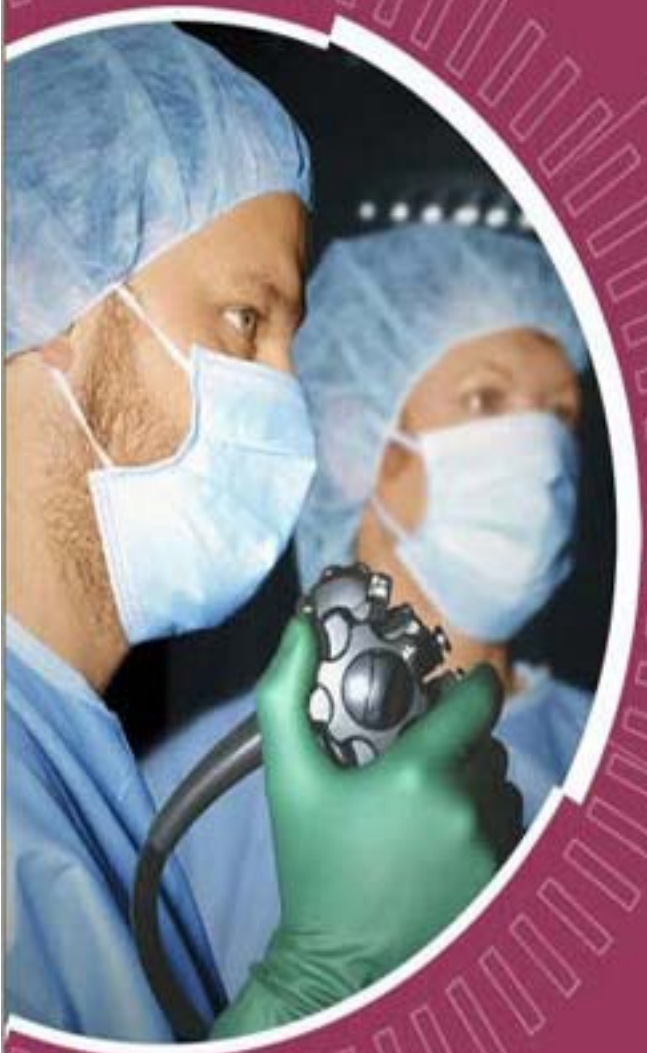

Scoping our practice

The 2004 Report of the National Confidential Enquiry into Patient Outcome and Death

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FOREWORD

SCOPING OUR PRACTICE

NCEPOD operates under the umbrella of the National Institute of Clinical Excellence (NICE) as an independent confidential enquiry, whose main aim is to improve the quality and safety of patient care. Evidence is drawn from all sections of hospital activity in England, Wales, Northern Ireland, Guernsey, the Isle of Man and the Defence Sector, both NHS and private, and we are very grateful to all those who take part, as advisors, local reporters or recipients of individual case reporting questionnaires. I would also like to express my sincere thanks to our clinical co-ordinators and all the permanent staff of NCEPOD for the enormous amount of work and enthusiasm which they have put into the production of this report and without whom we could not hope to create such detailed analysis of, and comment upon, clinically related hospital activity.

‘Scoping our practice’ represents a significant new direction for the work of NCEPOD in that it is the first report under our expanded remit to include medical cases. Based on the work of all gastrointestinal (GI) endoscopists, both medical and surgical, it emphasises our new title of the National Confidential Enquiry into Patient Outcome and Death. We have been keen to expand the work of the enquiry for some years and the physicians on our steering committee have provided an exciting new and critical angle on the design and recommendations of our reports. It is also the first NCEPOD report to be distributed on CD Rom instead of paper, which has allowed major advances in the presentation of our data. We are pleased that 93% of hospitals participated, although the questionnaire return rate of 66% is similar to that of anaesthetists and surgeons 10 years ago, when participation rates were 70%. This represents a serious challenge for NCEPOD in the future, if we are to produce credible results and evidence-based recommendations.

Interventional gastrointestinal endoscopy is an important area of work in all hospitals. The cases covered by this report (1,818) inpatient deaths within 30 days of the procedure) represent only a small proportion of the total endoscopies performed in a year in England, Wales and Northern Ireland (136,000) and it is important to stress that most GI therapeutic endoscopies are uneventful. Because it is frequently a multidisciplinary service, the facilities available have often grown up in a piecemeal fashion and while there is a wide range of established practices, training and protocols, there are also some areas of very individual practice which take little account of the major advances in monitoring and sedation techniques which are widely available. Some endoscopy units did not have the necessary monitoring equipment available in all rooms and where it was available, appropriate monitoring was not used in many situations when our advisors judged it was required on account of the patient’s condition. In 42% of cases no contemporaneous monitoring record was available in the notes and 14% of patients were judged by our advisors to have received an overdose of sedation.

GI endoscopy services are provided by a wide range of specialties, including general medicine, general surgery, radiology, specialist medicine and specialist GI, ENT and thoracic surgery. In addition nurse practitioners are becoming increasingly involved in diagnostic endoscopy and, as is shown in this report, in interventional treatment too. As a result it is vitally important that hospitals have clearly defined protocols for optimising the treatment of these patients and for ensuring satisfactory monitoring and safe sedation techniques.

Many endoscopy patients are severely ill, elderly and often poorly prepared for an interventional procedure. It was worrying that our advisors considered that 19% of the percutaneous endoscopic gastrostomy (PEG) procedures were futile or not indicated at all. Very few endoscopy patients have the benefit of pre-procedure optimisation or indeed time on a high dependency unit, their care taking place on a general ward as one of a number of seriously ill patients. Many have received large volume blood transfusions, with all the attendant problems. Anaesthetists are rarely involved in the care of these patients unless it is in an intensive care or high dependency unit setting in which the patient's condition can often be considerably improved prior to intervention. In most hospitals there is a clear working pattern for routine endoscopy lists but very poor provision for out of hours care. This report demonstrates that less than a third of hospitals have a dedicated out of hours emergency endoscopy service and that a third of patients are actually treated at a less than optimal time for a variety of reasons.

Although GI endoscopy as a specialty has produced good guidelines on training, the report highlights the need for national guidelines to assure continuing competence in endoscopy, particularly for those practitioners who only perform a small number of procedures each year. While the ability to perform endoscopy is an integral part of the training of many medical and surgical specialists, there is much more to the procedure than simply an ability to pass an endoscope and to make a diagnosis or instigate treatment. If we are to significantly improve the outcome of patients undergoing therapeutic endoscopy this report gives us many clear indications and recommendations about how this might be achieved. There is a major opportunity for multi disciplinary working and the setting up of clear guidelines for the management, optimisation, treatment and sedation of what are often seriously ill, elderly patients. Above all we should aim to provide timely and optimal care in the best interests of what is a significant proportion of sick patients in every hospital.

Dr Peter Simpson
Chairman

RECOMMENDATIONS

Recommendations are listed by chapter, and NCEPOD's view of who should take the recommendation forward is shown in brackets.

Organisational issues

Hospitals should ensure that the appropriate monitoring equipment and resuscitation equipment is available in each of their endoscopy rooms and recovery areas. ***(Local hospitals; Primary Care Trusts)***

In order to produce optimal care for what is a large group of severely ill patients, hospitals should consider establishing formal on-call arrangements. ***(Local hospitals)***

Patient assessment

Patients must be assessed by the referring clinician and the endoscopist to justify that the procedure is in the patient's interest. ***(Professional specialist associations)***

Patient consent

The risks and benefits of therapeutic endoscopy should be explained to the patient, and this should be documented on the consent forms as laid down in the Department of Health guidelines. ***(Local hospitals)***

The ability of those with dementia or acute confusion to provide consent should be tested and clearly documented. ***(Local hospitals)***

Training and education

There should be national guidelines for assuring continuing competency in endoscopy. ***(Professional specialist associations)***

All endoscopy units should perform regular audit and all deaths during, or within 30 days of, therapeutic endoscopy should be reviewed. ***(Local hospitals; Professional specialist associations)***

All those responsible for the administration of sedation should have received formal training and assessment. ***(Local hospitals)***

Sedation and monitoring

Sedation and monitoring practices within endoscopy units should be audited and reviewed. ***(Local hospitals; Professional specialist associations)***

There should be national guidelines on the frequency and method of the recording of vital signs during the endoscopy. ***(NPSA; Professional specialist associations)***

Clear protocols for the administration of sedation should be available and implemented. ***(Local hospitals)***

Percutaneous endoscopic gastrostomy

The decision to use a PEG feeding tube requires an in-depth assessment of the potential benefits to the individual. All patients in whom PEG feeding is proposed should be reviewed by a multidisciplinary team. ***(NICE)***

There is a need for more comprehensive national guidelines for the use of PEG feeding, including issues of patient selection. ***(NICE)***

Endoscopic retrograde cholangiopancreatography

Patients should be reviewed by the consultant endoscopist before therapeutic ERCP to ensure that the procedure is appropriate and that the patient's condition has been optimised. ***(Local hospitals)***

Oesophagogastroduodenoscopy

Only experienced endoscopists should treat patients with upper GI haemorrhage. Experience will vary by grade but competence should be assessed by the supervising consultant. ***(Local hospitals)***

Optimising the patient's pre-endoscopy condition will reduce both morbidity and mortality. Early involvement of an anaesthetist/intensivist if necessary, will assist this. ***(Local hospitals)***

Upper gastrointestinal dilation and tubal prosthesis insertion

A national audit across all specialties of specific techniques and equipment that is used for upper GI dilation and tubal prosthesis insertion is indicated. ***(NPSA)***

Pathology

The operative procedure should be included in the cause of death statement. ***(Undergraduate and post-graduate deans; ONS)***

Post-procedure deaths (i.e. those occurring during or within 24 hours of anaesthesia or sedation or those where it is known that the procedure is implicated in the death) should be reported to the coroner. ***(Local hospitals)***

Pathologists should think more carefully about all the clinical circumstances of a death, to produce an autopsy report more useful for clinical governance and audit. ***(Professional specialist associations particularly the Royal College of Pathologists)***

NCEPOD supports the reforms of the 'coronial system' and death certification, which will result in better scrutiny of deaths. ***(Home Office)***

1. INTRODUCTION

INTRODUCTION

The original gastrointestinal endoscopes were hollow reeds or bamboo canes that were illuminated by candles. These developments have been attributed to both the ancient Greeks and the Egyptians. However, the precise origin of endoscopy remains in doubt although Hippocrates was responsible for the first proctoscopy recorded in 370 BC.

The subsequent development was slow. The next major advancement was the rigid sigmoidoscope in 1795 by Bozzini, followed by the rigid oesophagoscope in 1868 by Kussaiaul. These instruments were very primitive in comparison with those in use today, and only allowed a limited examination. One of the major limitations was a suitable light source but this was overcome, in part, by Edison in 1890 who was able to make bulbs small enough to use inside the endoscope. This was followed by the discovery that glass fibres could transmit light by Baird in 1928.

The other limitation was scope rigidity. A ‘semi-flexible’ gastroscope was developed in 1932, followed in 1950 by the ‘gastrocamera’. This was superseded in 1957 by the flexible gastroscope developed by Hirchowitz and in 1963 the flexible sigmoidoscope developed by Overholt, both using optical fibres to connect the distal image lens to the proximal viewing lens that magnified the image for the endoscopist.

Diagnostic endoscopy was now a viable, valuable, clinical procedure. The only omission was full colonoscopy, which finally occurred in 1971 and was performed by Deyhle. Crucial, rapid developments included channels through the length of the scope that would allow air injection to distend the lumen, suction (to remove secretions), a water jet to clean the image lens, and mucosal biopsies. The potential of the biopsy channel was exploited rapidly, and numerous therapeutic procedures followed – including the first snare polpectomy by Niwa in 1970, and the first sphincterotomy for common bile duct stones in 1974.

The construction of the endoscope ensured that only the endoscopist saw mucosal images, and trainees could only view the image by adding a teaching aid to the endoscope. However, this resulted in a poor view of the mucosa for both teacher and trainee, and significantly increased the weight of the endoscope.

The development of video endoscopy by Welch-Allyn in 1983, produced high resolution images that ensured the territory previously the domain of the endoscopist could be seen by trainees, assistants, and observers.

The aim of this study is to improve the quality of therapeutic gastrointestinal endoscopy services in the future by critically appraising information from the notes of patients who have died during or following endoscopy. It is hoped that the intended benefits will include:

- fewer inappropriate procedures
- lower morbidity and mortality
- improved training
- recognition of poor performance
- reduced litigation
- better data collection.

Therapeutic gastrointestinal (GI) endoscopy is a common procedure. From Hospital Episode Statistics (HES) it has been established that in NHS hospitals in England, Wales and Northern Ireland in 2002/03 approximately 136,000 such procedures were performed[1]. Deaths reported following these procedures represented 3% of cases and it is therefore important that data in this report are taken in context. As a guide the mortality data for the four different GI therapeutic endoscopies covered in this report is summarised in Table 1. These figures have been calculated using data obtained from Hospital Episode Statistics (HES), which includes NHS data from Trusts in England only. However, this is representative of the majority (94%) of the data obtained from England, Wales and Northern Ireland.

Table 1. Mortality data for therapeutic endoscopies – 2002/03

Procedure type	Number of deaths	Total number of procedures	Mortality %
PEG	986	16,648	*6*
ERCP	381	23,606	*2*
Upper GI	2,200	47,931	*5*
Lower GI	102	40,378	*<1*
Total	**3,669**	**128,563**	***3***

Legend

PEG = Percutaneous endoscopic gastrostomy

ERCP = Endoscopic retrograde cholangiopancreatography

Anecdotally, it is believed that there is a significant amount of under-reporting of procedures, as many take place in an outpatient setting and these data are not recorded as part of the HES dataset; hence mortality may be overestimated. In addition, deaths following discharge from hospital are not captured by HES and this would tend to lead to an underestimate of mortality. These factors are both likely to affect the quoted mortality rates.

REFERENCES

[1] Hospital Episode Statistics, Table 10 (Total operations) NHS Hospitals, England, 2002-2003, Department of Health. Patient Episode Database for Wales, Health Solutions Wales. Department of Health, Social Services and Public Safety.

2. METHODS

INTRODUCTION

The data presented in this report relate to three datasets:

1. All deaths occurring in hospital within 30 days of a gastrointestinal (GI) therapeutic endoscopy between 1 April 2002 and 31 March 2003.
2. Upper GI dilations and tubal prosthesis insertions performed in adults (of 16 years of age and over) between 1 January and 31 March 2003, regardless of outcome.
3. Data collected from hospitals on organisational aspects of endoscopy services.

The method of data collection for each dataset is outlined below.

DATA COLLECTION

GI therapeutic endoscopies

All deaths occurring in hospital between 1 April 2002 and 31 March 2003 were reported to NCEPOD by designated local reporters for each hospital. Data were requested from all hospitals in England, Wales, Northern Ireland, Guernsey, the Isle of Man, the Defence Secondary Care Agency and hospitals in the independent sector.

Sample cases were identified from these data by Office of Population Censuses and Surveys (OPCS) codes, which were submitted for the last six procedures before death. Cases were included if death occurred within 30 days of a therapeutic endoscopy, regardless of whether it was the last procedure or not. If more than one endoscopy was recorded in the death data, only the last procedure before death was included.
The following OPCS codes[1] were included in the sample:

PEG	**G34:** Artificial opening into stomach
ERCP	**J38:** Endoscopic incision of sphincter of Oddi
	J40: Endoscopic retrograde placement of prosthesis in bile duct
	J41: Other therapeutic endoscopic retrograde operations on bile duct
	J42: Therapeutic endoscopic retrograde operations on pancreatic duct
Upper GI	**G14:** Fibreoptic endoscopic extirpation of lesion of oesophagus
	G15: Other therapeutic fibreoptic endoscopic operations on oesophagus

	G17: Endoscopic extirpation of lesion of oesophagus using rigid oesophagoscope
	G18: Other therapeutic endoscopic operations on oesophagus using rigid oesophagoscope
	G43: Fibreoptic endoscopic extirpation of lesion of upper gastrointestinal tract
	G44: Other fibreoptic therapeutic endoscopic operations on upper gastrointestinal tract
	G54: Therapeutic endoscopic operations on duodenum
	G64: Therapeutic endoscopic operations on jejunum
Lower GI	**H20:** Endoscopic extirpation of lesion of colon
	H21: Other therapeutic endoscopic operations on colon
	H23: Endoscopic extirpation of lesion of lower bowel using fibreoptic sigmoidoscope
	H24: Other therapeutic endoscopic operations on lower bowel using fibreoptic sigmoidoscope

The terminology used to describe procedures in this report is based on these OPCS codes.

Procedures coded as one of the above but carried out under radiological guidance, without endoscopy, were excluded. Likewise, procedures carried out at a hospital different to the one where the patient died were also excluded due to the complexity of linking patient data.

Data were collected retrospectively via a questionnaire (Appendix C), which requested information on pre-procedural investigations, the procedure, sedation and monitoring, the clinicians involved in the procedure, and training and audit. A questionnaire with a unique NCEPOD number and covering letter was sent to the clinician responsible for the patient at the time of their death. In order to reduce the burden on the clinicians, the number of questionnaires to be completed was limited to three per clinician. However, if a clinician returned more than three, the questionnaires were included in the study. A first reminder for return of questionnaires was sent two months after the questionnaire, followed by a second reminder one month later.

Copies of extracts of the casenotes, including the endoscopy report, monitoring charts and autopsy report were also requested. Both these and the questionnaires were anonymised by NCEPOD administrative staff to ensure that individual patients, clinicians and hospitals could not be identified.

NCEPOD wrote to all general practitioners from a list provided by the British Society of Gastroenterologists (BSG), and asked them if they performed therapeutic GI endoscopies. Those who reported that they carried out these procedures were requested to notify NCEPOD in the event of death within 30 days of a procedure.

Upper GI dilation and tubal prosthesis insertion

A second dataset was collected prospectively on all patients, of 16 years of age and over, undergoing an upper GI dilation or tubal prosthesis insertion between 1 January and 31 March 2003, regardless of outcome. NCEPOD local reporters were asked for a list of patients, from their information department, who had had one of the following eight procedures, identified by the OPCS codes[1] :

Upper GI dilation	**G15.2:** Fibreoptic endoscopic balloon dilation of oesophagus
	G15.3: Fibreoptic endoscopic dilation of oesophagus not elsewhere classified
	G18.2: Endoscopic balloon dilation of oesophagus using rigid oesophagoscope
	G18.3: Endoscopic dilation of oesophagus using rigid oesophagoscope not elsewhere classified
	G44.3: Fibreoptic endoscopic dilation of upper gastrointestinal tract
Tubal prosthesis insertion	**G15.4:** Fibreoptic endoscopic insertion of tubal prosthesis into oesophagus
	G18.4: Endoscopic insertion of tubal prosthesis into oesophagus using rigid oesophagoscope
	G44.1: Fibreoptic endoscopic insertion of prosthesis into upper gastrointestinal tract

The terminology used in this report is based on these OPCS codes. The term dilation and dilatation are used synonymously.

Questionnaires (Appendix C), which consisted of two sides of an A4 sheet, were sent prospectively to NCEPOD local reporters for dissemination to the consultant responsible for the procedure. No patient identifiers were collected on the questionnaire and pre-paid envelopes were provided so that questionnaires could be returned directly to NCEPOD; this ensured both patient and clinician confidentiality. No casenote extracts were requested.

General practitioners who performed upper GI dilations and tubal prosthesis insertions were identified, as before, and asked to notify NCEPOD when they performed a procedure included in the study.

Organisational questionnaire

An organisational questionnaire (Appendix C) requesting information about the endoscopy suite and organisational aspects of the endoscopy service was sent to the NCEPOD local reporter of each hospital for completion. The questions were based on the guidelines from the Working Party of the BSG Endoscopy Committee 2001[2].

DATA QUALITY AND VALIDATION

All data from the completed questionnaires were entered onto a computer system using scanning software and following data quality checks, the data were imported into a Microsoft Access© database. To ensure completeness and quality of the data submitted to NCEPOD, further data inconsistency checks were performed once the data had been imported into the database.

ADVISORY GROUPS

A multi-disciplinary group of experts were invited to take part in a series of advisory meetings between July 2003 and March 2004 during which the anonymised casenotes were reviewed and areas of concern highlighted. The group included upper and lower GI physicians and surgeons, anaesthetists, a senior endoscopy nurse, an endoscopy unit manager, a general practitioner and pathologists. During these meetings, advisors reviewed the questionnaires in association with the relevant casenotes, where available, and completed a questionnaire assessment form (Appendix C) based on their clinical knowledge and experience. A separate group of pathology advisors reviewed the autopsy reports and histopathology findings and completed the corresponding questionnaire assessment forms (Appendix C).

This peer review process remains a strength of NCEPOD methodology that is accepted and welcomed by clinicians. Advisors are able to review the patient journey and take into account many factors that are difficult to capture from a questionnaire. In this report, vignettes will be used to illustrate points highlighted during the advisory meetings.

DATA ANALYSIS

The data were aggregated and anonymised prior to analysis. The data obtained from the questionnaire assessment forms were analysed to determine areas of concern raised by the advisors. Where appropriate, these data were cross-referenced with the clinical information in order to clarify and expand findings. Where data presented are based on the opinions and finding from the advisory groups, this is clearly stated.

REFERENCES

[1] *Tabular list of the classification of surgical operations and procedures.* Fourth revision. Office of Population Censuses and Surveys. HMSO, 1993

[2] *Provision of endoscopy related services in District General Hospitals.* BSG Working Party Report, 2001. www.bsg.org.uk/pdf_word_docs/endo_related_services.pdf

3. DATA OVERVIEW

INTRODUCTION

Referral to most gastrointestinal (GI) endoscopy units falls into three main categories: open access, outpatient and urgent inpatients. Open access and outpatient referrals, of which there are approximately 530,000[1], account for much of the workload and are mostly diagnostic. Of these, health episode statistics[2] indicate that approximately 136,416 GI therapeutic endoscopies were performed during inpatient admissions in England, Wales and Northern Ireland in the year 2002-2003.

HOSPITAL PARTICIPATION

GI therapeutic endoscopies

A total of 252 hospitals and 11 non-NHS hospitals participated in the endoscopy study (Table 2). Participation is defined as 'a hospital that submitted at least one clinical questionnaire'. Non-NHS hospitals include the independent sector and hospitals in Guernsey and the Isle of Man.

20 hospitals, which were expected to participate as at least one sample case had been identified from the death data (Appendix D), failed to return any questionnaires. Many did not provide a reason for non-return but where indicated, reasons included *"casenotes unavailable", "correct physician could not be identified"* and *"physician who performed the procedures has left".*

Of the hospitals NCEPOD identified who should have participated, 93% of hospitals returned at least one questionnaire.

Table 2. Number of NHS and non-NHS hospitals participating in data collection

Hospital type	Did participate	*(%)*	Did not participate	*(%)*	**Total**
NHS	252	*(93)*	19	*(7)*	271
Non-NHS	11	*(92)*	1	*(8)*	12
Total	**263**		**20**		**283**

Although invited to take part in the study, no primary care centres participated as no therapeutic endoscopy-related deaths in primary care were reported during this period.

Upper GI dilation and tubal prosthesis insertion

259 hospitals submitted questionnaires on upper GI dilations and tubal prosthesis insertions performed, regardless of outcome. The exact potential sample size was difficult to determine as the local reporters were relied upon to identify the cases to be included and NCEPOD had no way of checking this.

Organisational questionnaire

194 organisational questionnaires were returned. This was comprised of 174 participating hospitals and a further 20 hospitals, from which no endoscopy related deaths were reported, also submitted an organisational questionnaire.

OVERVIEW OF COLLECTED DATA

GI therapeutic endoscopies

An overview of the data collected on GI therapeutic endoscopies is presented in Figure 1.

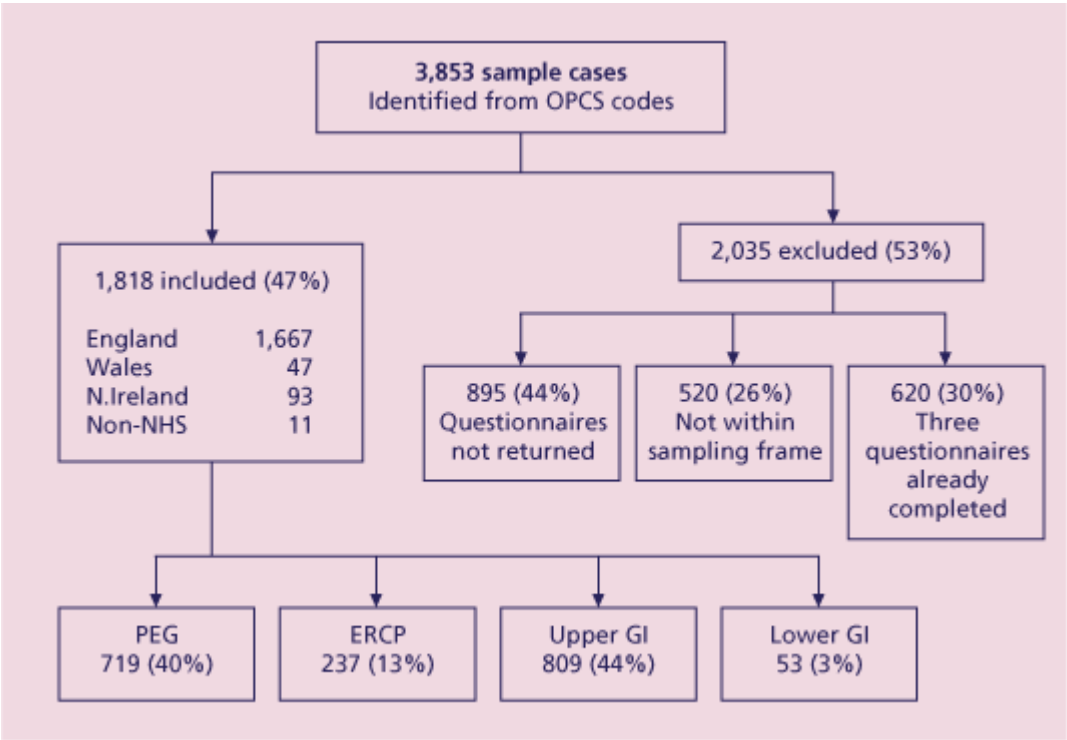


Figure 1. An overview of the data collected on GI therapeutic endoscopies

The upper GI data are presented in the chapter on oesophagogastroduodenoscopy (OGD) and the data on percutaneous endoscopic gastrostomy (PEG) and endoscopic retrograde cholangiopancreatography (ERCP) are contained in separate chapters. No specific analysis of the lower GI cases have been undertaken due to the small sample size.

Exclusions

3,853 cases were identified as sample cases from the death data received from hospitals. Of these, just over half (2,035) were excluded. As seen in Figure 1, 620 cases were excluded as the clinician responsible for performing the endoscopy had already completed three questionnaires. In many hospitals, the majority of endoscopies were performed by one or more endoscopists and therefore the limitation to three questionnaires per clinician, whilst reducing the workload of the clinicians involved, has resulted in a potential 16% (620/3,853) reduction in the sample size for analysis.

520 cases did not fall within the sampling frame as the endoscopy was carried out at another hospital, the patient died at another hospital, duplicate deaths were reported to NCEPOD, or the procedure was miscoded. Of these excluded cases miscoding resulted in 298 sample cases being excluded, either because an endoscopy was not performed, or the endoscopy was a diagnostic procedure. This once again highlights errors in hospital coding for which concern was raised in the 2001 NCEPOD report[3] and which severely limits its utility.

Return rate

A questionnaire was not returned for 33% (895/2,713) of the sampled cases eligible for inclusion (i.e. excluding those not within the sampling frame or exclusion due to limitation to three/clinician). This reflects a similar non-response rate to the first NCEPOD report in 1990[4] where approximately 30% of questionnaires were not returned by surgeons and anaesthetists. This fell to 12% in 2002 and it is hoped that as physicians become more involved with NCEPOD studies, a better response will be achieved.

The reasons for non-return are illustrated in Figure 2. Despite prior notification of the study and reminders, no reason was given for 65% (583/895) of unreturned questionnaires. This may be attributed to the fact that the clinician to whom the questionnaire was sent was often not the clinician who performed the endoscopy, with the result that questionnaires were passed internally and could not be traced. In 8% (72/895) of cases, the clinician who performed the endoscopy could not be identified. Equally concerning is that in an additional 8% (73/895) of cases, questionnaires were not returned due to problems in locating or retrieving patient records. In only ten cases (1%) did the clinician refuse to complete the questionnaire, six of these citing lack of time and pressures of work as the reason.

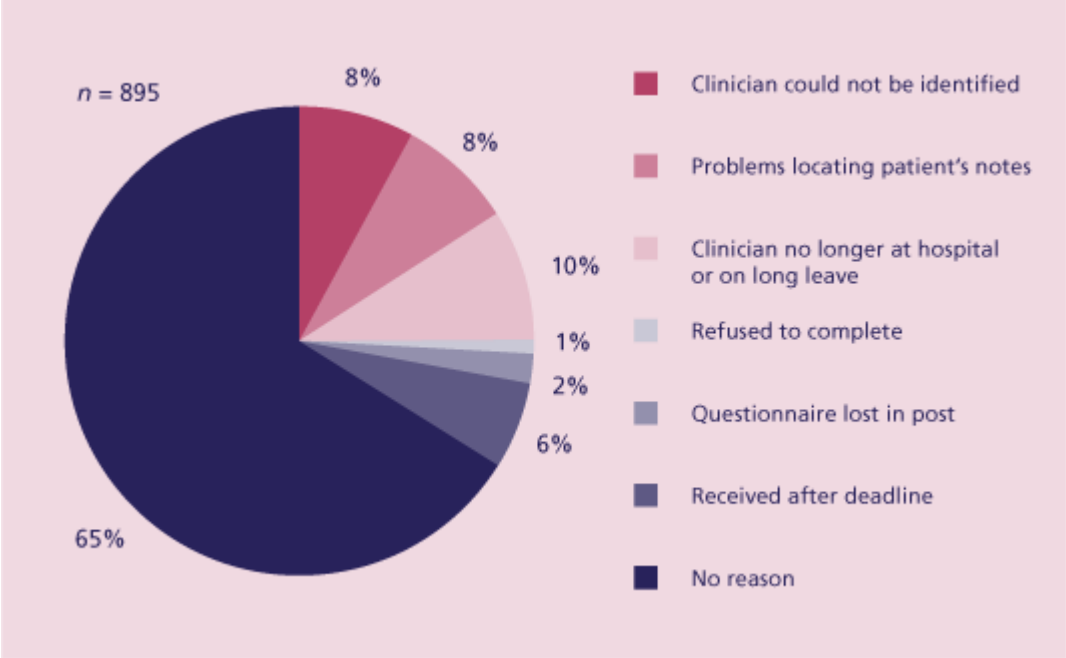


Figure 2. Reasons for non-return of questionnaires

Demographics

73% (1,320/1,818) of the cases were over the age of 70 years (Table 3) and the median age of patients undergoing GI therapeutic endoscopies was 78 years.

Table 3. Age by procedure type

	Procedure type				
Age	**PEG**	**ERCP**	**Upper GI**	**Lower GI**	**Total**
0-9	0	1	1	0	2
10-19	0	0	1	0	1
20-29	4	0	1	0	5
30-39	4	2	25	1	32
40-49	16	1	62	0	79
50-59	36	12	93	4	145
60-69	71	27	133	3	234
70-79	203	76	200	15	494
80-89	309	93	236	25	663
90-99	76	25	57	5	163
Median age	80	79	74	81	78
Total	**719**	**237**	**809**	**53**	**1,818**

Slightly more males than females were included in the sample (Table 4).

Table 4. Sex by procedure type

	Procedure type				
Sex	**PEG**	**ERCP**	**Upper GI**	**Lower GI**	**Total**
Female	327	120	324	23	794
Male	392	117	485	30	1,024
Total	**719**	**237**	**809**	**53**	**1,818**

Data quality

The 2003 NCEPOD report, 'Who Operates When? II'[5], highlighted ASA status and grade of clinician as being poorly completed and recommended that hospitals implement systems to record these data. Encouragingly, in this study 94% (1,709/1,818) of cases reported an American Society of Anaesthesiologists (ASA) status and 98% (1,773/1,818) completed the grade of the senior endoscopist. This is a commendable improvement!

Upper GI dilation and tubal prosthesis insertion

As shown in Figure 3, 3,021 upper GI dilations and tubal prosthesis insertion were reported to NCEPOD. 3% (76/3,021) were excluded as they related to procedures performed on children or were performed under radiological guidance, without endoscopy.

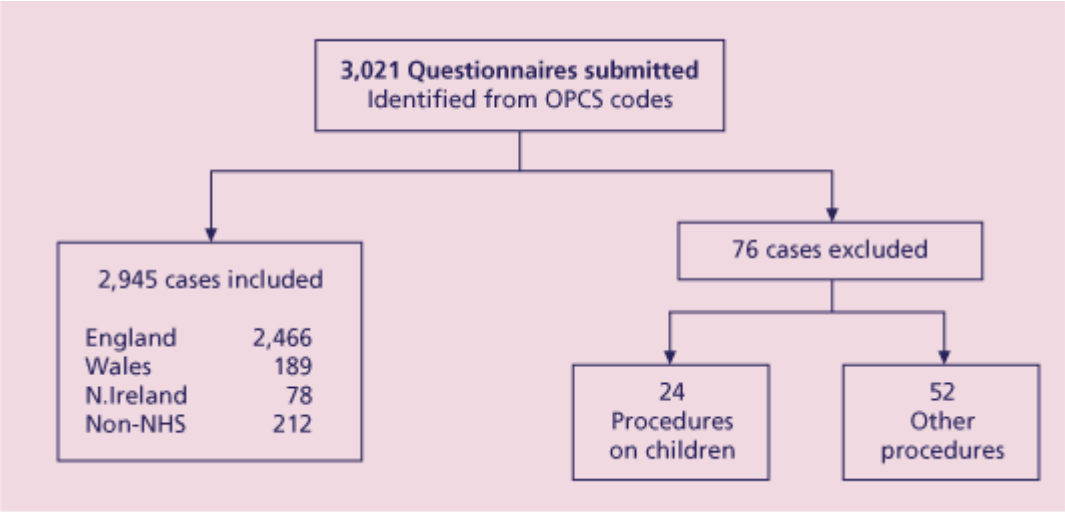


Figure 3. An overview of the data collected on upper GI dilations and tubal prosthesis insertions

DENOMINATOR DATA (NATIONALLY AVAILABLE)

GI therapeutic endoscopies

Approximately 2,400 sample cases were expected. This was based on Hospital Episode Statistics (HES) for the year 1999-2000 which reported just over 90,000 therapeutic endoscopies in the NHS in England, and the study designers estimating a mortality rate of approximately 2% for upper and lower GI procedures and 5% for ERCP and PEG procedures.

For comparative purposes, the total number of GI therapeutic endoscopies performed in NHS hospitals in England, Wales and Northern Ireland in the year 2002-2003 is summarised in Table 5. These data were provided by HES (England), the Patient Episode Database for Wales, and the Department of Health Social Services and Public Safety (Northern Ireland)[2]. No denominator data was available for non-NHS hospitals. These data include procedures listed within the last 12 and last four procedures within an episode for England and Northern Ireland respectively, and any mention of a procedure within the last hospital episode in Wales.

Table 5. The total number of finished consultant episodes in England, Wales and Northern Ireland, 2002 – 2003

Procedure type	England (last 12 procedures)	Wales (any mention of procedure)	Northern Ireland (last 4 procedures)
PEG	16,648	1,453	75
ERCP	23,606	1,343	20
Upper GI	47,931	2,569	129
Lower GI	40,378	2,256	8
Total	**128,563**	**7,621**	**232**

Upper GI dilation and tubal prosthesis insertion

The total numbers of upper GI dilations and tubal prosthesis insertions performed over the three month period between 1 January and 31 March 2003 are shown in Table 6. These data include procedures performed in children. The number of procedures reported to NCEPOD represents less than 72% (2,945/4,088) of those reported to HES, the Patient Episode Database for Wales and the Department of Social Services and Public Safety[2] . The denominator figure may be higher due to the inclusion of procedures that NCEPOD excluded, i.e. radiological procedures and procedures performed on children.

Table 6. Upper GI dilation procedures between 1 January and 31 March 2003

	England (last 12 procedures)	Wales (any mention of procedure)	Northern Ireland (last 4 procedures)	Non-NHS	Total
Denominator data	3,669	264	155	Not available	*4,088
NCEPOD data	2,466	189	78	212	2,945

* Excludes non-NHS data which are unavailable

REFERENCES

[1] BSG pers comm

[2] Hospital Episode Statistics, Table 10 (Total operations) NHS Hospitals, England, 2002-2003, Department of Health. Patient Episode Database for Wales, Health Solutions Wales. Department of Health, Social Services and Public Safety.

