

CHOLENZ Case Report Form (CRF)

Use with Data Dictionary from Protocol to help with data collection.

REDCap Unique ID				Date of Admission		___ / ___ / 2021		
Preoperative data fields				Date of Admission				
Age (years)	Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female		Weight (kg)	___ . ___ (1dp)	Height (m)	___ . ___ (2dp)	
Ethnicity	European / Māori / Pacific / Asian / Other			BMI (kg/m ²)	<input type="checkbox"/> Underweight (<18.5) <input type="checkbox"/> Normal range (18.5-24.9) <input type="checkbox"/> Overweight (25-30) <input type="checkbox"/> Obese (>30)			
ASA Grade	I / II / III / IV / V			<input type="checkbox"/> Current <input type="checkbox"/> Ex-smoker <1 month <input type="checkbox"/> Ex-smoker >1 month <input type="checkbox"/> Never smoker				
Prev abdominal surgery	<input type="checkbox"/> Yes <input type="checkbox"/> No	Smoking status		USS Date: ___ / ___ / 21 Thick walled gallbladder: Y/N CBD Dilated: Y/N CBD Diameter: ___ mm CT: ___ / ___ / 21 ERCP: ___ / ___ / 21 MRCP: ___ / ___ / 21 EUS: ___ / ___ / 21 HIDA: ___ / ___ / 21 Hb ___ g/L Platelets ___ /mm ³ WBC ___ . ___ 10 ⁹ /L (1dp) ALP ___ IU/L CRP ___ mg/L ALT ___ IU/L INR ___ Bilirubin ___ μmol/L				
Comorbidities	<input type="checkbox"/> 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"/> Connective Tissue Disease <input type="checkbox"/> Peptic Ulcer Disease <input type="checkbox"/> Hemiplegia <input type="checkbox"/> AIDS <input type="checkbox"/> Leukaemia <input type="checkbox"/> Lymphoma			Preoperative imaging				
Solid tumour	<input type="checkbox"/> None <input type="checkbox"/> Localised <input type="checkbox"/> Metastatic							
Diabetes	<input type="checkbox"/> Diet controlled <input type="checkbox"/> Uncomplicated (medical Mx) <input type="checkbox"/> End-organ damage			Last preoperative blood test				
CKD	Baseline Cr <input type="checkbox"/> <270 <input type="checkbox"/> >270 (μmol/L) <input type="checkbox"/> Dialysis <input type="checkbox"/> Prev kidney transplant <input type="checkbox"/> Uraemia							
Chronic Liver Disease	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate (prev. portal HTN) <input type="checkbox"/> Severe (prev. variceal bleeding)							
Indication for surgery	<input type="checkbox"/> Biliary colic <input type="checkbox"/> Acute/chronic calculous cholecystitis <input type="checkbox"/> Gallstone pancreatitis <input type="checkbox"/> CBD stone(s) <input type="checkbox"/> Gallbladder polyp <input type="checkbox"/> Dyskinesia <input type="checkbox"/> Acalculous cholecystitis <input type="checkbox"/> Other		Number and duration of admissions with biliary symptoms in last 24mo: (Does not count ED presentations)	<input type="checkbox"/> 1 st admission: ___ d <input type="checkbox"/> 2 nd admission: ___ d <input type="checkbox"/> 3 rd admission: ___ d <input type="checkbox"/> 4 th admission: ___ d <input type="checkbox"/> 5 th admission: ___ d <input type="checkbox"/> 6 th admission: ___ d Total days: _____ d		Antibiotics before going to theatre this admission? <input type="checkbox"/> Yes <input type="checkbox"/> No		
						Preoperative cholecystostomy? <input type="checkbox"/> Yes Date: ___ / ___ / 21 <input type="checkbox"/> No		

Operative data fields				Date of Operation				___ / ___ / 2021	
Urgency	<input type="checkbox"/> Acute (Index) →		Date decision made to operate?		___ / ___ / 2021		Planned day case?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Delayed →		Date of last discharge w/ symptomatic biliary disease?		___ / ___ / 2021				
	<input type="checkbox"/> Elective →		Date last seen in outpatient clinic?		___ / ___ / 2021				
Primary Surgeon	<input type="checkbox"/> Non-SET trainee <input type="checkbox"/> SET trainee <input type="checkbox"/> Fellow <input type="checkbox"/> MOSS <input type="checkbox"/> Consultant			Consultant in theatre?	<input type="checkbox"/> Yes <input type="checkbox"/> No		Prophylactic antibiotics?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Operative approach	<input type="checkbox"/> Open <input type="checkbox"/> Laparoscopic <input type="checkbox"/> Lap converted to open <input type="checkbox"/> Single incision lap (SILS). <input type="checkbox"/> Robotic <input type="checkbox"/> Robotic converted to open			Specialty of responsible consultant	<input type="checkbox"/> Oesophagogastric <input type="checkbox"/> Hepatobiliary <input type="checkbox"/> Colorectal <input type="checkbox"/> Breast/Endocrine <input type="checkbox"/> Other		Procedure duration (mins)	---	
Operation	<input type="checkbox"/> Full cholecystectomy <input type="checkbox"/> Subtotal cholecystectomy		IOC?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Critical view of safety documented?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Intraop blood transfusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Drain(s) inserted?	<input type="checkbox"/> Yes <input type="checkbox"/> No (does not count drains inserted postop)				CBD Exploration?		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Intraop Complications	<input type="checkbox"/> Bile spilt <input type="checkbox"/> Stones spilt <input type="checkbox"/> Bleeding (req adjuncts, clips, sutures, conversion) <input type="checkbox"/> Vascular injury. <input type="checkbox"/> Bowel injury <input type="checkbox"/> Injury to other structures (state): _____ <input type="checkbox"/> Other (state): _____			Bile duct injury	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes: Recognised Intraop / Postop Reconstructed: No / Immediate / Delayed				

Postoperative data fields				Date of Discharge				___ / ___ / 2021	
Postop Complications	<input type="checkbox"/> Bile leak <input type="checkbox"/> Bile duct injury <input type="checkbox"/> Intra-abdominal collection <input type="checkbox"/> Pancreatitis <input type="checkbox"/> CBD stones <input type="checkbox"/> Unplanned ICU/HDU <input type="checkbox"/> Cardiac complication <input type="checkbox"/> Respiratory complication <input type="checkbox"/> Urinary complication <input type="checkbox"/> Other (state): _____ <input type="checkbox"/> None		Wound infection?	<input type="checkbox"/> None <input type="checkbox"/> Superficial <input type="checkbox"/> Deep <input type="checkbox"/> Organ/Space		Postop antibiotics?	<input type="checkbox"/> Yes <input type="checkbox"/> No Total days: ___		
			Reimaging?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21		Re-laparoscopy?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21		
			Postop blood transfusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21		Re-laparotomy?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21		
			Radiological drainage?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21		Referral to tertiary HPB unit?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21		
			ERCP?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21					
Highest Clavien-Dindo Grade	<input type="checkbox"/> None <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V (death)		Admission Outcome:		<input type="checkbox"/> Discharged <input type="checkbox"/> Inpatient death <input type="checkbox"/> Current inpatient at 30d (no discharge)				
			Mortality within 30d?		<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21				
Postop ED presentation within 30d?	<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21 Reason: _____		Readmission to hospital within 30d?		<input type="checkbox"/> Yes <input type="checkbox"/> No Date: ___ / ___ / 21 Date (discharged): ___ / ___ / 21 Reason: _____				