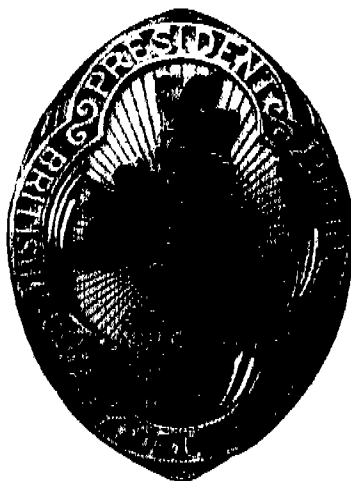


**The British Society of Gastroenterology Audit on ERCP
Availability Quality and Outcomes.**

PROFORMA 3: PROCEDURE QUESTIONNAIRE



PROFORMA SHOULD BE COMPLETED FOR:

All patients age 18 or over attending for ERCP

ERCP defined as any procedure where an endoscope is inserted with the intention of cannulating the pancreatic duct, bile duct or both. Patients listed for stent removal without attempted cannulation need not be included.

**QUERIES AND COMPLETED FORMS SHOULD BE ADDRESSED TO
Dr. Earl Williams, Research Fellow, Dept. of Clinical Information, 4th Floor
Linda McCartney Building, Royal Liverpool University Hospital, Prescot St.,
L7 8XP.**

Tel 0151 7063794, Fax 0151 7062313

Email Earl.Williams@rlbuht.nhs.uk

THANKYOU

The British Society of Gastroenterology Audit on ERCP

PROFORMA 3: Procedure questionnaire - to be completed at time of ERCP

Instructions

- 1. Inclusion criteria: ALL patients age 18 or over attending for ERCP**
- 2. ERCP defined as any procedure where an endoscope is inserted with the intention of cannulating the pancreatic duct, bile duct or both. Patients listed for stent removal without attempted cannulation need not be included.**
- 3. Note in emergency cases where patient too sick to consent prior to procedure consent will need to be obtained retrospectively before forwarding a questionnaire to Liverpool. Where patient is indefinitely incapable of consenting exclude.**
- 4. Endoscopist should answer questions in Section 1**
- 5. Where a patient experiences an adverse event during procedure or immediate recovery period section 2 should be completed by endoscopist performing procedure. In this context an adverse event is defined as a detrimental deviation from the patient's expected clinical course occurring at ERCP or shortly (<4hours) afterwards. Where an adverse event occurs >4 hours after ERCP or proforma 3 is unavailable to reporting doctor use proforma 4 to record details. Where an adverse event is recorded the chief investigator will contact unit at 30 days to establish outcome.**
- 6. To answer a question place a cross in one box only using black pen. i.e. If a question is labelled multiple response you may cross as many boxes as appropriate. Where a number or text is required print your response, keeping within the squares, if present. You do not need to prefix numbers with zero i.e. answer 3 rather than 003.**
- 7. If you make a mistake block the box out entirely (and if necessary write correct text or number adjacent to box)**

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Email Earl.Williams@rlbuht.nhs.uk**

**SECTION 1: TO BE COMPLETED
BY ENDOSCOPIST**

**IDENTIFYING CODES -
IMPORTANT, PLEASE COMPLETE FULLY**

DRUGS AND MONITORING

1. Hospital Code

Date of ERCP / /

Patient's Hospital Number

Patients Date Of Birth / /

Patients Sex Male Female

4. Was General Anaesthesia Used?

No **Go to question 5**

Yes. Specify Reason: **Now Go to question 7**

2. For each endoscopist involved in the procedure insert their code against the description that best describes their role. If you don't know an endoscopist's code ring 0151 706 3794 or speak to your consultant lead

Code	Role during Endoscopy
<input type="text"/> <input type="text"/> <input type="text"/>	Independent (ie. performed procedure without other endoscopist present to advise or assist)
<input type="text"/> <input type="text"/> <input type="text"/>	Not independent (ie. other endoscopist in room to provide advice or assistance)
<input type="text"/> <input type="text"/> <input type="text"/>	Supervising (i.e present to provide advice or assistance to trainee/other endoscopist.) Indicate level of help you gave during this ERCP: (multiple response)
<input type="checkbox"/>	Verbal instruction
<input type="checkbox"/>	assisted or performed cannulation (include precut)
<input type="checkbox"/>	assisted or performed post cannulation procedures
<input type="checkbox"/>	No help required by other endoscopist/trainee