[3] *Changing the way we operate.* The 2001 Report of the National Confidential Enquiry into Perioperative Deaths. NCEPOD. London, 2001. www.ncepod.org.uk/2001.htm

[4] *The Report of the National Confidential Enquiry into Perioperative Deaths 1990.* NCEPOD. London, 1990

[5] *Who Operates When? II*. The 2003 Report of the National Confidential Enquiry into Perioperative Deaths. NCEPOD. London, 2003. www.ncepod.org.uk/2003.htm

4. ORGANISATIONAL ISSUES

INTRODUCTION

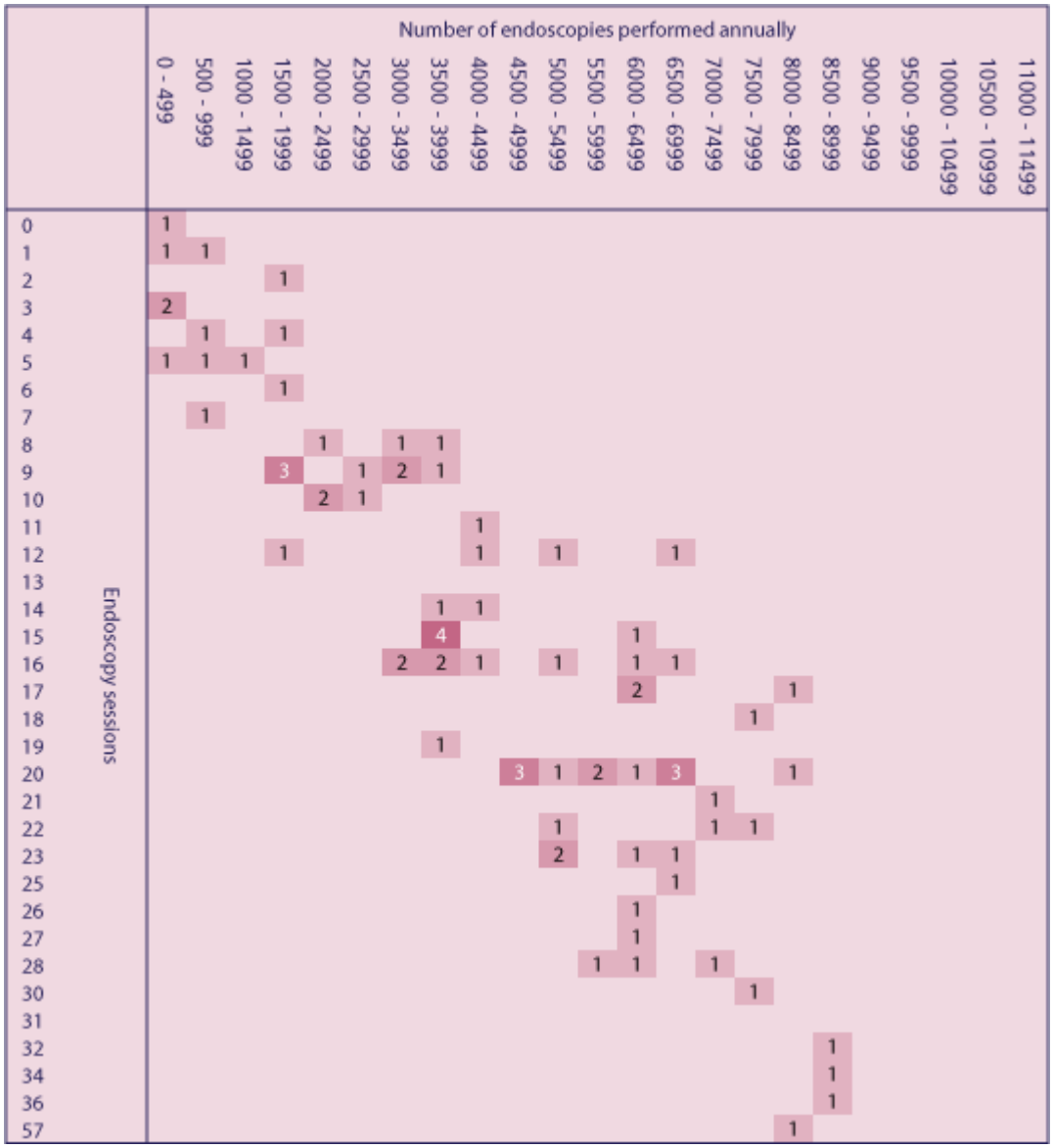
Each participating hospital was sent a questionnaire, which asked for details about the size of the hospital, the numbers of patients undergoing endoscopy within the hospital and the facilities available within the endoscopy unit. The information collected has been compared to the recommendations from the British Society of Gastroenterology Working Party in 2001[1] (the BSG Report) on the provision of endoscopy related services in district general hospitals. The BSG Report[1] focused on a number of key areas, including the requirements for endoscopy, where this should be performed and the facilities required in an endoscopy unit.

QUESTIONNAIRE RETURN

A total of 263 hospitals participated in the endoscopy study and 74% (194/263) returned the facilities questionnaire.

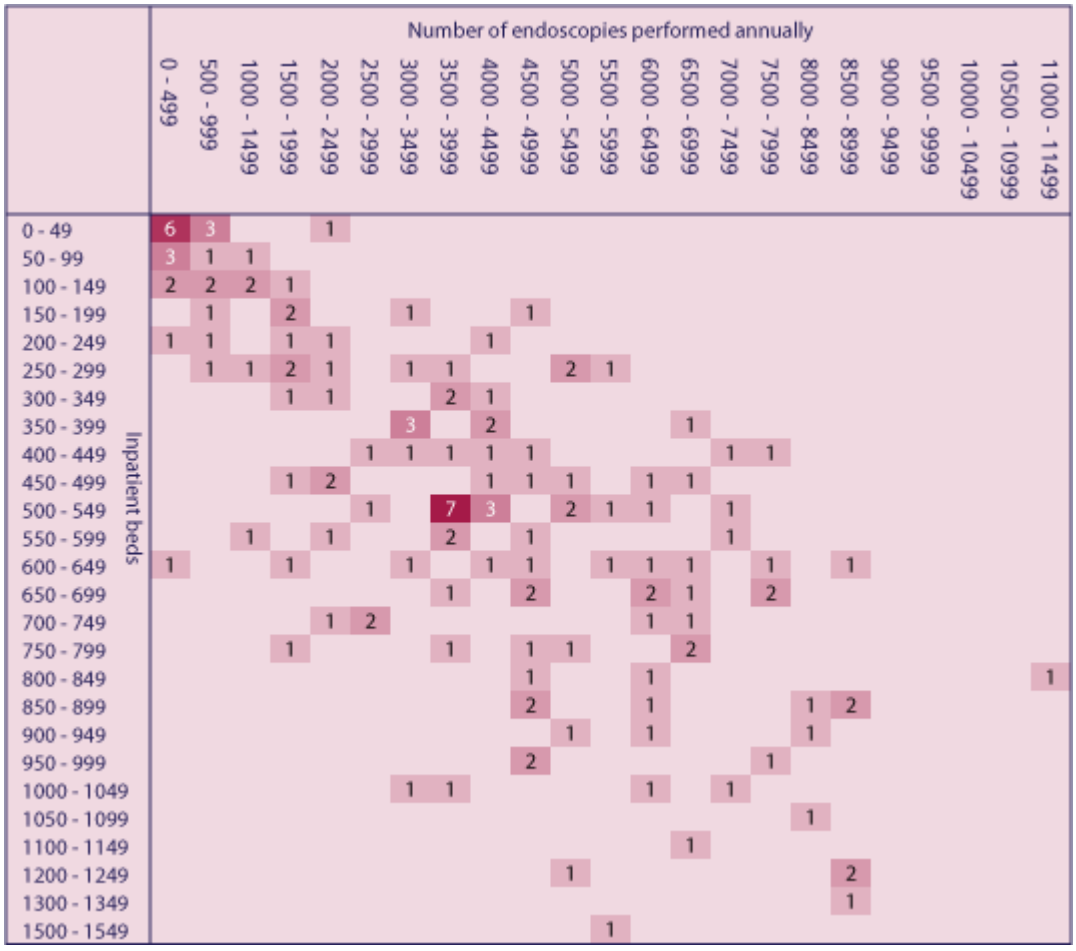
WORKLOAD OF ENDOSCOPY UNITS

The number of weekly endoscopy sessions is correlated with the annual number of patients undergoing an endoscopy within an endoscopy unit (Figure 4). However, it should be noted that the data represented includes only 42% (81/194) of the hospitals that submitted a questionnaire on endoscopy facilities. Missing data has prevented us showing a complete picture. Assuming that the information was not returned because it was unknown to the hospital then one has to question how departments can operate without knowing this basic information. The BSG Report[1] recommends that an average DGH performing 2,500-3,000 endoscopies per annum should allow 12-14 sessions per week which is broadly consistent with data reported in Figure 4. There is also a reasonable correlation between the number of endoscopies performed and the number of inpatient beds within the hospital (Figure 5). The data in this graph represents 74% (144/194) of the hospitals that submitted a questionnaire on endoscopy facilities.



NB: Only 42% (81/194) of hospitals are represented. The remaining hospitals did not provide this information.

Figure 4. Number of sessions by the annual numbers of patients undergoing endoscopy *(Numbers of hospitals are indicated by the figure within the shaded boxes)*



NB: 74% (144/194) of hospitals are represented. The remaining hospitals did not provide this information.

Figure 5. Annual number of endoscopies performed by number of inpatient beds

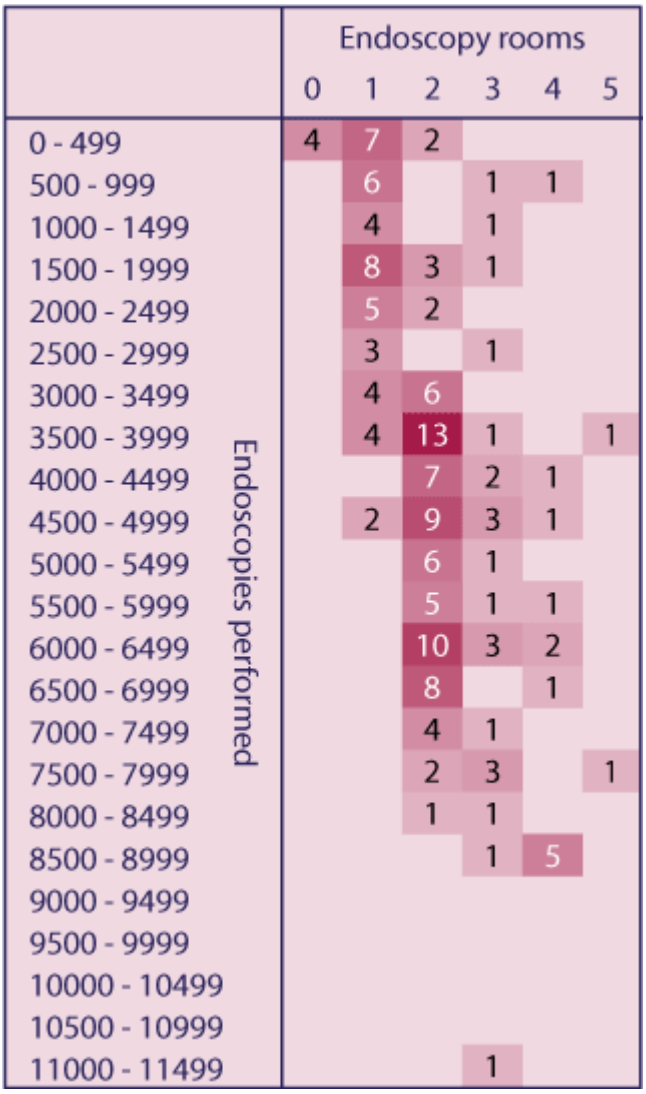
SIZE OF ENDOSCOPY UNIT

Key point

7% of hospitals (undertaking >2500 procedures) had only one endoscopy room.

The BSG Report[1] recommended that an average DGH (2,500-3,000 endoscopies per year) should have a minimum of two endoscopy rooms within the unit. Of the 185 hospitals that answered the question on endoscopy rooms, 7% (13/185) had less than two rooms. However, Figure 6 shows, there are clearly some hospitals which are very well equipped as well as some larger hospitals that appear to have fewer rooms than would appear adequate if they are going to provide an appropriate service for patients. As previously commented upon, it was a concern to NCEPOD that 17% of hospitals could not provide details of either the number of endoscopy procedures performed a year or the number of rooms that they had in their unit.

Anecdotally, however, we know that the issue of room efficiency is complex depending on issues such as where ERCP and bronchoscopies are performed. All hospitals should ensure that the best use of their facilities is being made.



Endoscopies performed	Endoscopy rooms 0	1	2	3	4	5
0 - 499	4	7	2			
500 - 999		6		1	1	
1000 - 1499		4		1		
1500 - 1999		8	3	1		
2000 - 2499		5	2			
2500 - 2999		3		1		
3000 - 3499		4	6			
3500 - 3999		4	13	1		1
4000 - 4499			7	2	1	
4500 - 4999		2	9	3	1	
5000 - 5499			6	1		
5500 - 5999			5	1	1	
6000 - 6499			10	3	2	
6500 - 6999			8		1	
7000 - 7499			4	1		
7500 - 7999			2	3		1
8000 - 8499			1	1		
8500 - 8999				1	5	
9000 - 9499						
9500 - 9999						
10000 - 10499						
10500 - 10999						
11000 - 11499				1		

Figure 6. Annual number of patients by number of endoscopy rooms

OUT OF HOURS ENDOSCOPY

Key point

62% of hospitals do not operate an out of hours on-call rota for emergency cases.

The majority of requests for emergency or out of hours endoscopy involve the management of patients with acute gastrointestinal bleeding. The BSG Report[1] states that it is essential that consultant gastroenterologists are available to come to the endoscopy unit when necessary to supervise the management of patients with acute gastrointestinal haemorrhage.

However, it is recognised that it is difficult for smaller units to provide 24 hour cover. In our sample 38% (69/180) of hospitals operate an out of hours on-call rota and 14 hospitals did not answer this question. Of the hospitals that completed the question on out of hours cases, 35% (67/190) performed these cases within the endoscopy unit. In 55% (105/190) of hospitals out of hours emergencies were dealt with in main theatres contrary to recommendations in the BSG Report: *"Emergency endoscopy should be performed in the main Endoscopy Unit with experienced nursing staff available – not as a rushed procedure, either in a side room on a medical ward, or in a main operating theatre, unless the endoscopy is being performed immediately prior to surgery."* However, NCEPOD recognises that in some circumstances, for example upper GI bleeds, it might be more appropriate to treat the patient in a fully-equipped operating theatre. It may also be too costly to ensure that an Endoscopy Department is open 24 hours a day to receive such patients, especially in small units.

NURSE ENDOSCOPISTS

Key point

In 17% of hospitals, nurse endoscopists perform only one session per week.

The majority of hospitals, 76% (138/182) use a nurse endoscopist for at least one session a week (12 hospitals did not answer the question on personnel). However, 17% (24/138) do only one session per week which goes against the recommendation in the BSG Report[1] that in order for nurses to remain competent they should undertake two or more sessions per week.

ENDOSCOPY ROOM EQUIPMENT

Key points

5% of hospitals do not have piped oxygen in any of their endoscopy rooms.

37% of hospitals do not have any ECG monitors in their endoscopy unit.

When equipping endoscopy units, the BSG Report[1] recommends that each room should contain piped oxygen, suction, pulse oximetry and facilities for ECG monitoring. Of the hospitals that completed the section on equipment, 5% (9/189) of hospitals had no oxygen in any endoscopy rooms and a further three (1.5%) only had it in some rooms. 99% (188/189) of hospitals had pulse oximetry in every room but only 47% (87/187) had ECG monitoring in every room and 37% (69/187) did not have any ECG monitors in the unit.

It is recommended[2] that ECG monitoring is needed for those patients with significant cardiac risk and therefore those units which do not have any ECG facilities should address this issue as a matter of urgency.

RECOVERY AREAS

6% of hospitals who provided information on recovery (12/187) did not have a dedicated recovery area within their endoscopy unit despite a recommendation within the BSG Report[1] which expects the same equipment that is in each endoscopy room, namely oxygen, pulse oximetry and ECG monitoring to be present in recovery. 81% of hospitals with recovery rooms (142/175) had oxygen and only 47% (82/175) had pulse oximetry.

RESUSCITATION FACILITIES

Despite the BSG Report[1] stating *"All units should have full resuscitation facilities available including a cardiac defibrillator…"* 19% (37/191) of units who provided information did not have a resuscitation trolley within the unit or shared facilities with other departments. Of these 37, 19 were hospitals that were undertaking more than 3,000 endoscopies a year within their unit. Three hospitals had no defibrillator in the endoscopy unit. Of concern, three hospitals did not have resuscitation training but where they did, it was provided regularly with 95% (178/188) of units saying they had training at least every year. Eight units had training only every three years, one unit said their training was 'sporadic' and one questionnaire was left blank.

AUDIT/GOVERNANCE MEETINGS

Key point

42% of hospitals do not hold audit meetings in their endoscopy department.

The BSG Report[1] recommends that there should be clear responsibility for the organisation of departmental meetings, which should form the basis of departmental audit. The Report also recommends that nurse endoscopists should undertake audit as a fundamental part of their role.

We asked whether units held regular audit/governance meetings as opposed to multidisciplinary team meetings. Five hospitals did not answer this question but of those that did, 58% (110/189) held audit meetings and 17% (19/110) of these were for doctors alone.

The frequency of meetings varied from weekly to greater than bi-monthly, with 68% (75/110) having meetings bi-monthly or more regularly (Figure 7).

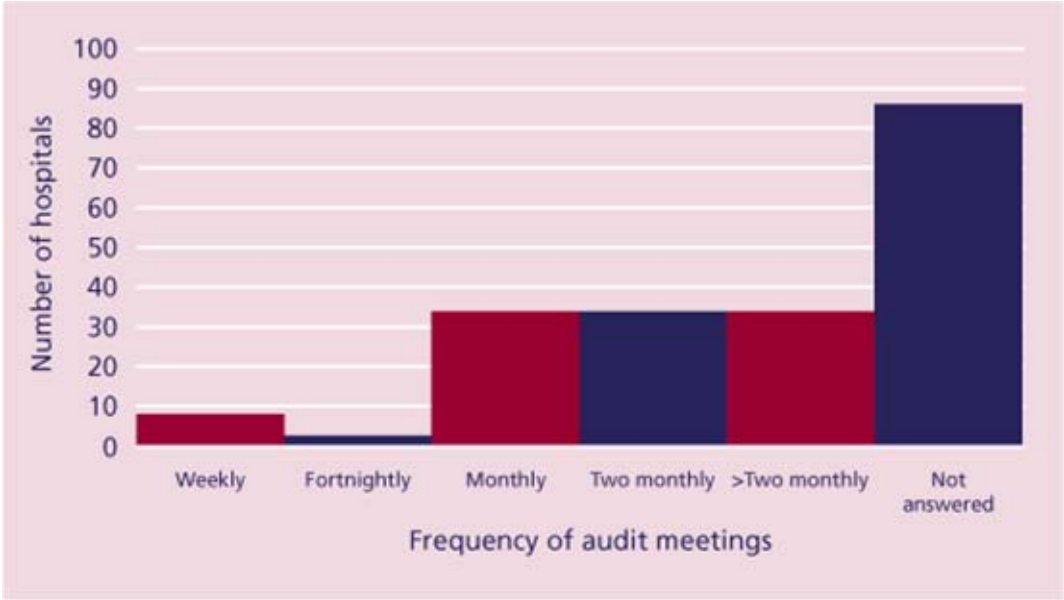


Figure 7. Frequency of audit meetings

Recommendations

Hospitals should ensure that the appropriate monitoring equipment and resuscitation equipment is available in each of their endoscopy rooms and recovery areas.

In order to produce optimal care for what is a large group of severely ill patients, hospitals should consider establishing formal on-call arrangements.

REFERENCES

[1] *Provision of endoscopy related services in District General Hospitals.* BSG Working Party Report, 2001. www.bsg.org.uk/pdf_word_docs/endo_related_services.pdf

[2] *Safety and sedation during endoscopic procedures.* British Society of Gastroenterology, 2003. www.bsg.org.uk/clinical_prac/guidelines/sedation.htm

5. PATIENT ASSESSMENT

INTRODUCTION

Endoscopy, both diagnostic and therapeutic, is a high volume, predominantly day case, procedure. According to the advisors' experience there is often no prior assessment to determine whether patients are suitable for endoscopy until the day of the procedure. Although patients may have been reviewed in the clinic before endoscopy, they may have to wait several months for their investigation during which time their clinical condition may have changed. Similarly, inpatients are rarely reviewed by the endoscopist before the procedure, unless they are a member of the team caring for the patient.

There has been a paucity of studies that have examined patient selection[1 2]. A recent report from Ireland identified a 16% 30 day mortality following PEG placement in 205 patients, indicating that selection criteria for this procedure may need to be refined[1]. In addition, careful patient selection can reduce the risk of ERCP associated pancreatitis. Patients are at a greater risk of pancreatitis if they have certain combinations of characteristics that include females, normal serum bilirubin, recurrent abdominal pain, and previous post-ERCP pancreatitis[2]. However, it is likely that those at greatest risk will be inpatients, because they will be sicker than those who are outpatients; those who have comorbidities (with an increased number of comorbidities associated with greater risk); and those who need immediate or emergency endoscopy. Clinicians should recognise that the general condition of inpatients undergoing endoscopy is likely to be different to the condition of routine outpatient endoscopy patients.

PRE-ENDOSCOPY PATIENT OVERVIEW

This study is not a review of a sample of all patients undergoing therapeutic endoscopy; it is a study of inpatients who died within 30 days of a therapeutic endoscopy which reflects a very small percentage of patients undergoing this procedure. Most of these inpatients, 91% (1,619/1,774), had been admitted as an emergency and in 44 cases the admission method was unknown.

One part of the endoscopy questionnaire required clinicians to provide an assessment of the patient's risk of death within 30 days of the proposed procedure. In the majority of cases where information was provided (74%, 1,303/1,753), death was either a definite risk (60%, 1,056/1,753) or expected (14%, 247/1,753). These values are reflected in the patient's ASA status (Table 7).

Key point

Most patients, 85%, were deemed to have an ASA status of 3 or poorer.

Table 7. Pre-endoscopy condition

ASA Status	None	Small	Definate	Expected	Sub-total	Not answered	Total
1	2	10	12	4	28	1	29
2	61	47	97	15	220	2	222
3	157	50	355	46	608	11	619
4	72	20	464	97	653	8	661
5	9	0	91	77	177	1	178
Sub-total	**301**	**127**	**1,019**	**239**	**1,686**	**23**	**1,709**
Not answered	15	7	37	8	67	42	109
Total *(%)*	**316 *(18)***	**134 *(8)***	**1,056 *(60)***	**247 *(14)***	**1,753**	**65**	**1,818**

Case Study

A very elderly patient was admitted following a severe stroke. After five weeks in hospital oral feeding was judged to be inadequate. Although their condition was very poor, assessed as ASA 5, a PEG was inserted. The patient deteriorated after the procedure and a decision was made to give only palliative care. The patient died two weeks after the PEG insertion.

In this case the endoscopist should have recognised that the severity of the patient's condition should have precluded this procedure. The opinion of the advisors was that there was no benefit to the patient's care, even in the two-week period before death. Issues relating to PEG insertion are discussed in more detail in a separate chapter later in this report.

Key point

Two or more co-existing medical conditions were present in 76% of patients.

Information was collected on the patients' concurrent medical conditions.

Table 8. Co-existing medical conditions (answers may be multiple)		
Co-existing medical condition		**Total** ***n = 1,755***
Respiratory	COPD	274
	Acute chest infection	456
	Asthma	65
Cardiac	Ischaemic heart disease/previous MI/angina	473
	MI within three months of the endoscopy	44
	Valvular heart disease	69
Neurological	CCF (at present or in the past)	253
	CVA/TIAs	548
	Dementia	197
	Acute confusion state	127
	Psychiatric disease	61
	Parkinson's disease	58
Hepatic/pancreatic		411
Alimentary		218
Renal failure	Acute	179
	Chronic	122
Endocrine	Non-insulin dependent diabetes mellitus	167
	Insulin dependent diabetes mellitus	51
	Hypothyroidism	53
Musculoskeletal		181
Haematological	Bleeding disorder	73
	Immunosupression	25
Sepsis		164
Other		534
Total		**4,803**
None		79
Not answered		63

Co-existing medical conditions were present in all except 79 patients (Table 8), with two or more conditions in 76% (1,341/1,755), and greater than 4 in 14% (249/1,755) (Table 9). It is interesting to note that cerebrovascular disease was the commonest co-existent condition, and this is likely to reflect the age distribution of the patients in this study.

Table 9. Count of co-existing medical conditions by procedure															
Procedure	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**12**	**Sub-total**	**Not answered**	**Total**
PEG	13	99	201	157	116	67	34	10	1	1	1	1	**701**	18	**719**
ERCP	27	56	47	39	28	16	7	7	0	0	0	0	**227**	10	**237**
Upper GI	37	174	223	146	102	56	22	10	7	1	1	0	**779**	30	**809**
Lower GI	2	6	14	8	11	4	1	1	1	0	0	0	**48**	5	**53**
Total *(%)*	**79** *(5)*	**335** *(19)*	**485** *(28)*	**350** *(20)*	**257** *(15)*	**143** *(8)*	**64** *(4)*	**28** *(2)*	**9** *(<1)*	**2** *(<1)*	**2** *(<1)*	**1** *(<1)*	1,755	63	1,818

CLINICAL INFORMATION

Clinicians were asked to provide information on the investigations and physiological measurements made before the procedure. Unfortunately, documentation of patient's pre-procedural investigations was limited and there are no obvious reasons as to why this section was so poorly completed.

From the limited data, 71 patients were shocked, as defined by a tachycardia (pulse rate greater than or equal to 100 bpm) and hypotension (systolic blood pressure less than or equal to 90 mmHg). In addition, three had both a bradycardia (pulse rate less than or equal to 50 bpm) and hypotension. Were all appropriate efforts made to improve the patients' condition before the procedures were carried out?

Key point

The patient's weight was recorded in only 24% of cases.

Data concerning the patient's weight were returned in only 24% (429/1,818) of cases (Table 10).

Table 10. Number of cases where weight was been recorded

Procedure	Total	Number where weight recorded	*(%)*
PEG	719	143	*(20)*
ERCP	237	65	*(27)*
Upper GI	809	209	*(26)*
Lower GI	53	12	*(23)*

The widespread failure to record patients' weight is surprising. The patient's weight is helpful when judging the doses of sedation for endoscopic procedures especially in those who are frail and sick. The weight is also an important marker of nutritional status but the proportion of patients weighed was lowest for the group of patients undergoing a PEG procedure. In nearly all cases it was possible to move the patient to another location prior to their endoscopic procedure so there can be few excuses for failing to weigh patients.

Advisors found that in many cases the correct investigations had not been carried out before procedures; for example, advisors judged that patients scheduled for ERCP should have their bilirubin level and clotting status checked before the procedure. In 93% (221/237) of patients the bilirubin level was available. However, in 80% (189/237) of ERCP patients there was no record of a clotting study having been performed. When appropriate investigations were performed, abnormal results were disregarded.

Case Study

An ERCP was done for common bile duct stones, despite the patient's haemoglobin of 7.0gm/dl and INR of 2.6.

The advisors thought the procedure was appropriate, but should only have been done after the patient's condition was optimised. Did the endoscopist see the test results before the ERCP? Did they appreciate the significance of the results?

As with any patient assessment it is always important to listen to the patient.

Case Study

A GP referred an elderly patient who was complaining of poor fluid intake and loss of appetite. Investigations showed extensive mediastinal tumour probably from a previous lung cancer. An OGD revealed a length of abnormal oesophageal mucosa but there was no evidence of malignancy on biopsy which might have indicated a need for a therapeutic procedure. In the notes the dietician had written "eating all meals, increasing appetite, BMI =22.7". Despite this evidence a stent was inserted at a subsequent OGD.

APPROPRIATE PROCEDURE?

Key point

14% of procedures were judged as inappropriate and 17% of procedures were performed at an inappropriate time.

Advisors were asked to decide in the light of the severity of the patient's condition, whether the type and the timing of the procedure were appropriate for the clinical scenario (Table 11).

Table 11. Appropriateness of procedure as determined by the advisors

	Yes	No	Insufficient information to assess
Type of procedure appropriate	1,395	230	193
Timing of procedure appropriate	1,287	258	273
Type and timing of procedure appropriate	1,225	0	593

The type of endoscopy was appropriate in 86% (1,395/1,625) of patients, and at an appropriate time in the admission in 83% (1,287/1,545). 63% of the procedures, where the type of procedure was deemed inappropriate, were thought to be futile (145/230) and the remainder were unnecessary.

Amongst the 258 procedures where the timing was deemed inappropriate, 135 were too late to be of any benefit and 21 were too early. Almost all of the patients in these two categories had PEGs placed, and further details can be found in the chapter on PEGs.

Inappropriate ERCPs were also common; these were performed especially on patients with disseminated malignancy.

Case Study

An elderly patient had a pancreatic mass and metastases in the liver, with no evidence of bile duct dilatation on either ultrasound or CT scanning. The pre-procedural INR was 1.7. The patient received 8 mg of midazolam and 50 mg of pethidine. The ERCP showed a duodenal stricture and narrowing of the common bile duct with no proximal dilatation. A "palliative stent" was inserted. The patient died three weeks later.

This was a procedure that would not have been of any benefit to the patient, who also received excessive sedation, compounded by the effect of the liver disease on drug breakdown.

Recommendation

Patients must be assessed by the referring clinician and the endoscopist to justify that the procedure is in the patient's interest.

REFERENCES

[1] Sheehan JJ, Hill AD, Fanning NP, Healy C, McDermott EW, O'Donoghue DP, O'Higgins NJ. *Percutaneous endoscopic gastrostomy: 5 years of clinical experience on 238 patients.* Ir Med J. 2003; 96(9):265-67

[2] Freeman ML, DiSario JA, Nelson DB, Fennerty MB, Lee JG, Bjorkman DJ, Overby CS, Aas J, Ryan ME, Bochna GS, Shaw MJ, Snady HW, Erickson RV, Moore JP, Roel JP. *Risk factors for post ERCP pancreatitis: a prospective, multicenter study.* Gastrointest Endosc 2001; 54(4):425-34

6. PATIENT CONSENT

INTRODUCTION

Consent for any medical intervention is a legal requirement. The General Medical Council (GMC)[1], the British Society of Gastroenterology (BSG)[2] and the Department of Health[3] have produced guidance on the legal and ethical considerations when seeking patient consent. This section is not intended to reproduce those guidelines, but to highlight the specific concerns that were raised by case review of this sample.

Key points

In 32% of cases, clinicians did not answer the question as to whether consent had been provided for the procedure.

Written consent was provided by 66% of patients with dementia or acute confusion who may not have had the capacity to consent.

DOCUMENTING CONSENT

Table 12. Written consent

Written consent obtained	Total	*(%)*
Yes	979	*(79)*
No	254	*(21)*
Sub-total	**1,233**	
Not answered	585	
Total	**1,818**	

NCEPOD asked whether written consent was obtained (Table 12) and 32% (585/1,818) of responders did not answer this question. It may be that the respondents failed to locate the document in what may on occasions be bulky casenotes. Consent for a medical intervention is a legal requirement, and the casenotes should contain a copy of the written consent. If the patient is not able to provide consent the clinical notes should explain the circumstances. There should be a record of why they are unable to, any discussions with the patient and their level of understanding, and any discussions that took place with the patient's relatives or carers. The medical notes should be able to demonstrate that the decision to proceed without the patient's consent was taken by the medical staff in the patient's best interest. It became apparent during the advisors' review of casenotes that some did contain this information, but many did not.

The written consent should accurately reflect the planned procedure. Review of the casenotes revealed a spectrum of detail on the consent forms, from those that included the risks of the procedure to some which stated "gastroscopy", with no indication as to the therapeutic procedure that was planned, or the risks. Examples of consent forms that provide information, including specifically the risks of gastroscopy, colonoscopy and ERCP, are published in the BSG guidelines for consent for endoscopic procedures[2]. This document gives valuable standards on the risks that should be discussed with the patients and what should be recorded. There is a case for standardised endoscopy consent forms for most endoscopy procedures – both diagnostic and therapeutic.

A number of centres use computer-generated reports for procedures and some state by default that written consent has been obtained. If written consent has not been obtained the endoscopist should adjust the computer record accordingly; not leave an erroneous entry.

SEEKING CONSENT

Providing information

Patients have a right to understand their condition and the options available to them, and that includes the details of the treatment[1]. NCEPOD advisors expressed disquiet regarding the extent and quality of information that some patients may have received before entering the endoscopy room. This was particularly so in cases where the decision for a PEG insertion was made by non-medical staff, e.g. speech and language therapists, nutritionists or nursing staff without reference to medical staff.

Informing decision

Patients have a right to know the prognosis if the condition is left untreated. In an attempt to quantify concerns about consent NCEPOD asked its advisors to decide whether the procedure was appropriate and, if not, why not (Table 13). In 14% (230/1,625) of cases the advisors thought the procedure inappropriate and in a further 92 cases they had some doubt.

Table 13. Reasons why the procedure was inappropriate (answers may be multiple)	
Reason	**Total** ***n = 230***
A different endoscopic procedure was indicated	8
Surgery in the first instance would have been more appropriate	1
No endoscopic procedure was indicated	55
Futile procedure	145
Other	41
Total	**250**

The high numbers of procedures considered futile and where no endoscopic procedure was indicated are of particular concern. Futile procedures were those in which death was considered inevitable with or without the endoscopic procedure. Those where no endoscopic procedure was indicated were mostly patients with disseminated carcinoma, or some other condition where the procedure could not reasonably offer improved quality of life. Were these patients provided information on the risks and benefits of the procedure they were to undergo? Of course, it is easier to determine futility with the benefit of hindsight and a further study to look at this issue in more detail may be called for.

Real dilemmas for the endoscopist arise when the clinician encounters unforeseen findings. What is the sensible way to proceed?

Case Study

A patient was undergoing a diagnostic OGD when the endoscopist saw blood in the base of a peptic ulcer. There was no history of haematemesis or melaena and the patient had a Hb of 11.5gm/dl. The ulcer was injected with adrenaline, and the patient subsequently suffered a perforation.

Respecting autonomy

A patient who is of sound mind has the right to withhold consent, irrespective of the medical advice. There were several cases in which patients withheld consent until coerced into a procedure, particularly for insertion of a PEG after a stroke. Clearly this is not acceptable; it reflects the clinician's view of what is in the best interest for the patient, not the patient's view. However, dilemmas on respecting autonomy such as the following case are less clear-cut.

Case Study

A patient was admitted from a residential home where they had been in respite care. In the early hours of the morning the patient was found to be less responsive and had passed a melaena stool. Later that day a diagnostic upper GI endoscopy revealed oesophagitis, a discrete oesophageal ulcer, a large amount of blood in the stomach and a 1 cm acute duodenal ulcer. Two days later, after 3 units of blood and with a Hb of 9.9gm/dl, the patient was refusing further medical treatment and refusing to return to respite care. Three days later the patient collapsed with melaena and was given a blood transfusion. Later that day, and without written consent, an experienced SpR performed an oesophagogastroscopy, during which the duodenal ulcer was injected with adrenaline. The bleeding could not be stopped and the case was discussed with the surgeon who, in view of the patient's age, frailty and previously expressed wishes, thought surgery not indicated.

It is evident that in the patient's collapsed state they were unable to provide consent for the second gastroscopy. Was it appropriate to proceed given the patient's express wishes after the first endoscopy?

The circumstances above make the decision to proceed difficult. However, the GMC states that the expressed wishes of the patient must take precedent. *"Any valid advance refusal of treatment - one made when the patient was competent and on the basis of adequate information about his/her choice - is legally binding and must be respected where it is clearly applicable to the patient's present circumstances and where there is no reason to believe that the patient had changed his/her mind"*[4]. In the case above, was the advance directive of this patient valid?

Capacity to consent

16% (290/1,818) of patients were suffering from dementia or acute confusion. Those patients that were reported to be suffering from dementia or acute confusion who provided written consent are presented in Table 14.

Table 14. Written consent for those with dementia and/or acute confusion

Written consent obtained	Total	*(%)*
Yes	134	*(66)*
No	70	*(34)*
Sub-total	**204**	
Not answered	86	*(30)*
Total	290	

We were surprised to find that in these patients written consent was obtained in 66% (134/204). This is of concern given the guidance now available from the Department of Health on consent and patients without the medical capacity to consent to medical treatment. From the casenote review it was difficult to judge the extent of dementia or confusion for many of the patients. Nevertheless, with this diagnosis their capacity to consent must be questioned. An adult is presumed to have the capacity to consent if they can comprehend and retain treatment information, believe it and weigh it up to arrive at a choice[5]. If a patient has a diagnosis of dementia then the capacity to retain treatment information should be tested.

The advisor's opinion from case review was that often the process of obtaining consent was not transparent and in 18% (322/1,818) of cases the benefits of the procedure were doubtful. Since April 2002, new consent forms stating the risks of a procedure have been available and since April 2003, the closure of data collection for this study, the Department of Health has directed that they be used. Included is a form to be signed by the clinician that makes a decision on behalf of a patient without the capacity to consent to medical treatment[3]. Use of these consent forms should provide greater clarity around issues of consent and decisions made on behalf of patients, including those with dementia. The evidence from this chapter suggests that local audit based on issues surrounding consent is indicated.

Recommendations

The risks and benefits of therapeutic endoscopy should be explained to the patient, and this should be documented on the consent forms as laid down in the Department of Health guidelines.

The ability of those with dementia or acute confusion to provide consent should be tested and clearly documented.

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7. TRAINING AND EDUCATION

INTRODUCTION

The acquisition of skills has an established broad research base. The acquisition of endoscopic skills involves knowledge, psychomotor development and technical awareness. Traditionally endoscopy was taught as a 'hands on' procedure, by an experienced endoscopist on a one-to-one basis. Initially, experience was related to the number of procedures. Training, however, was very variable and several courses were established in the United Kingdom by dedicated doctors who were both skilled enthusiastic endoscopists and well motivated teachers.

The British Society for Gastroenterology (BSG) has been instrumental in developing training programmes for endoscopy – in league with the relevant Royal Colleges and specialist societies[1].

