EAST MULTICENTER STUDY
DATA DICTIONARY

Current Management of Suspected Retained Common Bile Duct Stones in Gallstone Pancreatitis and Choledocholithiasis

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
Site ID	Each site's assigned number
Patient Number	6-digit number starting with your Site ID, ie. 12-001, 12-002, 12-003, and 12-004.
Demographics:	
Admit Date	Admission date of the patient enrolled
Admit Time	Admission time of the patient enrolled
Discharge Date	Discharge date of the patient enrolled
Age	Age of patient enrolled
Gender	Gender of Patient enrolled
Weight	How much patient weighs (in kg)
BMI	Calculate Body Mass Index
Insurance status	Indicate if patient insured or uninsured
Preoperative Diagnosis	Diagnosis of the patient at time of admission (Select single best choice for description of diagnosis: CDL = choledocholithiasis; GSP = Gallstone pancreatitis)
Pre-hospital comorbidities (check all that apply):	
Hypertension	Abnormally high blood pressure
Diabetes mellitus	A long-term metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin
Peripheral vascular disease	A circulation disorder characterized by narrowing or blockage of blood vessels

Coronary artery disease	An impedance or blockage of one or more blood vessels that supplies blood to the heart
Current smoker	If patient is an active smoker at the time of initial presentation, check yes
Alcohol abuse	A pattern of drinking that results in harm to one's health, interpersonal relationships, or ability to work
Substance abuse	The harmful or hazardous use of psychoactive substances, including illicit drugs
Prior abdominal operations	Any prior surgery in the abdomen (free text)
Steroids	Current use of any steroid medication
Chemothoerapy	Currently on chemotherapy for any reason
Other Immunosuppressant medications	List other immunosuppressive medications not listed above
Tobacco use	Indicate current use of any type of tobacco product

Admission Physiology

Temperature	Temperature at the time of presentation
Initial HR	Heart rate at the time of presentation
Initial SBP	Systolic blood pressure at the time of presentation
Duration of Symptoms	Indicate Duration of symptoms (in hours) from symptom onset until ED triage
RUQ pain	Single best choice for presentation or abscence of right upper quadrant (RUQ) tenderness to palpation (Yes or no)
Diffuse abdominal tenderness	Single choice for best description of presence or absence of diffuse abdominal tenderness to palpation (Options include yes or no)
Jaundice	Single choice for best description of presence or absence of jaundice (can include scleral icteris)
Admission Lab Values	Indicate date and time admission labs were collected:
WBC	Admission White Blood Cell Count (K/mcL)
HGB	Admission Hemoglobin (g/dL)
T. Bili	Admission Total Serum Bilirubin (mg/dL)
D. Bili	Admission Direct Serum Bilirubin (mg/dL)
AST (SGOT)	Admission Aspartate transaminase (U/L)
ALT (SGPT)	Admission Alanine transaminase (U/L)
ALP	Admission Alkaline Phosphatase (U/L)
Repeat Lab values:	Indicate date and time first set of **repeat** labs were collected:

WBC	Repeat White Blood Cell Count (K/mcL)
HGB	Repeat Hemoglobin (g/dL)
T. Bili	Repeat Total Serum Bilirubin (mg/dL)
D. Bili	Repeat Direct Serum Bilirubin (mg/dL)
AST (SGOT)	Repeat Aspartate transaminase (U/L)
ALT (SGPT)	Repeat Alanine transaminase (U/L)
ALP	Repeat Alkaline Phosphatase (U/L)

Management Variables

Preoperative Procedures:

Preoperative Ultrasound	Check if right upper quadrant ultrasound was performed preoperatively. Indicate date and time procedure was performed. Check off ultrasound findings such as presence of gallstones, pericholecystic fluid, gallbladder wall thickening. Indicate the diameter of the CBD in millimeters. Indicate whether stones were visualized in the common bile duct. Free text other findings
Preoperative ERCP	Check if Endoscopic Retrograde Cholangiopancreatography (endoscopic cannulation of the common bile duct with a side-viewing endoscope and a retrograde contrast injection) was performed prior to cholecystectomy. Indicate date and time procedure was performed. Indicate whether CBD stones were seen. Free text other findings ONLY if preoperative ERCP was performed. Leave blank if none performed
Preoperative MRCP	Check if Magnetic Resonance Cholangiopancreatography (non-invasive medical imaging technique) was performed prior to cholecystectomy. Indicate the date and time the procedure was performed. Indicate whether CBD stones were seen. Free text other findings ONLY if preoperative MRCP was performed, otherwise leave blank
Preoperative EUS	Check here if Endoscopic ultrasound was done prior to cholecystectomy. Include the date and time that it was performed. Indicate if stones were visualized in the CBD. Free text any other findings ONLY if preoperative endoscopic ultrasound was performed, otherwise leave blank
Preoperative CT Scan	Check here if CT scan was done prior to cholecystectomy. Include the date and time that it was performed. Indicate if stones were visualized in the CBD. Indicate if there was fluid around the gallbladder, stones in the gallbladder, presence of wall thickening, diameter of CBD, presence of CBD stones. Free text any other findings ONLY if CT was performed, otherwise leave blank

Preoperative Antibiotics

Type of antibiotics	Indicate if preoperative antibiotics were used. Free text entry for specific type of antibiotic initiated Generic or trade-name acceptable
Duration of antibiotic	Number of days antibiotic was used

Operative Procedures

Initial Operative Approach	Check single best option for initial operative approach (i.e. laparoscopic single incision, laparoscopic four incision, open, other)
IOC Intraoperative ERCP Intraoperative EUS	Check off if IOC (Intraoperative cholangiogram), intraoperative ERCP or intraoperative EUS were performed. Indicate whether CBD stones were visualized. Free text any other findings
Final Operative Approach	Check single best option for final operative approach (i.e. laparoscopic single incision, laparoscopic four incision, open via subcostal incision, open via midline incision)
Final Operation	Single best option for final operation
Intraoperative Findings	Options include (choose all that apply): Normal gallbladder with stones Normal gallbladder without stones Acutely inflamed gallbladder, intact Perforated gallbladder with local contamination Perforated gallbladder with abscess or phlegmon Perforated gallbladder with purulent contamination away from gallbladder Gangrenous gallbladder, intact Gangrenous gallbladder with local contamination Gangrenous gallbladder with abscess or phlegmon Gangrenous gallbladder with purulent contamination away from gallbladder
Intraoperative adverse event (iAE)	Single best option for presence or absence of iAE. Options include Yes or No
iAE Grade	Single best option for grade of intraoperative event 1 – injury requiring no repair within the same procedure (cauterization, use of prothrombotic material, small vessel ligation) 2 – injury requiring surgical repair, without organ removal or a change in the planned procedure (e.g. any suture repair, patch repair) 3 – injury requiring tissue or organ removal with completion of the originally planned procedure 4 – injury requiring a significant change (excluding minimally invasive to open conversions) and/or incompletion of the originally planned procedure 5 – missed intraoperative injury requiring reoperation within 7 days 6 – intraoperative death
iAE required transfusion of > or = 2 units pRBC	Indicate yes or no
Operative duration (min): (skin to skin)	Indicate duration of operation in minutes (enter -99 if N/A)
Surgical drains	Indicate whether surgical drains were placed
Postoperative Procedures:	Check off any postoperative procedures that were performed (ERCP or MRCP). Indicate the date and time that they were performed. Indicate

	whether CBD stones were visualized. Free text any other findings ONLY if that postoperative procedure was performed, otherwise leave blank
Postoperative Antibiotic use: Type of antibiotics	Indicate if postoperative antibiotics were used. Free text entry for specific type of antibiotic initiated Generic or trade-name acceptable
Duration of antibiotic	Number of days antibiotic was used

Outcomes:

Index hospitalization discharge date	Date of discharge
Hospital LOS (days)	Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1) LOS = Length of Stay
ICU LOS (days)	Free text entry of number of consecutive days patient required ICU admission (ICU = Intensive Care Unit, LOS = Length of Stay) - Day of admission = hospital day #1
Duration of Mechanical Ventilation (days)	Free text entry for total number of days patient required mechanical ventilation (Day of admission = hospital day #1)
Mortality	Indicated if patient expired during initial hospitalization

Complications (check all that apply and list hospital day encountered):
Note: for calculation of all complication days, day of admission = hospital day #1

Surgical Site Infection (SSI)	Defined as: signs and symptoms of infection (redness, tenderness, warmth, purulent drainage) requiring treatment (either incisional opening or antibiotic prescription)
Superficial Incisional SSI	Check if applies. SSI = Surgical Site infection. Indicate location of infection and date it was discovered.
Deep Incisional SSI	Check if applies. Indicate location, as well as date discovered.
Organ/Space SSI	Check if applies. Indicate location and date discovered.
SSI Grade	Grade 2 = localized, local intervention indicated Grade 3 = IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated Grade 4 = life-threatening consequences (eg, septic shock, hypotension, acidosis, necrosis) Grade 5 = death secondary to infection (National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE))
Intra-abdominal abscess	Defined as signs and symptoms of deep infection (abdominal tenderness, obstruction, nausea, diarrhea) confirmed by imaging

	(ultrasound or CT) and requiring treatment (either open or percutaneous drainage or antibiotic prescription)
Wound complication	
Wound Complication Grade	Wound complication Grade: Grade 1 = Incisional separation of < = 25% of wound, no deeper than superficial fascia Grade 2 = Incisional separation >25% of wound with local care; asymptomatic hernia Grade 3 = Symptomatic hernia without evidence of strangulation; fascial disruption/dehiscence without evisceration; primary wound closure or revision by operative intervention indicated; hospitalization or hyperbaric oxygen indicated Grade 4 = Symptomatic hernia with evidence of strangulation; fascial disruption with evisceration; major reconstruction flap, grafting, resection, or amputation indicated Grade 5 = Death
Bleeding	Check if applies. Refers to significant postoperative hemorrhage leading to drop in hemoglobin +/- transfusion and/or return to Operating room; indicate date bleeding first occurred
Bleeding Grade:	Grade 1 = hematoma with minimal symptoms, invasive intervention, not indicated Grade 2 = hematoma with minimally invasive evacuation or aspiration indicated Grade 3 = transfusion, interventional radiology, or operative intervention Grade 4 = bleeding with life-threatening consequences or major urgent intervention Grade 5 = death secondary to hemorrhage
Bile leak	Check if applies. Leak of bile from cystic duct, gallbladder bed or injury to major duct, diagnosed by laboratory studies and imaging. Indicate location of leak if known and date it was discovered
Retained stones	Check if applies. Laboratory or ultrasound evidence of postoperative choledocholithiasis that is confirmed on IOC, ERCP, MRCP, EUS
Shock	Check if applies. Condition in which abnormal distribution of blood flow results in inadequate blood supply to the body's tissues, resulting in ischemia and end-organ dysfunction. Indicate date diagnosed
Sepsis	Has a confirmed infectious process AND two or more of the following: Fluid unresponsive hypotension Serum lactate level >2 mmol/L Need for vasopressors to maintain mean arterial pressure >65 mmHg
Blood stream infection	Defined as positive cultures obtained from blood culture
Blood Stream Infection Grade:	Grade 2 = localized, local intervention indicated Grade 3 = IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated Grade 4 = life-threatening consequences (eg, septic shock, hypotension, acidosis, necrosis)