5. During procedure: (multiple response)

pulse oximetry was used

automated BP monitoring was used

ECG monitoring was used

6. Indicate medication given during ERCP: (multiple response)

Routinely Used Drugs	Total Dose by end of ERCP
<input type="checkbox"/> Midazolam	<input type="text"/> <input type="text"/> . <input type="text"/> mg
<input type="checkbox"/> Diazepam	<input type="text"/> <input type="text"/> . <input type="text"/> mg
<input type="checkbox"/> pethidine	<input type="text"/> <input type="text"/> <input type="text"/> mg
<input type="checkbox"/> fentanyl	<input type="text"/> <input type="text"/> <input type="text"/> mcg
<input type="checkbox"/> propofol	<input type="text"/> <input type="text"/> <input type="text"/> mg
<input type="checkbox"/> nalbuphane (nubaine)	<input type="text"/> <input type="text"/> mg
<input type="checkbox"/> buscopan	<input type="text"/> <input type="text"/> mg
<input type="checkbox"/> GTN	<input type="text"/> <input type="text"/> mg
<input type="checkbox"/> lignocaine spray	
<input type="checkbox"/> oxygen	

Antibiotic (If Used)

Antibiotics according to unit protocol

Antibiotics (individualised regimen)

Reversal Agents/Additional Drugs Required

<input type="checkbox"/> flumazenil	<input type="text"/> <input type="text"/> <input type="text"/> mcg
<input type="checkbox"/> naloxone	<input type="text"/> <input type="text"/> <input type="text"/> mcg
<input type="checkbox"/> glucagon	<input type="text"/> <input type="text"/> mg
<input type="checkbox"/> atropine	<input type="text"/> . <input type="text"/> mg
<input type="checkbox"/> Other, specify:	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/mcg

LOCATION

3. The ERCP was performed in

XRay Theatres

Endoscopy Other Imaging suite

PATIENT INFORMATION

7. Was the patient admitted as a daycase ie. in absence of adverse event expected to go home within 24 hours of arrival?

- yes no

8. What was the degree of urgency?

- Elective (at time to suit both clinician and patient)
 Scheduled (early ERCP but not immediately life saving)
 Urgent (as soon as possible after resuscitation)
 Emergency (immediate ERCP with simultaneous resuscitation)

9. What was the ASA Grading of patient immediately prior to ERCP?

- Class I. Healthy patient with localised pathology requiring ERCP
 Class II. Mild systemic disease e.g. non limiting heart disease, controlled diabetes, hypertension, obesity
 Class III. Severe systemic disease. Definite functional limitation e.g. Brittle diabetic, frequent angina, MI > 3 months ago
 Class IV. Severe systemic disease with acute/unstable symptoms e.g. MI within last 3/12, organ failure, uncontrolled asthma
 Class V. Moribund. Submitted to therapy as act of desperation

10. Indicate if the patient has been on any of the following medication in the last 3 days (multiple response)

- Oral anticoagulant
 NSAID (include aspirin => 300mg per day)
 Heparin (any form or dose)
 Antiplatelet treatment (include aspirin < 300mg/day)

11. Indicate if the patient's medical history includes (multiple response)

- Cirrhosis, definite or suspected
 Ongoing haemodialysis
 Currently obese (BMI > 30 - see definitions)

12. Indicate if the patient's surgical history includes (multiple response)

- Previous Cholecystectomy
 Previous Bilroth II
 Whipples or Roux en Y procedure

13. The patient's ERCP was

- Their 1st ERCP **Go To question 15**
 A repeat procedure planned at the time of their last ERCP
 A repeat procedure unplanned at the time of their last ERCP

14. Indicate if the patient has history of (multiple response)

- Post ERCP pancreatitis
 Previous biliary sphincterotomy
 ERCP performed in the last 3/12

15. Indicate if today's ERCP (multiple response)

- Involved a combined percutaneous/endoscopic approach
 Is part of extracorporeal shock wave lithotripsy treatment

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PRIOR INVESTIGATION AND INDICATION