Interestingly, despite the specific recommendations for training[2 3 4 5], there is no specific guidance about skill maintenance especially the number of techniques needed to remain proficient[6 7]. The BSG recommends that endoscopists should have a professional commitment to two or more endoscopy sessions per week[8]. This is extremely important in the era of revalidation and clinical governance, especially as endoscopic complications are directly related to inadequate and inappropriate training – and not all endoscopists have received correct training[5 9 10 11].

ENDOSCOPY PROFICIENCY

74% (1,312/1,773) of the procedures performed in this sample were by experienced consultant endoscopists. Despite this fact, some were only doing a few procedures a year (Table 15).

Table 15. Number of procedures by endoscopist in the study period 2002-2003

Number of procedures performed	PEG	ERCP	Upper GI	Lower GI
<5	12	0	4	1
6-10	65	0	10	0
11-20	163	1	46	3
21-50	245	22	124	9
51-100	84	60	126	23
>100	19	119	431	10
Sub-total	**588**	**202**	**741**	**46**
Not answered	131	35	68	7
Total	**719**	**237**	**809**	**53**

The number of procedures performed does not necessarily equate to competency, however it would seem unlikely that fewer than 20 procedures in a year is sufficient to remain proficient and skilled. Oesophagogastroduodenoscopy (OGD) is a common diagnostic and therapeutic procedure. Thus it was surprising that 184 responses indicated that some endoscopists were doing a maximum of only 50 upper GI endoscopies a year. However, this may be an over estimate of clinicians undertaking few procedures, as some endoscopists would have had several patients in this study. The Joint Advisory Group (JAG) guidelines[1] on training in diagnostic upper GI endoscopy state that trainees should carry out at least 200 diagnostic examinations within the course of a year.

Although there may be a finite number of PEGs to insert in any one Trust, of the PEGs inserted in this study, 41% were performed by endoscopists who did fewer than 20 PEGs a year. This is likely to be insufficient to maintain competency. ERCP and the associated techniques provide the greatest challenge for any endoscopist. It is important to question whether 50 procedures are sufficient to maintain skills? The JAG guidelines on training in endoscopy state that trainees should carry out at least 100 ERCPs a year under supervision and achieve a 90% success rate in cannulating the desired bile duct; the document notes that most trainees need to perform twice this number to achieve competence. The advisors felt that as the numbers of endoscopies are increasing, and there is potential for consultant expansion, the BSG should recommend guidelines for continuing competency in endoscopy and that these include a minimum number of procedures to be performed each year.

APPROPRIATE ENDOSCOPIST

The issues relating to proficiency and competency in endoscopic skills have been discussed in the context of training and revalidation. The advisors assessed whether the endoscopist was of an appropriate grade and had the correct experience for the related therapeutic procedure (Table 16). These assessments were based on the seniority of the endoscopist, the number of similar cases done in the last year, and the type and complexity of the procedure.

Table 16. Grade and experience of endoscopist

	Appropriate grade	*(%)*	Appropriate experience	*(%)*
Yes	1,641	*(94)*	1,507	*(91)*
No	27	*(2)*	49	*(3)*
Undecided	26	*(2)*	43	*(2)*
Senior endoscopists also present	47	*(3)*	58	*(4)*
Sub-total	**1,741**		**1,657**	
Insufficient information to assess	73		154	
Not answered	4		7	
Total	**1,818**		1,818	

Key point

In over 90% of cases the grade and experience of the endoscopist was appropriate for the type of procedure.

In 94% (1,641/1,741) of cases, where the question was answered, the grade of the endoscopist was appropriate for the type and complexity of the procedure. In addition, in 3% (47/1,741) of cases a more senior endoscopist was present. In 27 cases the advisors judged that the grade of operator was not appropriate. The cases were a mixture of procedures and degree of urgency. In 22 cases the supervising consultant was in the hospital. Consultants should not expect members of their team to perform procedures beyond their competence and trainees must be encouraged to seek help when cases are more difficult than they were expecting.

The experience of the endoscopist was appropriate in 91% (1,507/1,657) of cases where the information was provided. There were 49 cases where the advisors considered the experience of the operator not appropriate. In 14 of the 49 cases the operator was a consultant and the operator gave their specialty as a specialised GI physician or surgeon in 35. Some of the 49 procedures were urgent or emergency upper GI endoscopies. Others were PEG insertions in sick patients graded ASA 4. Doctors should be aware that in some circumstances even consultants may not possess all the experience necessary and that it may be wise to consult a colleague.

Case Study

A patient with decompensated alcoholic liver disease was endoscoped by a first-year specialist registrar who was unable to control bleeding from varices with sclerotherapy. After inserting a Minnesota tube the gastric balloon was inflated with 250 ml of air. Immediately on inflating the oesophageal balloon the patient developed cardiac arrest (pulseless electrical activity). Although oesophageal rupture is a possibility, the patient should have received at least a fluid challenge in view of the previous blood loss. No autopsy was performed.

This case illustrates the potential problems associated with an inexperienced doctor attempting therapeutic endoscopy in an immediately life threatening situation, and using a potentially life saving device incorrectly.

SEDATION TRAINING

Key point

Only 35% of endoscopists were known to have attended courses on safe sedation.

Good, controlled, conscious sedation is often the key to a successful therapeutic endoscopy. Many of the drugs used can interfere with airway integrity and ventilation; thus it is important that endoscopists are appropriately trained in airway management and sedation skills.

Of the 1,368 cases where we had a response 47% (645/1,368) of endoscopists had attended a course on sedation techniques, whilst 53% (723/1,368) had not done such a course. Many endoscopies are done following referral, and in these cases someone other than the endoscopist will have medically assessed the patient. The BSG 1991 guidelines for sedation[12] recommend the use of a checklist to identify the medical risks. Such checklists are used in some centres and non-medical staff in the endoscopy units usually complete them. Nevertheless, the endoscopist needs to review the findings. Ultimately it is the responsibility of the person providing sedation to ensure they have training in sedation and know the risks and how to respond to them[13]. Training in sedation is part of the endoscopy skills courses run by the Royal College of Surgeons of England [14] and they also run courses on safe sedation for non-anaesthetists. Other than these, there appear to be few courses in sedation available for the endoscopist. The guidelines of the UK Academy of Medical Royal Colleges recommend that each hospital should appoint two consultants (one an anaesthetist and the other a user of sedation from another speciality) to lead and support implementation of their recommendations on sedation at hospital level. These consultants should be able to review sedation practices within their Trust, identify deficiencies in sedation training in colleagues and trainees, and respond to them.

Of the 71% (1,244/1,760) of cases where sedation was given (58 were not answered), concerns were raised about the appropriateness of their practice in 218 patients (Table 17). The advisors made an assessment whether sedation was appropriate, and if not the reasons why. Their answers were based on the patient's clinical condition, the type of procedure, and the type and amount of sedation and /or analgesia and there is no statistical significant difference between those who have attended a course and those who have not when considering poor practice.

Table 17. Sedation training and the numbers and types of sedation problems in cases where concerns were raised about good practice

	Attended course				
Problem	**Yes**	**No**	**Sub-total**	**Not answered**	**Total**
Excess opiod	2	4	**6**	3	**9**
Excess benzodiazepine	44	58	**102**	30	**132**
Insufficient sedation	0	1	**1**	0	**1**
Excess opiod and benzodiazepine	8	5	**13**	2	**15**
Other	2	4	**6**	5	**11**
Sub-total	**56**	**72**	**128**	**40**	**168**
Not answered	20	19	**39**	11	**50**
Total	**76**	**91**	**167**	**51**	**218**

Considering that in 14% (218/1,579) of cases the sedation practice was questioned by advisors, and that these problems at times occurred even though the endoscopist had received sedation training, it is felt that the issue of sedation training should be reviewed regardless of whether clinicians have attended a course or not.

SUPERVISION

Correct supervision is essential for all training endoscopists[1], irrespective of their grade (Table 18). In 45 cases this was not answered, therefore in 26% (461/1,773) of cases the most senior endoscopist was not a consultant. Supervision has to be tailored to the experience of the trainee, and their competence in a particular technique. In most cases, the more junior an endoscopist, the more supervision is required – unless a senior colleague is learning a new technique.

Table 18. Location of supervising consultant when most senior endoscopist was not a consultant.

Grade of operator	In endoscopy room	In unit but not in room	Available in hospital	Available by phone	Other	Sub-total	Not answered	Total
SAS	10	18	79	7	4	**118**	32	**150**
General practitioner	0	0	0	0	0	**0**	7	**7**
Nurse practitioner	4	2	3	0	0	**9**	0	**9**
SpR post CCST	8	7	13	3	0	**31**	6	**37**
SpR year 3+	32	40	73	25	0	**170**	33	**203**
SpR year 1/2	13	11	11	3	1	**39**	6	**45**
SHO	0	0	0	1	0	**1**	1	**2**
Other trainee	1	1	3	1	0	**6**	2	**8**
Sub-total	**68**	**79**	**182**	**40**	**5**	**374**	**87**	**461**
Not answered	2	1	3	1	0	**7**	38	**45**
Total	**70**	**80**	**185**	**41**	**5**	**381**	**125**	**506**

On most occasions (88%, 329/374), the supervising endoscopist was somewhere in the hospital during the procedure; either the endoscopy room (18%, 68/374), or the endoscopy unit (21%, 79/374), or elsewhere in the hospital (49%, 182/374). JAG guidelines[1] do not define 'supervision' but it is difficult to teach a trainee if one is not present in the endoscopy room. Table 18 indicates that SHO and SpR year 1/2 trainees without a senior endoscopist in the room performed therapeutic procedures. The JAG guidelines[1] should specify explicitly what level of supervision is acceptable for trainees performing endoscopic procedures. Endoscopy units should audit their practice to ensure that such junior trainees are competent to carry out therapeutic procedures independently.

It is surprising that there was no response to this question where the senior endoscopist was a GP. It is our belief that a consultant should also supervise GPs undertaking endoscopies in hospitals.

In the opinion of the advisors, supervision was inappropriate in four cases for the experience of the trainee endoscopist. All of these patients had presented with haematemesis and/or melaena – and senior support was not requested.

Case Study

An elderly patient presented with melaena. The patient had a number of comorbidities, a haemoglobin less than 6 gm/dl, and was assessed as ASA 4. A senior specialist registrar year 3+ was unable to control the bleeding from two duodenal ulcers despite injection with adrenaline, 2 ml of 1 in 10,000 into each ulcer. No senior help was sought although a consultant was in the hospital. The patient died from continuing bleeding.

CONTINUED PROFESSIONAL DEVELOPMENT (CPD)

The educational importance of audit in CPD has been extolled by the Royal Colleges[15 16]. Regular review of patient management will improve the standard of care, and reduce morbidity and mortality. In particular, this is true where current practice can be compared with specific guidelines. Surgery is well versed in this area, but peer review audit of endoscopic practice is uncommon in the United Kingdom.

Using data from the individual patient questionnaires, no answer was given in 458 cases. Therefore of the 1,360 cases, 78% (1,063/1,360) of procedures were performed in hospitals that held endoscopy audit meetings which correlates well with the figure above. However only 26% (359/1,360) of cases had been reviewed at an audit meeting (Figure 8).

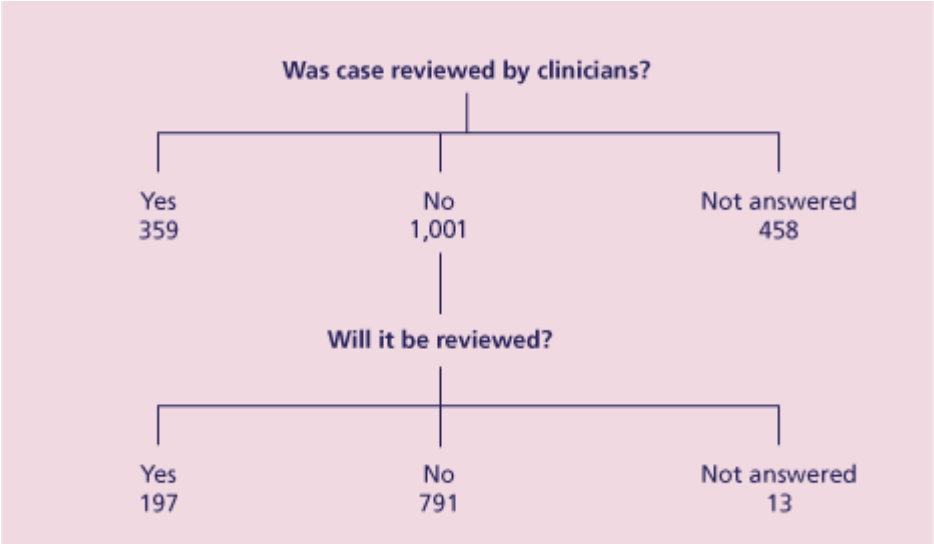

Figure 8. Morbidity and mortality audit

In 20% (197/1,001) of cases the person completing the questionnaire answered that the case would be reviewed at an audit meeting in the future. Overall a maximum of a third of all deaths following therapeutic endoscopy would have been subject to review.

Audit is important for personal continuing professional development and for the improvement of endoscopy services within a Trust. All endoscopy units should run regular audit meetings within their clinical governance activities. A review of all deaths following endoscopy should be part of the programme for such audit meetings.

Recommendations

There should be national guidelines for assuring continuing competency in endoscopy.

All endoscopy units should perform regular audit and all deaths during, or within 30 days of, therapeutic endoscopy should be reviewed.

All those responsible for the administration of sedation should have received formal training and assessment.

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8. SEDATION AND MONITORING

INTRODUCTION

Many diagnostic endoscopic procedures can be carried out without sedation using reassurance and oropharyngeal local anaesthesia. However, therapeutic endoscopy, particularly of the upper gastrointestinal tract, may be unpleasant and painful, and often requires adjunctive pain relief and sedation. In this chapter we examine the conduct of monitoring and sedation for therapeutic endoscopy.

Conscious sedation is *"A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation should carry a margin of safety wide enough to render loss of consciousness unlikely"*[1] . There are two recent key guidelines for sedation and monitoring. The British Society of Gastroenterology (BSG) guidelines 'Safety and sedation during endoscopic procedures'[2] and the Academy of Medical Royal Colleges, 'Implementing and ensuring safe sedation practice for healthcare procedures in adults'[1]. All endoscopists and their assistants using sedation and monitoring patients should be familiar with these and a copy of each should be available to those in the endoscopy suite.

SEDATION TECHNIQUES

Key points

In 33% of patients who recieved sedation, this was combined with oropharyngeal local anaesthesia.

14% of patients had sedation overdose.

1,579 cases were analysed after exclusion of patients who had a general anaesthetic (GA) or were already on intermittent positive pressure ventilation (IPPV) at the time of their endoscopy. A breakdown of the type of sedation by the category of procedure is presented in Table 19.

Table 19. Type of sedation by type of procedure (GA and IPPV excluded)						
	PEG	**ERCP**	**Upper GI**	**Lower GI**	Total	*(%)*
None	15	1	24	15	55	*(4)*
Local anaesthesia (LA)	39	1	62	0	102	*(7)*
Intravenous sedation	349	136	317	30	832	*(60)*
LA and intravenous sedation	198	46	168	0	412	*(29)*
Sub-total	**601**	**184**	**571**	**45**	**1,401**	
Not answered	67	28	81	2	178	*(11)*
Total	**668**	**212**	**652**	**47**	1,579	

4% (55/1,401) of patients received no sedation or analgesia and 7% (102/1,401) received local anaesthesia alone. Of those patients undergoing lower GI therapeutic endoscopy, 33% (15/45) had no sedation or local anaesthesia compared with 4% (24/571) of those undergoing an upper GI procedure. In a study of colonoscopy practice in three NHS regions, sedation was used in 95% of cases[3]. The lesser use of sedation in the present study may reflect the advanced age or poor physical status of the patients.

Sedation and analgesia

79% (1,244/1,579) of patients received some form of intravenous sedation. The drug or drug combinations for these 1,244 are presented in Table 20.

Table 20. Intravenous sedation used during the endoscopy		
Sedation and/or analgesia	Total	*(%)*
Intravenous opiod	31	*(2)*
Intravenous benzodiazepine sedation	927	*(75)*
Other intravenous sedation	6	*(<1)*
Benzodiazepine and opiod	247	*(20)*
Other intravenous sedation in combination with benzodiazepine and/or opiod	33	*(3)*
Total	1,244	

The most commonly used benzodiazepine was midazolam, which was used in 82% (1,019/1,244) of cases. The most commonly used opiod was pethidine, which was used in 16% (205/1,244) of cases. The others were propofol (4), ketamine (1) and not specified (37). These may have been cases where sedation was provided by an anaesthetist.

Of those given sedation, in 33% (412/1,244) of cases, the patient received both intravenous sedation and topical oropharyngeal local anaesthesia (Table 19). An audit of two regions in England into diagnostic and therapeutic upper gastrointesinal gastroscopy in 1995 showed that there was an association between combined sedation with oropharyngeal LA and the development of pneumonia after gastroscopy[4].

In that audit there was also regional variation in the use of combined sedation with oropharyngeal LA; it being used in 77% of patients in the North West vs. 41% in East Anglia. In this sample many patients were severely unwell or had swallowing difficulties and so the use of combined sedation with oropharyngeal LA for 33% of patients was thought to be too high. It suggests this is a practice guided by rote, with little consideration of individual circumstance.

Case Study

An elderly patient with a history of myocardial infarction and stroke was admitted following a further stroke. Swallowing difficulties and a GI bleed 12 days after admission prompted a gastroscopy and insertion of PEG. Combined sedation with oropharyngeal local anaesthesia was used during the procedure. Two days later the patient was severely unwell with aspiration pneumonia.

For a patient of this age and comorbidity with obtunded swallowing reflex the use of combined sedation with oropharyngeal LA was probably contraindicated.

Of those who received sedation or LA, 43% (575/1,346) of patients developed respiratory complications after their endoscopy. In many cases, the advisors thought that combined sedation with oropharyngeal LA might have contributed to the development of this problem. They reasoned that in a fit patient with a sensitive gag reflex, the use of combined sedation with oropharyngeal LA greatly facilitates upper GI endoscopy and minimises sedatives, especially if the procedure is uncomfortable or prolonged. However, for those patients who are more than normally sensitive to the effects of sedation, or who have difficulty swallowing, the combined effects of sedation with oropharyngeal LA may increase the risk of aspiration. Further studies are indicated to determine whether combined sedation with oropharyngeal LA is associated with an increased risk of pulmonary aspiration or other morbidity and, if so, which patients are most at risk.

Reversal of sedation was used in 14% (176/1,244) of cases. The use of reversal was almost universally to counteract unanticipated central nervous system depression (i.e. an overdose). There is a practice of routine reversal of sedation[5], however, in only two cases did the clinician say that he or she recognised the frailty of the patient and planned reversal of sedation. In an audit of all upper GI endoscopic procedures, the incidence of specific sedation reversal was 0.5-4.2%[4] . In the present study, the reason so many needed reversal of sedation appeared to be due to poor recognition by the endoscopists of how sensitive those with comorbidity can be to the effects of sedatives and consequently giving patients a ‘standard’ dose of sedation, most commonly IV midazolam 5mg, which was clearly too much for many.

Case Study

A patient with severe alcoholic liver disease, Childs-Pugh C, and bacterial peritonitis had undergone previous gastroscopies for bleeding. Bleeding continued and an endoscopist, who had received training in sedation, performed what was the patient's second gastroscopy in two days. Sedation comprised IV midazolam 5mg and further IV midazolam 2mg. Pulse oximetry was recorded as 87-91% during the whole of the procedure and flumazenil was used to reverse the effects of midazolam following it.

This dose of sedation, which would have been appropriate in a fit adult, was excessive in this patient. In sick patients, sedation should be given in very small doses with sufficient time to assess the effects between increments.

On case review advisors to NCEPOD provided an opinion on the likelihood that sedation was appropriate, considering the physical status of the patient. There was sufficient clinical information for the advisors to consider sedation inappropriate in 14% (218/1,579) of cases. The reasons given are presented in **Table 21.**

Table 21. Reasons why sedation was judged to be inappropriate (answers may be multiple)

Reason why sedation was inappropriate	Total *n = 185*
Excessive opiod	24
Excessive benzodiazepine	161
Insufficient sedation	1
Other*	28
Total	**214**
No reason stated	33

*These included LA & IV sedation (5), patient unfit for sedation procedure (1) and in 22 cases the reasons were not specified.

The advisors most often commented on excessive sedation in patients with upper GI bleeds, severe liver disease, obtunded consciousness (stroke or dementia) or acute chest infection. One advisor commented in the case of an elderly female, *"My old bug-bear! If she needs flumazenil and her sats are <90% on oxygen you have given too much sedation, even if it isn't very much!!"*

PATIENT MONITORING

Key points

In 27% of cases patient monitoring was deficient.

In 20% of cases ECG monitoring was indicated where it was not used.

In 14% of cases automatic blood pressure monitoring was indicated where it was not used.

Table 22. Critical events during the procedure (answers may be multiple)

Critical event	Total *n = 1,688*
Cardiac arrest	8
Respiratory arrest	5
Hypoxaemia (SpO_2< 90%)	68
Pulmonary aspiration	1
Hypotension (less than or equal to 100mm Hg systolic)	68
Tachycardia (greater than or equal to 100 beats/minute)	86
Local haemorrhage	41
Viscus perforation	5
Other	24
Total	**306**
None	1,493
Not answered	130

93% (1,688/1,818) responded to the question relating to critical events. From the review of cases it is likely that these were under-reported (Table 22) or undiagnosed, possibly reflecting a deficiency in monitoring. Nevertheless, from the questionnaires, 4% (68/1,688) of patients suffered from hypoxaemia during the procedure.

The type of monitoring used should be determined by the procedure and physical status of the patient. Respondents were asked to state the monitoring used during the procedure. This question was answered in 94% (1,701/1,818) of cases. There should always be a record of monitoring used during endoscopy, particularly when sedation is used. A summary of monitoring is presented in Table 23.

Table 23. Monitoring during the procedure (answers may be multiple)

Monitors used	Total *n = 1,701*
Pulse oximetry	1,668
ECG	384
Automatic BP	729
Total	**2,781**
Not answered	117

NCEPOD advisors were asked to provide an opinion on deficiencies in monitoring in cases where there was sufficient information for them to assess. Monitoring of the patient during the procedure was considered deficient in 27% (377/1,398) of cases.

Pulse oximetry

The question on patient monitors used during the procedure was completed in 1,701 cases. Monitoring by pulse oximetry was performed during endoscopy in 98% (1,668/1,701) of patients. On review, the advisors thought monitoring pulse oximetry was specifically indicated in a further 27 cases. The BSG guidelines on the provision of endoscopy services recommend that pulse oximetry should be available in all rooms[6]. Pulse oximetry is a simple, non-invasive monitor and evidence from this report suggests that it is widely available for endoscopy patients; the chapter entitled organisational issues reports that 99% of hospitals had access to pulse oximetry in every room in their endoscopy unit. It was used with relatively few exceptions, but it should be used for all therapeutic and diagnostic endoscopies.

Electrocardiography (ECG)

In this sample, 23% (384/1,701) of patients received continuous ECG monitoring during the procedure. This was considered low in a sample where 38% (639/1,701) of patients had known cardiac disease and 86% (1,458/1,701) were ASA 3 or poorer. On review, the advisors thought ECG monitoring was indicated in a further 345 cases where it was not used.

Case Study

A patient was admitted with an acute inferior myocardial infarction. Four weeks later the patient suffered a large haematemesis, became hypotensive and their haemoglobin decreased by 2.5gm/dl. A CVP line was inserted to monitor resuscitation. The next day an endoscopy was performed and adrenaline was injected into two large gastric ulcers. Pulse oximetry and automatic blood pressure were monitored, but ECG was not.

Why was ECG monitoring not used?

There is evidence that despite endoscopy being, in general, a minor low risk procedure it can affect cardiac function. In a study of patients with stable coronary heart disease undergoing gastroscopy 42% developed Holter monitoring, evidence of silent myocardial ischaemia[7] and in another study of patients with heart disease aged 80 years or older, upper GI endoscopy induced an increased number of ventricular ectopics[8]. ECG monitoring enables the detection of life threatening arrhythmia and ST segment changes and the

person responsible for monitoring the patient must be sufficiently trained to detect such abnormalities. The factors that should be considered when deciding on ECG monitoring are cardiovascular disease, ASA status and the potential for haemodynamic instability. The guidelines of the Academy of Medical Royal Colleges[1] state that monitoring of blood pressure and ECG may not be necessary in young healthy patients, but is essential in older patients, especially if there are any cardiovascular problems. However, an ECG monitor should be available in all endoscopy rooms and any patient with a history of cardiac problems or haemorrhage must receive ECG monitoring.

Automatic blood pressure monitoring

Automatic blood pressure monitoring was used in 43% (729/1,701) of patients during the procedure. On review, the advisors thought automatic blood pressure monitoring was indicated in a further 231 cases where it was not used. Although it is not an invasive monitor, many patients find automatic blood pressure monitoring unpleasant, particularly when it is first applied when the inflation pressure is high.

Case Study

A patient was admitted with pain from bilateral loosened hip prostheses. Their medical history included atrial fibrillation, congestive cardiac failure and a NSAID induced GI bleed. Nevertheless diclofenac was prescribed. Six days later the patient became acutely short of breath due to a chest infection and left ventricular failure. The patient then suffered an upper GI bleed, following which they developed hypotension, tachycardia and acute renal failure. When the patient had their gastroscopy they were described as "very poorly" and were treated with inotropes. No ECG or blood pressure monitoring was used in the endoscopy suite, either before, during, or after the procedure.

All endoscopy rooms should have an automatic blood pressure machine. Automatic blood pressure monitoring should be used in any patient whose condition including comorbidities makes hypotension likely. This includes haemodynamic instability and a recent severe GI bleed.

Supplemental oxygen

Oxygen should be given during all endoscopies[2] as it dramatically reduces the incidence of hypoxaemia[9]. Table 24 gives details of oxygen administered in the sample.

Table 24. Oxygen administered during the procedure		
	Total	*(%)*
Administered	1,584	*(95)*
Not administered	88	*(5)*
Sub-total	**1,672**	
Not answered	146	*(8)*
Total	**1,818**	

Hypoxaemia can occur during upper GI endoscopy with or without sedation, particularly in those with pre-existing respiratory disease, hepatic cirrhosis, obesity, advanced age or undergoing an emergency procedure[9 10 11 12]. It can also occur during colonoscopy with sedation[13]. Moreover hypoxaemia is common. For example, in a study of non-sedated patients undergoing upper GI endoscopy, 24% had a SpO_2 of 90% to 94% and a further 6.5% had a SpO_2< 90%[10]. When sedation is used, the incidence of hypoxaemia is higher. In a study of patients undergoing sedated upper GI endoscopy, SpO_2<94% was detected in 47%[9] and in a study of patients undergoing sedated colonoscopy, hypoxaemia was detected in 45% (8/18)[13]. However, even with supplemental oxygen, patients can become hypoxic and therefore pulse oximetry should still be used.

MONITORING PERSONNEL

Key point

In 3% of cases the endoscopist alone was responsible for monitoring the patient during the endoscopy.

94% (1,707/1,818) told us who monitored the patient. Someone other than a doctor was responsible for monitoring most patients, and this was a nurse in 84% (1,439/1,707) of cases and an operating department assistant in ten cases. It is expected that a non-medical practitioner can effectively monitor the patient during endoscopy provided they have been sufficiently trained. This means at least they will have received formal training and undergo regular updates in resuscitation and revalidation of knowledge[1].

In 3% (58/1,707) of cases the endoscopist was the only person responsible for monitoring the patient. It is unacceptable that the person performing an endoscopy should also be responsible for monitoring the condition of the patient.

Guidelines of the BSG state that the endoscopist is responsible for the wellbeing and clinical observation of the patient *'in conjunction with another individual'* (our own emphasis)[2 14], and the Academy of the Royal Colleges[1] state that one member of the care team must have a defined responsibility for patient observation and record keeping. This individual should be dedicated to monitoring the patient and have no other responsibilities

during the endoscopy. The name, specialty and grade of the person responsible for monitoring the patient should be clearly recorded on the endoscopy report.

RECORD KEEPING

Key point

In 49% of cases no contemporaneous monitoring record was available in the notes.

Table 25. Monitoring chart for the procedure in the patient's notes

Monitoring chart	Total	*(%)*
Yes	807	*(51)*
No	761	*(49)*
Sub-total	**1,568**	
Not answered	250	*(14)*
Total	**1,818**	

A monitoring chart was not present in the patient's notes in 49% of cases (Table 25). This was not acceptable particularly considering the age and physical status of this sample. For 14% of cases the question was not answered, but surely, if a chart is used it should be filed in the casenotes. Respondents were asked to forward the monitoring chart for the procedure to NCEPOD. However, it was submitted for only 62% (501/807) of cases where one was used. Of the monitoring charts that were submitted, many were deficient. Some contained a record of oxygen saturation, heart rate and blood pressure before and after the procedure, but few contained contemporaneous recordings during the procedure. The UK Academy of Medical Royal Colleges[1] recommends making a written record, but there are no published recommendations on the frequency of recording vital signs during sedation. For many therapeutic procedures, particularly if the procedure is long and/or complicated and some of the procedures reported in this study took several hours, or the patient is sick, a contemporaneous record of vital signs on a suitable monitoring chart should be kept. The question of frequency should be addressed.

POST-ENDOSCOPY RECOVERY

Key point

8% of patients who had their endoscopy in a dedicated endoscopy room went immediately to a ward without apparent recovery facilities.

Where answered, 76% (1,349/1,786) of patients had their endoscopy in a dedicated endoscopy room. Immediate post-procedural locations are shown in Table 26.

Table 26. Post-procedure location for patients who underwent endoscopy in a dedicated endoscopy unit		
Location	Total	*(%)*
Dedicated recovery area within the endoscopy unit	1,160	*(88)*
General or other ward	105	*(8)*
ICU/HDU	33	*(3)*
Dedicated recovery area within an operating theatre's department	18	*(1)*
Died in the endoscopy suite	5	*(<1)*
Transferred to surgery	1	*(<1)*
Sub-total	**1,322**	
Not answered	27	*(2)*
Total	**1,349**	

The practice of returning a patient directly to a general ward after endoscopy may be unsafe.

Case Study

A patient with alcoholic liver disease (Childs-Pugh score B), non-insulin dependent diabetes and poor LV function was admitted on a Friday following a haematemesis. Two days later (Sunday morning) they underwent a gastroscopy and injection of oesophageal varices under sedation in a dedicated endoscopy room. Following the procedure the patient was returned directly to the general ward. That evening the patient went into respiratory failure. Chest x-ray was consistent with left and right lower lobe consolidation, and the patient died at 01.30 the following morning.

The organisational questionnaire completed for this hospital indicated that there was a dedicated recovery unit and the advisors' view was that had this been used it may have assisted the patient's progress.

It is not acceptable that 8% (105/1,349) of patients who had their endoscopy in a dedicated endoscopy unit went from there directly to a ward, especially those who had received sedation. It represents a failure of organisation for the patient's post-procedure care that should be addressed by the endoscopist and their hospital. Following endoscopy, patients should be nursed in an area that has similar equipment and staff to that recommended for a recovery facility. This applies regardless of the timing of the procedure.

A ward providing level 1 care is an area that is unlikely to have dedicated recovery staff or appropriate facilities. The BSG [6] stress the importance of a fully-equipped recovery area in proximity to the endoscopy room, which should include pulse oximetry, piped oxygen and suction, electronic blood pressure cuffs, facilities for ECG monitoring and tipping trolleys, as well as full resuscitation equipment. (For the survey of endoscopy suite facilities see the earlier chapter entitled 'Organisational issues').

Recommendations

Sedation and monitoring practices within endoscopy units should be audited and reviewed.

There should be national guidelines on the frequency and method of the recording of vital signs during the endoscopy.

Clear protocols for the administration of sedation should be available and implemented.

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9. PERCUTANEOUS ENDOSCOPIC GASTROSTOMY

INTRODUCTION

Percutaneous endoscopic gastrostomy (PEG) for enteral feeding has been used since 1980[1] and it is indicated in those patients where enteral feeding is likely to be needed for more than four to six weeks[2] ; the indications for its use are shown in Table 27. The procedure of inserting a PEG is straightforward for most patients and it has advantages over nasogastric feeding in that it is more comfortable, less unsightly and less prone to becoming displaced. However, it is invasive and may result in complications, and therefore the appropriateness of its use needs careful consideration in every case.

Table 27. Indications for the use of PEG feeding[2]

Indication	Example
Neurological disorders of swallowing	Cerebrovascular accident (CVA), multiple sclerosis, motor neurone disease, Parkinson's disease, cerebral palsy
Cognitive impairment and depressed consciousness	Head injury
Mechanical obstruction to swallowing	Oropharyngeal or oesophageal cancer, radiation enteropathy
Long term partial failure of intestinal function requiring supplemental intake	Short bowel, fistulae, cystic fibrosis

PATIENT PROFILE

Key point

One in five PEG procedures were futile or not indicated.

In this sample 40% (719/1,818) of patients underwent a PEG procedure for enteral feeding, of which 55% (392/719) of patients were male. The age profile of the sample is presented in Figure 9 and shows that 588/719 (82%) patients were aged 70 years or older.

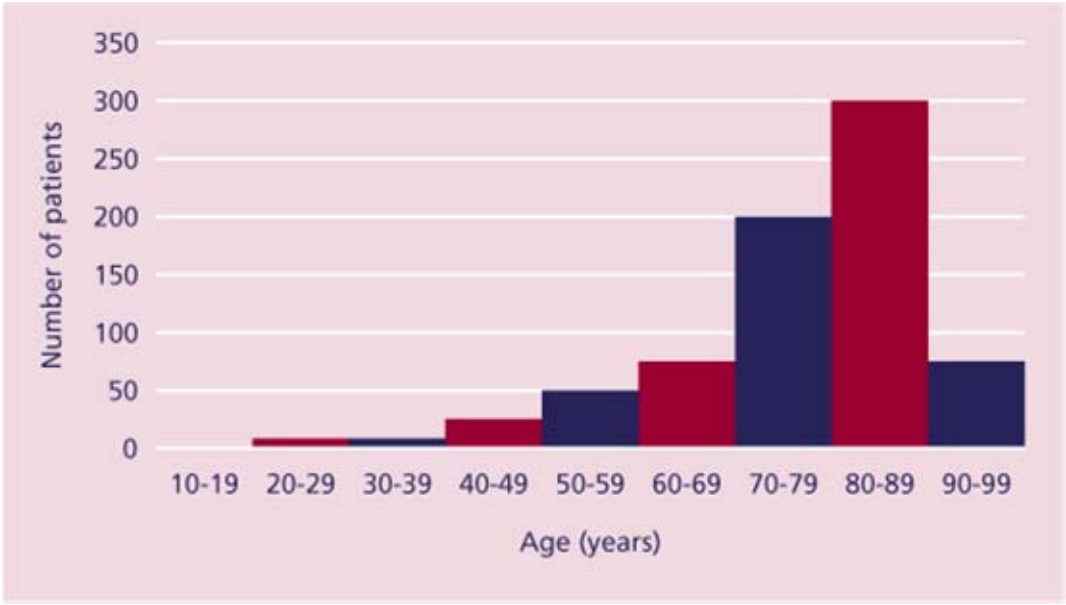

Figure 9. Age profile of patient undergoing PEG procedure

There is little evidence that PEG insertion in older persons can increase survival per se. A meta-analysis by Mitchell and co-workers[3] who used a MEDLINE search of studies between 1980-1998 inclusive found that 19% died within one month, a further 11% within two months and a further 14% died within six months. Only 38% survived for one year. An earlier study of American hospitalised Medicare beneficiaries aged 65 years or older discharged in 1991 found an overall 30-day mortality rate of 24%[4]. None of the five cohort studies reviewed, that compared survival in nursing homes with or without feeding tubes, demonstrated a benefit. Another of the studies reviewed showed increased survival in those patients with amyotrophic lateral sclerosis. With such depressing mortality figures the indications for insertion of PEG in older patients should be strongly influenced by a consideration of its benefit to quality of life as much as for survival. The patient needs to understand this and take part in the decision. It may be appropriate for a study to be undertaken which would further examine who would benefit from this procedure.

Figure 10 shows that 84% (607/719) of patients were ASA 3 or poorer.

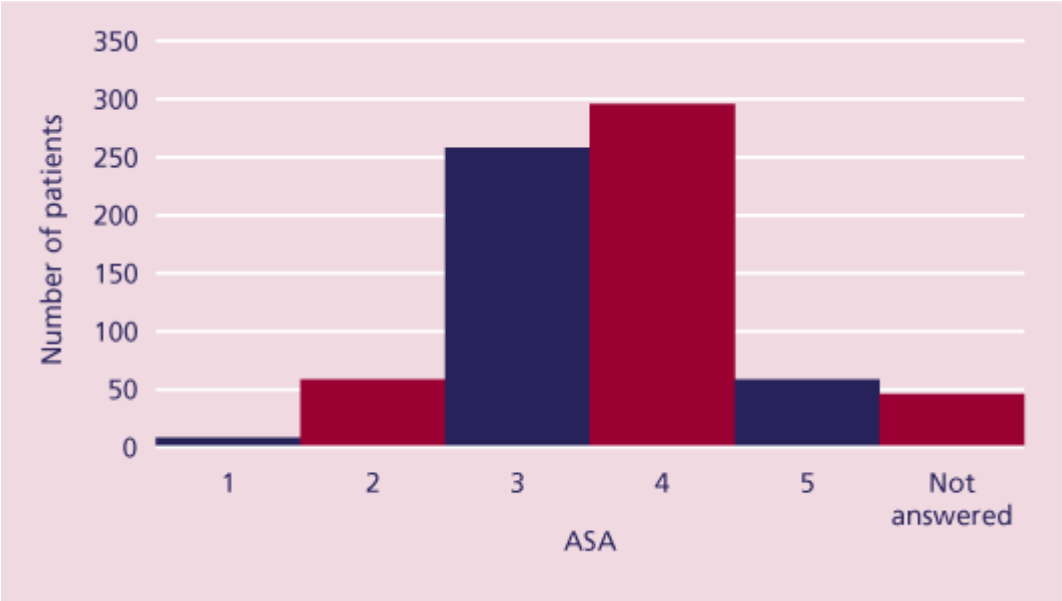

Figure 10. Physical status of patients undergoing PEG procedure

Table 28 lists the medical disorders of the patients.