	Grade 5 = death secondary to infection (National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE))
Catheter-associated urinary tract Infection (UTI)	All criteria must be met: Patient has indwelling urinary catheter within 7 days before urinary culture Positive urine culture that is $\geq 10^5$ microorganisms/mL of urine with no more than two species of microorganisms Urine culture has 10 WBC/HPF
Catheter-associated UTI Grade:	Grade 2 = localized, local intervention indicated Grade 3 = IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated Grade 4 = life-threatening consequences (eg, septic shock, hypotension, acidosis, necrosis) Grade 5 = death secondary to infection (National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE))
Post-operative ileus	Check if applies.
Post-operative ileus Grade:	Grade 1 = asymptomatic, radiographic findings only Grade 2 = symptomatic; altered GI function (eg, altered dietary habits); IV fluids indicated for < 24 h Grade 3 = symptomatic and severely altered GI function; IV fluids, tube feeding, or TPN indicated for ≥ 24 h Grade 4 = life-threatening consequences Grade 5 = death secondary to ileus (National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE))
Hospital acquired pneumonia	Check if applies. HAP = hospital acquired pneumonia; indicate date diagnosed Definition below

Hospital Acquired Pneumonia: Confirmed by the presence of the following after 48 hours of hospitalization:

1. Purulent sputum
2. Associated systemic evidence of infection:
   a. WBC > 11,000 or < 4,000
   b. Fever > 100.4 degrees F / 38 degrees Celsius
3. Two or more serial chest radiographs with new or progressive and persistent infiltrate, consolidation or cavitation.
4. BAL, mini-BAL or sterile endotracheal specimen with:
   a. Limited number of epithelial cells
   b. WBC (2-3+)
   c. Dominant organism(s) identified on gram stain or culture with quantitative culture > 100,000 cfu/mL

Hospital Acquired Pneumonia Grade:	Grade 2 = localized, local intervention indicated Grade 3 = IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated Grade 4 = life-threatening consequences (eg, septic shock, hypotension, acidosis, necrosis) Grade 5 = death secondary to infection

	(National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE))
ARDS	Check if applies. ARDS = Acute respiratory distress syndrome. Indicate date diagnosed Definition below

ARDS: Berlin definition will be utilized

-Mild ARDS: 201 - 300 mmHg (≤ 39.9 kPa)
-Moderate ARDS: 101 - 200 mmHg (≤ 26.6 kPa)
-Severe ARDS: ≤ 100 mmHg (≤ 13.3 kPa)
-New onset of bilateral infiltrates (patchy, diffuse, or homogenous) consistent with pulmonary edema
-No clinical evidence of left atrial hypertension

AKI	Check if applies. AKI = Acute kidney injury; indicate date diagnosed. Defined for the purpose of this study as elevation of serum creatinine greater or equal to 1.5 x ULN during hospitalization in patient without antecedent renal dysfunction
AKI Grade:	Grade 1 = creatinine between upper limit of normal (ULN) and 1.5 x ULN Grade 2 = creatinine between 1.5 to 3.0 x ULN Grade 3 = creatinine between 3.0 to 6.0 x ULN Grade 4 = creatinine > 6.0 x ULN Grade 5 = death
DVT/PE:	Check if applies. DVT/PE = Deep vein thrombosis/Pulmonary embolus; indicate date diagnosed
DVT/PE Grade:	Grade 2 = intervention (e.g., anticoagulation, lysis, filter, invasive procedure) not indicated Grade 3 = intervention (e.g., anticoagulation, lysis, filter, invasive procedure) indicated Grade 4 = embolic event including pulmonary embolism or life-threatening thrombus Grade 5 = death (National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE))
Myocardial infarction (MI)	Check if applies. Indicate date diagnosed. Definition below.

