “time-out” performed prior to clipping ductal structures? Y/N

See Appendix C for description of critical view of safety.

28. **Intraoperative cholangiogram attempted - Y /N**

29. **Intraoperative ultrasound Y/N**

30. **Cholangioscopy Y/N**

31. Called for help – Y / N

- a. Who came to help – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other (please specify)
- b. Specialty of above - HPB / UGI / Colorectal / Vascular / Endocrine / Breast / Emergency / General / Transplant

32. Injury recognised on table? Y/ N

33. Were HPB centre contacted perioperatively? Y / N

Section C Bile duct injury and management

34. Presentation of BDI:

Intraoperative / Bile leak from abdominal drain / Pain due to uncontrolled bile leak/ Obstructive jaundice or cholangitis / Intra-abdominal collection or biloma / Other (please specify)

- a. If NOT Intraoperative how many days post-surgery was injury recognised

35. BDI Classification – Strasberg B / C / D / E 1-5 (see Appendix C for Strasberg Classification)

36. Referral to HPB centre made? Y/ N

- b. If yes, how many days after surgery was referral made?
- c. If no, was injury in tertiary referral centre? Y / N

37. Concomitant vascular injury – Y / N

- d. If yes – Right hepatic artery / Common hepatic artery / Right portal vein / main portal vein

38. Imaging modality to confirm BDI – USS / CT / MRCP / ERCP / PTC / Tubogram / None / Other (Please specify)

39. Initial management of BDI? Roux-en-Y HJ / CBD or CHD repair +/- T-tube / Drain only / Other (please specify)

- e. If Roux-en-Y HJ – immediate/delayed.
 - i. If Delayed Number of days after bile duct injury

40. Operating Surgeon Specialty for repair – HPB / UGI / Other (please specify)

41. Vascular repair – Y / N

42. Admission to critical care – Y / N

43. Total length of hospital stay from index cholecystectomy? Stay in days where day 0 is the day of the index cholecystectomy.

44. Mortality during index admission or within 30 days? Y/N

- f. If yes, list day of death with day 0 being day of index procedure:
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Section D Follow-up

45. Mortality during 1-year follow-up

- a. If yes, list day of death with day 0 being day of index procedure:

46. Please give number of readmissions within first year from index procedure

47. Complications within 1 year (select all the apply) – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / re-repair / None

48. Highest LFT value within 1 year (list 0 if not tested)

- a. Bilirubin
- b. Alkaline Phosphatase
- c. Gamma glutamyl transferase

49. Mortality during 2-year follow-up

- d. If yes, list day of death with day 0 being day of index procedure:

50. Please give number of readmissions within two years from index procedure (include all admissions within first two years)

51. Complications within 2 years (select all the apply) – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / re-repair / None

52. Highest LFT value from 12-24 months after bile duct injury (list 0 if not tested)

- e. Bilirubin
- f. Alkaline Phosphatase
- g. Gamma glutamyl transferase

53. Mortality during 3-year follow-up

- h. If yes, list day of death with day 0 being day of index procedure:

54. Please give number of readmissions within three years from index procedure (include all admissions within the first three years)

55. Complications within 3 years (select all the apply) – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / re-repair / None

56. Highest LFT value from 24-36 months after bile duct injury (list 0 if not tested)

- i. Bilirubin
- j. Alkaline Phosphatase
- k. Gamma glutamyl transferase

Appendix C – Study definitions

1. American Society of Anesthesiologists (ASA) Classification ASA Classification

Definition Examples

Grade I: A normal healthy patient Healthy, non-smoking, no or minimal alcohol use.

Grade II: A patient with mild systemic disease Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity ($30 < \text{BMI} < 40$), well-controlled DM/HTN, mild lung disease

Grade 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 ($\text{BMI} \geq 40$), 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.

Grade 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

Grade 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.

2. Indication for Surgery Definitions

Biliary colic The presence of colicky right upper quadrant pain associated with gallstones or sludge on an USS, but no signs of acute cholecystitis.

Acute calculous cholecystitis Clinical (right upper quadrant pain, with or without fever, $\text{WCC} > 11 \times 10^9/\text{l}$) OR ultrasound evidence (thick-walled gallbladder ($\geq 3\text{mm}$), OR USS tenderness over the gallbladder, the presence of gallstones)

Acute acalculous cholecystitis Clinical OR ultrasound evidence (thick-walled gallbladder and/or pericholecystitis, USS tenderness over the gallbladder) in the absence of gallstones

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

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.

3. Tokyo Guidelines 2018 for Grading of Acute Cholecystitis

Grade I (mild): No organ dysfunction and mild inflammatory changes in the gallbladder.

Grade II (moderate):
o Elevated WBC count ($>18,000/\text{mm}^3$)
o Palpable tender mass in the right upper abdominal quadrant
o Duration of complaints >72 hours
o Marked local inflammation (gangrenous cholecystitis, pericholecystic abscess, hepatic abscess, biliary peritonitis, emphysematous cholecystitis)

Grade III (severe):
o Cardiovascular dysfunction: hypotension requiring treatment with dopamine $\geq 5 \mu\text{g/kg per min}$, or any dose of norepinephrine or
Neurological dysfunction: decreased level of consciousness
o Respiratory dysfunction: $\text{PaO}_2/\text{FiO}_2$ ratio <300
o Renal dysfunction: oliguria, creatinine $>2.0 \text{ mg/dl}$
o Hepatic dysfunction: PT-INR >1.5
o Haematological dysfunction: platelet count $<100,000/\text{mm}^3$

4. Urgency of Surgery

The urgency of index cholecystectomy is defined as:

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.