Table 28. Co-existing medical disorders in patients undergoing PEG procedures (answers may be multiple)	
System involved	**Total *n = 710***
Neurological	695
Respiratory	402
Cardiac	338
Renal	57
Total	**1,492**
Not answered	9

Table 29. Urgency of PEG procedure		
Urgency	Total	*(%)*
Elective/scheduled	641	*(95)*
Urgent	34	*(5)*
Emergency	2	*(<1)*
Sub-total	**677**	
Not answered	42	
Total	**719**	

Predictably, most PEGs were inserted as an elective or scheduled procedure (Table 29). The urgent procedures were likely to be patients with a mechanical obstruction to swallowing where the passing of a nasogastric tube was impractical. However, the advisors were of the opinion that a PEG insertion should never be an urgent procedure and were concerned about the role of PEG feeding in those receiving palliative care. One of the emergencies was for mechanical obstruction. The other case which may have been poorly categorised, received a PEG three weeks after admission.

Table 30. Days between PEG procedure and death

Days between procedure and death	Total	*(%)*
0	14	*(2)*
1-3	126	*(18)*
4-7	156	*(23)*
8-14	183	*(26)*
15-21	112	*(16)*
22-30	101	*(15)*
Sub-total	**692**	
Procedure date unknown	27	
Total	**719**	

There was an alarming association between PEG insertion and early death (Table 30). Out of 692 cases 2% (14/692) of patients died on the day of the procedure, of whom three died in the recovery room, and a further 18% (126/692) died between the first and third post endoscopy day. A total of 43% (296/692) of deaths occurred within one week and a further 26% (183/692) in the second week.

On review of these cases NCEPOD advisors often expressed concern about the timing of the procedure indicating that these procedures were futile or precipitated death. In one case where a patient was over 90 years-of-age an advisor commented, *"The PEG placement was technically OK - but the timing was wrong. The patient was very ill, dehydrated and had pneumonia. They should not have had a PEG at this time and died six days later. There is no information about the last few days of life."*

Early death after PEG procedure is an area where things are going badly wrong. Endoscopists who perform the procedures may not be aware of the patient's outcome following transfer back to the referring clinician.

Clinicians were asked to state the expectation of death (Figure 11). In 22 cases no answer was given and in 6% (42/697) death was expected.

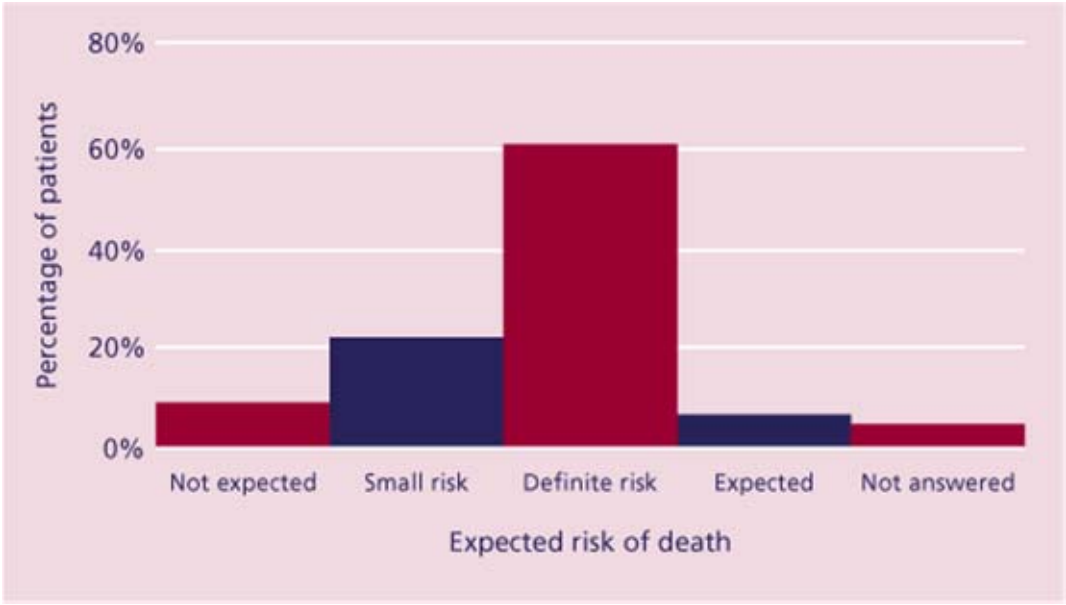

Figure 11. Expectation of death following PEG procedure

Many of these had malignant disease such as oesophageal cancer, and the PEG was to palliate hunger. It was surprising that in 63% (440/697) of cases the patient was classified as having a definite risk of death. On review of the cases NCEPOD advisors were asked to give an opinion on whether the procedure was appropriate for that patient. One in five (19%, 135/719) of PEG procedures were thought to be either futile or no procedure was indicated. For these cases, the quality of information provided to the patient and their relatives must be questioned.

PREOPERATIVE ASSESSMENT AND PREPARATION

Key points

40% of PEG patients had a co-existing diagnosis of acute chest infection.

59% of PEG patients had suffered a stroke or neurological trauma before the insertion of their PEG.

42% of patients had no antibiotic prophylaxis for their PEG insertion.

Pre-existing medical condition

The co-existing conditions leading to the decision for the PEG procedure are presented in Table 31.

Table 31. Indications for PEG procedure (answers may be multiple)	
Indication	**Total** ***n = 706***
Nutritional failure due to non-malignant disease	284
Motor neurone/other degenerative disease	52
Neurological disease – acute (stroke, trauma)	418
Neurological disease – chronic (degenerative neurological disease)	94
Dementia	128
Malignancy – oropharyngeal cancer	27
Malignancy – oesophageal cancer	11
Malignancy – gastric cancer	2
Malignancy – other	40
Total	**1,056**
Not answered	13

NCEPOD did not ask specifically for the primary indication of the procedure. However, the commonest indication for PEG insertion was for feeding problems following an acute neurological disease, mostly a stroke. For a general discussion on patient selection for GI endoscopy see the earlier chapter discussing patient assessment.

Aspiration pneumonia

At the time of PEG insertion, 40% (281/710) of cases, where information was provided, had a co-existing diagnosis of acute chest infection. Many of these had swallowing difficulties, due to comorbidities such as motor neurone disease or following a stroke, and had aspiration pneumonia. There appeared to be a misconception that PEG feeding would prevent aspiration pneumonia as clinicians had indicated on some questionnaires that this was the reason for PEG insertion when in fact aspiration pneumonia is the most common cause of death in these patients. PEG feeding does not prevent aspiration and it offers no protection from aspiration of colonised oral secretions as scintigraphic studies have shown evidence of aspiration of gastric contents in gastrostomy fed patients[5 6].

Dementia

18% (128/706) of patients had a diagnosis of dementia and in many of these the PEG was inserted because patients were feeding poorly. All relevant studies have shown that PEG feeding for those with dementia does not improve outcome[6 7 8 9] and an increasing number of clinicians are of the opinion that dementia is not an indication for PEG feeding[6 8 10]. NCEPOD advisors in their discussions were clear that for those patients with severe dementia and significant comorbidity such as those confined to bed with pressure sores and limb contractures, PEG feeding was unlikely to improve their quality of life and may not be a preferred option. They found the ethical decision on withholding feeding more difficult for those patients with dementia and poor nutrition but no other comorbidity.

The ethical considerations of artificial nutrition and hydration are discussed in the General Medical Council's (GMC) booklet on withholding and withdrawing life-prolonging treatments. In summary, the GMC advises using up-to-date professional advice on the particular clinical consideration and assessing quality of life issues. In addition, it advises wide consultation by seeking other expert opinion and involving the health care team and those close to the patient in decision making[11]. Little evidence was found in the casenotes regarding this type of discussion which either reflects poor record keeping or lack of consultation.

Acute neurological disorder

418/706 (59%) of patients were admitted following a stroke or acute neurological trauma. Patients with a stroke or neurological trauma are most commonly admitted to hospital as an emergency and have PEG feeding established later if required. There is evidence that PEG feeding, compared with nasogastric feeding after a stroke may result in improved nutritional status[12 13]. The time between admission and PEG procedure for those with an acute neurological disorder was examined. 92% (384/418) of patients had their procedure within 60 days of admission and the duration between admission and procedure is shown in Figure 12.

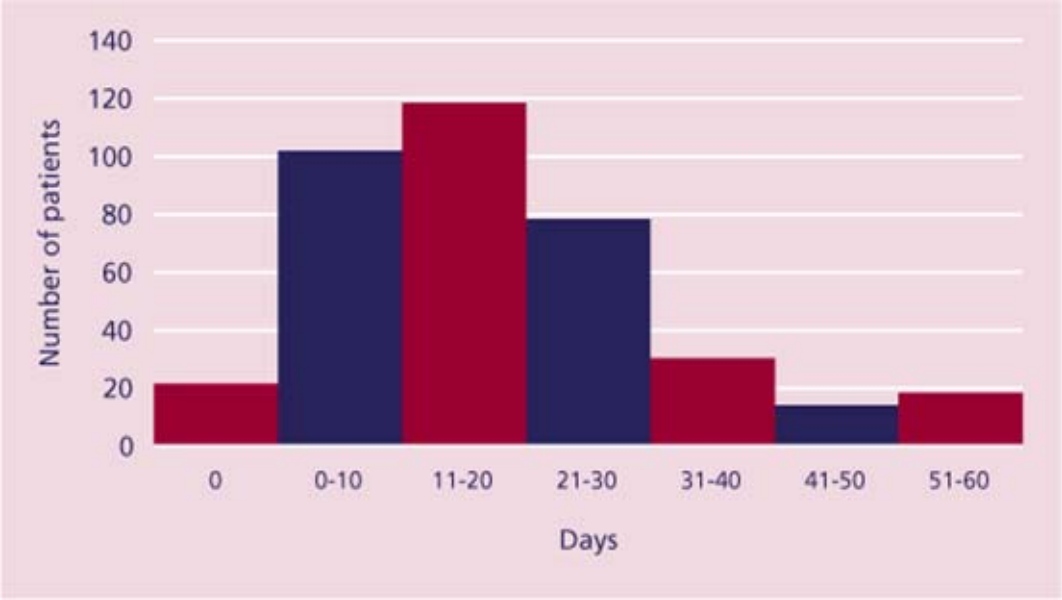

Figure 12. Days between admission and PEG procedure for those with acute neurological disorder

There are few data on the best timing for PEG feeding after a stroke. Historically, it was often deferred for four to six weeks to assess any improvement in dysphagia. However, there is some evidence from a 30 patient study that it should be considered earlier, at 14 days[13] and further trials are ongoing.

An advisor commented about a patient in their late sixties, *"Died two days after PEG insertion from 'inhalation pneumonia', but was admitted nine days before with rigors and a chest infection. It would appear that the PEG was placed too soon after an acute admission with pneumonia".*

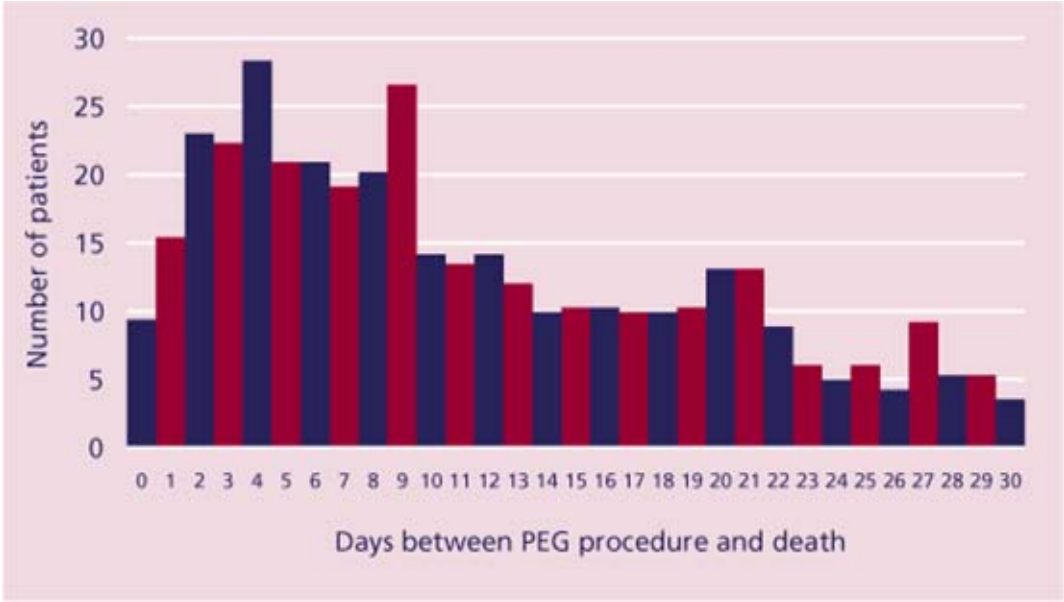

Figure 13. Days between PEG procedure and death for those with acute neurological disorder

Despite PEG feeding for acute neurological disorder being an elective procedure, nine patients died on the day of operation (Figure 13) and 38% (159/418) died on or before postoperative day 7. Why were there so many early deaths? Patient selection must be implicated, but in their discussions advisors were concerned that PEGs may sometimes be inserted to facilitate discharge to community nursing care and, medical considerations that should affect timing may be overlooked, in order to achieve this.

Antibiotic prophylaxis

The British Society of Gastroenterologists (BSG) in their guidelines on antibiotic prophylaxis for GI endoscopy recommends antibiotic prophylaxis for all PEG insertions[14]. There is evidence that antibiotics can reduce peristomal wound infection[15 16], particularly in those with underlying malignancy[17].

Table 32. Antibiotic prophylaxis administered for PEG procedure

	Total	*(%)*
Yes	305	*(58)*
No	220	*(42)*
Sub-total	**525**	
Not answered	194	
Total	**719**	

The data shown in Table 32 do not take account of patients who may have been receiving antibiotics for other reasons. Nevertheless, it would appear that antibiotic prophylaxis is not used universally and this requires urgent review.

OPERATIVE EVENTS

Key points

In 6% of PEG procedures no oxygen was administered.

30% of patients had combined topical anaesthesia and sedation.

9% of patients required reversal of sedation following their PEG insertion.

Table 33. Critical incidents during PEG procedures (answers may be multiple)

Critical incident	Total *n = 660*
Cardiac arrest	1
Hypoxaemia (SpO_2 less than or equal to 90%)	21
Hypotension (systolic less than or equal to 100mm Hg)	2
Tachycardia (greater than or equal to 100 beats/minute)	8
Local haemorrhage	1
Viscus perforation	1
Other	5
Total	**39**
None	622
Not answered	59

Hypoxaemia, the most frequently reported critical event (Table 33), occurred in 3% (21/660) of cases where information was received. However, it is thought that critical events were under-reported as the review of casenotes by advisors revealed several instances of hypoxaemia and perforated viscus which were not acknowledged in the associated questionnaires.

Sedation and monitoring

For further comments on sedation and monitoring during GI endoscopy please refer to the earlier chapter entitled ‘Sedation and Monitoring’.

Table 34. Oxygen administered during PEG procedure		
Oxygen administered	Total	*(%)*
Yes	606	*(94)*
No	41	*(6)*
Sub-total	**647**	
Not answered	72	
Total	**719**	

Oxygen should be given to all patients undergoing a PEG procedure, yet at least 6% (41/647) of patients did not receive it (Table 34).

Table 35. Sedation and analgesia during PEG procedure (answers may be multiple)	
Sedation and analgesia	**Total** ***n = 679***
None	16
Local anaesthesia	245
Intravenous benzodiazepine sedation	542
Intravenous opiod sedation	47
Other intravenous sedation	15
Total	**865**
Not answered	40

Table 35 includes 27 patients who had a GA or were in ICU receiving IPPV. Where local analgesia was used, 6% (42/679) had the procedure done under topical local anaesthesia to the oropharynx alone and 30% (203/679) had topical anaesthesia to the oropharynx combined with some form of sedation.

NCEPOD advisors repeatedly expressed concerns that the use of sedation and local anaesthetic spray to the oropharynx may be implicated in pulmonary aspiration and postoperative respiratory complications. This concern was expressed particularly with regard to patients with dysphagia and a history of aspiration, in whom the supine position of the patient during the PEG procedure might facilitate further contamination to the respiratory tree.

The use of flumazenil and naloxone reversal during PEG procedure is presented in Table 36. The high number of questionnaires not answered may reflect missing data but it is more likely that the patient did not need their sedation reversed. The questionnaire should have made this question clearer.

Table 36. Flumazenil or naloxone administered during PEG procedure		
	Total	*(%)*
Flumazenil	65	*(96)*
Naloxone and Flumazenil	2	*(3)*
Naloxone	1	*(1)*
Sub-total	**68**	
Not answered	651	
Total	**719**	

Reversal of sedation was required in 9% (68/719) of patients. This might reflect that some endoscopists have little awareness of the sensitivity that those with neurological disease have to sedative drugs. Best practice guidelines on sedation for PEG procedure may be helpful.

POSTOPERATIVE OUTCOME

The systems implicated in the cause of death are presented in Table 37.

Table 37. Systems implicated in death following PEG procedures (answers may be multiple)	
Systems implicated in death	**Total** ***n = 670***
Cardiovascular	173
Respiratory	508
Renal	37
Hepatic	9
CNS	35
Total	**762**
Not answered	49

76% (508/670) of patients suffered from respiratory complications after their PEG procedure. It is known that over the long-term, aspiration pneumonia is the most common cause of death for gastrostomy tube-fed patients[5]. However, that patients should die of respiratory complications so early after PEG placement is of concern. Possible reasons for this are patient selection and the timing of the procedure. During the procedure, the supine position of the patient with swallowing problems, perhaps particularly when combined with topical LA and sedation is used, may contribute to aspiration complications. Postoperatively, the position of the patient during and after feeds and the timing and volumes of feed may be contributory factors.

Recommendations

The decision to use a PEG feeding tube requires an in-depth assessment of the potential benefits to the individual. All patients in whom PEG feeding is proposed should be reviewed by a multidisciplinary team.

There is a need for more comprehensive national guidelines for the use of PEG feeding, including issues of patient selection.

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10. ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an exacting and challenging endoscopic technique and in this sample 13% (237/1,818) of patients underwent ERCP. ERCP has a reported complication rate of between 10 and 14%, with a death rate of 0.1 to 1%[1 2]. Complications are directly related to both patient selection and the experience of the operator[3 4 5]. It is a serious concern that trainees accredited in gastroenterology who are not always competent in ERCP and related techniques have reported their intention to perform this procedure without supervision or further training[6 7]. With the exception of the Joint Advisory Group (JAG) guidelines for training[8], there are currently no British Society of Gastroenterology (BSG) guidelines specifically relating to ERCP, but this is the focus of an in-depth audit by the BSG that commenced in March 2004.

PATIENT PROFILE

Key point

77% of patients undergoing an ERCP had an ASA status of 3 or poorer.

Of all patients having an ERCP 82% (194/237) were aged 70 years or older (Figure 14) and 49% were male.

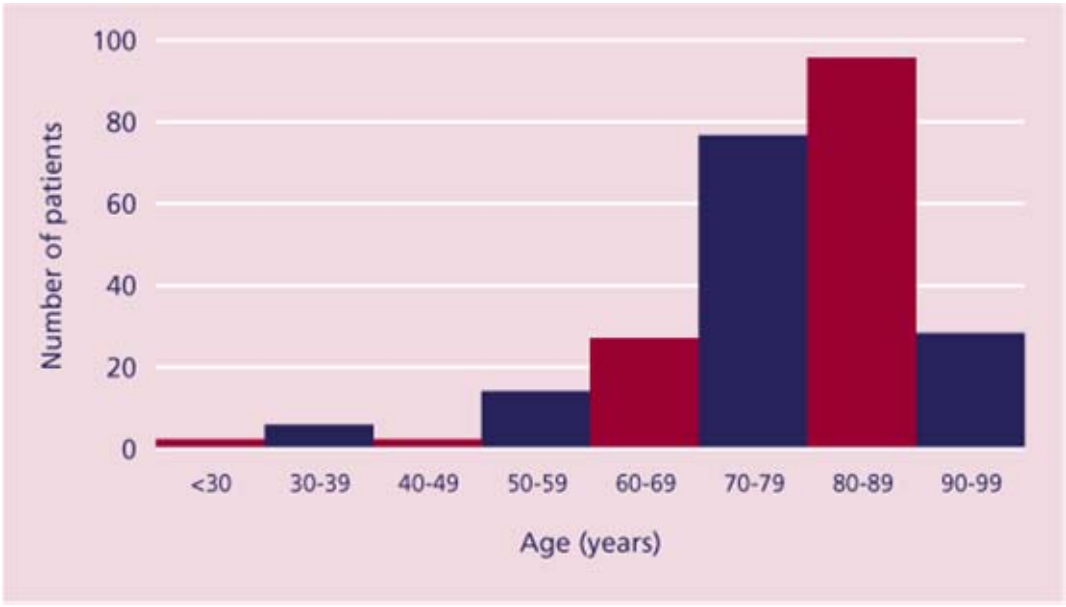

Figure 14. Age profile of patients undergoing ERCP

Table 38. ASA Status		
ASA Status	Total	*(%)*
1	10	*(5)*
2	41	*(18)*
3	96	*(43)*
4	61	*(27)*
5	16	*(7)*
Sub-total	**224**	
Not answered	13	*(6)*
Total	**237**	

Of all patients having an ERCP 77% (173/224) were graded ASA3 or poorer (Table 38). Interestingly 16 were graded 5, but no specific details were available to the advisors to enable them to assess whether a therapeutic ERCP was appropriate.

Considering the data in Table 38, it is not surprising that patients had the co-morbid conditions as listed in Table 39.

Table 39. Comorbidities for patients undergoing ERCP (answers may be multiple)	
System	**Total** ***n = 227***
Respiratory	48
Cardiac	90
Neurological	42
Hepatic	114
Renal	42
Total	**336**
None	27
Not answered	10

From the data available 65% (153/234) of ERCPs were 'expected' procedures (Table 40). The advisors thought that approximately one third of patients having an urgent/emergency ERCP was appropriate, and that in their experience the commonest causes were biliary sepsis especially from an obstructed common bile duct, bile leaks e.g. post laparoscopic cholecystectomy and gall stone related pancreatitis.

Table 40. Urgency of procedure for ERCP		
Urgency of procedure	Total	*(%)*
Elective/scheduled	153	*(65)*
Urgent	74	*(32)*
Emergency	7	*(3)*
Sub-total	**234**	
Not answered	3	*(1)*
Total	**237**	

In 69% (155/224) of cases, death within 30 days of the procedure was thought to be a definite risk or expected (Table 41). This reflects that in these patients ERCP was often palliative where the patient had a malignant disease. Overall the patient profile indicates that mostly these were sick patients of advanced age. Of interest is the advisors view that 68% (162/237) of therapeutic ERCPs were futile, with 90% (146/162) of these patients having an ASA status of 3 or more. The advisors were concerned that patients with hepatic metastases and no biliary obstruction were having therapeutic ERCPs.

Table 41. Anticipated risk of death for ERCP

Anticipated Risk of Death	Total	*(%)*
Not expected	20	*(9)*
Small but significant	49	*(22)*
Definite risk	129	*(58)*
Expected	26	*(12)*
Sub-total	**224**	
Not answered	13	*(6)*
Total	**237**	

THE PROCEDURE

Key point

Only 87% of patients had prophylactic antibiotics for their ERCP.

Of the 237 procedures, almost all involved the biliary tree (Table 42). These comprised of two major groups, sphincterotomy (88) and stenting (216), of which 50 were preceded by a sphincterotomy.

Table 42. Type of procedure (answers may be multiple)

	Total ***n = 237***
Sphincterotomy and removal of calculus	34
Sphincterotomy and insertion of stent	50
Sphincterotomy of accessory ampulla	4
Insertion of stents into both hepatic ducts	8
Insertion of stent into bile ducts	123
Renewal of stent in bile duct	19
Removal of stent from bile duct	15
Dilation of bile duct	8
Insertion of stent into pancreatic duct	1
Removal of calculus from pancreatic duct	1
Total	**263**

87% (195/224) of patients having a therapeutic ERCP received prophylactic antibiotics (Table 43).

Table 43. Antibiotic prophylaxis for ERCP		
Antibiotic prophylaxis	Total	*(%)*
Yes	195	*(87)*
No	29	*(13)*
Sub-total	**224**	
Not answered	13	*(6)*
Total	**237**	

6% of patients undergoing ERCP without duct occlusion and 10% of those with duct occlusion are likely to develop bacteraemia[9]. In the BSG guidelines on the use of antibiotics[9], the BSG recommends antibiotic prophylaxis for all patients undergoing ERCP with evidence of biliary sepsis, pancreatic pseudo-cyst or previous cholangitis as well as patients who are either at risk of infective endocarditis or are neutropenic. Antibiotic prophylaxis should more closely approach 100% in this high-risk group. Although there may be local protocols regarding antibiotic prophylaxis, it is the responsibility of the endoscopist to ensure the patient has received appropriate antibiotics before the procedure.

Table 44. Duration of ERCP procedures		
Duration of procedure (minutes)	Total	*(%)*
0-10	1	*(<1)*
11-20	22	*(18)*
21-30	44	*(36)*
31-40	18	*(15)*
41-50	16	*(13)*
51-60	12	*(10)*
61-70	4	*(3)*
71-80	1	*(<1)*
81-90	2	*(2)*
91-100	2	*(2)*
>100	1	*(<1)*
Sub-total	**123**	
Not answered	114	*(48)*
Total	**237**	

One could anticipate that a therapeutic ERCP would take in the region of 45 minutes. It is disappointing that for 48% (114/237) of cases the respondents were not able to provide times for the procedures; they should be available (Table 44). When times were provided 55% of procedures took under 30 minutes, 38% between 30 and 60 minutes and only 8% lasted for more than one hour. The procedure that lasted more than 100 minutes in fact lasted six hours!

THE ENDOSCOPIST

Key point

A consultant was the senior endoscopist for 97% of ERCPs.

From the data available it could be seen that a consultant was the senior endoscopist for 97% (226/233) of ERCPs performed (Table 45).

Table 45. Specialty and grade of endoscopist for ERCP

Specialty	Grade	Total	*(%)*
Physician	Consultant	154	*(66)*
	Associate specialist	1	*(<1)*
	Staff grade	2	*(<1)*
	SpR of three years or more	1	*(<1)*
Surgeon	Consultant	57	*(24)*
	Associate specialist	1	*(<1)*
	SpR - post CCT	1	(<1)
	Not answered	1	*(<1)*
Radiologist	Consultant	15	*(6)*
Sub-total		**233**	
Not answered		4	*(2)*
Total		**237**	

Where the data were available, in 11% (23/202) of cases the senior endoscopist performed less than 50 ERCPs a year. The exacting nature of this procedure, with its high complication rate, suggests that when an individual or unit is performing few ERCPs the advisability of them undertaking these procedures should be considered. However, there is no evidence on the number required to maintain competency and departments and individuals should be reviewing their own perfomance. Rationalising the service with internal referral to lead endoscopists for ERCP or inter-hospital referral may be indicated. (For a more detailed discussion on training and the problems of assessing competency, please refer to the chapter entitled ‘Training and Education’).

COMPLICATIONS AND DEATH

Critical incidents

Critical incidents during ERCP procedures were reported in 9% (19/221) of cases (Table 46). However, it is suspected that critical incidents during the procedure were under-reported.

Hypotension and tachycardia may reflect pre-procedural pathology such as pancreatitis or septicaemia, but the risk of hypotension should be minimised by optimising the patient's condition before endoscopy. Tachycardia may be associated with the use of anticholinergic agents to inhibit peristalsis during the procedure. Hypoxaemia should be preventable in most patients, all of whom should receive supplemental oxygen.

Table 46. Critical incidents during therapeutic ERCP (answers may be multiple)

Critical incident	Total *n = 221*
Hypotension (systolic less than or equal to 100 mmHg)	7
Tachycardia (greater than or equal to 100 beats/min)	6
Hypoxaemia (SpO_2 less than or equal to 90%)	5
Respiratory arrest	2
Cardiac arrest	1
Pulmonary aspiration	1
Local haemorrhage	1
Other	3
Total	**26**
None	202
Not answered	16

Postoperative complications

Table 47. Complications in the 30 days after therapeutic ERCP (answers may be multiple)

Complication	Total *n = 216*
Progress of medical condition	76
Sepsis	57
Respiratory problems	51
Renal failure	40
Cardiac problems	33
Hepatic failure	16
Upper or lower GI haemorrhage	9
Electrolyte imbalance	8
Subsequent related operation	6
Viscus perforation	4
Stroke	2
Haematological problems	2
Other	20
Total	**324**
None	56
Not answered	21

In comparison with 'progress of medical condition', the second most common complication following ERCP was sepsis (Table 47). Sepsis may be related to the high incidence of biliary stasis and infection in these patients, coupled with their age, underlying comorbidities and poor physical status. However, it does underline the need for an appropriate antibiotic strategy. There were two complications, perforation 2% (4/216) and haemorrhage 4% (9/216), that were directly attributable to the ERCP, and both of these are the most likely reason for the subsequent surgery in six patients.

Death

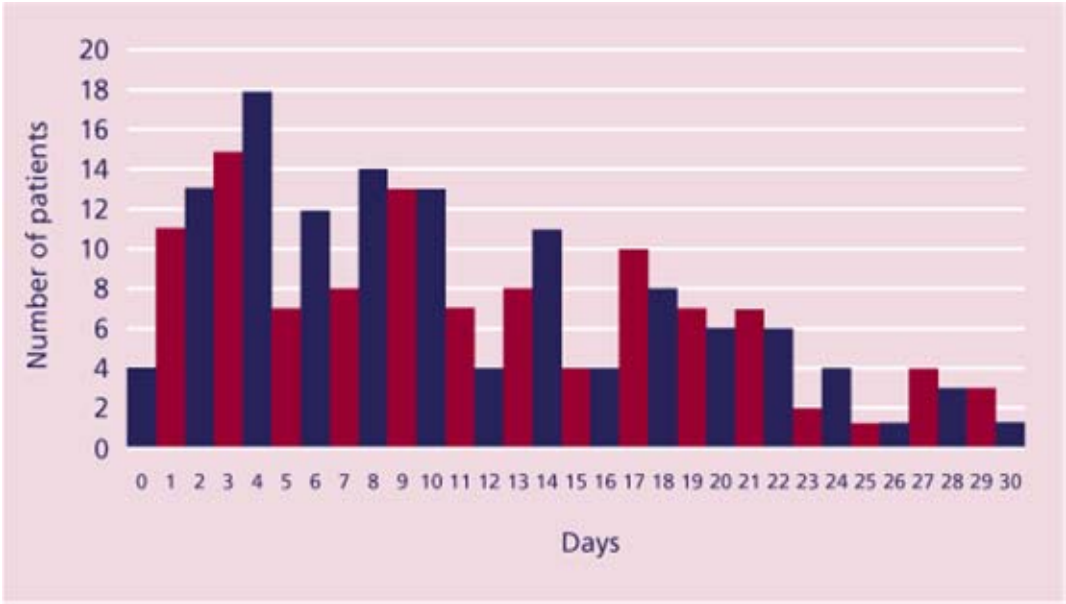

Figure 15. Number of days between the ERCP procedure and death

37% (88/237) of deaths occurred in the first week and 30% (70/237) in the second week. One patient died in the endoscopy suite.

Recommendation

Patients should be reviewed by the consultant endoscopist before therapeutic ERCP to ensure that the procedure is appropriate and that the patient's condition has been optimised.

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11. OESOPHAGOGASTRO-DUODENOSCOPY

INTRODUCTION

Oesophagogastroduodenoscopy (OGD) is the commonest procedure in the gastroenterologist's repertoire and in this sample 44% (809/1,818) of patients underwent an OGD. Of these, 65% (524/809) of patients had suffered an upper gastrointestinal (GI) haemorrhage. Upper GI haemorrhage is a condition that accounts for between 1 - 4% of all emergency admissions, and 11% of patients admitted with upper GI haemorrhage will die[1]. Inflammation and ulceration are responsible for the majority of cases and only 5 - 10% are due to oesophageal varices[1]. This chapter will focus mainly on patients with upper GI haemorrhage. Guidelines for the management of variceal and non-variceal upper GI haemorrhage have been produced by the British Society of Gastroenterology (BSG)[2 3].

PATIENT PROFILE

The age of all patients who underwent OGD is presented in Figure 16. 61% (493/809) were aged 70 years or older and 60% (485/809) were male.

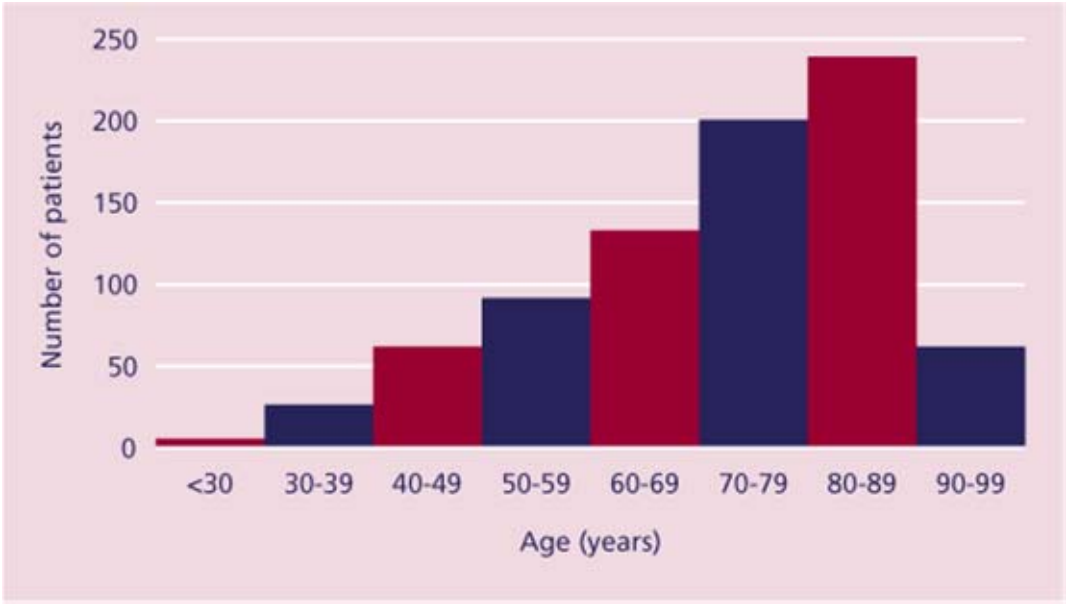

Figure 16. Age profile of patients undergoing OGD procedure

The diagnoses providing the reason for OGD, which were analysed from assessment of the free text for the procedure performed, are presented in Table 48.

Table 48. The reason for OGD			
Diagnosis		Total	*(%)*
Variceal disease		355	*(44)*
Ulcer		163	*(20)*
Stricture	Malignant	165	*(20)*
	Benign	119	*(15)*
Polyp		5	*(<1)*
Sub-total		**807**	
Not answered		2	*(<1)*
Total		**809**	

The commonest diagnosis, 44% (355/807), was of variceal disease and in only 20% (163/807) was there a diagnosis of ulcer. This was surprising as ulcer disease is very common, and bleeding ulcers are more common than varices[1]. However, it suggests that patients with bleeding ulcers are more likely to survive compared with those who suffer variceal haemorrhage. This may reflect the severity of shock associated with variceal haemorrhage and the associated comorbidity, particularly hepatic disease[1].

The complications or events that occurred within 30 days of the procedure are presented in Table 49.

Table 49. Complications after therapeutic upper GI endoscopy (answers may be multiple)	
Complication	**Total** ***n = 740***
Progress of medical condition	203
Respiratory problems	175
Haemorrhage	141
Cardiac problems	111
Renal failure	81
Hepatic failure	67
Sepsis	45
Subsequent related surgery	30
Haematological problems	30
Electrolyte imbalance	25
Viscus perforation	21
Stroke	14
Total	**850**
None	93
Not answered	69

This shows that, other than the progress of the medical condition, the most common complications were respiratory problems 21% (175/850), haemorrhage 17% (141/850) and cardiac problems 13% (111/850).

These data are similar to previous studies that have shown cardio-respiratory complications to be the most prominent[4 5] following both therapeutic and diagnostic upper GI endoscopy. The complications of viscus perforation and haemorrhage and the need for surgery may be related to the procedure, and these are presented in Table 50.

Table 50. Procedure versus operative complication (answers may be multiple)

Procedure (total performed)	Perforation	Haemorrhage	Surgery	Total *n = 809*
Snare (5)	1	0	1	2
Coagulation (104)	0	23	6	29
Laser (9)	0	1	0	1
Sclerosis (400)	1	71	15	87
Banding (41)	0	6	0	6
Dilation (125)	15	5	0	20
Stenting (259)	4	35	8	47
Total	**21**	**141**	**30**	**192**

The techniques used to secure haemostasis were argon/plasma coagulation, laser treatment, injection with either adrenaline or sclerosing agents, or banding, or a combination of these techniques. Most were used appropriately and followed BSG guidelines[2 3]. However, in a number of patients with bleeding oesophageal varices adrenaline was injected into either the oesophageal mucosa and /or the adjacent varix in an attempt to control bleeding, which is not recommended in the UK guidelines of management of variceal haemorrhage[2].