16. What symptoms/findings have prompted further investigation of the patient (multiple response):

- Jaundice
- Abdominal Pain
- Fever/Signs of sepsis
- Weight Loss
- Abdominal Mass
- Abnormal LFTs
- Abnormal Radiology
- Other, specify

17. Indicate the results of any investigations that the patient has had in the last 3 months. If the patient has had a test duplicated in the last 3 months then report the result of the most recent (multiple response):

	Normal	Abnormal
Trans-Abdominal Ultrasound (USS)	<input type="checkbox"/>	<input type="checkbox"/>
Computed Tomography	<input type="checkbox"/>	<input type="checkbox"/>
Magnetic Resonance Cholangio-Pancreatography	<input type="checkbox"/>	<input type="checkbox"/>
Endoscopic Ultrasound	<input type="checkbox"/>	<input type="checkbox"/>
Percutaneous Trans-hepatic Cholangiography	<input type="checkbox"/>	<input type="checkbox"/>
Intra-Operative Cholangiography	<input type="checkbox"/>	<input type="checkbox"/>

18. If you have indicated that the patient has had an abnormal USS, does the report identify:

- Dilated common bile duct
 - Intraductal stone(s)
 - A pancreatic mass
 - Other abnormality, specify
- multiple response**

19. If the patient has had blood tests in the last 7 days document the most recent available results (multiple entry)

PT . s

or

INR .

WCC . 000 per mm³

Platelets 000 per mm³

Albumin . g/L

Bilirubin mM

Creatinine mcM

20. What was your suspected diagnosis BEFORE ERCP was performed (multiple response)

- Intra ductal stones
- Sphincter of Oddi Dysfunction/Functional pain
- Acute Cholangitis - Unresolved at time of ERCP
- Acute Cholangitis - Resolved by time of ERCP
- Malignancy-Unspecified
- Carcinoma of Pancreas
- Cholangiocarcinoma
- Acute Pancreatitis - Unresolved at time of ERCP
- Acute Pancreatitis - Resolved by time of ERCP
- Chronic Pancreatitis
- Benign Extra-Hepatic Stricture
- Biliary Leak
- Primary Sclerosing Cholangitis
- Stent dysfunction
- Unknown
- Other, Specify

PRE-PROCEDURE INTENT AND CANNULATION

21. Which ducts did you intend to cannulate BEFORE starting the ERCP

- Common Bile Duct (ie. cholangiogram via main papilla)
- Main Pancreatic Duct (ie. pancreatogram via main papilla)
- Accessory Duct (ie. pancreatogram via minor papilla)

22. BEFORE starting the ERCP did you expect to perform any of the following procedures? (multiple response)**A. STENT REMOVAL**

- Remove Biliary Stent currently insitu

B. SPHINCTEROTOMY

- Biliary Sphincterotomy
- Pancreatic Sphincterotomy

C. STONE EXTRACTION

- Common Bile Duct Stone Extraction
- Intrahepatic Duct Stone Extraction
- Pancreatic Duct Stone Extraction

D. STENT INSERTION

- Common Bile Duct Stent Insertion
- Hilar/Intrahepatic Bile Duct Stent Insertion
- Pancreatic Duct Stent Insertion

E. BALLOON DILATATION

- Balloon Dilatation of papilla
- Balloon Dilatation of CBD
- Intra-Hepatic Biliary Duct Dilatation
- Pancreatic Duct Dilatation

F. DRAIN INSERTION

- Nasobiliary Drainage
- Nasopancreatic Drainage

G. HISTOLOGY, CYTOLOGY AND SAMPLING

- Biopsy (of ampulla or duct)
- Brush Cytology of Bile Duct
- Brush Cytology of Pancreatic Duct
- Sampling

H. SPHINCTER OF ODDI MANOMETRY

- Manometry

I. OTHER PROCEDURES

- Other specify

23. Was the ampulla successfully visualised?

- Yes
- No, unable to intubate oesophagus
- No, pyloric stenosis present
- No, specify other reason if identified

if No go to
question
34, page 7

24. What was the ampullary appearance?

- Normal
- Patulous/Gaping
- Bulging
- Tumour
- Within or on edge of diverticulum
- Adjacent to diverticulum
- Other, specify