5. Critical View of Safety

I) Clear Cystohepatic Triangle (borders: common hepatic duct, cystic duct and inferior surface of liver):

The triangle must be completely cleared of all fat and fibrous tissue.

II) Two structures entering the gallbladder:

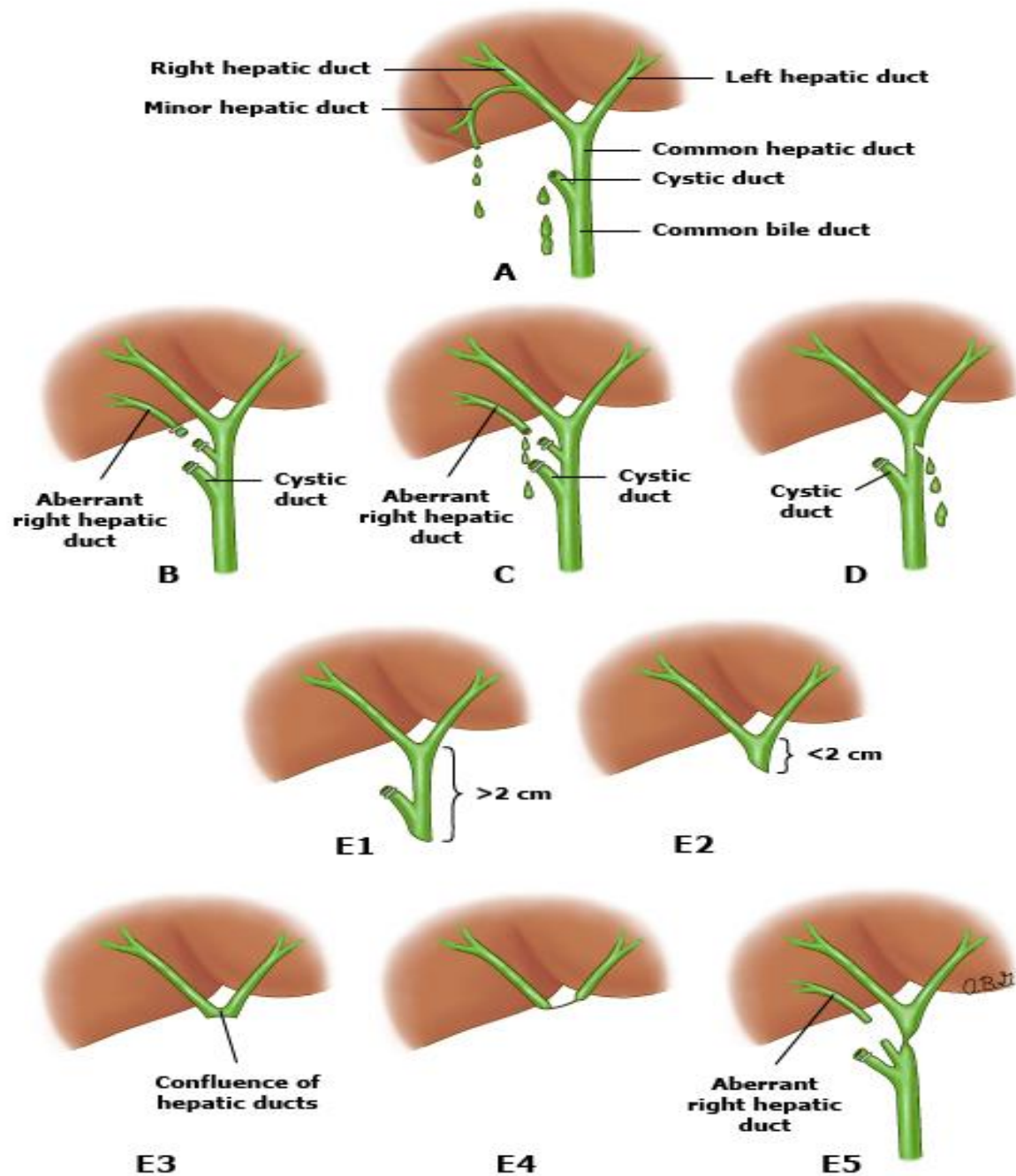
Only two structures attached to the gallbladder, which are the cystic duct and the cystic artery.

III) Gallbladder dissected from the Cystic Plate:

The lower one third of the gallbladder should be completely separated from the underlying liver's cystic plate.

6. Common bile duct injury: Any injury to the main biliary tree will be classified using the Strasberg Classification System (see diagram below):

In this registry we will only include patients with Strasberg grade B to E injuries.



Description of injury grades:

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.

7. Clinical Frailty Score:

- i) Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
- ii) Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.
- iii) Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.
- iv) Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day.
- v) Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.
- vi) Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.

- vii) Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).
- viii) Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.
- ix) Terminally Ill - Approaching the end of life. This category applies to people with a life expectancy.