Although continued or recurrent haemorrhage can occur after haemostatic attempts with either argon/plasma coagulation (22%, 23/104), or sclerotherapy (18%, 71/400), or banding (15%, 6/41), there appeared to be a surprisingly high incidence following stenting (14%, 35/259).

The following case illustrates that repeat endoscopy can be indicated, and the fact that different pathologies can co-exist.

Case Study

A young patient with known cirrhosis presented with haematemesis. The pre-endoscopy management was exemplary. Subsequent endosopy revealed bleeding varices, which were banded. The patient received terlipressin, but continued to bleed. A further endoscopy 12 hours later confirmed that the treated varices were not bleeding, but there was a haemorrhage from a duodenal ulcer. Despite surgical intervention the patient continued to bleed, and died from disseminated intravascular coagulation.

UPPER GASTROINTESTINAL HAEMORRHAGE

Key point

In 79% of cases the procedure was performed too late to benefit the patient.

To identify patients who had suffered from upper GI haemorrhage, NCEPOD identified patients who had laser destruction or cauterisation of their lesion, or where 'other' procedure suggested treatment for haemorrhage. From this 65% (524/809) of patients were identified as having suffered an upper (GI) haemorrhage.

Urgency of the procedure and patient's physical status

In 1995 Rockall and co-workers[1] devised a scoring system for the risk of rebleeding and death after acute gastrointestinal bleeding, which is widely used by upper GI specialists in guiding their local protocols. The risk factors that accurately predict death at the time of admission are summarised here (from the BSG in their guidelines for the management of non-variceal upper GI haemorrhage)[3] :

- **Age:** death in patients less than 40 years is rare while the risk of death is 30% in those over 90 years of age
- **Comorbidity:** particularly advanced renal or liver disease, or disseminated cancer. But it is crucial that diseases of the heart, respiratory system and central nervous system are recognised and appropriately managed
- **Shock:** defined as a heart rate >100 beats/min and systolic blood pressure <100mmHg
- **Endoscopy findings:** Mallory Weiss tear or finding no stigmata of recent haemorrhage are low risk whereas active bleeding in a shocked patient carries a 80% risk of continued bleeding or death.

For those with liver disease the prognosis is related to the severity of liver disease rather than to the magnitude of haemorrhage.

With these factors in mind NCEPOD analysed the urgency of the procedure (Table 51) and the patient's physical status (Figure 17).

Table 51. Urgency of the procedure for upper GI haemorrhage

Urgency	Total	*(%)*
Elective/scheduled	70	*(14)*
Urgent	243	*(50)*
Emergency	175	*(36)*
Sub-total	**488**	
Not answered	36	*(7)*
Total	**524**	

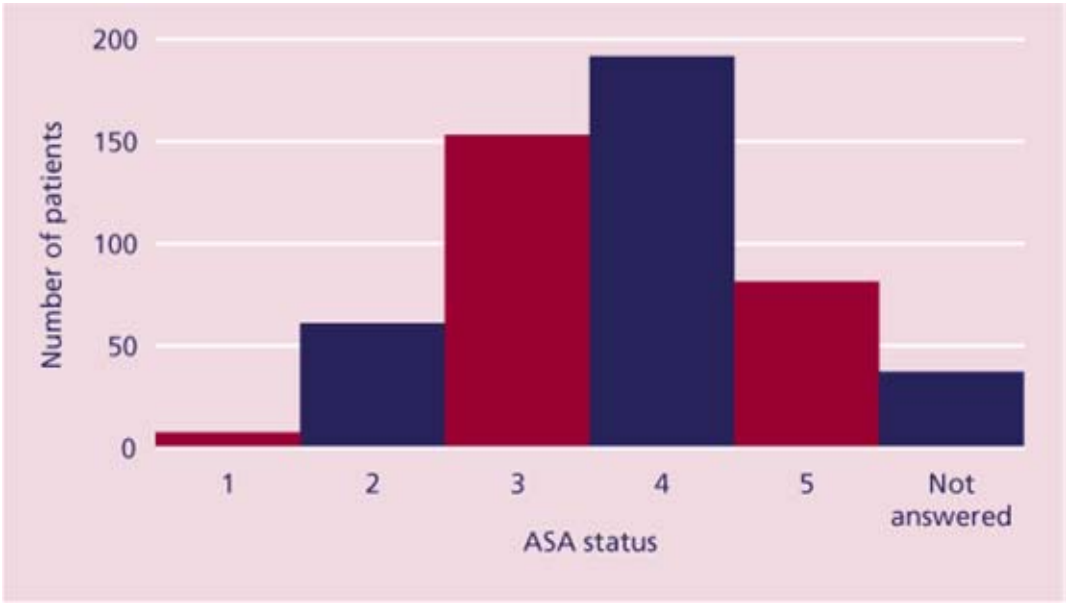

Figure 17. ASA status of those with upper GI haemorrhage

Of the 524 upper GI endoscopies for haemorrhage, 50% (243/488) were classed as urgent and 36% (175/488) as emergency (Table 51). Most of the patients were also assessed as being either severely ill (ASA 3), 31% (154/492), having a severe illness that is a constant threat to life (ASA 4), 38% (188/492), or moribund (ASA 5), 16% (80/492). Four patients who were classified as ASA 5 were apparently having a scheduled procedure. Table 52 presents the comorbidities at the time of the procedure.

Table 52. Comorbidities for upper GI haemorrhage (answers may be multiple)

System	Total *n = 515*
Respiratory	148
Cardiac	173
Neurological	128
Hepatic	59
Renal	122
Total	**630**
None	18
Not answered	9

Of these, 24% (123/515) had ischaemic heart disease and 15% (77/515) had an acute chest infection. Cardiac disease in association with an upper GI haemorrhage should indicate the need for ECG monitoring, and respiratory disease the need for pulse oximetry and supplemental oxygen during the endoscopy (see earlier chapter entitled ‘Sedation and monitoring’). From a separate question 38% (199/524) of patients with upper GI haemorrhage had cirrhosis. The Childs-Pugh score for those patients with cirrhosis is presented in Table 53.

Table 53. Childs-Pugh score of those patients with cirrhosis and upper GI haemorrhage		
Childs-Pugh Score	Total	*(%)*
A	16	*(8)*
B	35	*(19)*
C	138	*(73)*
Sub-total	**189**	
Not answered	10	*(5)*
Total	**199**	

The high proportion of patients with advanced cirrhosis reinforces the association between the severity of liver disease and death following upper GI haemorrhage. Table 54 presents the anticipated risk of death in the opinion of the clinician at the time of the procedure.

Table 54. Anticipated risk of death for upper GI haemorrhage		
Risk of death	Total	*(%)*
Not expected	17	*(4)*
Small but significant risk	37	*(7)*
Definite risk	330	*(65)*
Expected	124	*(24)*
Sub-total	**508**	
Not answered	16	*(3)*
Total	**524**	

In total, 89% (454/508) had a definite risk of death or death was expected indicating that the sample contained an exceptionally high-risk group of patients.

Appropriateness of the procedure and organisation of care

In their review of the cases NCEPOD advisors assessed the appropriateness and timing of the procedure for those with upper GI haemorrhage. Table 55 presents the advisors' opinion on the appropriateness of the procedure and Table 56 the reasons why the procedure was considered inappropriate.

Table 55. The appropriateness of the procedure for those with upper GI haemorrhage		
Procedure appropriate	Total	*(%)*
Yes	473	*(92)*
No	25	*(5)*
Undecided	17	*(3)*
Sub-total	**515**	
Insufficient information	8	
Not answered	1	*(<1)*
Total	**524**	

Table 56. Reasons for inappropriate procedures (answers may be multiple)	
Reason	**Total** ***n = 23***
Futile procedure	13
No endoscopic procedure indicated	4
Different endoscopic procedure indicated	2
Surgery in the first instance would have been more appropriate	1
Other	6
Total	**26**
Not answered	2

It is reassuring that for 92% (473/515) of cases the procedure was assessed as appropriate. For these 473 cases the advisors were asked to consider whether the procedure was also appropriately timed. In 33/473 (7%) of cases the timing was considered inappropriate and the reasons for this are presented in Table 57.

Table 57. Reasons why the timing of the procedure was inappropriate (answers may be multiple)	
Reasons	**Total** ***n = 31***
Late, delayed referral	10
Late, inappropriate prolonged resuscitation	5
Late – other	16
Early, further preoperative resuscitation indicated	4
Early – other	2
Total	**37**
Not answered	2

On reviewing the cases NCEPOD advisors were also concerned about delays for a variety of non-clinical reasons, for example there were 21 delays for organisational issues, including nine cases that should have been done as emergencies but were deferred until normal working hours.

There were also 20 cases where there may not have been delays, but there were other concerns about the organisation of care. Table 58 presents the advisors' opinion on the overall quality of care.

Table 58. Advisor opinion on the overall quality of care provided for upper GI haemorrhage

	Total	*(%)*
Good practice	308	*(73)*
Room for improvement	79	*(19)*
Less than satisfactory	33	*(8)*
Sub-total	**420**	
Insufficient information submitted to assess	90	*(1)*
Not answered	14	*(3)*
Total	**524**	

The reasons for less than satisfactory care were diverse. They were clinical, e.g. inadequate or delayed resuscitation, or organisational, e.g. lack of ICU beds, poor referral policies, inadequate out-of-hours care etc. However, that there was room for improvement or the care provided was less than satisfactory in 27% of patients who suffered upper GI haemorrhage suggests that Trusts should review the provision of care for these patients in order to identify deficiencies locally.

Case Study

An elderly patient with cirrhosis (no cause stated) and ischaemia related biventricular failure presented with a haematemesis that was not considered to be severe by the admitting clinican as the "urea is only 6.5". The patient was tachypnoeic, tachycardic and hypotensive. Before endoscopy, the patient did not receive either supplemental oxygen or intravenous fluids – which in view of the cardiac condition should have been governed by central venous monitoring.

The clinician failed to consider the:

1. effect of liver disease on blood urea levels
2. significance of a tachycardia and hypotension
3. likelihood of abnormal clotting, and no test was requested until two days after admission.

Case Study

A young patient with alcoholic cirrhosis presented after a haematemesis and melaena. On examination the patient was confused, tachycardic and hypotensive. Initial results included a glucose of 2.6 mmol/l, Hb 5gm/dl, platelets 30x10^9/L and an INR of 2.6. The pre-endoscopy treatment was resuscitation with normal saline, gelofusin and blood, and intravenous glypressin. Unfortunately no supplemental oxygen was given, and the hypoglycaemia, throbocytopenia and prolonged INR were not corrected.

Specialty and grade of endoscopist

Key point

The endoscopists managing patients with upper GI haemorrhage were mostly of an appropriate specialty. However, 24% were trainees.

The BSG guidelines recommend that patients admitted with upper GI bleeding should be the responsibility of a medical or surgical gastroenterologist who collaborates with a consultant in the other discipline. Ideally, specialist gastroenterologists (physicians or surgeons) should admit and manage these patients[3].

Table 59. Specialty of senior endoscopist for upper GI haemorrhage

Specialty	Total	*(%)*
Specialised GI physician	410	*(80)*
Other physician	13	*(3)*
Specialised GI surgeon	72	*(14)*
Other surgeon	10	*(2)*
Radiologist	1	*(<1)*
General practitioner	3	*(<1)*
Nurse practitioner	1	*(<1)*
Other	2	*(<1)*
Sub-total	**512**	
Not answered	12	*(2)*
Total	**524**	

As can be seen from Table 59, 94% (482/512) of patients with upper GI haemorrhage had their endoscopy performed by a specialised GI physician (80%) or surgeon (14%).

Table 60. Grade of senior endoscopist for upper GI haemorrhage

Grade	Total	*(%)*
Consultant	351	*(68)*
Staff grade and associate specialist	37	*(7)*
General practitioner	2	*(<1)*
Nurse practitioner	1	*(<1)*
SpR - year 3 or over	109	*(21)*
SpR - year 1/2	12	*(2)*
SHO	1	*(<1)*
Other trainee	4	*(<1)*
Sub-total	**517**	
Not answered	7	*(1)*
Total	**524**	

Consultants did most of the endoscopies (68%, 351/517) (Table 60). Most, but not all, of the remainder were done by specialist registrars (23%, 121/517), and staff grade and associate specialists (7%, 37/517). That one fifth of these very sick patients were done by SpR year 3 or over looks to be too high, but that would also depend on the time of the procedure and the level of supervision. The SpRs year 1/2 and the SHO were all physicians. Although their experience is not known one would suspect that emergency GI endoscopy for haemorrhage carried out by these grades would be inappropriate.

Location, sedation and monitoring

Key points

13% of patients with upper GI haemorrhage received excessive sedation.

23% of patients received insufficient monitoring during the procedure.

Most patients presenting with upper GI haemorrhage (87%, 448/516) had their endoscopy in an appropriate location (Table 61) according to BSG recommendations[3]. However, it is also likely that the critical care areas (ICU/HDU) have facilities similar to those in a theatre environment. Thus, the location would seem appropriate in 98% of cases (506/516). This figure may be even higher, but there are no specific details about facilities in the remaining locations.

Table 61. Endoscopy location for those with upper GI haemorrhage

Location	Total	*(%)*
Dedicated endoscopy suite	386	(75)
Operating theatres	62	(12)
ICU/HDU	58	(11)
Admissions ward	3	(<1)
A&E	2	(<1)
Day surgery unit	2	(<1)
X-ray department	2	(<1)
Other ward	1	(<1)
Sub-total	**516**	
Not answered	8	
Total	**524**	

Endoscopists differ in their use of analgesia and sedation, based on personal preference, experience and the clinical condition of the patient. In the context of upper GI haemorrhage the combinations used are shown in Table 62.

Table 62. Analgesia and sedation during endoscopy for those with upper GI haemorrhage (answers may be multiple)	
Analgesia and sedation	**Total** ***n = 477***
Local anaesthesia	167
Intravenous benzodiazepine	308
Intravenous opiod	46
Other intravenous sedation	36
Total	**557**
None	28
Not answered	47

In interpreting these data it should be remembered that the endoscopist did not sedate all patients. For example those on ICU/HDU may have been in receipt of sedation and IPPV and those in the operating theatres may have had an anaesthetist present. This may account for some cases where no sedation was given and that the other intravenous sedatives included propofol, which is usually given by an anaesthetist. It is of concern that almost one third of these patients who by the evidence of their physical status and anticipated risk were very sick, received local anaesthesia to the oropharynx, including 25% (20/80) of patients who had an ASA status of 5. Local anaesthetic to the oropharynx alone may be appropriate for a sick patient. 30% (167/557) had local anaesthesia alone but 25% (139/557) had local anaesthesia combined with sedation. The risk of local anaesthesia to the oropharynx and aspiration is discussed further in the chapter entitled ‘Sedation and monitoring'.

In 13% (68/524) of cases the advisors thought the sedation provided was inappropriate, mostly because of excessive benzodiazepine. 9% (49/524) of patients required reversal of their sedation with flumazenil and/or naloxone following the procedure, mostly because of sedation overdose, and this figure is too high. In 23% (123/524) of cases the advisors thought that there were deficiencies in patient monitoring. The reason for deficiencies is presented in Table 63.

Table 63. Reasons for deficiencies in monitoring for those with upper GI haemorrhage (answers may be multiple)	
Reasons for deficiencies in monitoring	**Total** ***n = 123***
No pulse oximetry	6
No ECG recording	103
No BP recording	65
No dedicated person to monitor patient	5
Other	3
Total	**182**
Not answered	2

As discussed more fully in the chapter on ‘Sedation and monitoring’ the under use of ECG and blood pressure monitoring in these patients, who have the potential for haemodynamic instability, represents poor monitoring practice. 4% (19/495) of patients were not given supplemental oxygen during the procedure and this is clearly unacceptable.

The location of patients immediately following the procedure is presented in Table 64.

Table 64. Location of patient immediately after the procedure for those with upper GI haemorrhage

Location	Total	*(%)*
Dedicated recovery area within the endoscopy unit	321	*(63)*
Dedicated recovery area within the operating theatres	47	*(9)*
ICU/HDU	97	*(19)*
General ward	31	*(6)*
Died during the procedure	4	*(1)*
Other	12	*(2)*
Sub-total	**512**	
Not answered	12	*(2)*
Total	**524**	

It is unacceptable that any patient who has had an endoscopy for upper GI bleeding, particularly if they have received sedation, should go to an area without full recovery and resuscitation facilities such as a general ward.

Death and audit

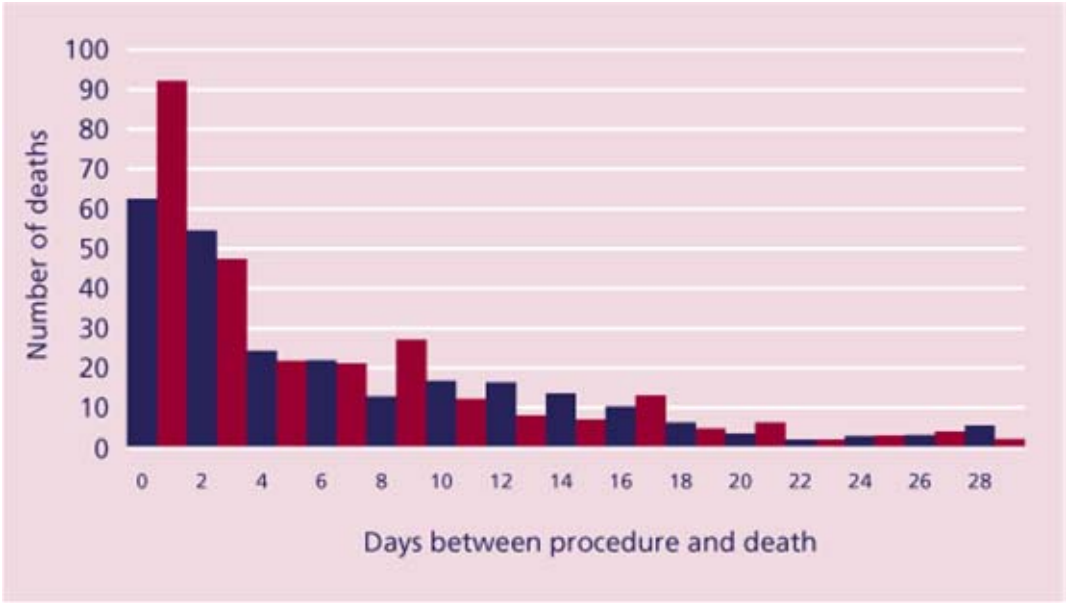

Figure 18. Days between procedure and death in cases with upper GI haemorrhage

Deaths within 72 hours (41%, 209/514) of the endoscopy (Figure 18) were likely to be due to either continuing haemorrhage, or associated complications. Deaths in the second week were probably mainly due to sepsis and organ dysfunction, and organ dysfunction was likely to be the main cause in the remainder of the thirty days.

Table 65 presents whether the department of the endoscopist who undertook the procedure held audit/morbidity/mortality meetings and Table 66 presents whether the case was considered at a meeting.

Table 65. Were audit meetings held in the department of the endoscopist?

	Total	*(%)*
Yes	325	*(67)*
No	157	*(33)*
Sub-total	**482**	
Not answered	42	*(8)*
Total	**524**	

Table 66. Were deaths considered at an audit meeting?

	Total	*(%)*
Yes	104	*(25)*
No	305	*(75)*
Sub-total	**409**	
Not answered	115	*(22)*
Total	**524**	

Of the 305 cases not considered at an audit/morbidity/mortality meeting it was intended to discuss 62 at a later date. However, this leaves 59% of cases where a patient died following an upper GI haemorrhage not being discussed at audit and a further 22% where audit was not specified.

Recommendations

Only experienced endoscopists should treat patients with upper GI haemorrhage. Experience will vary by grade but competence should be assessed by the supervising consultant.

Optimising the patient's pre-endoscopy condition will reduce both morbidity and mortality. Early involvement of an anaesthetist/intensivist if necessary, will assist this.

REFERENCES

[1] Rockall TA, Logan RF, Devlin HB, Northfield TC. *Incidence and mortality from acute upper gastrointestinal haemorrhage in the United Kingdom. Steering committee and members of the national audit of acute upper gastrointestinal haemorrhage*. BMJ 1995; 311(6999):222-6

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12. UPPER GASTROINTESTINAL DILATION AND TUBAL PROSTHESIS INSERTION

INTRODUCTION

NCEPOD examined endoscopic upper gastrointestinal (GI) dilation and tubal prosthesis insertion in patients over a three-month period (Jan-Mar 2003), regardless of outcome. The primary aim was to determine the occurrence of common complications during and within 48 hours of the procedure. The follow-up time period of 48 hours was selected as it was thought that a longer follow-up would be onerous for busy departments, resulting in poor compliance. The complications for which information was sought were oesophageal perforation, oesophageal haemorrhage, cardiac or respiratory arrest, pulmonary aspiration, chest infection, sepsis related to the procedure and stroke. Secondary aims included determining the age, sex and physical status profile of patients, grade of operator, type of endoscope, anaesthesia or sedation used and the incidence of death. In 2004, after the data collection period, the British Society of Gastroenterology (BSG) produced guidelines on the use of oesophageal dilation in clinical practice[1] and reference is made to these.

PROCEDURES AND PATIENTS

Key point

94% of all endoscopic oesophageal dilations and/or tubal prosthesis insertions were performed using a flexible endoscope.

Questionnaires were completed for 2,945 cases. The procedures identified are presented in Table 67.

Table 67. Procedure type

	Total	(%)
Flexible endoscopic dilation	2,217	(75)
Flexible endoscopic dilation followed by tubal prosthesis	64	(2)
Flexible endoscopic insertion of tubal prosthesis	496	(17)
Rigid endoscopic dilation	148	(5)
Rigid endoscopic dilation followed by tubal prosthesis	9	(<1)
Endoscopic insertion of tubal prosthesis other than oesophagus	11	(<1)
Total	**2,945**	

In total, 94% (2,777/2,945) of all endoscopic oesophageal dilations and or tubal prosthesis were performed using a flexible endoscope and only 5% (157/2,945) using a rigid endoscope and for 11 the type of endoscope was not known.

There is no evidence as to the safest method and the use of a flexible or rigid endoscope is related to the personal preference and training of the endoscopist. Whether the underlying condition was benign or malignant is presented in Table 68.

Table 68. Underlying condition		
	Total	*(%)*
Benign	1,784	*(63)*
Malignant	1,052	*(37)*
Sub-total	**2,836**	
Not answered	109	*(4)*
Total	**2,945**	

It is recognised that complications are less common after dilation of benign strictures, compared to malignant ones[2].

The age distribution is presented in Figure 19 and 51% of patients were aged 70 years or older.

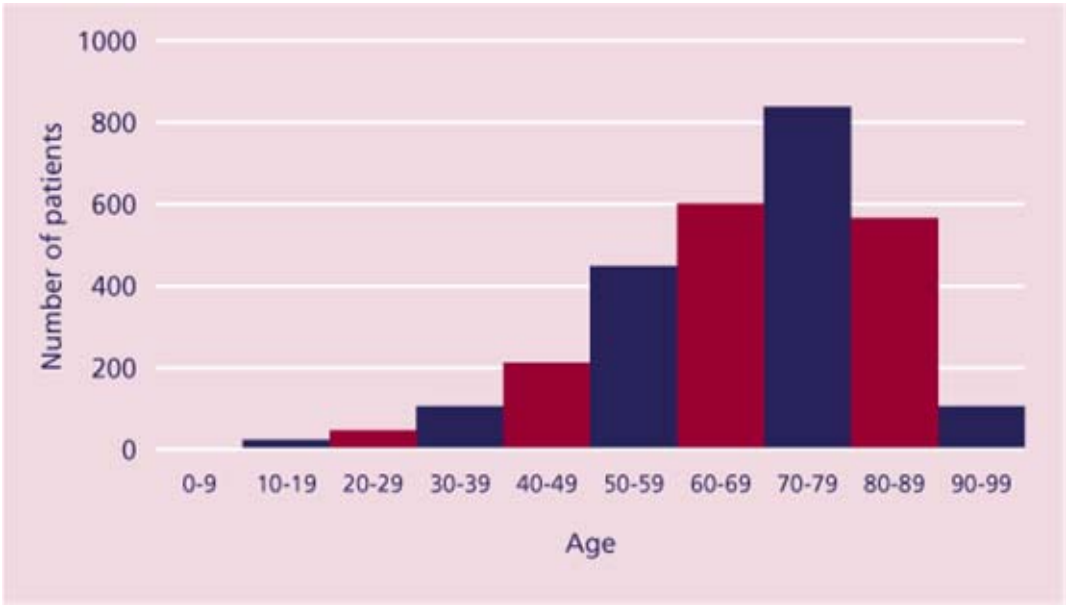

Figure 19. Age distribution

The sex distribution of cases, where provided, was 45% (1,323/2,926) male and 55% (1,603/2,926) female and 19 were not answered. The physical status of the patient (ASA) is presented in Figure 20.

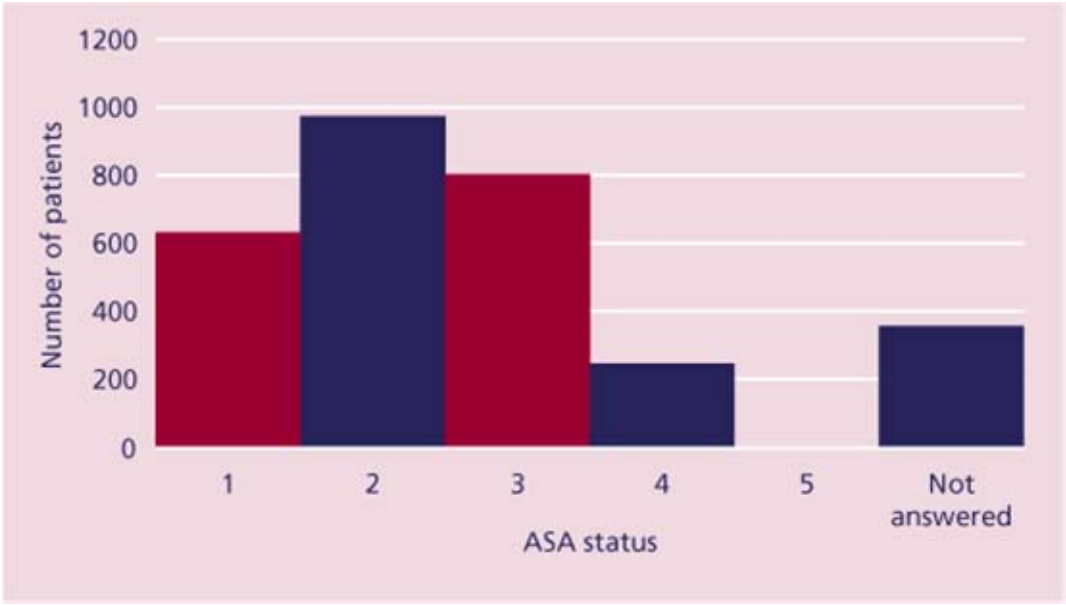

Figure 20. ASA status

11% (322/2,945) of those that responded were unable to provide an ASA status for the patient, despite ASA status being defined on the questionnaire. This is perhaps not surprising since surgeons and anaesthetists have used this classification for many years, but physicians have not and many may not be familiar with it.

SPECIALTY AND GRADE OF ENDOSCOPIST

Key points

76% of procedures were performed by specialised upper GI physicians or surgeons.

A rigid oesophagoscope was used in 39% of thoracic and 92% of ENT cases.

In 84% of cases a consultant endoscopist was present.

Physicians or surgeons who were specialised in upper GI work did 76% (2,211/2,925) of all procedures. The other surgeons were general 6% (164/2,925), thoracic 7% (211/2,925) or ENT 2% (48/2,925) surgeons. Most of the other physicians were general physicians; one was a paediatrician, yet the patient was 56 years old. All the cases done by general practitioners were done within a hospital environment.

Table 69. Procedure type by specialty of most senior endoscopist								
	Flexible			Rigid		Other	Total	(%)
	Dilation	Dilation & tubal prosthesis	Insertion of tubal prosthesis	Dilation	Dilation & tubal prosthesis	Other		
Specialised physician	1,176	39	268	8	1	5	1,497	(51)
General physician	125	3	29	0	0	1	158	(5)
Specialised surgeon	560	15	125	8	3	3	714	(24)
General surgeon	126	2	30	6	0	0	164	(6)
Radiologist	61	2	24	0	1	2	90	(3)
General practitioner	22	0	1	0	0	0	23	(1)
Nurse endoscopist	9	1	0	0	0	0	10	(<1)
Other	7	0	0	1	1	0	9	(<1)
Thoracic surgeon	114	1	13	80	3	0	211	(7)
ENT surgeon	1	0	3	44	0	0	48	(2)
Paediatrician	1	0	0	0	0	0	1	(<1)
Sub-total	**2,202**	**63**	**493**	**147**	**9**	**11**	**2,925**	
Not answered	15	1	3	1	0	0	20	(1)
Total	**2,217**	**64**	**496**	**148**	**9**	**11**	2,945	

Table 69 illustrates that a rigid endoscope was used in 39% (83/211) of thoracic cases and 92% (44/48) of ENT cases. This perhaps reflects a difference in surgical subspecialty training for specific endoscopic procedures.

Table 70. Grade of the most senior endoscopist		
Grade of most senior endoscopist	Total	(%)
Consultant	2,453	(84)
Associate specialist	73	(2)
Staff grade	63	(2)
Clinical assistant/hospital practitioner	17	(<1)
General practitioner	13	(<1)
Nurse endoscopist	11	(<1)
SpR-year 3 or over	243	(8)
SpR-year 1/2	41	(1)
SHO	9	(<1)
Other	4	(<1)
Sub-total	**2,927**	
Not answered	18	(<1)
Total	**2,945**	

A consultant was the most senior endoscopist for 84% (2,453/2,927) of these procedures. An SpR-year 1/2 would not appear to be an appropriate grade for upper GI dilation or insertion of tubal prosthesis; it is unlikely that they would have had sufficient experience to perform these procedures unsupervised.

However, NCEPOD does not know their experience before starting their SpR training, which, for those coming from SAS to training grades, can sometimes be considerable. 41 cases were done by SpRs of year 1/2, 35 were flexible endoscopic dilation, 4 were flexible endoscopic insertion of tubal prosthesis and 2 were rigid endoscopic dilation. An unsupervised SHO should never be the most senior endoscopist for upper GI dilation or insertion of tubal prosthesis. Nine cases were undertaken by SHOs. Of particular concern was that seven of the nine were rigid endoscopic dilations that were done by surgical SHOs. Of the remainder, one was a flexible endoscopic dilation and one a flexible endoscopic insertion of a tubal prosthesis. Consultants should ensure that all doctors who are under their supervision have the training and experience to perform the procedures that they are undertaking.

ANALGESIA AND ANAESTHESIA

Table 71. Analgesia and anaesthesia used for the procedure

	None	LA	Sedation	GA	Sub-total	Not answered	Total
Flexible endoscopic dilation	18	728	1,252	202	2,200	17	2,217
Flexible endoscopic dilation followed by tubal prosthesis	0	17	41	6	64	0	64
Flexible endoscopic insertion of tubal prosthesis	4	136	294	56	490	6	496
Rigid endoscopic dilation	0	2	13	131	146	2	148
Rigid endoscopic dilation followed by tubal prosthesis	0	0	1	7	8	1	9
Endoscopic insertion of tubal prosthesis other than oesophagus	0	4	4	3	11	0	11
Total	**22**	**887**	**1,605**	**405**	**2,919**	**26**	**2,945**

*Local anaesthesia = topical local anaesthesia to the oropharynx.

Although clinicians were invited to give multiple answers to the type of anaesthesia/analgesia used, interestingly, none did. It can only be assumed therefore that none used a combined topical local anaesthesia with either sedation or general anaesthesia. From Table 71, 58% (1,587/2,754) of the flexible endoscopic procedures were performed under sedation, 32% (881/2,754) under topical local anaesthesia and 10% (264/2,754) under a general anaesthetic. 9% (14/154) of the rigid endoscopic procedures were performed under sedation and 90% (138/154) under a general anaesthetic.

The high use of general anaesthesia for rigid endoscopic procedures may reflect the discomfort of the technique which is being used mainly by thoracic and ENT surgeons on lists with an attendant anaesthetist.

METHODS OF DILATION, COMPLICATIONS AND DEATH

Key points

X-ray control was used in 63% of procedures that included a tubal prosthesis insertion.

Oesophageal perforation during or within 48 hours occurred in 2.8% of cases.

Death within 48 hours occurred in 0.7% of cases.

Methods of dilation

Table 72. Methods of dilation of the oesophagus

Method of dilation	Total	*(%)*
Graduated bougie	1,362	*(49)*
Forced pneumatic balloon	191	*(7)*
Through the endoscope balloon	861	*(31)*
Two methods used	9	*(<1)*
None	369	*(13)*
Sub-total	**2,792**	
Not answered	153	*(5)*
Total	**2,945**	

Table 73. X-ray screening for the types of procedure

Type of procedure	**Yes**	**No**	**Sub-total**	**Not answered**	**Total**
Flexible endoscopic dilation	569	1,458	**2,027**	190	**2,217**
Flexible endoscopic dilation followed by tubal prosthesis	34	19	**53**	11	**64**
Flexible endoscopic insertion of tubal prosthesis	320	153	**473**	23	**496**
Rigid endoscopic dilation	36	82	**118**	30	**148**
Rigid endoscopic dilation followed by tubal prosthesis	5	4	**9**	0	**9**
Endoscopic insertion of tubal prosthesis other than oesophagus	6	3	**9**	2	**11**
Total	**970**	**1,719**	**2,686**	**256**	**2,945**

As seen in Table 73, X-ray screening was used in 29% (603/2,080) of flexible endoscopic dilation procedures and in 63% (354/526) of procedures that included insertion of a tubal prosthesis.

BSG guidelines recommend that radiographic screening is helpful when the stricture is tortuous or complex or associated with a large hiatus hernia or diverticulae, and when difficulty is encountered passing the guidewire[1]. NCEPOD advisors consider X-ray control mandatory for dilation using a guidewire if the endoscope cannot be passed into the stomach, i.e. the guidewire cannot be placed under direct vision. X-ray control was thought to be highly desirable for placement of a tubal prosthesis, and that not to use it is unwise. They also believe that X-ray control is not required for routine endoscopic oesophageal dilation if flexible tipped dilators are used.

Complications

During the procedure 1.5% (45/2,945) of patients had one or more of the complications listed on the questionnaire (Table 74).

Table 74. Complications during the procedure (answers may be multiple)

Complication	Total *n = 45*
Perforated oesophagus followed by surgery	12
Perforated oesophagus followed by medical treatment	18
Oesophageal haemorrhage	10
Cardio-respiratory arrest	1
Pulmonary aspiration	1
Chest infection	5
Sepsis	2
Total	**49**

In the 48 hour period after the procedure 2.5% (73/2,945) of patients had one or more of the complications listed on the questionnaire (Table 75).

Table 75. Complications within 48 hours after the procedure (answers may be multiple)

Complication	Total *n = 73*
Perforated oesophagus followed by surgery	35
Perforated oesophagus followed by medical treatment	18
Oesophageal haemorrhage	4
Cardio-respiratory arrest	3
Respiratory arrest	3
Pulmonary aspiration	4
Chest infection	6
Sepsis	3
Total	**76**

The perforation rate for patients with malignant disease was 4.3% (45/1,052) and for benign disease 2% (35/1,784).

Table 76. Dilation methods and oesophageal perforation during or within 48 hours of procedure

Dilation method	Total	Perforation
None	369	15
Graduated bougie	1,362	27
Forced pneumatic balloon	191	8
Through the endoscope balloon	861	21
Two methods used	9	0
Sub-total	**2,792**	**71**
Not answered	153	10
Total	**2,945**	**81**

In this study, a total of 2.8% (81/2,945) of patients suffered oesophageal perforation in association with upper GI dilation and/or insertion of oesophageal tubal prosthesis during or within 48 hours of the procedure (Table 76). There was a trend for oesophageal tubal prostheses without dilation and oesophageal dilation using a forced pneumatic balloon to be associated with a greater incidence of oesophageal perforation than the graduated bougie or through the endoscope method. The findings suggest that a larger national audit of specific techniques and equipment may be indicated.

Death

Where the outcome was known, 0.7% (20/2,828) of patients died within 48 hours of the procedure (Table 77).

Table 77. Dilation method and death

Dilation method	Died	Survived	Unknown	Sub-total	Not answered	Total
None	4	328	21	**353**	16	**369**
Graduated bougie	11	1,227	74	**1,312**	50	**1,362**
Forced pneumatic balloon	2	165	11	**178**	13	**191**
Through the endoscopic balloon	2	801	28	**831**	30	**861**
Two methods used	0	7	1	**8**	1	**9**
Sub-total	**19**	**2,528**	**135**	**2,682**	**110**	**2,792**
Not answered	1	137	8	**146**	7	**153**
Total	**20**	**2,665**	**143**	**2,828**	**117**	**2,945**

Recommendation

A national audit across all specialties of specific techniques and equipment that is used for upper GI dilation and tubal prosthesis insertion is indicated.