Myocardial infarction: detection of a rise of cardiac biomarker values (preferably troponin) with at least one of the following:

-Symptoms of ischemia
-New or presumed new significant ST-segment-T wave (ST-T) changes or new left bundle branch block
-Development of pathological Q waves in the EKG
-Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
-identification of an intracoronary thrombus by angiography or autopsy

Myocarcdial infarction Grade:	Grade 1 = asymptomatic arterial narrowing (on angiography) without ischemia Grade 2 = asymptomatic and testing suggesting ischemia; stable angina Grade 3 = symptomatic and testing consistent with ischemia; unstable angina; intervention indicated Grade 4 = acute myocardial infarction Grade 5 = death

	(National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)
Congestive heart failure (CHF)	Check if applies. Indicate date diagnosed. Heart failure in which the heart is unable to maintain adequate circulation of blood in the bodily tissues or to pump out the venous blood returned
Clavien-Dindo surgical complication	Check yes or no
Clavien-Dindo Grade: _____	
	Grade 1 = Any deviation from the normal postoperative course without the need for (If multiple, choose highest grade) pharmacological treatment or surgical, endoscopic,and radiologic interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound nfections opened at the bedside. Grade 2 = Requiring pharmacological treatment with drugs other than such allowed for Grade 1 complications. Blood transfusions and total parenteral nutrition are also included. Grade 3a = Requiring surgical, endoscopic, or radiologic intervention. Intervention NOT under general anesthesia Grade 3b = Requiring surgical, endoscopic, or radiologic intervention. Intervention under general anesthesia Grade 4a = Life-threatening complication (including CNS complications) requiring ICU management. Single organ complication (including dialysis) Grade 4b = Life-threatening complication (including CNS complications)* requiring ICU management. Multiorgan dysfunction Grade 5 = Death of a patient (*brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks)
Was patient suffering from this complication at the time of discharge?	Indicate yes or no
Secondary intervention	Select other secondary interventions performed related to CDL or GSP during the initial hospitalization; free text if other intervention not listed
<u>Pathology</u> Intraoperative cultures taken	Indicate yes or no and whether cultures were positive or negative; if positive, free text organisms that were cultured
Final pathologic diagnosis	Free text pathology
<u>30-day Outcomes</u>:	
Return to ED within 30 days	Check if patient returned to ED within 30 days of index hospitalization (with or without admission) for abdominal complaints and indicate if gallbladder related
Readmission within 30 days	Check if applies. Indicate number of days post-discharge and reason for readmission

Reoperation within 30 days	Check if applies. Indicate date and reason for reoperation. Free text type of reoperation performed
30-day Complications	Check all complications and grades that occurred within 30 days after discharge from index hospitalization
30-day Hospitalization LOS	Readmission length of stay in days
30-day ICU LOS	Readmission length of ICU stay (in days)
Secondary intervention	Indicate if secondary interventions occurred during 30-day readmission period
Mortality within 30 days of index hospitalization	Indicate yes or no

DATA COLLECTION SHEET

Current Management of Retained Common Bile Duct Stones in Gallstone Pancreatitis and Choledocholithiasis

Site ID:

Patient Number (6-digit number starting with your Site ID, ie. 12-001, 12-002, 12-003, and 12-004.

Demographic Information:

Admit Date: ____ Admit Time: ____ Discharge Date: ____

Age: _____ Gender: ____

Weight: _____ BMI: _____

Insurance status:
Insured (Y/N): Type of Insurance: _____

Preoperative Diagnosis (circle one): CDL vs. GSP

Pre-hospital comorbidities (check all that apply):
Hypertension: ____
Diabetes mellitus: ____
Peripheral vascular disease: ____
Coronary artery disease: ____
Current smoker: ____
Alcohol abuse: ____
Substance abuse: ____

Prior abdominal operations (Y/N)
List of prior abdominal operations _____
Steroids (Y/N)
Chemothoerapy (Y/N)
Immunosuppressant medications (Y/N)
Name of immunosuppressant medications _____
Tobacco use (Y/N)

Charlson Comorbidity Index:

1 point each for:
History of myocardial infarction ____
PVD (includes AAA ≥ 6cm) ____
CVA with mild or no residual or TIA ____
Dementia ____
Chronic pulmonary disease ____
Connective tissue disease ____
Peptic ulcer disease ____
Mild liver disease (without portal hypertension, includes chronic hepatitis) ____
Diabetes without end-organ damage (excludes diet-controlled alone) ____