25. What were the total number of cannulations / cannulation attempts during procedure (Defined as each episode of contact with major or minor papillae by any endoscopist using any device and including each recannulation but excluding over the wire exchanges)

26. Was a PRECUT papillotomy required?

- Yes No

27. Was there visible intramucosal injection during ERCP?

- yes no

28. Indicate total number of times contrast (of any volume) injected into the pancreatic duct during ERCP

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FINDINGS AND POST-CANNULATION INTENT

29. INDICATE WHICH DUCTS WERE CANNULATED AND SUBSEQUENT FINDING: No ducts cannulated - Go To Question 33 (page 7) **Common Bile duct cannulated - specify cholangiogram findings: (Multiple response)**

- Insufficient cannulation or contrast injected
- Normal
- Dilated common bile duct (>10mm corrected for magnification)
- Bile duct leak
- Suspected sclerosing cholangitis
- Stones within gall bladder
- Probable or definite bile duct stones,specify location and size:
- Location(s) extrahepatic intrahepatic cystic duct
- Size largest<1cm largest>=1cm
- Number <3 >=3
- Probable or definite bile duct stricture(s), specify location/type:
- Location(s) distal to hilum hilum or above both
- Type: Benign Malignant Indeterminate
- Other,specify:

 Pancreatic duct and/or Accessory duct cannulated - specify pancreatogram findings: (Multiple response)

- Normal
- Insufficient cannulation or contrast injected
- Pancreatic divisum
- Probable or definite stones
- Dilated (corrected diameter>6mm within head or >3mm within tail)
- Acinirization (ie.blush of pancreatic parenchymal contrast)
- Definite chronic pancreatitis (Cambridge criteria-see definitions):
- Main duct irregularity/dilatation >3 side branches abnormal
- Probable or definite stricture,specify type:
- Malignant Benign Indeterminate
- Other, specify:

30. In light of cholangiogram/pancreatogram/ampullary findings:

- I intended to perform procedures as listed in question 22- **Go To Q 32**
- No further procedure was required as part of this ERCP- **Go To Q 33,page 7**
- My intent as indicated in question 22 was altered

31.Specify what your intent was FOLLOWING CANNULATION (multiple response)**A. STENT REMOVAL**

-
- Remove Biliary Stent currently insitu

B. SPHINCTEROTOMY

- Biliary Sphincterotomy
- Pancreatic Sphincterotomy

C. STONE EXTRACTION

- Common Bile Duct Stone Extraction
- Intrahepatic Duct Stone Extraction
- Pancreatic Duct stone extraction

D. STENT INSERTION

- Common Bile Duct Stent Insertion
- Hilar/Intrahepatic Bile Duct Stent Insertion
- Pancreatic Duct Stent Insertion

E. BALLOON DILATATION

- Balloon Dilatation of Papilla
- Balloon Dilatation of CBD
- Intra-Hepatic Biliary Duct Dilatation
- Pancreatic Duct Dilatation

F. DRAIN INSERTION

- Nasobiliary Drainage
- Nasopancreatic Drainage

G. HISTOLOGY,CYTOLOGY AND SAMPLING

- Biopsy (of ampulla or duct)
- Brush Cytology of Bile Duct
- Brush Cytology of Pancreatic Duct
- Sampling

H. SPHINCTER OF ODDI MANOMETRY

-
- Manometry

I. OTHER PROCEDURES

-
- Other specify

ATTEMPTED PROCEDURES AND OUTCOME

32. Fill in sections A-I (page s 6 and 7) as appropriate. List all attempted procedures and also indicate if attempted procedure was completed according to definitions given in each box. If no procedures were attempted go straight to question 33 on page 7

32A. STENT REMOVAL

Stent removal attempted

Stent removal completed*

***DEFINITION OF COMPLETED: stent removed from biliary tree/pancreatic duct**

32B. SPHINCTEROTOMY

Type(s) attempted

- Bile Duct Sphincterotomy
 Pancreatic Duct Sphincterotomy

Indicate type of current setting

- Pure cutting current throughout
 Blended current for all or part of procedure(s)
 ERBE/Endocut device used

