UK&I BDI
UK and Ireland Bile Duct Injury Registry

Appendix A – data entry form for UK&I Bile Duct Injury Registry

Data entry can be completed directly onto REDCap when Caldicott approvals are in place.

To begin data collection prior to Caldicott approval then please use the paper form until approvals are in place.

Section A Pre-operative data

1. Age at operation (whole years) _____
    a. (If under 18) Age in months in addition to age in years (whole months up to 11) _____
2. Male / Female
3. ASA Grade I / II / III / IV / V
4. Clinical Frailty Score 1 (Very fit) / 2 (Well) / 3 (Managing Well) / 4 (Vulnerable) / 5 (Mildly Frail) / 6 (Moderately Frail) / 7 (Severely Frail) / 8 (Very Severely Frail) / 9 (Terminally Ill)
5. Comorbidities (please select all that apply)
   Myocardial Infarction (MI) / Other ischaemic heart disease / Congestive Heart Failure (CHF) / Peripheral Vascular Disease (PVD) / Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) / Dementia / Chronic Obstructive Pulmonary Disease (COPD) / Connective Tissue Disease (CTD) / Peptic Ulcer Disease (PUD) / Hemiplegia / Leukaemia / Lymphoma / Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS) / Hypertension / Inflammatory Bowel Disease (IBD) / 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 _____

6. Prior intraperitoneal abdominopelvic surgery (Open / Laparoscopic / Robotic / None)
   a. If Yes Above Umbilicus / All below umbilicus
7. Weight _____
8. Height _____
9. BMI _____
10. Previous acute admissions in past 12 months (how many?) _____
11. History of acute cholecystitis or cholangitis? Y/N
12. Pre-operative Imaging?
   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) _____
   c. Pericholecystic fluid Y/N
   d. Dilated CBD Y/N/Specific measurement
      i. Measurement (if provided) _____
   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) _____

15. Days between decision to operate and surgery performed: _____
16. Pre-operative blood tests:
   a. Bilirubin _____
   b. Alkaline phosphatase _____
   c. Gamma glutamyl transferase _____
17. Prior Biliary Procedures
   a. Cholecystostomy Y/N
   b. Subtotal cholecystectomy Y/N

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 within 12 months

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

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Section B Operative Details

19. Urgency of surgery
    a. Emergency / Delayed / Elective
    b. If Emergency, was patient on elective WL Y/N
20. Date of initial operation _____
21. Type of Hospital – DGH / Teaching / Private / Treatment Centre
22. Operating Surgeon – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other _____
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 / General / Transplant
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. Y/N
    d. Is there a description of the hepatocystic triangle being completely cleared of all adipose and fibrous tissue. Y/N

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

28. Intraoperative cholangiogram - Y /N
29. Intraoperative ultrasound Y/N
30. Cholangioscopy Y/N
31. Called for help – Y / N
    a. Who came to help – Consultant / Associate Specialist / Specialist Registrar / Trust Grade / Other (please specify) / No additional help sought
    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
36. Referral to HPB centre made? Y/ N
    a. If yes, how many days after surgery was referral made? _____
    b. If no, was injury in tertiary referral centre? Y / N
37. Concomitant vascular injury – Y / N
    a. 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 / Other (Please specify) _____

39. Initial management of BDI? Roux-en-Y HJ / CBD or CHD repair +/- T-tube / Drain only / Other (please specify) _____
    a. 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? _____
44. Mortality during index admission or within 30 days? Y/N
    a. If yes, list day of death with day 0 being day of index procedure: _____

Section D Follow-up

45. Mortality during 1-year follow-up Y/N
    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
    a. 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)
    a. Bilirubin _____
    b. Alkaline Phosphatase _____
    c. Gamma glutamyl transferase _____
53. Mortality during 3-year follow-up Y/N
    a. 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)
    a. Bilirubin _____
    b. Alkaline Phosphatase _____
    c. Gamma glutamyl transferase _____