REFERENCES

[1] Riley SA, Attwood SE. *Guidelines on the use of oesophageal dilatation in clinical practice.* Gut, 2004; 53 Suppl 1:i1-6

[2] Quine MA, Bell GD, McCloy RF, Charlton JE, Devlin HB, Hopkins A. *Prospective audit of upper gastrointestinal endoscopy in two regions of England: safety, staffing and sedation methods.* Gut 1995; 36(3):462-7

13. PATHOLOGY

INTRODUCTION

The sample for analysis was small, only 85 autopsy reports available from 1,818 deaths in the study, and hence the conclusions to be drawn are more limited, in comparison with recent NCEPOD reports. These looked at a 10% sample of all perioperative deaths up to 30 days following surgery[1], and all perioperative deaths up to three days following surgery[2], which reviewed 350 and 500 autopsy reports respectively.

The standards used for assessing autopsy reports were the 1993 Royal College of Pathologists guidelines[3], although in the qualitative assessment of quality, note was also made of the more recently issued Royal College Guidelines for Autopsy Practice[4], which were issued midway through the time of the study. Also the advisors were familiar with the recent NCEPOD reports on autopsy report quality, and focussed on quality issues that have been repeatedly emphasised in these reports for more than a decade

AUTOPSY RATES

Key point

Deaths following therapeutic endoscopy are under-reported to coroners - only 24% - and are then less likely to be examined at autopsy (only 30%) compared with the national average.

In England & Wales in 2002, more than 90% of autopsies of patients outside the perinatal age group were authorised by a coroner[4 5]. These follow reports from clinicians who consider that the death comes into one or more of the categories that by custom, though not by law, should be reported to a coroner; the commonest of these is uncertainty over the actual cause of death.

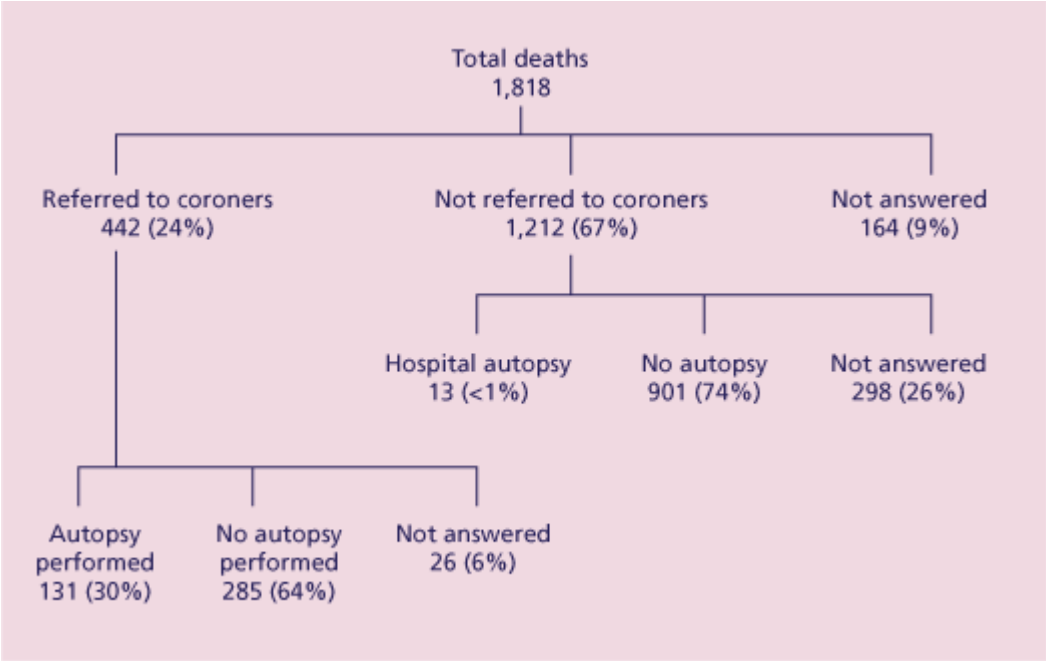

Figure 21. Deaths and autopsy rates

Of the 1,818 deaths that occurred amongst patients who had undergone an endoscopic procedure within 30 days, only 27% (442/1,654) were definitely known to have been reported to a coroner (Figure 21); physicians reported a smaller proportion of deaths (22%) compared with surgeons (36%) (Table 78). These are a small proportion of the possible 100% rate of reporting, since in the standard instructions provided for doctors and bereavement affairs staff on the cases that should be reported to a coroner, it is clearly stated that deaths following procedures in hospital qualify[6]. Even if the 164 unanswered cases are included, where it is unclear whether or not they were reported to a coroner (but the coroner might not have accepted the case), only a maximum of 33% (606/1,818) of these deaths were reported. In 2002, the overall proportion of deaths in England & Wales reported to a coroner was 38%[5], so the reporting rate in this sample is low.

Table 78. Cases reported to a coroner, by senior endoscopist specialty

	Total deaths	Number reported to a coroner	*(%)*
Physician	1,365	294	*(22)*
Surgeon	334	120	*(36)*
Radiologist	34	9	*(26)*
Nurse practitioner	8	1	*(13)*
General practitioner	7	0	*(0)*
Other (not specified)	4	0	*(0)*
Sub-total	**1,752**	**424**	
Not answered	66	18	*(4)*
Total	**1,818**	**442**	

Of those cases known to have been reported to a coroner, only 30% (131/442) were accepted as cases and an autopsy authorised. This contrasts with the overall average in 2002 in England & Wales, when 58% of cases reported were accepted and had an autopsy[5].

In addition to the known 131 coronial autopsies amongst these patients, a further 13 had a consented autopsy, where the medical certificate of cause of death (MCCD) had been completed and the clinicians requested an autopsy examination with the agreement of the relatives. Therefore only 9% (131+13 = 144/1,654) of this sample had an autopsy. Nationally, in 2002, about 23% of deaths resulted in an autopsy[7], the great majority for a coroner. So this category of patient deaths is significantly under-investigated by autopsy after death compared with the national average for all causes of death. Had the average 23% of these deaths been so examined, a potential 400 cases for review would have been available, instead of one third of this number (144/400).

The median age overall of the patients in the study was 78 years. Of the deaths following a percutaneous endoscopic gastrostomy (PEG), where the median age was 80 years, only 21% (140/653) were reported to a coroner. It suggests that deaths in the very elderly may be under-reported to the coroner when they occur in hospital, despite the fact that they follow operative procedures.

The rate of consented autopsies was only 0.8% (13/1,654), which appears to be even lower than the usual current low autopsy rate for UK in-hospital deaths (~5%[8]) that are not reported to a coroner.

The lack of interest of clinicians in the use of autopsies as part of the follow-up of their patients is probably multifactorial:

- The advanced age of the patients
- The knowledge that the endoscopic procedure was in many cases a palliative procedure (e.g. PEG insertion in 40% (719/1,818 patients in the study) in a patient with known advanced and probably terminal disease
- The impression that the patients had already ‘had enough medical interventions’.

AUTOPSY REPORTS

Of the patients autopsied, NCEPOD received reports, complete or partial, on 59% (85/144) and it was not possible to identify the source of one. Table 79 shows that 90% (76/84) were ordered by a coroner and 10% (8/84) followed consent from relatives.

Table 79. Source of autopsy reports received		
	Total	*(%)*
Coronial	76	*(90)*
Consent	8	*(8)*
Undetermined	1	*(1)*
Total	**85**	

Clinical History

All the reports of consented autopsies contained a clinical history, whilst 86% (65/76) of the coronial reports did so. These were graded as satisfactory or good in 74% (54/73) and all the 18 unsatisfactory reports were in coronial cases.

One third of the unsatisfactory cases were so categorised because they failed to mention the pre-mortem endoscopy procedure or the insertion of a PEG feeding tube (even in cases where it was also mentioned in the external description). Failure to note important documented peri-mortem infections such as MRSA and *Clostridium difficile* were also unsatisfactory. The remaining unsatisfactory histories were telegraphic and too brief.

The absence of a clinical history in autopsy reports is a long-running complaint in NCEPOD reports, particularly in coronial autopsy reports. In 2001, a similar proportion also had no such history. It is counter to established and more recent autopsy reporting guidelines, but the pathologists are not helped by an instruction given by many coroners to omit clinical histories from reports. One reason given is that the pathologist may easily make a simple factual transcription or interpretation error such as the date of an operation. This can lead relatives, if they are seeking substance for a complaint against a hospital or clinician, to cast doubt on the rest of the report and raise further and often irrelevant issues. Relatives are increasingly receiving and studying autopsy reports, and so the issue of how much detail to include about what may have been a very complicated clinical situation requires further consideration.

Description of external appearances

The majority of external cadaveric descriptions (89%, 67/75) were graded as good or satisfactory. The eight unsatisfactory cases were marked as such because descriptions were absent, perfunctory, or did not mention a PEG tube or a stent.

43% (36/83) of reports did not give the height of the patient and 51% (42/83) omitted the weight. These are the same proportions as noted in 2001[3]. Many mortuaries, anecdotally, still do not have body scales – though all have rod measures for height – and this persistent omission deprives the reports of significant detail, particularly when concerned with a group of patients who are, by definition, malnourished (i.e. candidates for PEG insertion).

Gross descriptions of organs and operation areas

All but 10 of the autopsies were full standard procedures, examining all the body cavities. In nine cases, the head was not opened, and in one case the thorax was not inspected, so that the autopsy was focussed on the abdomen. This is not necessarily a critical issue, since the purpose of the autopsy is to answer questions relating to a death and if, for example, the patient is mentally alert and neurologically normal until the time of death, little is generally to be gained by examination of the brain.

All autopsy guidelines indicate that organ weights must be included in reports.
The justification is not so much the intrinsic usefulness of organ weights, which apart from that of the heart, is not necessarily high. It is a surrogate marker of quality, in that if weights are presented then the organs must have been inspected to a certain extent. Excluding the limited autopsies, as outlined above, one or more organs were not weighed in 9% (7/75) of cases. This is a higher proportion than noted in 2001[2] .

13% (11/82) of the internal organ descriptions were unacceptably poor, mainly on account of excessive brevity.

Case Study

A patient who died of liver cirrhosis (although no histology was undertaken to confirm that gross diagnosis), was found to have a gut full of blood but there was no evaluation of where the source of bleeding might have been.

Autopsy histopathology

Taking histological samples at autopsy is now an even more contentious subject than hitherto, with the well-publicised repercussions of pathologists taking organs at Bristol[6] and Alder Hey Hospitals[7] without the knowledge of the relatives of the deceased children. In consented autopsies, tissue sampling is explicitly agreed in effectively all cases, whereas in coronial autopsies it is matter of agreement between coroner and pathologist. The Coroners' Rules[9] governing tissue taking are not precise, and the net effect is a huge variation across the 127 coronial jurisdictions of England & Wales; the range being from nearly zero to 100% of cases with tissue samples being taken. Many coroners expressly forbid taking histological samples unless it is absolutely necessary to determine a cause of death or the case is one of suspected unlawful killing. This non-standardisation should change with the presaged reform of the coronial system – see below.

The Royal College of Pathologists indicates that best practice involves systematic histological sampling in all cases, but the situation is complex: the need and subsequent usefulness depends on the actual questions being raised by a death. An example is death from peritonitis following perforation of previously documented benign gastric or duodenal ulcer, where autopsy histopathology provides limited additional information concerning the sequence of events leading to death. However, it must be emphasised that the highest quality autopsy reporting can only come from repeated observations and deep understanding of autopsy histopathology, which in turn demand regular and systematic tissue sampling.

Table 80. Organ and tissue retention for histopathology

	Number	*(%)*	**Comparative % in 2002 NCEPOD report**	**Comparative % in 2001 NCEPOD report**
Organs retained	3	*(4)*	n/a	n/a
Tissue histology taken	31	*(36)*	*27*	*28*
No samples taken	49	*(58)*	n/a	n/a
Unclear whether samples taken	2	*(2)*	n/a	n/a
Total	**85**			

n/a = not available

In only three autopsies were whole organs retained (Table 80), but there is no current database against which to compare this figure.

In two reports, it was unclear whether or not histological samples had been taken, and in only 37% (31/83) of evaluable cases was histology performed. This is actually higher than the 28% rate noted in the 2001 report but the overall sample is smaller. A histology report was returned to NCEPOD in 77% (24/31) of the cases where histology was taken. In terms of quality, i.e. the usefulness in explicating the circumstances of death, 21 were good or satisfactory and three (13%) unsatisfactory. In the latter were:

- kidneys not studied although the cause of death related to renal failure
- the primary origin of metastatic carcinoma not fully explored.

Did the lack of histological sampling detract from the quality of the autopsy in the non-sampled cases? The advisors considered this to be the case in 24% (12/49) of cases.

Case Study

A patient had therapeutic endoscopy to dilate a stricture of the oesophagus of unknown cause. The patient died of pneumonia and the stricture was noted at the autopsy but no histological sample was taken to determine whether it was benign or the result of a malignancy.

Case Study

A patient with pancreatic disease required an ERCP. The autopsy report suggests that the underlying disease was carcinoma, but no histology was taken to confirm this.

National statistics on gastro-intestinal cancer are not well served by this non-investigative approach.

Case Study

The pathologist specifically noted that the Coroner had not permitted taking histology to investigate the aetiology of previously undiagnosed cirrhosis of the liver, which had resulted in upper GI tract bleeding, requiring banding of the oesophageal varix. However, the report was also compromised by a poor appreciation of the circumstances of death, as evidenced by lack of mention of the oesophageal varices and of the endoscopic procedure. The resulting cause of death was stated:

1a. *ischaemic heart disease*
2. *decompensated cirrhosis.*

As will be discussed below, this is the wrong cause of death (cirrhosis should be in Part 1) and a misuse of the term ischaemic heart disease.

Clinico-pathological summary

Key point

Nearly half the autopsy reports (44%) had a poor, or no, clinico-pathological summary.

While it is critical that a systematic autopsy and report are essential to identify and consider all aspects of a death where there has been uncertainty, it is increasingly emphasised in guidelines[4] that the construction of an overview clinico-pathological summary, containing all the essential features of a case, is an essential part of an autopsy report. The summary is there to answer (if possible) the questions raised by a death, more descriptively than the necessarily compressed formulation of the ONS standard death certification lines.

In this sample, the proportion of autopsy reports that included such a summary was the same (63%, 53/84) as that reported in 2001[2]. Of these 11% (6/53) were graded as unsatisfactory, making a grand total of 44% (37/84) of reports that had either no clinico-pathological summary or an unsatisfactory one.

In addition to examples quoted above and below, other poor summaries included a lack of discussion on the significance of a colon stent that had evidently moved after insertion and the contribution of ERCP in causing fatal sepsis of the biliary tree.

ONS cause of death formulation

Key point

Depiction of the cause of death sequence (i.e. the death certificate) by pathologists was not consistent with the clinical and pathological data in one third of cases.

A constant lament from the Office of National Statistics[10] is the poor quality of construction and completion of the Medical Certificate of Cause of Death (MCCD). This relates not just to the actual diseases indicated (although the Home Office considers that about 30% of death certificates are significantly incorrect in that respect[7]), but also to the logical depiction of disease states and sequence, ending with the main clinical pathology as the lowest line of 'Part 1'of the MCCD. 'Part 2' of the MCCD should include only additional diseases that contributed to death or the timing of death, but not the main disease that resulted in death. Diseases listed in 'Part 2' are not included in the annual ONS tabulations of causes of death for the nation. So placing the main disease in this part inevitably distorts the statistical appreciation of disease burden.

In consented autopsies, the MCCD has already been completed and registered by the time of autopsy. In coronial autopsies, the pathologist is effectively writing the death certificate, since the coroner will take his/her formulation (sometimes modified by an inquest) and copy it into the death certificate.

Table 81. Evaluation of the content and structure of death certificate statements in autopsy reports.

	Evaluable reports	Number incorrect	*(%)*
Depiction of circumstances of death	85	29	*(34)*
Structure of the MCCD	76	10	*(13)*

All but five autopsy reports included an ONS standard formulation, and these were consented autopsies where there is no necessity to include an ONS cause of death if the clinico-pathological summary has already discussed the circumstances of death. However, guidelines[4] do recommend the formulation in all autopsy reports, in part because it should concentrate the mind of the pathologist on what really happened.

13% (10/76) of the evaluable causes of death were incorrectly structured (Table 81), and 34% (29/85) were considered by the panel not to reflect correctly the real circumstances of the death as evidenced from the autopsy reports.

The following case studies illustrate typical examples of incorrectly completed MCCDs.

Case Study

A patient dies following stent and resection of a colon cancer, with metastases to the liver. There was moderate coronary artery disease in the heart. The cause of death was stated to be:

1a. *Cardio-respiratory failure*
1b. *Ischaemic heart disease*
2. *Surgically resected carcinoma of colon.*

The carcinoma was obviously the major determinant of the patient's final illness and death. Better would be:

1a. Disseminated carcinoma
1b. Cancer of colon (operation and date)
2. Ischaemic heart disease.

Case Study

In an otherwise excellent report, including histology, of a patient who died of cholangio-carcinoma, and who also had documented 60-70% stenoses of the coronary arteries, the cause of death was stated to be:

1a. *Myocardial insult due to anaemia following ERCP (August 2002)*
1b. *ischaemic heart disease.*

The mention of the operative procedure and its date fulfils the updated guidelines on MCCD formulation, but the non-inclusion of what was the main actual cause of death – the carcinoma – is odd. Better would be:

1a. Cholangio-carcinoma (ERCP August 2002)
2. Ischaemic heart disease.

The ischaemic heart disease (if the 60-70% coronary artery stenoses were significantly obstructive) perhaps contributed to the timing of the death, but was not the fundamental cause.

Case Study

A patient with myasthenia gravis was progressively malnourished and required a PEG for feeding, but died. At autopsy he had "severe coronary atheroma", but no evident acute myocardial infarction. A clinico-pathological summary was not included, and the cause of death was stated to be:

1a. *Myocardial infarction*
1b. *Coronary artery atheroma.*

The myasthenia gravis was not mentioned, yet must have been the major underlying disease that resulted in the patient's death; the ischaemic heart disease should be in Part 2 as a contributor to the timing of death. Therefore in our opinion the certificate should read:

1a. Malnutrition
1b. Myasthenia gravis (PEG tube inserted and date)
2. Ischaemic heart disease.

Case Study

A patient died of dysphagia and malnutrition due to a large obstructing thyroid goitre. No clinico-pathological summary was included. The cause of death:

1a. *Pulmonary embolism*
1b. *Septicaemia*
1c. *Bronchopneumonia*
2. *Multinodular goitre.*

Better would have been:

1a. Sepsis and malnutrition
1b. Multinodular goitre obstructing the oesophagus
2. Deep vein thrombosis and pulmonary embolism.

The fundamental cause of death was the large thyroid, not the pulmonary embolism.

Case Study

A patient had gall stones. Following ERCP they developed sepsis and heart failure. The report states "Biliary tract patent. Hepatic duct dilated with abscess formation. Gall bladder normal". There was no clinico-pathological summary, but the cause of death was stated:

1a. *Ischaemic heart disease*
2. *Hepatic duct abscess.*

There was no mention of the underlying cause of hepatic duct abscess – gall stone disease – and no discussion of the role of ERCP in the development of an abscess and fatal sepsis. Better would have been:

1a. Cholangitis and sepsis
1b. Gallstones in bile duct (ERCP and date)
2. Ischaemic heart disease.

These examples demonstrate a consistent tendency throughout the autopsy reports studied of this sample, and in general observation of autopsy reports by the review panel, to pick on a readily observable pathology as the cause of death, rather than consider more deeply the relative contribution of all pathologies and procedures that resulted in the death. In an elderly population, a high proportion of patients has a degree of coronary artery disease that, according to circumstance, could be consistent with causing an acute cardiac arrest or arrhythmia. But the real causes of death are often elsewhere, and this practice reflects lazy thinking among pathologists. It contributes to blurring of national statistics on cause of death, with over-emphasis on common cardiovascular disease and under-representation of the necessarily more complicated multiple pathologies found in an elderly population.

Mention of the endoscopic procedure in the autopsy report

Only 18% (15/85) of the autopsy reports mentioned the procedure in the cause of death formulation. Updated guidelines[4] indicate that relevant pre-mortem interventions should be listed and dated in the cause of death, but there is no clarity on what constitutes a relevant intervention. Does a PEG feeding tube that has caused no direct complication (e.g. peritonitis) count as a mentionable procedure, in contrast to a stent that perforates a viscus, which evidently does? NCEPOD considers that it does.

Overall quality of the autopsy examination and report

Taking all aspects of the autopsy reports into consideration, the advisors judged that 71% (60/85) of the reports were satisfactory to excellent (Table 82). The small number of unacceptable reports indicated circumstances in which the pathologists could find themselves open to criticism from a professional body for producing low standard, uninformative and incorrect work.

The distribution of quality scores is broadly similar to those noted in the recent NCEPOD reports[1 2].

Table 82. Overall quality of autopsy examination and report				
	Number	*(%)*	**Comparative % in 2002 NCEPOD report *n = 499***	**Comparative % in 2001 NCEPOD report *n = 346***
Excellent	5	*(6)*	*5*	*5*
Good	27	*(32)*	*19*	*21*
Satisfactory	28	*(33)*	*40*	*43*
Poor	18	*(21)*	*33*	*28*
Unacceptable	4	*(5)*	*2*	*2*
Unevaluable	3	*(4)*	-	-
Total	**85**			

Overview of the available autopsy reports

Most of the advisors' criticisms of the autopsy reports are familiar repeats from previous reports:

- lack of clinical history
- imperfect description of external and internal appearances
- lack of mention of pre-mortem endoscopic procedures
- lack of histological sampling where it matters
- lack of a clinico-pathological summary
- omitting mention of the intervention procedure on the cause of death statement
- imperfect formulation of the cause of death in terms of structure and content.

What is particularly striking from this review is the very small number of cases that actually had an autopsy. 27% (442/1,654) of the deaths were reported to a coroner, who accepted only 31% (131/416) of them for further examination, and a further 0.8% (13/1,654) of cases resulted in a consented autopsy.

The categories of deaths that should be reported to a coroner are not laid down in statute, but it is generally agreed that the following principles apply[11] :

- if the death occurred during an operation or before full recovery from the effects of an anaesthetic or was in any way related to the anaesthetic (in any event a death within 24 hours should normally be reported)
- if the death may be related to a medical procedure or treatment, whether invasive or not
- if the death may be related to lack of medical care.

Following these criteria, a greater proportion of the deaths in this sample should have been reported to a coroner; the lowest rate of referral was among patients endoscoped by physicians (only 22%).

It is the responsibility of clinicians, who themselves may be liable to criticism concerning their care of a patient, to report a death under his care to the coroner if that death is related to a procedure he has undertaken. The anomalies of the current system should be addressed in the reform of the 'Coroner and Death Certification Service' which is discussed below.

Previous NCEPOD reports have not considered this issue since the data on reporting rates were not requested. There may be an increase in reporting and further investigation of deaths following procedures if the recommendations of the review of the coronial and death certification systems develop into actual practice.

THE REFORM OF THE CORONER AND DEATH CERTIFICATION SERVICE

Under the proposed new 'Coroner and Death Certification System'[12], all deaths – whether in the community or hospital – will be reported to and scrutinised by a medically qualified medical examiner (ME), who will consult with the certifying clinician on the cause of death. If the ME considers that further investigation, including autopsy, is required, there will be consultation with the regional coroner.

The criteria for authorising an autopsy will probably remain similar to those currently operating, but it is intended that there be more national consistency in the proportion of cases resulting in autopsy and in the scope of those examinations. A positive intention is to facilitate the better use of post-mortem medical examinations in clinical governance, including mortality audit.

The ME will advise on the minimum level of invasiveness of autopsies, including possibly the use of magnetic resonance imaging (MRI) evaluation in place of standard dissection and organ examination. Unless and until the use of MRI is properly validated, this has serious implications for the value of autopsies in future NCEPOD studies since it is not evident that MRI technology is as sensitive as open examination in determining the circumstances of post-intervention deaths[13]. The usefulness of MRI in evaluating perioperative deaths, as opposed to deaths in the community, is so far unexplored and it may be that the current capacity of MRI machines could not cope.

Another potentially detrimental aspect of the proposed reforms of the coronial system is further pressure not to take organs and tissue samples for histopathology. As paragraph 67 of the position paper states[12], 'retention should only take place *where absolutely necessary*' (our emphasis).

It is the view of NCEPOD that this will necessarily inhibit pathologists further in seeking to investigate post-intervention deaths fully, since there is already no uniformity and clarity about taking histopathology samples. The results will not be to the benefit of clinical governance and, ultimately, of the public.

A new position, that of Medical Adviser to the Chief Coroner, is proposed under the coronial system reform, and that person should have a significant influence upon the national standards of autopsy performance.

It is important for pathological organisations in the UK to continue to emphasise and publicise the significance and benefits to the families and to the medical profession of the well-performed and reported autopsy in the audit and improvement of standards of medical care. This is a view that NCEPOD has consistently held since its inception.

In the current medico-political climate, there is intended to be a reduction in the proportion of deaths that eventuate in an autopsy – England & Wales has a significantly higher overall autopsy rate than countries with comparable medico-legal systems[7]. If this reduction is inevitable, it is important that the autopsy firstly is focussed on those cases where the information will be the most useful, particularly those following medical interventions, and secondly is performed well and to measurable quality standards.

Recommendations

The operative procedure should be included in the cause of death statement.

Post-procedure deaths (i.e. those occurring during or within 24 hours of anaesthesia or sedation or those where it is known that the procedure is implicated in the death) should be reported to the coroner.

Pathologists should think more carefully about all the clinical circumstances of a death, to produce an autopsy report more useful for clinical governance and audit.

NCEPOD supports the reforms of the coronial system and death certification, which will result in better scrutiny of deaths.

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DATA SUPPLEMENT

INTRODUCTION

This data supplement should be read in conjunction with the 2004 NCEPOD Report, *'Scoping our practice'* (The 2004 Report of the National Confidential Enquiry into Patient Outcome and Death. NCEPOD. London, 2004).

The question numbers in the supplement correspond to those in the questionnaires with which the data were collected.

Where a question is omitted from the supplement, the information collected for this field was in the form of free text.

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A. GASTROINTESTINAL THERAPEUTIC ENDOSCOPY STUDY

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Date of admission	1,817

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B. Other elective	122
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C. Emergency	1,619
Not answered	44

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B. Respiratory	COPD	274
	Acute chest infection	456
	Asthma	65
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	MI within three months of the endoscopy	44
	Valvular heart disease	69
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	Parkinson’s disease	58
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	Chronic	122
H. Endocrine	Non-insulin dependent diabetes mellitus	167
	Insulin dependent diabetes mellitus	51
	Hypothyroidism	53
Musculoskeletal		181
Haematological	Bleeding disorder	73
	Immunosupression	25
Sepsis		163
Other		534
Not answered		42

5. Liver cirrhosis	
Yes	1,509
No	224
Not answered	85
If yes, Childs-Pugh Score	
A	25
B	38
C	152
Not answered	1,603

6. ASA status	
1	29
2	222
3	619
4	661
5	178
Not answered	109

7. Anticipated risk of death within 30 days of the proposed endoscopic procedure	
A. Not expected	134
B. Small but significant risk	316
C. Definite risk	1,056
D. Expected	247
Not answered	65

8. Patient's weight	
Patient's weight	429

9. Patient's blood pressure at the start of the procedure	
Patient's blood pressure at the start of the procedure	1,328

10. Patient's heart rate at the start of the procedure	
Patient's heart rate at the start of the procedure	1,401

11. Pre-procedural investigations		
Pre-procedural investigations		1,752
A. None		6
B. Haemoglobin		1,615
C. White cell count		1,614
D. Platelets		1,600
E. INR		946
F. Serum Na		1,605
G. Serum K		1,594
H. Blood urea		1,587
I. Serum creatinine		1,587
J. Serum albumin		1,397
K. Blood glucose		781
L. Serum amylase		204
M. Total bilirubin		1,276
N. Blood gas analysis	Inspired oxygen	230
	pH	216
	PaCO 2	228
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P. ECG		694
Q. ECHO cardiography		88
R. Other		303

Procedure

12. Date of procedure	
Date of procedure	1,789

13. Time of start of procedure	
Time of start of procedure	1,235

14. Time of finish of procedure	
Time of finish of procedure	1,071

Upper digestive tract (excluding PEGs)

16. a Oesophagus – Fibreoptic oesophagoscope	
Snare resection of lesion	0
Laser destruction of lesion	10
Cauterisation of lesion (Argon beam)	23
Sclerotherapy of varices	99
Other destruction of lesion	13
Removal of foreign body	5
Balloon dilatation	27
Bougie dilatation	60
Insertion of tubal prosthesis	111
Other	73

16. a Oesophagus – Rigid oesophagoscope	
Snare resection of lesion	0
Laser destruction of lesion	0
Cauterisation of lesion (Argon beam)	0
Sclerotherapy of varices	0
Other destruction of lesion	0
Removal of foreign body	0
Balloon dilatation	0
Bougie dilatation	5
Insertion of tubal prosthesis	1
Other	0

16. b Upper GI tract, stomach to the proximal duodenum, using fibreoptic scope	
Snare resection of lesion	3
Laser destruction of lesion	4
Cauterisation of lesion	40
Sclerotherapy to lesion	113
Other destruction of lesion	8
Insertion of prosthesis	40
Removal of foreign body	0
Endoscopic dilatation of the pylorus	7
Other	69

16.c Remainder of the upper digestive tract - Duodenum	
Removal of lesion	1
Dilatation of lumen	0
Insertion of prosthesis	10
Other	15

16.c Remainder of the upper digestive tract – Jejenum	
Removal of lesion	0
Dilatation of lumen	0
Insertion of prosthesis	8
Other	5

16.c Remainder of the upper digestive tract – Ileum	
Removal of lesion	0
Dilatation of lumen	0
Insertion of prosthesis	0
Other	0

17. PEGs	
Creation of new (first) gastrostomy	675
Creation of a second (subsequent) gastrostomy	14
Replacement of gastrostomy feeding tube	13
Removal of gastrostomy feeding tube	3
Attention to a gastrostomy tube (not requiring removal)	1
Other	4

18. Lower digestive tract - Colonoscope	
Snare resection of lesion	14
Cauterisation of lesion	2
Laser destruction of lesion	0
Cryotherapy	0
Other destruction of lesion	0
Dilatation of lumen	0
Coagulation of blood vessel	0
Removal of foreign body	0
Insertion of tubal prosthesis	6
Other	5

18. Lower digestive tract – Fibre optic sigmoidoscope	
Snare resection of lesion	5
Cauterisation of lesion	2
Laser destruction of lesion	0
Cryotherapy	0
Other destruction of lesion	0
Dilatation of lumen	1
Coagulation of blood vessel	1
Removal of foreign body	0
Insertion of tubal prosthesis	3
Other	2

18.Lower digestive tract – Rigid sigmoidoscope	
Snare resection of lesion	0
Cauterisation of lesion	0
Laser destruction of lesion	0
Cryotherapy	0
Other destruction of lesion	0
Dilatation of lumen	1
Coagulation of blood vessel	1
Removal of foreign body	0
Insertion of tubal prosthesis	3
Other	2

19. ERCP	
Sphincterotomy sphincter of Oddi and insertion of calculus	4
Sphincterotomy sphincter of Oddi and insertion of tubal prosthesis	51
Sphincterotomy of accessory ampulla of Vater	4
Insertion of tubal prosthesis into both hepatic ducts	7
Insertion of tubal prosthesis into bile duct	119
Renewal of tubal prosthesis in bile duct	16
Removal of tubal prosthesis from bile duct	15
Dilatation of bile duct	8
Insertion of prosthesis into pancreatic duct	1
Renewal of prosthesis in pancreatic duct	0
Removal of calculus from pancreatic duct	1
Drainage of lesion of pancreas	0
Dilatation of pancreatic duct	0
Other	7

20. Urgency of the procedure	
A. Elective	250
B. Scheduled	822
C. Urgent	437
D. Emergency	197
Not answered	112

21. Previous endoscopic procedures within the last 2 years	
Previous endoscopic procedures within the last 2 years	1,103

Upper digestive tract endoscopy

22. Conditions diagnosed before endoscopy	
A. Pharyngeal pouch	2
B. Malignant oesophageal stricture	155
C. Benign oesophageal stricture	30
D. Achalasia	3
E. Oesophageal diverticulum	0
F. Gastric ulcer	26
G. Gastric cancer	29
H. Duodenal ulcer	59
I. Pyloric stenosis	8
J. Other	102

22. Conditions diagnosed during endoscopy	
A. Pharyngeal pouch	3
B. Malignant oesophageal stricture	54
C. Benign oesophageal stricture	27
D. Achalasia	1
E. Oesophageal diverticulum	0
F. Gastric ulcer	6
G. Gastric cancer	10
H. Duodenal ulcer	171
I. Pyloric stenosis	8
J. Other	80

PEGs

23. Conditions at the time of the endoscopy		
A. Nutritional failure due to non-malignant disease		300
B. Motor neurone/other degenerative disease		65
C. Neurological disease	Acute	421
	Chronic	100
D. Dementia		138
E. Malignancy	Oropharyngeal cancer	31
	Oesophageal cancer	29
	Gastric cancer	10
	Other	56

Lower digestive tract endoscopy

24.a Previous history of pelvic surgery	
Yes	3
No	57

24.b Patient known to suffer from diverticular disease	
Yes	7
No	53

24.c Previously “difficult” colonoscopy	
Yes	2
No	56

24.d Prior contrast examination	
Yes	13
No	53

24.e Conditions diagnosed before endoscopy	
A. Diverticular disease	7
B. Malignant stricture	14
C. Benign stricture	2
D. Pedunculated polyp(s)	1
E. Flat polyp(s)	0
F. Non-stricturing carcinoma	0
G. Angiodysplagia	0
H. Ulcerative colitis	0
I. Crohn’s disease	1
J. Other	8

24.e Conditions diagnosed during endoscopy	
A. Diverticular disease	5
B. Malignant stricture	8
C. Benign stricture	2
D. Pedunculated polyp(s)	14
E. Flat polyp(s)	0
F. Non-stricturing carcinoma	2
G. Angiodysplagia	2
H. Ulcerative colitis	0
I. Crohn's disease	0
J. Other	4

ERCP

25. Conditions diagnosed before endoscopy	
A. Bile duct stone (possible/definite)	59
B. Bacterial cholangitis	40
C. Benign biliary stricture	4
D. Malignant biliary stricture	85
E. Carcinoma of the pancreas	56
F. Acute pancreatitis	6
G. Chronic pancreatitis	2
H. Sclerosing cholangitis	1
I. Choledochal cyst	0
J. Other	5

25. Conditions diagnosed during endoscopy	
A. Bile duct stone (possible/definite)	29
B. Bacterial cholangitis	11
C. Benign biliary stricture	4
D. Malignant biliary stricture	67
E. Carcinoma of the pancreas	36
F. Acute pancreatitis	1
G. Chronic pancreatitis	1
H. Sclerosing cholangitis	0
I. Choledochal cyst	1
J. Other	6

26. Written consent obtained for the procedure	
Yes	979
No	254
Not answered	585

27. Antibiotic prophylaxis for the procedure	
Yes	561
No	636
Not answered	621

Movement of patient through the hospital/endoscopy unit

(Answers may be multiple)

28. Pathway for this referral	
A. Admission following an outpatient consultation	96
B. Direct referral from a general practitioner (open access)	101
C. Admission via A&E	665
D. Tertiary referral from within own hospital	729
E. Transfer from another hospital or general practitioner endoscopy unit	83
F. Self-referral by patient	12
G. Other	100
Not answered	73

29. Tertiary referral speciality	
A. Care of the elderly	329
B. Other medical	349
C. Surgical	132
D. Other	104
Not answered	904

30. Department of hospital immediately before the procedure	
A. A&E department	46
B. Emergency admissions unit	73
C. Medical ward	1,095
D. Surgical ward	286
E. Day case ward	17
F. Out-patient department	3
G. High dependency unit	53
H. Intensive care unit	87
I. Other	112
Not answered	46

31. Location of procedure	
A. Dedicated endoscopy unit/room	1,349
B. Day-case surgery unit	15
C. Operating theatres	161
D. X-ray department	171
E. ICU/HDU	78
F. A&E	3
G. Admission unit or A&E ward	3
H. Other ward	5
I. Other	1
Not answered	32

32. Post procedure location	
A. A dedicated recovery area within the endoscopy unit	1,247
B. A dedicated recovery area within the operating theatres department	144
C. ICU	115
D. HDU	36
E. General ward	163
F. Died during the procedure	5
G. Other	54
Not answered	54

33. If patient went directly to recovery, post recovery location	
A. ICU	30
B. HDU	55
C. Directly to the operating theatre for an operation	7
D. General ward	1,237
E. Died in the recovery area	11
F. Home	13
Not answered	38

Operating endoscopists

34. Specialty of the most senior operating endoscopists	
A. Specialised GI physician	1,279
B. Other physician	86
C. Specialised GI surgeon	278
D. Thoracic surgeon	12
E. Other surgeon	44
F. Radiologist	34
G. General practitioner	7
H. Nurse practitioner	8
G. Other	4
Not answered	66

35. Grade of the most senior operating endoscopist career grades	
A. Consultant	1,312
B. Associate specialist	80
C. Staff grade	70
D. General practitioner	7
E. Nurse practitioner	9
Trainee grades and year of training	
F. Specialist registrar – post CCST	37
G. Specialist registrar – year 3/4	203
H. Specialist registrar – year 1/2	45
I. Senior house officer	2
J. Other trainee	8
Not answered	45

36. Higher diplomas of most senior operating endoscopist (Answers may be multiple)	
A. None	13
B. Full Fellowship/Membership of a Royal Medical College	1,093
C. Part Fellowship/Membership of Royal Medical College	23
D. ENB course A87	1
E. Other	7
Not answered	122