Indicate if length of (the externally visible) cut was >5mm for the

- Bile Duct Sphincterotomy
 Pancreatic Duct Sphincterotomy

Indicate if sphincterotome introduced over wire (ie. wire guided procedure) for the

- Bile Duct Sphincterotomy
 Pancreatic Duct Sphincterotomy

Indicate if Visible bleeding at end of procedure was >5mls as a result of the

- Bile Duct Sphincterotomy
 Pancreatic Duct Sphincterotomy

Of sphincterotomies attempted the following were completed*

- Bile Duct Sphincterotomy
 Pancreatic Duct Sphincterotomy

***DEFINITION OF COMPLETED: Where subsequent procedures requiring access to duct (eg stent insertion/stone extraction) were attempted these were also completed. Where no subsequent procedures were attempted operator judges whether sphincterotomy successfully completed or not.**

32C. STONE EXTRACTION

Attempted stone extraction from the:

- Common Bile Duct
 Intra-Hepatic Ducts
 Pancreatic Duct

Devices used during attempted stone extraction

- Balloon
 Basket
 Mechanical lithotripsy
 Other, specify

Attempted extraction completed* from the

- Common Bile Duct
 Intra-Hepatic Ducts
 Pancreatic Duct

*** DEFINITION OF COMPLETED: Duct CLEARED of suspected stones (no residual stones)**

32D. STENT INSERTION

Location(s) where placement was attempted

- Common Bile Duct
 Hilum/Intra Hepatic Duct
 Pancreatic Duct

Location(s) where attempts were completed*

- Common Bile Duct
 Hilum/Intra Hepatic Duct
 Pancreatic Duct

Type(s) of Stent in situ at end of procedure

1. plastic pigtail plastic straight metal
length (cm) Diameter mm/fr
2. plastic pigtail plastic straight metal
length (cm) diameter mm/fr

***DEFINITION OF COMPLETED: stent within duct with top of stent above selected pathology and bottom outside papilla**

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ATTEMPTED PROCEDURES AND OUTCOME

32E. BALLOON DILATATION

Dilatation attempted in the following location(s)

- At papilla
- Within common bile duct
- Within intrahepatic ducts
- Within Pancreatic Duct

Attempted dilatation completed* in the following location(s)

- At papilla
- Within common bile duct
- Within intrahepatic ducts
- Within Pancreatic Duct

*DEFINITION OF COMPLETED: able to insert balloon across selected stricture and inflate

32H. SPHINCTER OF ODDI MANOMETRY

Manometry attempted

Where attempted manometry completed*

*DEFINITION OF COMPLETED: trace assists in diagnosis

32I. OTHER PROCEDURES

Attempted

Indicate if you judged procedure successfully completed

Specify procedure:

[Empty box for specifying procedure]

32F. DRAIN INSERTION

Insertion of following attempted

- Nasobiliary drain
- Nasopancreatic drain

Attempted insertion of the following completed*

- Nasobiliary drain
- Nasopancreatic drain

*DEFINITION OF COMPLETED: Drain inserted with distal tip above any obstructing lesion /stone

OUTCOME

33. Total volume of contrast injected by end of ERCP

[] [] [] mls

34. At start of ERCP was there complete biliary obstruction

No

Yes If yes was this obstruction relieved: no yes

35 .Did the patient experience any adverse event during ERCP

Yes Fill in section 2 (NEXT PAGE)

No USE QUESTION 36 TO ENTER ANY FURTHER COMMENTS YOU FEEL ARE NECESSARY AND FORWARD COMPLETED FORM TO ADDRESS ON PAGE 1

32G. HISTOLOGY, CYTOLOGY AND SAMPLING

Following attempted

- Biopsy (of ampulla or duct)
- Brush cytology of bile duct
- Brush cytology of pancreatic duct
- Sampling

Of those attempted following completed*

- Biopsy (of ampulla or duct)
- Brush cytology of bile duct
- Brush cytology of pancreatic duct
- Sampling

*DEFINITION OF COMPLETED: operator judges adequate specimens taken

36. PLEASE USE THIS SPACE IF YOU NEED TO CLARIFY A RESPONSE

[Large empty box for clarifying a response]