2 points each for:
Hemiplegia ____
Moderate or severe renal disease ____

Diabetes with end-organ damage (retinopathy, neuropathy, or brittle diabetes) ____
Tumor without metastases (exclude if >5 y from diagnosis) ____
Leukemia (acute or chronic) ____
Lymphoma ____

3 points for:
Moderate or severe liver disease ____

6 points each for:
Metastatic solid tumor ____
AIDS (not just HIV positive) ____
NOTE: for each decade > 40 years of age, a score of 1 is added to the above score ____

TOTAL SCORE: _____

Admission Physiology:

Temperature: _____ initial HR: _____ Initial BP: _____

Duration of Symptoms (from symptom onset until ED triage): ____

RUQ pain (Y/N)

Diffuse abdominal tenderness (Y/N)

Jaundice (Y/N)

Admission Lab values: Date/Time Collected: _____

WBC: ____
Hgb: ____
Tbili: ____
Dbili: ____
ALP: ____
AST: ____
ALT: ____

Repeat Lab values: Date/Time Collected: _____

WBC: ____
Hgb: ____
Tbili: ____
Dbili: ____
ALP: ____
AST: ____
ALT: ____

Management Variables:

Preoperative Procedures (Check all that apply):

Preoperative Ultrasound (Y/N) Date/Time: _____
Cholelithiasis (Y/N)

Pericholecystic Fluid (Y/N)
Wall thickening (Y/N)
CBD Diameter ____
CBD stones (Y/N)
Other findings: ____

Preoperative ERCP (Y/N) Date/Time: _____
CBD stones (Y/N)
Other findings: ____

Preoperative MRCP (Y/N) Date/Time: _____
CBD stones (Y/N)
Other findings: ____

Preoperative EUS (Y/N) Date//Time: _____
CBD stones (Y/N)
Other findings: ____

Preoperative CT Scan (Y/N)
Cholelithiasis (Y/N)
Pericholecystic Fluid (Y/N)
Wall thickening (Y/N)
CBD Diameter: ____
CBD stones (Y/N)
Other findings: _____

Initial Operative Procedures/Treatment strategy (Check all that apply):

Preoperative antibiotic use (Y/N)
Preoperative antibiotic duration? <24 or >/= 24h
Duration of pre-operative antibiotics (Days) _____
Class of post-intervention antibiotics (Circle all that apply)
Penicillin
1st generation cephalosporin
2nd generation cephalosporin
3rd generation cephalosporin
4th generation cephalosporin
beta lactam
Fluoroquinolone
Vancomycin
Clindamycin
Macrolide
Aminoglycoside
Flagyl
Tetracycline
Sulfonamide
Pipercillin/tazobactam (Zosyn)
Amoxicillin/clavulanate (Augmentin)
Ampicillin/sulbactam (Unasyn)

Initial Operative Approach:
Date of Surgery _____
Laparoscopic single incision (Y/N)
Laparoscopic four incision (Y/N)

Percutaneous drainage (Y/N)
Open
Other

IOC (Y/N)
    CBD stones (Y/N)
    Other findings: ____

Intraoperative ERCP (Y/N)
    CBD stones (Y/N)
    Other findings: ____

Intraoperative EUS (Y/N)
    CBD stones (Y/N)
    Other findings: ____

Other Operative approach: ____

Final operative approach:
Laparoscopic single incision (Y/N)
Laparoscopic four incision (Y/N)
Percutaneous drainage (Y/N)
Open
Other

Final Operation (Check one):
Cholecystectomy
Partial cholecystectomy
Percutaneous drainage without cholecystectomy
Cholecystectomy with common bile duct exploration

Intraoperative findings (Check one):
    Normal gallbladder with stones
    Normal gallbladder without stones
    Acutely inflamed gallbladder, intact
    Perforated gallbladder with local contamination
    Perforated gallbladder with abscess or phlegmon
    Perforated gallbladder with purulent contamination away from gallbladder
    Gangrenous gallbladder, intact
    Gangrenous gallbladder with local contamination
    Gangrenous gallbladder with abscess or phlegmon
    Gangrenous gallbladder with purulent contamination away from gallbladder