37. Upper digestive tract therapeutic endoscopic procedures performed by senior operator in the last 12 months	
<5	8
6-10	13
11-20	65
21-50	159
51-100	177
>100	665

38. PEG procedures performed by senior operator performed in the last 12 months	
<5	33
6-10	82
11-20	192
21-50	283
51-100	98
>100	26

39. Lower digestive tract therapeutic endoscopic procedures performed by senior operator in last 12 months	
<5	11
6-10	8
11-20	17
21-50	43
51-100	51
>100	104

40. ERCP procedure performed by senior operator in the last 12 months	
<5	47
6-10	9
11-20	6
21-50	43
51-100	91
>100	177

41. Senior operating endoscopist attended a formal sedation techniques course	
Yes	645
No	723
Not answered	450

42. Availability of consultant supervising operator	
A. In, or came to the operating/endoscopy room during the procedure	92
B. In the operating/endoscopy unit but not directly involved with the case	84
C. Available in the hospital, not present in the operating/endoscopy unit	186
D. Not in the hospital but was available by phone	40
E. Other	4
Not answered	100

Sedation and monitoring

43. Forms of sedation and analgesia used during the procedure (may be multiple)	
A. None	68
B. Local anaesthesia	426
C. Intravenous opiate sedation	314
Drug used	315
Total dose	302
D. Intravenous benzodiazepine sedation	1,237
Drug used	1,406
Total dose	1,372
E. Other intravenous sedation	83
Drug used	55
Total dose	27
Not answered	311

44. Naloxone or Flumazenil	
A. Naloxone	7
B. Flumazenil	158
C. Naloxone and Flumazenil	18
Not answered	1,635

45. Patient monitors used (Answers may be multiple)	
A. Pulse oximetry	1,668
B. ECG	384
C. Automatic non-invasive blood pressure	729
D. Manual non-invasive blood pressure	120
E. Invasive blood pressure	76
F. CVP	147
G. None of the above	16

46. Oxygen administered during the procedure	
Yes	1,584
No	88
Not answered	146

47. Patient monitoring responsibility (Answers may be multiple)	
A. A qualified nurse	1,439
B. The operator	166
C. An anaesthetist	193
D. Another doctor	33
E. A radiographer	0
F. An operating department assistant	10
G. A support worker/health care worker	3
H. Not known	12
Not answered	111

48. Monitoring chart for the procedure in the patient's notes	
Yes	807
No	761
Not answered	250

49. Critical incidents during the procedure (Answers may be multiple)	
A. None	1,439
B. Cardiac arrest	8
C. Respiratory arrest	5
D. Hypoxaemia (SpO2 90% or less)	72
E. Pulmonary aspiration	1
F. Hypotension (systolic less than 100mm Hg)	63
G. Tachycardia (more than 100 beats per minute)	86
H. Local haemorrhage	41
I. Viscus perforation	5
J. Other	24
Not answered	130

Post-endoscopy complications

50. Complications/events in the 30 days after the procedure (Answers may be multiple)	
A. None	340
B. Viscus perforation	41
C. Upper or lower bowel haemorrhage	206
D. Subsequent related operation	67
E. Cardiac problems	241
F. Respiratory problems	603
G. Hepatic failure	127
H. Renal failure	177
I. Sepsis	317
J. Progress of medical condition	521
K. Stroke	57
L. Electrolyte imbalance	64
M. Haematological problems	45
N. Other	105
Not answered	162

51. Date of death	
Date of death	1,818

52. Death reported to the coroner	
Yes	442
No	1,212
Not answered	164

52a. If yes, coroner's post-mortem examination performed	
Yes	131
No	285
Not answered	26

52b. If no, hospital post-mortem performed	
Yes	13
No	901
Not answered	298

53. System(s) implicated in the patient's death (Answers may be multiple)	
A. Cardiovascular	586
B. Respiratory	935
C. Renal	266
D. Hepatic	329
E. Central nervous system	436
F. Not answered	279

54. Cause of death (according to the death certificate)	
1(a)	1,269
1(b)	771
1(c)	201
2	441
Cause of death - no certificate	436

55. Department of the endoscopist hold audit/morbidity/mortality meetings	
Yes	1,063
No	527
Not answered	228

55a. Case considered at an audit/mortality/morbidity meeting	
Yes	359
No	1,001
Not answered	458

55b. If no, case will be considered	
Yes	197
No	791
Not answered	13

56. Problems obtaining the patient notes	
Yes	231
No	1,453
Not answered	134

56a. If yes, number of weeks to get notes	
1- 10	165
11 -20	22
21-30	8
31-40	1
<40	3
Not answered	32

57. Position of person completing questionnaire where not the senior operating endoscopist (multiple answers)	
A. Chair of the department/lead clinician for endoscopy	731
B. Duty consultant	134
C. Non-consultant career grade	55
D. Trainee	36
E. Other	58

B. UPPER GASTROINTESTINAL DILATION AND TUBAL PROSTHESIS STUDY

1. Age	
10-19	12
20-29	37
30-39	107
40-49	204
50-59	445
60-69	606
70-79	827
80-89	566
90-99	103
Not answered	38

2. Sex	
Male	1,603
Female	1,323
Not answered	19

3. Operation - OPCS codes (Answers may be multiple)	
G15.2	860
G15.3	896
G15.4	320
G18.2	11
G18.3	137
G18.4	9
G44.1	242
G44.3	548

4. ASA Status	
1	634
2	957
3	806
4	226
5	0
Not answered	322

5. Underlying condition	
Malignant	1,052
Benign	1,784
Not answered	109

6. Specialty of most senior operator		
A. General physician		158
B. Specialised GI physician		1,497
C. General surgeon		164
D. Specialised GI surgeon		714
E. Radiologist		90
F. General Practitioner		23
G. Nurse Endoscopist		10
H. Other	Thoracic Surgeon	211
	ENT	48
	Paediatrics	1
	Not specified	9
Not answered		20

7. Grade of most senior operator	
A. Consultant	2,453
B. Associate specialist	73
C. Staff Grade	63
D. Clinical assistant/hospital practitioner	17
E. General practitioner	13
F. Nurse endoscopist	11
G. SpR – post CCST	46
H. SpR – year 3+	197
I. SpR – year 1/2	41
J SHO 9	9
K. Other	4
Not answered	18

8. Analgesia/anaesthesia used during the procedure	
A. None	22
B. Topical local anaesthetic	887
C. Intravenous sedation	1,605
D. General anaesthesia	405
Not answered	26

9. X-ray screening	
Yes	970
No	1,719
Not answered	256

10. Method of dilating oesophagus (Answers may be multiple)	
A. None	369
B. Graduated Bougie	1,370
C. Forced pneumatic balloon	193
D. General anaesthesia	869

11. Problems encountered during the procedure (Answers may be multiple)	
A. Perforated oesophagus followed by surgery	12
B. Perforated oesophagus followed by medical treatment	18
C. Oesophageal haemorrhage during or within 48 hours of procedure	10
D. Cardiac arrest during or within 48 hours of procedure	1
E. Respiratory arrest during or within 48 hours of procedure	1
F. Pulmonary aspiration during or within 48 hours of procedure	1
G. Chest infection during or within 48 hours of procedures	1
H. Sepsis secondary to procedure	0
Not answered	2,900

11. Problems encountered within 48 hours of procedure (Answers may be multiple)	
A. Perforated oesophagus followed by surgery	35
B. Perforated oesophagus followed by medical treatment	19
C. Oesophageal haemorrhage during or within 48 hours of procedure	4
D. Cardiac arrest during or within 48 hours of procedure	3
E. Respiratory arrest during or within 48 hours of procedure	3
F. Pulmonary aspiration during or within 48 hours of procedure	4
G. Chest infection during or within 48 hours of procedures	6
H. Sepsis secondary to procedure	3
Not answered	2,872

12. Patient died within 48 hours of procedure	
Yes	20
No	2,665
Unknown	143
Not answered	117

Questionnaire Assessment Form
GI Therapeutic Endoscopy - 2002/2003
Endoscopic Histopathology

☐☐☐☐☐☐ Questionnaire No. ☐ M ☐ F ☐☐☐ Age

Section A – Endoscopic Histopathology

1. Was a histopathological examination performed on samples taken at the endoscopy? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

2. If Yes, was the histopathology report forwarded? ☐ Yes ☐ No

3. Was clinical information included on the histopathology report? ☐ Yes ☐ No

3a. If Yes, is this clinical information relevant to the clinical problem? ☐ Yes ☐ No

4. Are the sites of the biopsy tissue samples correctly indicated on the pathology report? ☐ Yes ☐ No

5. Are the samples described macroscopically on the pathology report? ☐ Yes ☐ No

6. Does the histopathology report address/answer the clinical questions posed? ☐ Yes ☐ No ☐ Borderline ☐ Insufficient information to assess

7. Does the diagnosis line ('bottom line') contain a clear statement of the site(s) evaluated? ☐ Yes ☐ No

8. Does the diagnosis line ('bottom line') contain a clear statement of the pathology diagnoses or processes? ☐ Yes ☐ No

9. Are there any features that might be quoted in the NCEPOD report? ☐ Yes ☐ No

10. If Yes, please state:

_____

_____

_____

_____

_____

_____

_____

☐ Initials ☐ Date

Questionnaire Assessment Form
GI Therapeutic Endoscopy - 2002/2003
Endoscopy

Questionnaire No. | Sex | Age

Was the endoscopy ☐ Therapeutic ☐ Diagnostic If Diagnostic please exclude

Section A – Clinical Care

1. Was the endoscopic procedure appropriate for this patient? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

1a. If No, please specify why, multiple answers may be given:

☐ A A different endoscopic procedure was indicated.
☐ B Surgery in the first instance would have been more appropriate.
☐ C No endoscopic procedure was indicated.
☐ D Futile procedure
☐ E Other

1b. If Other, please state:

2. Was the timing of the procedure appropriate in the clinical interest of the patient? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

2a. If No, please specify why:

☐ A Late, delayed referral
☐ B Late, inappropriate prolonged resuscitation/optimisation
☐ C Late, other – please state:
☐ D Late, cause unknown
☐ E Early, further preoperative resuscitation/optimisation indicated
☐ F Early, other, please state:

(c)

(f)

3. Were appropriate investigations performed pre-endoscopy? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

4. Was the *grade* of the endoscopist performing this procedure appropriate for the condition of the patient? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess ☐ Senior endoscopist present

5. Was the *grade* of the endoscopist performing this procedure appropriate for the complexity of the procedure in this case? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess ☐ Senior endoscopist present

6. Was the *experience* of the endoscopist performing this procedure appropriate for the condition of the patient? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess ☐ Senior endoscopist present

7. Was the *experience* of the endoscopist performing this procedure appropriate for the complexity of the procedure in this case? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess ☐ Senior endoscopist present

8. Were two endoscopy assistants present during the procedure? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

9. Was the procedure performed under general anaesthesia? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

10. Was the patient already in receipt of intermittent positive pressure ventilation (e.g. in ICU)? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

11. Were there any deficiencies in monitoring during the procedure (equipment or personnel? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

11a. If Yes, please specify why:

☐ A No pulse oximetry

☐ B No ECG recording

☐ C No BP recording

☐ D No dedicated person to monitor the patient

☐ E Other, please specify:

(e) _____

_____

_____

_____

12. Was sedation used? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

12a. If Yes, was the sedation appropriate to the condition of the patient? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

12b. If No, please specify why:

☐ A Excessive opiate

☐ B Excessive benzodiazepine

☐ C Insufficient sedation

☐ D Other, please specify:

(d) _____

_____

13. Was the patient recovered in a dedicated recovery area? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

13a. If Yes, did dedicated recovery nurses staff the recovery area? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

14. Were there any deficiencies in monitoring during the patient's recovery (equipment or personnel?

☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

14b. If Yes, please specify why:

☐ A No pulse oximetry

☐ B No ECG recording

☐ C No BP recording

☐ D No dedicated person to monitor the patient

☐ E Other, please state:

(e) _____

_____

_____

_____

15. Were there any clinical deficiencies, other than those stated above?

☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

15a. If Yes, please state: _____

_____

_____

_____

Section B – Organisational Care

16. Were there any delays because of organisation issues?

☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

16a. If Yes, please specify why:

☐ A Should have been performed as an emergency

☐ B Inappropriate as it was out-of-hours

☐ C Delayed, previous list overrun

☐ D Delayed, for other emergency

☐ E Delayed, reason unknown

☐ F Other, please state:

_____

_____

_____

_____

17. Were there any deficiencies in communication within or between specialties in respect of this case?

☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

17a. If Yes, please state: _____

_____

_____

_____

18. Were there any other deficiencies in the organisation of this case? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

18a. If Yes, please state: _____

_____

_____

_____

Section C – Quality of data returned

19. Was the tick box information completed satisfactorily? ☐ Yes ☐ No

20. Was the case summary on page 2 completed? ☐ Yes ☐ No

21. Were the admission medical notes forwarded? ☐ Yes ☐ No

22. Were clinical notes relevant to the procedure forwarded? ☐ Yes ☐ No This may be the admission notes

22a. If Yes, were they sufficient to allow assessment of the case? ☐ Yes ☐ No

23. Was a monitoring chart for the procedure forwarded? ☐ Yes ☐ No

24. Was an endoscopy report for the procedure forwarded? ☐ Yes ☐ No

25. Was a discharge summary forwarded? ☐ Yes ☐ No

26. Do you have any other comments on the quality of the data? ☐ Yes ☐ No

26a. If Yes, please state: _____

_____

_____

_____

Section D – Endoscopic Histopathology

27. Was a histopathological examination performed on samples taken at the endoscopy? ☐ Yes ☐ No ☐ Undecided ☐ Insufficient information to assess

27a. If Yes, was the histopathology report forwarded? ☐ Yes ☐ No If Yes, please pass the case to the pathologists

28. Was clinical information included on the histopathology report? ☐ Yes ☐ No

28a. If Yes, was this clinical information relevant to the clinical problem? ☐ Yes ☐ No

29. Are the sites of the biopsy tissue samples correctly indicated on the pathology report? ☐ Yes ☐ No

30. Are the samples described macroscopically on the pathology report? ☐ Yes ☐ No

31. Does the histopathology report address/answer the clinical questions posed? ☐ Yes ☐ No ☐ Borderline ☐ Insufficient information to assess

32. Does the diagnosis line ('bottom line') contain a clear statement of the site(s) evaluated? ☐ Yes ☐ No

33. Does the diagnosis line ('bottom line') contain a clear statement of the pathology diagnoses or processes? ☐ Yes ☐ No

Section E - Autopsy

34. Was an autopsy performed? ☐ Yes ☐ No

34a. If Yes, was the autopsy report forwarded? ☐ Yes ☐ No

34b. If Yes, did it explain the clinico pathological circumstances well? ☐ Yes ☐ No

34c. If No, in your opinion, should an autopsy have been performed? ☐ Yes ☐ No

Section F – Summary Assessment of Care

NCEPOD considers the quality of care, not specifically the cause of death.

35. How would you categorise the quality of care of this patient?

☐ 1 Good practice – a standard you would accept from yourself, your trainees and your institution.

☐ 2 Room for improvement – in general this is given when the advisors note two or more aspects of care that could have been better, whether clinical or organisational

☐ 3 Less than satisfactory – This is a case in which the advisor has serious concerns about the patient care, although recognising that NCEPOD has incomplete information and does not know fully the local circumstances.

☐ 4 Insufficient information submitted to assess the quality of care.

36. Are there any features that might be quoted in the NCEPOD report? ☐ Yes ☐ No

36a. If Yes, please state:

_____

_____

_____

_____

_____

_____

_____

☐ Initials ☐ Date

Questionnaire Assessment Form
GI Therapeutic Endoscopy 2002/2003
Autopsy

☐☐☐☐☐☐ Questionnaire No. ☐ M ☐ F ☐☐ Age

Type of autopsy ☐ Hospital ☐ Coroner ☐ Other _____
Please specify

Section A – Demographics/clinical history

1. Does the report include the following?
   - ☐ A Name
   - ☐ B Hospital number
   - ☐ C Date of birth
   - ☐ D Date of death
   - ☐ E Location of death
   - ☐ F Name of consultant responsible
   - ☐ G Name of operator (if different)
   - ☐ H Location of autopsy
   - ☐ I Coronial jurisdiction ☐ n/a

2. Is a clinical history provided? ☐ Yes ☐ No

2a. If present is it ☐ Good ☐ Satisfactory ☐ Unsatisfactory

2b. If unsatisfactory please specify why:

_____

_____

_____

_____

3. Is the description of external appearances ☐ Good ☐ Satisfactory ☐ Unsatisfactory

3b. If unsatisfactory please specify why:

_____

_____

_____

_____

4. Was the patient's height recorded? ☐ Yes ☐ No

5. Was the patient's weight recorded? ☐ Yes ☐ No

6. Were scars and incisions measured? ☐ Yes ☐ No

7. Were IV line insertion, tubes etc. listed ☐ Yes ☐ No

8. Was the autopsy ☐ Full ☐ Limited

8a. If limited, please state which areas were not examined

_____

_____

_____

_____

9. Which organs were NOT weighed?
   - ☐ A Brain
   - ☐ B Lungs
   - ☐ C Heart
   - ☐ D Liver
   - ☐ E Spleen
   - ☐ F Kidneys

Section B – Gross Anatomy

10. Is the gross description of internal organs ☐ Good ☐ Satisfactory ☐ Unsatisfactory

10a. If unsatisfactory please specify why:

_____

_____

_____

_____

Section C – Operation (endoscopy) Site

11. Is the operation (endoscopy) site described? ☐ Yes ☐ No

12. Was the gross examination of the operation site appropriate to the clinico-pathological problem? ☐ Yes ☐ No

12a. If No, please specify why:

_____

_____

_____

_____

Section D – Organ Retention

13. Were whole or part organs retained? ☐ Yes ☐ No

13a. If retained, were they itemised? ☐ Yes ☐ No

14. Is the consent basis for organ retention clear from the report? ☐ Yes ☐ No

15. Were samples taken for histology? ☐ Yes ☐ No

15a. Were other samples taken e.g. toxicology ☐ Yes ☐ No

15b. If other samples were taken, please state:

_____

_____

_____

_____

16. If autopsy histology samples were taken, is the report included with the PM report? ☐ Yes ☐ No

16a. If Yes, was it ☐ Good ☐ Satisfactory ☐ Unsatisfactory

16b. If unsatisfactory, please specify why:

_____

_____

_____

_____

16c. If not taken, did the lack of histology detract significantly from the report in its account of answering the questions raised by death? ☐ Yes ☐ No

Section E – Clinico-pathological Summary

17. Is there a summary of lesions present? ☐ Yes ☐ No

18. Is there a clinico-pathological correlation and summary present? ☐ Yes ☐ No

18a. If Yes, is it? ☐ Good ☐ Satisfactory ☐ Unsatisfactory

18b. If unsatisfactory, please specify why:

_____

_____

_____

_____

Section F – Cause of Death Statement

19. Is an ONS cause of death present? ☐ Yes ☐ No

19a. If Yes, does it follow ONS formatting rules ☐ Yes ☐ No

20. Does the cause of death in Parts 1 or 2 include reference to the operation (endoscopy) and its date? ☐ Yes ☐ No

21. Does the cause of death in Parts 1 & 2 take into appropriate account the clinical course (including the endoscopy) and the autopsy findings? ☐ Yes ☐ No

21a. If No, please specify why:

_____

_____

_____

_____

22. Please tick one of the following as the main cause of death (i.e. main pathology, Part 1 of ONS statement)

☐ A Sepsis or significant organ infections (e.g. HIV related)

☐ B Malignant disease

☐ C Ischaemic heart disease

☐ D Pulmonary embolism

☐ E Other cardiovascular disease (non-malignant)

☐ F Cerebrovascular disease

☐ G Pneumonia

☐ H Aspiration pneumonia

☐ I Other lung disease (non-malignant)

☐ J Gastrointestinal disease (non-malignant)

☐ K Primary postoperative haemorrhage

☐ L Trauma

☐ M Cirrhosis

☐ N Medical intervention, including drug related

Please state: _____

☐ O Other

Please state: _____

☐ P Not stated

23. My overall score for this autopsy is:

- ☐ A Excellent (meets all standards set by RCPath booklet)
- ☐ B Good
- ☐ C Satisfactory
- ☐ D Poor
- ☐ E Unacceptable (laying the pathologist open to serious professional criticism)

Section G - Summary

24. Clinical Relevance – This autopsy report demonstrates (more than one answer will often apply):

- ☐ A Confirmation of essential clinical findings.
- ☐ B A discrepancy in the cause of death or in a major diagnosis, which if known, might have affected treatment, outcome or prognosis.
- ☐ C A discrepancy in the cause of death or in a major diagnosis, which if known, would probably not have affected treatment, outcome or prognosis.
- ☐ D A failure to explain some important aspect of the clinical problem, as a result of a satisfactorily performed autopsy.
- ☐ E A failure to explain some important aspect of the clinical problem, as a result of an unsatisfactory autopsy (performance and/or report).
- ☐ F A minor discrepancy.
- ☐ G An interesting incidental finding.

25. Are there any features that might be quoted in the NCEPOD report? ☐ Yes ☐ No

25a. If Yes, please state:

NATIONAL CEPOD

OESOPHAGEAL DILATION & TUBAL PROSTHESIS STUDY

This questionnaire should be completed for the following procedures:
G15.2, G15.3, G15.4, G18.2, G18.3, G18.4 (GI dilation and insertion of tubal prosthesis)
and for G44.1 & G44.3 (but only when the multiple procedure involved the oesophagus)

This form will be scanned. Please use a black pen and complete all questions with printed capitals or a bold tick.
If you make a mistake, please "black out" the box and re-enter the correct information.

Examples: [A][B][1][2][3] or: Yes [✓] No [ ] To correct an error: Yes [■] No [✓]

---

1. Age [ ][ ][ ] *(years)*

2. Sex [ ] Male [ ] Female

3. What operation was undertaken?

G15.2	Fibreoptic endoscopic balloon dilation of oesophagus	A
G15.3	Fibreoptic endoscopic dilation of oesophagus nec	B
G15.4	Fibreoptic endoscopic insertion of tubal prosthesis into oesophagus	C
G18.2	Endoscopic balloon dilation of oesophagus using rigid oesophagoscope	D
G18.3	Endoscopic dilation of oesophagus using rigid oesophagoscope nec	E
G18.4	Endoscopic insertion of tubal prosthesis into oesophagus using rigid oesophagoscope	F
G44.1	Fibreoptic endoscopic insertion of prosthesis into upper gastrointestinal tract	G
G44.3	Fibreoptic endoscopic dilation of upper gastrointestinal tract	H

4. What was the ASA status of the patient?

ASA1	A normal healthy patient	1
ASA2	A patient with a mild systemic disease	2
ASA3	A patient with severe systemic disease that limits activity but is not incapacitating	3
ASA4	A patient with incapacitating systemic disease that is a constant threat to life	4
ASA5	A moribund patient that is not expected to survive 24 hours with or without an operation	5

5. Which was the underlying condition? A. Malignant [ ] A B. Benign [ ] B

6. What was the specialty of the most senior operator?

A. General physician	A	E. Radiologist	E
B. Specialised GI physician	B	F. General practitioner	F
C. General surgeon	C	G. Nurse endoscopist	G
D. Specialised GI surgeon	D	H. Other (please specify)	H

Other (H) [ ]

please continue overleaf

7. What was the grade of the most senior operator?

Career grades

A. Consultant ☐ A

B. Associate specialist ☐ B

C. Staff Grade ☐ C

D. Clinical assistant/hospital practitioner ☐ D

E. General practitioner ☐ E

F. Nurse endoscopist ☐ F

Trainee grades

G. Specialist registrar – post CCST ☐ G

H. Specialist registrar – year 3/4/5 ☐ H

I. Specialist registrar – year 1/2 ☐ I

J. Senior house officer ☐ J

K. Other (please specify below) ☐ K

Other (K) ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

8. What analgesia/anaesthesia was used during the procedure? *(answers may be multiple)*

A. None ☐ A

B. Topical local anaesthetic ☐ B

C. Intravenous sedation ☐ C

D. General anaesthesia ☐ D

9. Was X-ray screening used? Yes ☐ No ☐

10. What was the method of dilating the oesophagus?

A. None ☐ A

B. Graduated bougie (e.g. Savary-Guillard/Celestin) ☐ B

C. Forced pneumatic balloon ☐ C

D. Through the endoscope balloon ☐ D

11. Were any of the following problems encountered during the procedure (i.e. within endoscopy suite/recovery room) or later? *(answers may be multiple)*

	During	Later
A. Perforated oesophagus followed by surgery	☐ A	☐ A
B. Perforated oesophagus followed by medical treatment	☐ B	☐ B
C. Oesophageal haemorrhage during or within 48 hours of the procedure	☐ C	☐ C
D. Cardiac arrest during or within 48 hours of the procedure	☐ D	☐ D
E. Respiratory arrest during or within 48 hours of the procedure	☐ E	☐ E
F. Pulmonary aspiration during or within 48 hours of the procedure	☐ F	☐ F
G. Chest infection during or within 48 hours of the procedure	☐ G	☐ G
H. Sepsis secondary to the procedure	☐ H	☐ H

12. Did the patient die within 48 hours of the operation? Yes ☐ No ☐ Not known ☐

Thank you for participating

Please return this form to the designated contact within your hospital

NATIONAL CEPOD

ENDOSCOPY UNIT QUESTIONNAIRE

This form will be electronically scanned. Please use a black or blue pen and complete all questions with either printed capitals or a bold cross. **For example:** A B 1 2 3 4

or: X (y) ☐ (n)

If you make a mistake, please "black out" the box and re-enter the correct information: ■ (y) X (n)

The hospital

1. Does this hospital have an Accident and Emergency department? ☐ (y) ☐ (n)

2. How many inpatient beds are there in this hospital?
   (Include obstetric and mental health beds) ☐☐☐☐

3. Does the hospital have the following facilities? (i.e. on the same geographical site)

	Not available	Available during working hours and limited out-of-hours	Available on call 24 hours-a-day
A. CT Scanner	☐	☐	☐
B. MRI scanner	☐	☐	☐
C. Angiography facility	☐	☐	☐
D. Interventional radiology	☐	☐	☐

Endoscopy facilities

Definitions
The endoscopy room is the room where endoscopies are performed.
The endoscopy unit is a complex of endoscopy rooms, recovery rooms and any attached rooms e.g. preparation/cleaning rooms.
Please give data for the financial year 2001/02

4. How many endoscopy rooms are there in the endoscopy unit? ☐☐

5. What is the total number of patients undergoing endoscopy within the hospital? ☐☐☐☐☐☐☐

6. What is the total number of patients undergoing endoscopy within the endoscopy unit as

A. a day case?

B. an inpatient?

7. Where are out-of-hours emergency endoscopies usually performed?
(please select only one answer)

A. Endoscopy unit

B. Main theatres

C. Not performed on this site

D. Other (please specify below)

Resuscitation

8. Do the endoscopy staff undergo regular update resuscitation training? y n

8a. If yes, how often?

A. More frequently than once a year

B. Every year

C. Every two years

D. Every three years

E. Other (please specify below)

9. Where is the nearest resuscitation trolley to the endoscopy rooms?

A. Within the endoscopy room

B. Shared between endoscopy rooms but within the endoscopy unit

C. Outside of the endoscopy unit

D. Other (please specify below)

10. Are the tables in the endoscopy room able to be tipped head down?
    - A. In all rooms ☐
    - B. In some rooms ☐
    - C. In no rooms ☐

11. Are the following drugs available in all endoscopy rooms? (as opposed to the endoscopy unit)
    - A. Naloxone ☐
    - B. Flumazenil ☐

12. Is piped oxygen available?
    - A. In all endoscopy rooms ☐
    - B. In some endoscopy rooms ☐
    - C. In no endoscopy rooms ☐

13. Is pulse oximetry available?
    - A. In all endoscopy rooms ☐
    - B. In some endoscopy rooms ☐
    - C. In no endoscopy rooms ☐

14. Is ECG monitoring available?
    - A. In all endoscopy rooms ☐
    - B. In some endoscopy rooms ☐
    - C. In no endoscopy rooms ☐

Recovery

15. Is there a dedicated recovery area within the endoscopy unit? ☐ y ☐ n

    If yes, how many spaces are there for:
    - A. Beds/trolleys ☐☐☐
    - B. Chairs ☐☐☐

16. Is piped oxygen available for each bed/trolley space in the recovery area? ☐ y ☐ n

17. Is pulse oximetry available for each bed/trolley space in the recovery area? ☐ y ☐ n

Personnel

18. How many endoscopy sessions per week are designated for the following staff?

	Total number of endoscopy sessions per week
Consultant	☐☐☐
Non-consultant career grade	☐☐☐
General practitioner	☐☐☐
Trainee	☐☐☐
Nurse endoscopist	☐☐☐

19. Is there an out-of-hours on call rota for the endoscopy staff? ☐ y ☐ n

Audit

20. Does the endoscopy department hold regular audit/governance meetings? ☐ y ☐ n
(as opposed to multidisciplinary team meetings)

If yes are these
- A. Medical audit (doctors only) ☐
- B. Clinical (multidisciplinary with all endoscopy staff) ☐

If yes how often?
- Weekly ☐
- Fortnightly ☐
- Monthly ☐
- Two monthly ☐
- >Two monthly ☐

If you have any queries, please contact the NCEPOD office on:

Tel: 020 7831 6430
Fax: 020 7430 2958
Email: info@ncepod.org.uk

Please return the completed questionnaire in the envelope provided to:
NCEPOD, 35-43 Lincoln's Inn Fields, London, WC2A 3PE

GI THERAPEUTIC ENDOSCOPY STUDY
2002/2003

QUESTIONNAIRE No. | | | | | | |

DO NOT PHOTOCOPY ANY PART OF THIS QUESTIONNAIRE ONCE COMPLETED

NCEPOD looks at clinical practice in order to identify remediable factors in the practice of medicine in its broadest sense. The advisors who read this questionnaire are not apportioning blame; our aim is to help clinicians to improve the care of patients. Neither the questions, nor the choices for answers, are intended to suggest standards of practice.

INSTRUCTIONS FOR COMPLETION

This questionnaire should be completed with reference to the final GI therapeutic procedure before death, of the patient specified by NCEPOD on the accompanying letter. This includes upper GI, lower GI, ERCP and PEG procedures. It should be completed even if there was a subsequent procedure performed before death.

Please use a black or blue pen, completing all questions using printed capitals.

Please answer all 'yes/no' or multiple choice questions with a tick (✓) in the appropriate box(es).

Please use the free text areas to clarify events and communicate your opinions.

PLEASE ENCLOSE THE FOLLOWING SINGLE SIDED PHOTOCOPIES:

- Admission medical clerking notes
- Any clinical notes relevant to the procedure, or to the patient's medical condition before or after the procedure
- Endoscopy report for the procedure
- Monitoring chart or anaesthetic chart covering the duration of the procedure
- Discharge summary
- Histology report(s)
- Post-mortem report

All correspondence with NCEPOD is confidential, and we advise you not to retain copies of your correspondence for legal reasons. This questionnaire and enclosures will be shredded when data collection and reporting is complete.

For further information or for assistance, please contact the NCEPOD office on:

Tel: 020 7831 6430
Fax: 020 7430 2958
email: info@ncepod.org.uk

1. Date of admission

d d m m y y

2. Admission method

A Elective day-case ☐ A
(i.e. admitted on the day of procedure and planned discharge on that day)

B Other elective ☐ B
(at a time agreed between patient and endoscopy services with planned in-hospital stay)

If elective (A or B) then date of decision to admit

d d m m y y

C Emergency ☐ C
(immediately following referral/consultation)

Case Summary

3. Please provide a brief summary of this case, adding any comments or information you feel relevant. Please write clearly for the benefit of the specialist advisory group who will be reviewing the questionnaires.

NCEPOD attaches great importance to this summary. Please give as much information as possible about the perioperative care of this patient.

4. Co-existing medical diagnoses (please specify as accurately as possible. Answers may be multiple)

A	None		A
B	Respiratory	COPD	B1
		Acute chest infection	B2
		Asthma	B3
C	Cardiac	Ischaemic heart disease/previous MI/angina	C1
		MI within three months of the endoscopy	C2
		Valvular heart disease	C3
		CCF (at present or in the past)	C4
D	Neurological	CVA/TIAs	D1
		Dementia	D2
		Acute confusion state	D3
		Psychiatric disease	D4
		Parkinson's disease	D5
E	Hepatic/pancreatic		E
F	Alimentary		F
G	Renal failure	Acute	G1
		Chronic	G2
H	Endocrine	Non-insulin dependent diabetes mellitus	H1
		Insulin dependent diabetes mellitus	H2
		Hypothyroidism	H3
I	Musculoskeletal		I
J	Haematalogical	Bleeding disorder	J1
		Immunosupression	J2
K	Sepsis (please specify site)		K

L Other (please specify) L

5. Did the patient have liver cirrhosis? ☐ y ☐ n

If Yes, what was the Childs-Pugh Score?

Category	Encephalopathy	Ascites	Bilirubin (micro mol.l^{-1})	Albumin (gm.l^{-1})	INR
A ☐	0	0	<34	>35	<1.3
B ☐	I/II	Mild/moderate	34-51	28-35	1.3-1.5
C ☐	III/IV	Severe	>51	<28	>1.5

6. ASA status

ASA1	(a normal healthy patient)	☐ 1
ASA2	(a patient with mild systemic disease)	☐ 2
ASA3	(a patient with severe systemic disease)	☐ 3
ASA4	(a patient with severe systemic disease that is a constant threat to life)	☐ 4
ASA5	(a moribund patient who is not expected to survive without the operation)	☐ 5

7. What was the anticipated risk of death within 30 days of the proposed endoscopic procedure?

A Not expected ☐ A

B Small but significant risk ☐ B

C Definite risk ☐ C

D Expected ☐ D

8. Patient's weight (if recorded) ☐☐☐.☐ kg

9. Patient's blood pressure at the start of the procedure ☐☐☐ / ☐☐☐ mmHg

10. Patient's heart rate at the start of the procedure ☐☐☐ per min

11. Pre-procedural investigations. Please tick each investigation performed and give the value where indicated

A	None	☐	
B	Haemoglobin	☐	☐☐.☐☐ $gm.dl^{-1}$
C	White cell count	☐	☐☐.☐☐ $x10^9.l^{-1}$
D	Platelets	☐	☐☐☐ $x10^9.l^{-1}$
E	INR	☐	☐☐.☐
F	Serum Na	☐	☐☐☐ m $mol.l^{-1}$
G	Serum K	☐	☐.☐ m $mol.l^{-1}$
H	Blood urea	☐	☐☐.☐ m $mol.l^{-1}$
I	Serum creatinine	☐	☐☐☐ micro $mol.l^{-1}$
J	Serum albumin	☐	☐☐ $gm.l^{-1}$
K	Blood glucose	☐	☐☐.☐ m $mol.l^{-1}$
L	Serum amylase	☐	☐☐☐ $IU.l^{-1}$
M	Total bilirubin	☐	☐☐☐ micro $mol.l^{-1}$
N	Blood gas analysis	☐	Inspired oxygen ☐☐ %
			pH ☐.☐☐
			$PaCO_2$ ☐☐.☐☐ kPa
			PaO_2 ☐☐.☐☐ kPa
O	Chest X-ray	☐	(please specify abnormalities)
P	ECG	☐	(please specify abnormalities)
Q	ECHO cardiography	☐	(please state findings)
R	Other (please specify)	☐	

Procedure

12. Date of procedure d d m m y y

13. Time of start of procedure (please use 24-hour clock) h h m m

14. Time of finish of procedure (please use 24-hour clock) h h m m

15. What procedures were performed?

Please also tick the appropriate box(es) below for OPCS coding of the *therapeutic* part(s) of the procedure (Q16 to Q19). For this study we are not reviewing diagnostic procedures. Then proceed to Q20 on page 9.