**SECTION 2: TO BE COMPLETED IF ADVERSE EVENT
NOTED IN ENDOSCOPY ROOM OR RECOVERY**

1. Onset of symptoms/signs (of adverse event) relative to ERCP

- Pre-procedure (from starting preparation)
 During Procedure (in endoscopy room)
 Early recovery (<4 hours after ERCP)

**2. Nature of adverse event
(for each section a-g you may cross more than one box)**

a. Events relating to medication given at time of procedure and sufficient to alter aftercare or require specific treatment:

- Generalised allergic reaction (rash +/- any of below)
 Wheezing
 Hypoxia
 Hypertension
 Hypotension
 Neuropsychiatric reaction
 Reaction at IV Site

b. Recognized Local Complications of ERCP, sufficient to alter aftercare or require specific treatment :

- Perforation, suspected or definite
 GI bleeding
 Basket impaction
 Other Equipment failure or malfunction, specify:

c. Other events following ERCP sufficient to alter aftercare or require specific treatment:

- Abdominal pain of uncertain origin
 Chest pain of uncertain origin
 Unstable coronary syndrome/Myocardial infarct
 Cardiac arrhythmia
 Cerebro-Vascular Accident/Stroke

d. Other event or diagnosis that altered aftercare or required specific treatment

e. Indicate if as a result of adverse event(s):

- ERCP was not started
 ERCP was stopped prematurely

f. Change in aftercare as result of event(s):

- None
 Extra consultation eg in outpatient or endoscopy recovery
 Planned discharge cancelled - patient to stay in
 Extra treatment required in pre-existing inpatient
 Admission to ITU

g. Medical interventions received or planned at time of writing as result of event(s):

- Reversal agents (flumazenil or naloxone)
 Atropine
 Oxygen
 Transfusion <5 units
 Transfusion > or equal to 5 units
 Ventilatory assistance eg bag and mask
 Tracheal intubation
 Crash call

h. Other (invasive) interventions received or planned at time of writing as result of event(s):

Endoscopic	<input type="text"/>
Radiological/Percutaneous	<input type="text"/>
Surgery	<input type="text"/>
Other	<input type="text"/>

3. Outcome at time of writing (cross one box):

- Unknown as yet
 Full recovery
 Permanent disability/loss of function expected
 Death

Date / /

Ia

Cause of death Ib

II

Thankyou - please forward to Dr Earl Williams at address shown on page 1

DEFINITIONS

Complications - Definitions for questionnaire (Cotton, Lehman et al. 1991), (Cotton 1994)

Complication	Mild	Moderate	Severe	Fatal
Bleeding	Clinical (not just endoscopic) evidence of bleeding; HB drop <3g; no transfusion	Transfusion (4U or less), no angiographic or surgical intervention	Transfusion (5U or more) or intervention (angiographic or surgical)	Results in death
Perforation	Possible or slight leak of contrast; treated by fluids & suction for 3 days or less	Any definite perforation treated medically for 4-10 days	Hospitalisation for >10 days or any intervention (percutaneous or surgical).	Results in death
Pancreatitis (Abdo pain + amylase >3N after 24 hrs)	requiring admission or prolongation of planned admission beyond 48 hrs	requiring of 4-10 days hospitalisation	admission > 10 days; haemorrhagic pancreatitis; pseudocyst; intervention required	Results in death
Infection (cholangitis)	>38 °C 24-48 hrs	Febrile or septic illness requiring >3 days hospitalisation or endoscopic/percutaneous intervention	Septic shock or surgery	Results in death
Miscellaneous (include symptomatic IHD, aspiration pneumonia, drug reactions)	Onset of relevant symptoms within 3 days of ERCP. Requires 1-3 days hospitalisation/ prolongation of stay	Onset of relevant symptoms within 3 days of ERCP. Requires 4-10 days hospitalisation	Onset of relevant symptom within 3 days of ERCP. Requires >10 days hospitalisation or ITU or surgical/radiological intervention	Results in death

Chronic Pancreatitis: Cambridge Classification

Terminology	Main duct	Abnormal side branches	Additional features
normal	normal	none	
equivocal	normal	<3	
mild	normal	3 or more	
moderate	abnormal	>3	
marked	abnormal	>3	One or more of: large cavity, obstruction, filling defects, severe dilatation or irregularity

Chart Depicting body weight to height ratio.

■ = OBESE