Intraoperative adverse event (Y/N)

iAE Grade:
    1 – injury requiring no repair within the same procedure (cauterization, use of prothrombotic material, small vessel ligation)
    2 – injury requiring surgical repair, without organ removal or a change in the planned procedure (e.g. any suture repair, patch repair)
    3 – injury requiring tissue or organ removal with completion of the originally planned procedure
    4 – injury requiring a significant change (excluding minimally invasive to open conversions) and/or incompletion of the originally planned procedure
    5 – missed intraoperative injury requiring reoperation within 7 days
    6 – intraoperative death

iAE required transfusion of > or = 2 units pRBC (Y/N)

Operative duration (min): (skin to skin) _____

Surgical drains (Y/N)

Postoperative Procedures

Postoperative ERCP (Y/N) Date/Time: _____
- CBD stones (Y/N)
- Other findings: ____

Postoperative MRCP (Y/N) Date/Time: _____
- CBD stones (Y/N)
- Other findings: ____

Postoperative Antibiotic use:

Preoperative antibiotic use (Y/N)
Preoperative antibiotic duration? <24 or >/= 24h
Duration of pre-operative antibiotics (Days)
Class of post-intervention antibiotics (Check all that apply):
- Penicillin
- 1st generation cephalosporin
- 2nd generation cephalosporin
- 3rd generation cephalosporin
- 4th generation cephalosporin
- beta lactam
- Fluoroquinolone
- Vancomycin
- Clindamycin
- Macrolide
- Aminoglycoside
- Flagyl
- Tetracycline
- Sulfonamide
- Pipercillin/tazobactam (Zosyn)
- Amoxicillin/clavulanate (Augmentin)
- Ampicillin/sulbactam (Unasyn)

Outcomes:

Index hospitalization discharge date: _____
Hospital LOS: _____ ICU LOS: _____
Ventilator Days: _____ Mortality (circle one): YES / NO
Disposition: _____

Complications (check all that apply):

Superficial SSI: ____ POD: _____
- Location ____

Deep SSI: ____ POD: _____
- Location: ____

Organ/Space SSI: ____ POD: _____
- Location: ____

Intra-abdominal abscess: ____ HD: _____
- Location: ____

SSI Grade: ____

Wound complications: ____ POD: _____
Wound complication Grade:

Grade 1 = Incisional separation of < = 25% of wound, no deeper than superficial fascia
Grade 2 = Incisional separation >25% of wound with local care; asymptomatic hernia
Grade 3 = Symptomatic hernia without evidence of strangulation; fascial disruption/dehiscence without evisceration; primary wound closure or revision by operative intervention indicated; hospitalization or hyperbaric oxygen indicated
Grade 4 = Symptomatic hernia with evidence of strangulation; fascial disruption with evisceration; major reconstruction flap, grafting, resection, or amputation indicated
Grade 5 = Death

Bleeding: ____ HD: _____ (HD#1 is day of ED admission)
Bleeding Grade: ____
Bile leak: ____ HD: _____
Retained stones: ____ HD: _____
Shock: ____ HD: _____
Sepsis: ____ HD: _____
Blood stream infection: ____ HD: _____
Blood stream infection Grade: ____
Catheter-associated UTI: ____ HD: _____
Catheter-associated UTI Grade: ____
Post-operative ileus: ____ HD: _____
Post-operative ileus Grade: ____
HAP: ____ HD: _____
HAP Grade: ____
ARDS: ____ HD: _____
ARDS Severity: ____
AKI: ____ HD: _____
AKI Grade: ____
DVT/PE: ____ HD: _____
DVT/PE Grade: ____
Myocardial Infarction: ____ HD: _____
Myocardial Infarction Grade: ____
Congestive heart failure: ____ HD: _____

Clavien-Dindo surgical complication (Y/N)
Clavien-Dindo Grade: _____

Grade 1 = Any deviation from the normal postoperative course without the need for (If multiple, choose highest grade) pharmacological treatment or surgical, endoscopic,and radiologic interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound nfections opened at the bedside.

Grade 2 = Requiring pharmacological treatment with drugs other than such allowed for Grade 1 complications. Blood transfusions and total parenteral nutrition are also included.

Grade 3a = Requiring surgical, endoscopic, or radiologic intervention. Intervention NOT under general anesthesia

Grade 3b = Requiring surgical, endoscopic, or radiologic intervention. Intervention under general anesthesia

Grade 4a = Life-threatening complication (including CNS complications) requiring ICU management. Single organ complication (including dialysis)

Grade 4b = Life-threatening complication (including CNS complications)* requiring ICU management. Multiorgan dysfunction

Grade 5 = Death of a patient (*brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks)

Was patient suffering from this complication at the time of discharge?

Secondary intervention: ____ HD: _____
Type: ____
Reason: ____

Pathology
Intraoperative cultures taken (Y/N)
Cultures positive (Y/N) If yes, cultured organisms _____

Final pathologic diagnosis _____

30-day Outcomes
Return to ED (within 30 days of index hospitalization) for abdominal complaints? (Y/N)
How many days post-discharge _____
Gallbladder related (Y/N)

Readmission within 30 days: ____ # days post discharge: _____
Reason for readmission:____

Reoperation within 30 days: ____ HD: _____
Reason for reoperation: ____

Superficial SSI: ____ POD: _____
Location ____
Deep SSI: ____ POD: _____
Location: ____
Organ/Space SSI: ____ POD: _____
Location: ____
Intra-abdominal abscess: ____ HD: _____
Location: ____
SSI Grade: ____

Wound complications: POD: _____
Wound complication Grade: ____
Grade 1 = Incisional separation of < = 25% of wound, no deeper than superficial fascia
Grade 2 = Incisional separation >25% of wound with local care; asymptomatic hernia
Grade 3 = Symptomatic hernia without evidence of strangulation; fascial disruption/dehiscence without evisceration; primary wound closure or revision by operative intervention indicated; hospitalization or hyperbaric oxygen indicated
Grade 4 = Symptomatic hernia with evidence of strangulation; fascial disruption with evisceration; major reconstruction flap, grafting, resection, or amputation indicated
Grade 5 = Death

Bleeding: ____ HD: _____ (HD#1 is day of ED admission)
Bleeding Grade: ____
Bile leak: ____ HD: _____
Retained stones: ____ HD: _____
Shock: ____ HD: _____
Sepsis: ____ HD: _____
Blood stream infection: ____ HD: _____
Blood stream infection Grade: ____
Catheter-associated UTI: ____ HD: _____
Catheter-associated UTI Grade: ____
Post-operative ileus: ____ HD: _____
Post-operative ileus Grade: ____
HAP: ____ HD: _____
HAP Grade: ____
ARDS: ____ HD: _____
ARDS Severity: ____
AKI: ____ HD: _____
AKI Grade: ____
DVT/PE: ____ HD: _____
DVT/PE Grade: ____
Myocardial Infarction: ____ HD: _____
Myocardial Infarction Grade: ____
Congestive heart failure: ____ HD: _____

Clavien-Dindo surgical complication (Y/N)
Clavien-Dindo Grade: _____

Was patient suffering from this complication at the time of discharge (Y/N)

30 day hospitalization LOS (days) _____
30-day ICU LOS _____
Secondary intervention within 30 days of index hospitalization discharge (Y/N) (Do not code if already coded in previous sections)
Secondary intervention (check all that apply)

- Failure of medical management
- Percutaneous drainage
- Lysis of adhesions
- SBO
- Bile leak
- Duct injury
- Surgical repair of leak
- Surgical repair of bile duct injury
- Hernia repair
- Endoscopy
- Other _____

Mortality within 30 days of index hospitalization discharge (Y/N)