For **upper digestive tract (excluding PEGs)** please refer to **Q16a, Q16b & Q16c** (page 7)
For **PEGs** please refer to **Q17** (page 8)
For **lower digestive tract** please refer to **Q18** (page 8)
For **ERCP** please refer to **Q19** (page 9)

16. Upper digestive tract (excluding PEGs)

16a Oesophagus

	Fibreoptic oesophagoscope	Rigid oesophagoscope *(oesophagus or stomach)*
Snare resection of lesion	☐	☐
Laser destruction of lesion	☐	☐
Cauterisation of lesion (Argon beam)	☐	☐
Sclerotherapy of varices	☐	☐
Other destruction of lesion	☐	☐
Removal of foreign body	☐	☐
Balloon dilatation	☐	☐
Bougie dilatation	☐	☐

Insertion of tubal prosthesis ☐ ☐

Other (please specify below) ☐ ☐

16b **Upper GI tract, stomach to the proximal duodenum, using fibreoptic scope.**

Snare resection of lesion ☐

Laser destruction of lesion ☐

Cauterisation of lesion ☐

Sclerotherapy to lesion ☐

Other destruction of lesion ☐

Insertion of prosthesis ☐

Removal of foreign body ☐

Endoscopic dilatation of the pylorus ☐

Other (please specify below) ☐

16c **Remainder of the upper digestive tract**

	Duodenum	Jejunum	Ileum
Removal of lesion	☐	☐	☐
Dilatation of lumen	☐	☐	☐
Insertion of prosthesis	☐	☐	☐
Other (please specify below)	☐	☐	☐

Please go to Q20 (page 9)

17. **PEGs**

Creation of new (first) gastrostomy ☐

Creation of a second (subsequent) gastrostomy ☐

Replacement of gastrostomy feeding tube ☐

Removal of gastrostomy feeding tube ☐

Attention to a gastrostomy tube (not requiring removal) ☐

Other (please specify below) ☐

Please go to Q20 (page 9)

18. **Lower digestive tract**

Using -	Colonoscope	Fibreoptic sigmoidoscope	Rigid sigmoidoscope
Snare resection of lesion	☐	☐	☐
Cauterisation of lesion	☐	☐	☐
Laser destruction of lesion	☐	☐	☐
Cryotherapy	☐	☐	☐
Other destruction of lesion	☐	☐	☐
Dilatation of lumen	☐	☐	☐
Coagulation of blood vessel	☐	☐	☐
Removal of foreign body	☐	☐	☐
Insertion of tubal prosthesis	☐	☐	☐
Other (please specify below)	☐	☐	☐

Please go to Q20 (page 9)

19. **ERCP**

- Sphincterotomy sphincter of Oddi and insertion of calculus ☐
- Sphincterotomy sphincter of Oddi and insertion of tubal prosthesis ☐
- Sphincterotomy of accessory ampulla of Vater ☐
- Insertion of tubal prosthesis into both hepatic ducts ☐
- Insertion of tubal prosthesis into bile duct ☐
- Renewal of tubal prosthesis in bile duct ☐
- Removal of tubal prosthesis from bile duct ☐
- Dilatation of bile duct ☐
- Insertion of prosthesis into pancreatic duct ☐
- Renewal of prosthesis in pancreatic duct ☐
- Removal of calculus from pancreatic duct ☐
- Drainage of lesion of pancreas ☐
- Dilatation of pancreatic duct ☐
- Other (please specify below) ☐

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

20. Urgency of the procedure

- A **Elective** – Procedure at a time to suit both patient and operator ☐ A
- B **Scheduled** - Early procedure (usually within 3 weeks) but not immediately life saving (e.g. malignancy) ☐ B
- C **Urgent** - Procedure as soon as possible after resuscitation ☐ C
- D **Emergency** - Immediate life-saving procedure, resuscitation simultaneous with the procedure ☐ D

21. List any previous endoscopic procedures within the last 2 years, and their dates.

Date	Endoscopy procedure

We want to have more specific detail on the gastrointestinal findings before and during the endoscopy

For **upper digestive tract endoscopy** go to **Q22** (page 10)
For **PEG** go to **Q23** (page 11)
For **lower digestive tract endoscopy** please go to **Q24** (page 12)
For **ERCP** please go to **Q25** (page 12)

Upper digestive tract endoscopy

22. Which of the following conditions did the patient have at the time of the endoscopy?

	Diagnosed before this endoscopy	Diagnosed during this endoscopy
A Pharyngeal pouch	☐	☐
B Malignant oesophageal stricture	☐	☐
C Benign oesophageal stricture	☐	☐
D Achalasia	☐	☐
E Oesophageal diverticulum	☐	☐

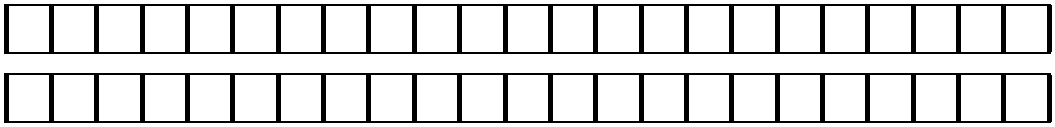
F Gastric ulcer ☐ ☐

G Gastric cancer ☐ ☐

H Duodenal ulcer ☐ ☐

I Pyloric stenosis ☐ ☐

J Other (please specify below) ☐ ☐



Go to Q26 (page 13)

PEGs

23. Which of the following conditions did the patient have at the time of the endoscopy?

A	Nutritional failure due to non-malignant disease		☐ A
B	Motor neurone/other degenerative disease		☐ B
C	Neurological disease	Acute (CVA, trauma etc)	☐ C1
		Chronic (degenerative neurological disease e.g. MS)	☐ C2
D	Dementia		☐ D
E	Malignancy	Oropharyngeal cancer	☐ E1
		Oesophageal cancer	☐ E2
		Gastric cancer	☐ E3
		Other	☐ E4

Go to Q26 (page 13)

Lower digestive tract endoscopy

24a Did the patient have a previous history of pelvic surgery e.g. hysterectomy? ☐ y ☐ n

24b Was the patient known to suffer from diverticular disease? ☐ y ☐ n

24c Had the patient previously had a "difficult" colonoscopy? ☐ y ☐ n

24d Did the patient have prior contrast examination? ☐ y ☐ n

24e Which of the following conditions did the patient have at the time of the endoscopy?

	Diagnosed before this endoscopy	Diagnosed during this endoscopy
A Diverticular disease	☐	☐
B Malignant stricture	☐	☐
C Benign stricture	☐	☐
D Pedunculated polyp(s)	☐	☐
E Flat polyp(s)	☐	☐
F Non-stricturing carcinoma	☐	☐
G Angiodysplagia	☐	☐
H Ulcerative colitis	☐	☐
I Crohn's disease	☐	☐
J Other	☐	☐

Go to Q26 (page 13)

ERCP

25. Which of the following conditions did the patient have at the time of the endoscopy?

	Diagnosed before this endoscopy	Diagnosed during this endoscopy
A Bile duct stone (possible/definite)	☐	☐
B Bacterial cholangitis	☐	☐

C Benign biliary stricture	☐	☐
D Malignant biliary stricture	☐	☐
E Carcinoma of the pancreas	☐	☐
F Acute pancreatitis	☐	☐
G Chronic pancreatitis	☐	☐
H Sclerosing cholangitis	☐	☐
I Choledochal cyst	☐	☐
J Other	☐	☐

26. Was written consent obtained for the procedure? ☐ y ☐ n

27. Did the patient receive antibiotic prophylaxis for the procedure? ☐ y ☐ n

Movement of the patient through the hospital/endoscopy unit

28. What was the pathway for this referral?

A Admission following an outpatient consultation	☐ A
B Direct referral from a general practitioner (open access)	☐ B
C Admission via A&E	☐ C
D Tertiary referral from within own hospital	☐ D
E Transfer from another hospital or general practitioner endoscopy unit	☐ E
F Self-referral by patient	☐ F
G Other (please specify)	☐ G

29. If a tertiary referral which specialty

A Care of the elderly A

B Other medical B

C Surgical C

D Other (please specify) D

30. Which department of the hospital was the patient in immediately before the procedure?

A A&E department A

B Emergency admissions unit B

C Medical ward C

D Surgical ward D

E Day case ward E

F Out-patient department F

G High dependency unit G

H Intensive care unit H

I Other (please specify) I

31. Where was the procedure performed?

A Dedicated endoscopy unit/room ☐ A

B Day-case surgery unit ☐ B

C Operating theatres ☐ C

D X-ray department ☐ D

E ICU/HDU ☐ E

F A&E ☐ F

G Admission unit or A&E ward ☐ G

H Other ward (please specify) ☐ H

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

I Other (please specify) ☐ I

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

32. Where was the patient nursed *immediately* after the procedure?

A A dedicated recovery area within the endoscopy unit ☐ A

B A dedicated recovery area within the operating theatres department ☐ B

C ICU ☐ C

D HDU ☐ D

E General ward ☐ E

F Died during the procedure ☐ F

G Other (please specify) ☐ G

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

33. If the patient went initially to a dedicated recovery area where did they go next?

A ICU ☐ A

B HDU ☐ B

C Directly to the operating theatre for an operation ☐ C

D General ward ☐ D

E Died in the recovery area ☐ E

F Home ☐ F

Operating endoscopist

34. What was the specialty of the most senior operating endoscopist?

A Specialised GI physician ☐ A

B Other physician ☐ B

C Specialised GI surgeon ☐ C

D Thoracic surgeon ☐ D

E Other surgeon (please specify) ☐ E

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

F Radiologist ☐ F

G General practitioner ☐ G

H Nurse practitioner ☐ H

I Other (please specify) ☐ I

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

35. What was the grade of the most senior operating endoscopist?

Career grades

A Consultant ☐ A

B Associate specialist ☐ B

C Staff grade ☐ C

D General practitioner ☐ D

E Nurse practitioner ☐ E

Trainee grades and year of training

F Specialist registrar – post CCST ☐ F

G Specialist registrar – year 3/4/5 ☐ G

H Specialist registrar – year 1/2 ☐ H

I Senior house officer ☐ I

J Other trainee (please specify) ☐ J

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

36. Which higher diplomas did the most senior operating endoscopist hold at the time of the procedure, and their dates?

		Year
A None	☐	☐☐☐☐
B Full Fellowship or Membership of a Royal Medical College	☐	☐☐☐☐
C Part Fellowship or Membership of a Royal Medical College	☐	☐☐☐☐
D ENB course A87	☐	☐☐☐☐
E Other (please specify)	☐	☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐		☐☐☐☐

If the procedure performed was on the **upper digestive tract**, please answer **Q37** (page 17)
If the procedure performed was a **PEG**, please answer **Q38** (page 18)
If the procedure performed was on the **lower digestive tract**, please answer **Q39** (page 18)
If the procedure performed was an **ERCP**, please answer **Q40** (page 18)

37. How many upper digestive tract therapeutic endoscopic procedures had the senior operator performed in the last 12 months? *(please tick one box)*

<5	6-10	11-20	21-50	51-100	>100
☐	☐	☐	☐	☐	☐

Go to Q41 (page 18)

38. How many PEG procedures had the senior operator performed in the last 12 months? *(please tick one box)*

<5	6-10	11-20	21-50	51-100	>100
☐	☐	☐	☐	☐	☐

Go to Q41 (page 18)

39. How many lower digestive tract therapeutic endoscopic procedures had the senior operator performed in the last 12 months? *(please tick one box)*

<5	6-10	11-20	21-50	51-100	>100
☐	☐	☐	☐	☐	☐

Go to Q41 (page 18)

40. How many ERCP procedures had the senior operator performed in the last 12 months? *(please tick one box)*

<5	6-10	11-20	21-50	51-100	>100
☐	☐	☐	☐	☐	☐

41. Has the senior operating endoscopist attended a formal course of instruction in the use of sedation techniques? ☐ y ☐ n

42. If the senior operator was *not* a consultant or general practitioner where was the consultant supervising this operator available?

A A consultant was in, or came to the operating/endoscopy room during the procedure ☐ A

B A consultant was in the operating/endoscopy unit but not directly involved with the case ☐ B

C A consultant was available in the hospital, but not present in the operating/endoscopy unit ☐ C

D A consultant was not in the hospital but was available by phone ☐ D

E Other (please specify) ☐ E

Sedation and the monitoring of events during the procedure

43. What forms of sedation and analgesia were used during the procedure? *(answers may be multiple)*

A None ☐ A

B Local anaesthesia ☐ B

C Intravenous opiate sedation ☐ C

Drug used

Total dose

D Intravenous benzodiazepine sedation ☐ D

Drug used

Total dose

E Other intravenous sedation (please specify) ☐ E

Drug used

Total dose

44. Did the patient receive either of the following?

A Naloxone ☐ A

B Flumazenil ☐ B

45. Which of the following patient monitors were used? *(Answers may be multiple)*

A Pulse oximetry ☐ A

B ECG ☐ B

C Automatic non-invasive blood pressure ☐ C

D Manual non-invasive blood pressure ☐ D

E Invasive blood pressure ☐ E

F CVP ☐ F

G None of the above ☐ G

46. Was oxygen administered to the patient during the procedure? ☐ y ☐ n

47. Who was the person mainly responsible for continuously monitoring the general condition of the patient during the procedure?

A A qualified nurse ☐ A

B The operator ☐ B

C An anaesthetist ☐ C

D Another doctor ☐ D

E A radiographer ☐ E

F An operating department assistant ☐ F

G A support worker/health care worker ☐ G

H Not known ☐ H

48. Is there a monitoring chart for the procedure in the patient's notes? ☐ y ☐ n

If so, please enclose a photocopy of this chart

49. Did any critical incidents occur during the procedure? *(Answers may be multiple)*

A None ☐ A

B Cardiac arrest ☐ B

C Respiratory arrest ☐ C

D Hypoxaemia (SpO_2 90% or less) ☐ D

E Pulmonary aspiration ☐ E

F Hypotension (systolic less than 100mm Hg) ☐ F

G Tachycardia (more than 100 beats per minute) ☐ G

H Local haemorrhage ☐ H

I Viscus perforation ☐ I

J Other (please specify) ☐ J

Post-endoscopy complications

50. What complications/events were there in the 30 days after the procedure?
(Answers may be multiple)

A None ☐ A

B Viscus perforation ☐ B

C Upper or lower bowel haemorrhage ☐ C

D Subsequent related operation (please specify below) ☐ D

E Cardiac problems ☐ E

F Respiratory problems ☐ F

G Hepatic failure ☐ G

H Renal failure ☐ H

I Sepsis (please specify the source) ☐ I

J Progress of medical condition ☐ J

K Stroke ☐ K

L Electrolyte imbalance ☐ L

M Haematological problems ☐ M

N Other (please specify) ☐ N

51. What was the date of death? ☐☐ d d ☐☐ m m ☐☐ y y

52. Was the death reported to the coroner? ☐ y ☐ n

a. If Yes, was a coroner's post-mortem examination performed? ☐ y ☐ n

b. If No, was a hospital post-mortem performed? ☐ y ☐ n

53. Which of the following system(s) were implicated in the patient's death?

A	Cardiovascular	☐	A
B	Respiratory	☐	B
C	Renal	☐	C
D	Hepatic	☐	D
E	Central nervous system	☐	E

54. What was the cause of death (according to the death certificate)?

1(a)

1(b)

1(c)

2

If death certificate not available, please state the clinical cause of death

55. Does the department of the endoscopist hold audit/morbidity/mortality meetings? ☐ y ☐ n

a. Has this case been considered at an audit/mortality/morbidity meeting? ☐ y ☐ n

b. If not, will it be? ☐ y ☐ n

56. Did you have any problems obtaining the patient notes? ☐ y ☐ n
(e.g. more than one week)

a. If Yes, how many weeks did they take to reach you? ☐☐ weeks

57. If you were not the senior operating endoscopist and have filled this questionnaire on behalf of another please state your position

A Consultant responsible for the patient ☐ A

B Chair of the department/lead clinician for endoscopy ☐ B

C Duty consultant ☐ C

D Non-consultant career grade (please specify below) ☐ D

E Trainee (please specify below) ☐ E

F Other (please specify below) ☐ F

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE

REMINDER

Have you enclosed photocopies of:	**Enclosed**	**Not available**	**Not applicable**
• Admission medical clerking notes	☐	☐	☐
• Any clinical notes relevant to the procedure, or to the patient's medical condition before or after the procedure	☐	☐	☐
• Endoscopy report for the procedure	☐	☐	☐
• Monitoring chart or anaesthetic chart covering the duration of the procedure	☐	☐	☐
• Discharge summary	☐	☐	☐
• Histology report(s)	☐	☐	☐
• Post-mortem report	☐	☐	☐

If you wish to inform NCEPOD of any other details of this case, please do so on a separate sheet and remember to write the number of this questionnaire on the sheet.

You are advised for legal reasons not to keep a copy of this questionnaire, since this would form a part of the patient's medical record. All material sent to NCEPOD is destroyed when data collection is complete.

Please return the questionnaire and accompanying papers in the reply-paid envelope provided.

APPENDIX A. GLOSSARY

American Society of Anesthesiologists (ASA) classification of physical status

ASA 1: A normal healthy patient.
ASA 2: A patient with mild systemic disease.
ASA 3: A patient with severe systemic disease.
ASA 4: A patient with severe systemic disease that is a constant threat to life.
ASA 5: A moribund patient who is not expected to survive without the operation.
ASA 6: A declared brain-dead patient whose organs are being removed for donor purposes.

Childs-Pugh classification

A classification (A,B,C) used to determine the severity of liver cirrhosis based on physiological factors.

Category	Encephalopathy	Ascites	Bilirubin (micro mol.1^{-1})	Albumin (micro mol.1^{-1})	INR
A ☐	0	0	<34	>35	<1.3
B ☐	I / I I	Mild / moderate	34-51	28-35	1.3-1.5
C ☐	I / I V	Severe	>51	<28	>1.5

Classification of operation (NCEPOD definition)

EMERGENCY: Immediate life-saving operation, resuscitation, simultaneous with surgical treatment (e.g. trauma, ruptured aortic aneurysm). Operation usually within one hour.

URGENT: Operation as soon as possible after resuscitation (e.g. irreducible hernia, intussusception, oesophageal atresia, intestinal obstruction, major fractures). Operation within 24 hours.

SCHEDULED: An early operation but not immediately life-saving (e.g. malignancy). Operation usually within three weeks.

ELECTIVE: Operation at a time to suit both patient and surgeon (e.g. cholecystectomy, joint replacement).

APPENDIX B. ABBREVIATIONS

Abbreviation	
ASA	American Society of Anesthesiologists
BMA	British Medical Association
BSG	British Society of Gastroenterology
CCF	Chronic Cardiac Failure
COPD	Chronic Obstructive Pulmonary Disease
CPD	Continuing Professional Development
CT	Computed Tomography
CVA	Cerebrovascular Accident (stroke)
CVP	Central Venous Pressure
DGH	District General Hospital
DPA	Data Protection Act
ECG	Electrocardiogram
ERCP	Endoscopic Retrograde Cholangiopancreatography
GA	General Anaesthetic
GI	Gastrointestinal
GMC	General Medical Council
GP	General Practitioner
HES	Hospital Episode Statistics
HDU	High Dependency Unit
ICU	Intensive Care Unit
INR	International Normalised Ratio
IPPV	Intermittent Positive Pressure Ventilation
IV	Intraveneous
LA	Local Anaesthetic
LV	Left Ventricular
MCCD	Medical Certificate of Cause of Death
ME	Medical Examiner (proposed as part of coroner reforms)
MI	Myocardial Infarction
MRI	Magnetic Resonance Imaging
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NSAID	Non-Steroidal Anti-Inflammatory Drug
OGD	Oesophagogastroduodenoscopy
ONS	Office of National Statistics
OPCS	Office of Population, Census and Surveys
PAS	Patient Administration System
PEG	Percutaneous Endoscopic Gastrostomy
SAC	Specialist Advisory Committee
SHO	Senior House Officer
SpR	Specialist Registrar
StHA	Strategic Health Authority
TIA	Transient Ischaemic Attack

APPENDIX D. DEATHS REPORTED TO NCEPOD

INTRODUCTION

Prior to 1 April 2002, NCEPOD collected data on deaths occurring within 30 days of a surgical procedure performed by a surgeon or gynaecologist. These data acted as a sample pool from which to select study cases. However, since 1 April 2002, the remit of NCEPOD has been extended to include medical as well as surgical deaths, regardless of whether a procedure was performed. So for the first time since the inception of NCEPOD, data were requested on ALL inpatient deaths regardless of length of stay in hospital. This dataset then acted as a sample pool from which to identify the cases of GI therapeutic endoscopy relevant to this study. The extension to the dataset resulted in a greater than tenfold increase in the number of deaths reported to NCEPOD on an annual basis and the sample endoscopy cases selected for this study represented only a small proportion of the data.

DATA COLLECTION

The data presented in this chapter relates to all inpatient deaths occurring between 1 April 2002 and 31 March 2003. Data were reported from all acute NHS Trusts in England, Wales and Northern Ireland and Primary Care Trusts where appropriate. Data were also reported from Guernsey, the Isle of Man, the independent sector and the Defence Secondary Care Agency.

In each hospital a nominated member of staff acts as a local link between the hospital and NCEPOD and is known as the NCEPOD local reporter. A member of the clinical governance, audit or information department most commonly fills the role as the data collection requirements of NCEPOD have evolved and the use of electronic data increased. Data on inpatient deaths was, in the majority, submitted on a password-protected spreadsheet, for which a template was provided. Whilst most hospitals were able to meet this request, in fact some found it easier than the previous data selection of 30 day deaths as no filtering was required, a small proportion of hospitals were unable to generate the information from their patient administration system (PAS). In such cases, a paper form was completed for each death. As full electronic submission was a new process for NCEPOD some initial difficulties were to be expected. However, even after one year it was extraordinary that some hospitals were not able to provide basic information on patients that had died in hospital either electronically or manually.

DATA ANALYSIS

Exclusions

Unlike many previous NCEPOD reports, the criteria by which cases were excluded were minimal. Previously cases would have been excluded if the procedure was minor such as the insertion of an intravenous infusion or if a physician performed it. For the first time no such exclusions were made. However, only data returned before the deadline of 31 July 2003 were included.

Cleaning

Once data collection had closed, all data in the database were cleaned to ensure that the data in each field was of the same format and that date fields such as date of birth, date of admission and date of death were all in the correct order, e.g. date of procedure was after date of birth and before date of death, and procedure codes were held in the same way as the Hospital Episode Statistics (HES) data, to make comparisons easier. All duplicate records were removed.

OVERVIEW OF DATA RECEIVED

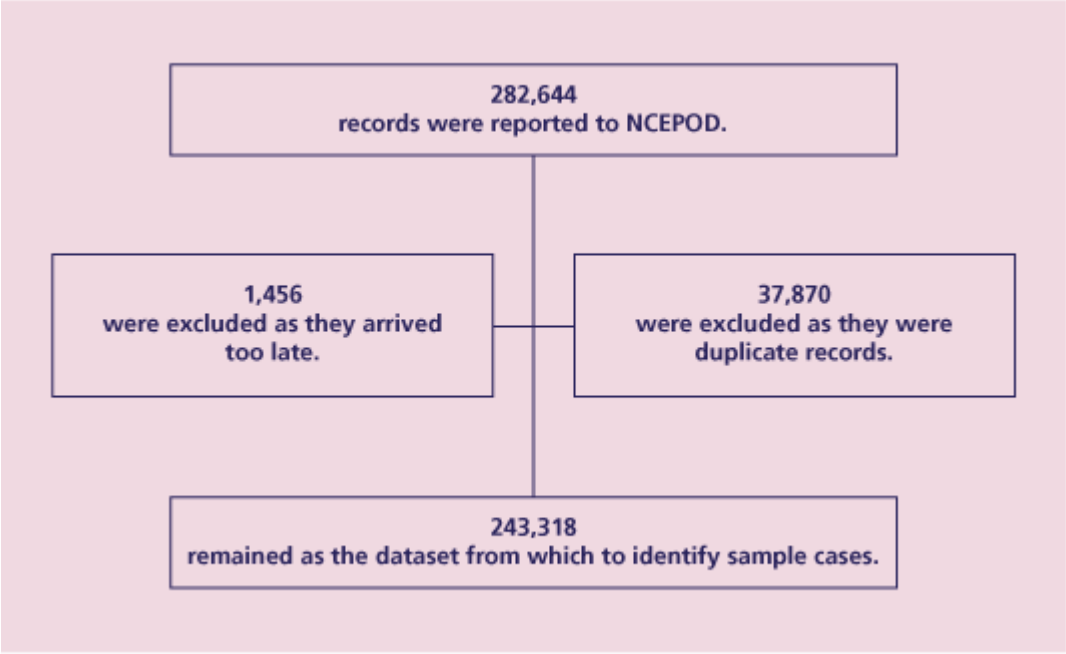


Figure 22. Numbers of records received (inpatient deaths 2002/03)

This year saw a dramatic increase in the percentage of duplicate records submitted; 13% compared with approximately 1% last year (Figure 22). The main reason for this, which had not been predicted, was the ability to provide cumulative submissions with updated records during the year. As the PAS records became more complete, data were re-submitted to replace the record held.

Duplicate records were accepted initially to ensure a more accurate dataset, only being deleted once the dataset was complete. The percentage of data returned after the deadline was very similar to last year: 0.5% compared with 0.4%.

Regional spread

Since the introduction of Strategic Health Authorities (StHA) the previous regional boundaries used by NCEPOD no longer apply. NCEPOD's current database does not facilitate the display of deaths by StHA therefore Table 83 shows the number of deaths reported to NCEPOD by country or sector.

Table 83. Number (%) of inpatient deaths by region

Region	2002 - 03 *n=243,318*	*(%)*	2001 - 02 *n=20,130*	*(%)*
England	221,100	*(91)*	18,342	*(91)*
Wales	14,929	*(6)*	1,093	*(5)*
Northern Ireland	4,902	*(2)*	436	*(2)*
Guernsey	319	*(<1)*	22	*(<1)*
Jersey	No cases reported		16	*(<1)*
Isle of Man	382	*(<1)*	31	*(<1)*
Defence Secondary Care Agency	0	*(0)*	0	*(0)*
Independent	1,686	*(0.7)*	190	*(0.9)*

Interestingly, it can be seen from Table 83 that despite the enormous increase in the total number of deaths recorded by NCEPOD, the percentage spread has changed very little, indicating a consistent return of data from hospitals.

Completeness of data

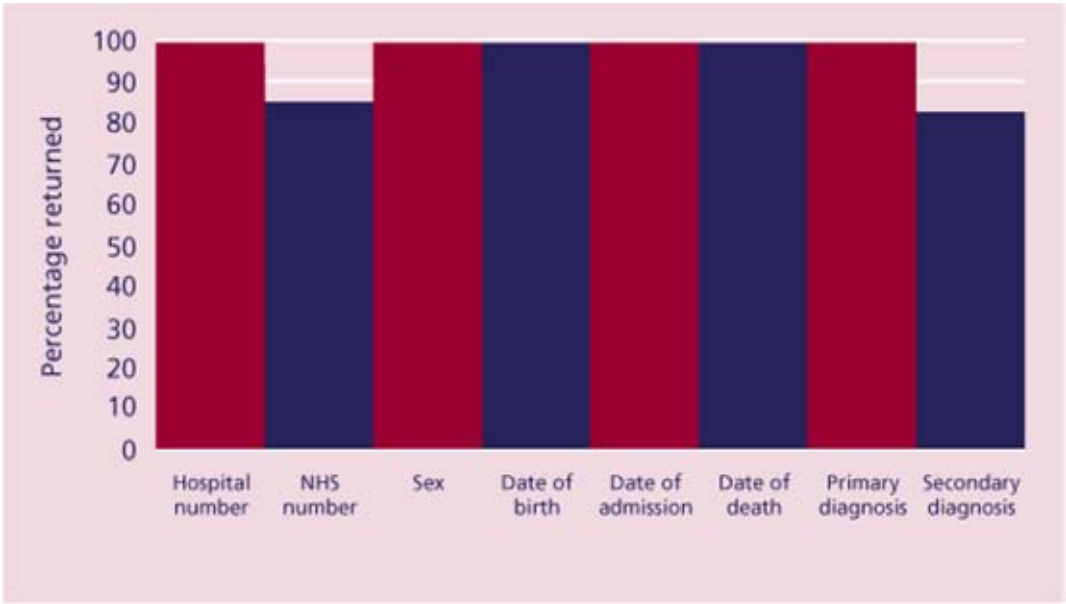


Figure 23. Completeness of data returned

The dataset was reviewed to determine how well fields were completed and the results are displayed in Figure 23. Dates of birth and dates of death were obtained for all patients, as these were required fields. The hospital casenote number was absent in less than 1% (105/243,318) of records compared with the NHS number that was absent in 15% (36,573/243,318), although these include the majority of cases from the independent sector who do not use an NHS number routinely. Of the diagnosis fields, primary diagnosis was absent in less than 1% (199/243,318) of the cases compared with first subsidiary (secondary) diagnosis, which was absent 18% (43,377/243,318) of the time. The sex of the patient could not be supplied in 8 (<1%) of the cases and the date of admission in 47 (<1%).

Age and sex

As the new remit included all deaths it was anticipated that a slight reduction in the mean age of patients would have been seen this year. However, despite the dataset being more than ten times larger, with a median (range) age of 80 (<1 to 109) years, the age distribution are comparable with those reported in previous NCEPOD reports (Figure 24).

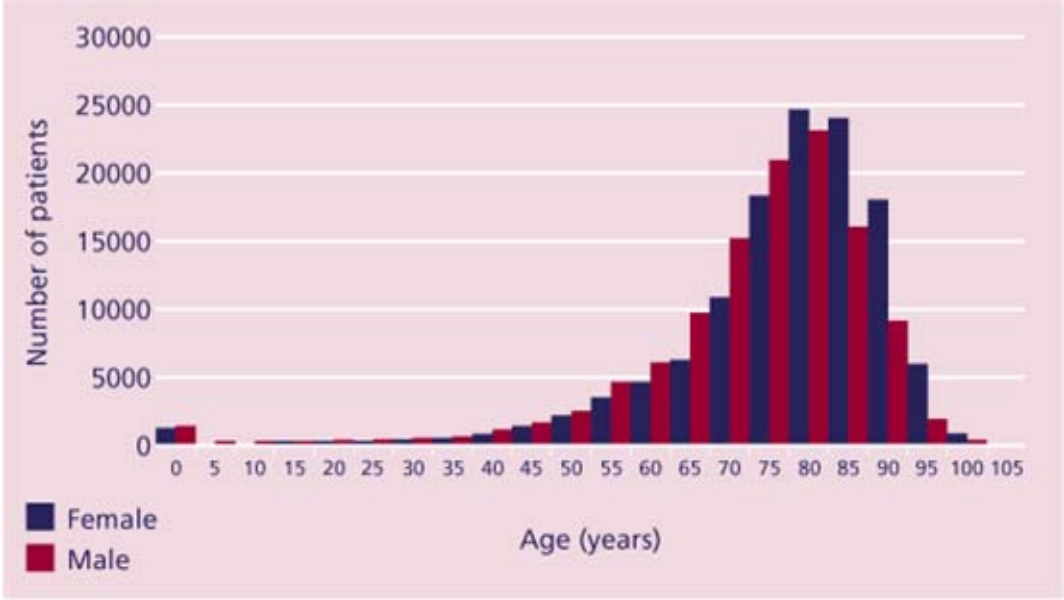


Figure 24. Distribution of age and sex (Inpatient deaths 2002/03)

Duration between admission and death

It can be seen from Figure 25 that more patients died during the first three days following admission than on any subsequent three-day period. Whilst that has been seen in previous NCEPOD reports following surgery, it is interesting to note that these data were similar regardless of whether a procedure was performed or not. It is likely therefore that this simply reflects the fact that many patients admitted to hospital, especially for no procedure, are extremely ill.

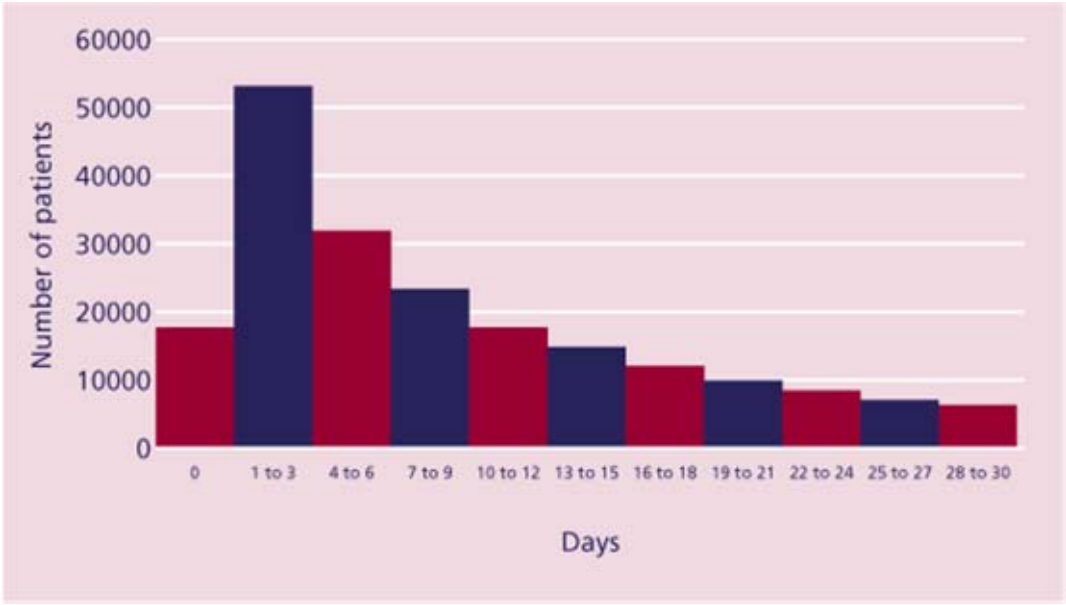


Figure 25. The duration between admission to hospital and death for all patients

Final primary diagnosis

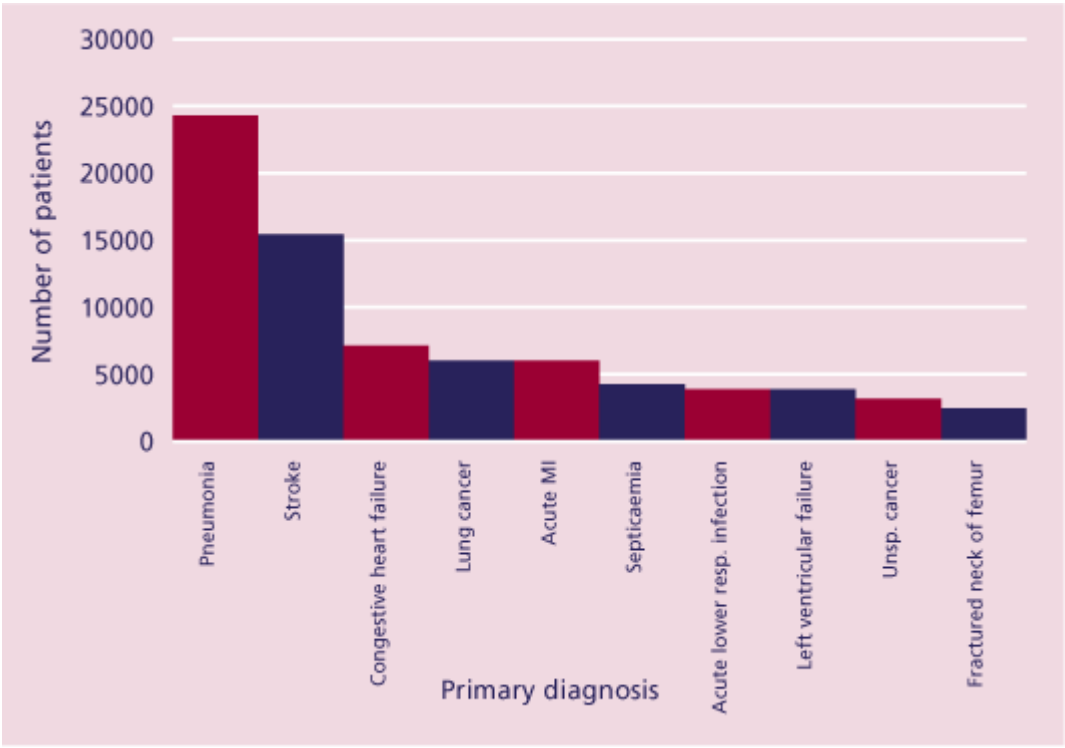


Figure 26. Ten most common final primary diagnoses

Figure 26 displays the most common primary diagnoses for inpatient deaths.

Procedures performed

For the dataset, we requested that the last six procedures prior to death be recorded. Of the 243,318 cases, 69,536 (29%) patients had at least one procedure performed. However, where data on procedures were not supplied it is not possible to state for certain that a procedure was not performed, simply that the data were not available.

COMPARISON OF DEATH DATA FROM NCEPOD AND HOSPITAL EPISODE STATISTICS

NCEPOD has previously been involved with comparative studies between the data submitted to NCEPOD and the data submitted to HES. These studies have shown inconsistent differences between the two datasets in reference to the number of deaths reported to each from the same Trusts. However, such comparisons have always been performed on specifically filtered data e.g. deaths within 30 days of a surgical procedure and any difference in definitions between the two datasets would automatically introduce errors. Therefore, as NCEPOD had data on all inpatient deaths for the 2002-03 data year, it was felt to be a more robust dataset with which to compare the HES dataset of the same year. However, instead of comparing the total number of deaths reported to each dataset by the same Trust, both datasets were sampled for cases of GI therapeutic endoscopy to determine whether by sampling directly from HES, the same sample group, as used in this report, would have been identified.

The HES dataset for all inpatient deaths in England NHS Trusts during 1 April 2002 to 31 March 2003 was obtained by NCEPOD following approval by the Department of Health's Security and Confidentiality Advisory Group.

To ensure an accurate comparison only acute English NHS Trusts were selected from the NCEPOD and the HES datasets. This gave a total of 213,855 records from NCEPOD and a total of 262,293 records from HES.

Both datasets were then sampled for the last therapeutic gastrointestinal endoscopy performed within 30 days of death, using the OPCS codes defined in the chapter outlining the study method.

Matching of the two sets of sample cases was then performed over a number of stages, described below. Whilst the ideal match would be based on a number of fields, the more fields added to match on, the more likely there would have not been a match due to slight differences in the data available and missing data. The method adopted was to match initially on only NHS number and casenote number and then to manually compare the data to confirm the matched status by looking at the remaining fields.

Stage 1 Cases were matched if both the NHS number and the casenote numbers were identical.

Stage 2 Cases were matched on NHS number alone. These were then checked manually to ensure the data in the other fields confirmed the match.

Stage 3 The remaining unmatched samples from each dataset were compared with all the non-sample cases in the opposing dataset to determine if a match was not being found because it had not been identified as a sample case but was recorded as a death.

Stage 4 All remaining samples that had not been matched to a sample case or to a death record were reviewed individually. Matching was attempted using date of birth, date of death and date of admission and comparing all fields in any matches to identify simple reasons why the cases had not matched, e.g. NHS number not available, casenote number was different, unavailable or had an additional letter in one dataset and the date of admission was different by one day. In such a case, the source hospital was checked to ensure that they matched and all fields were compared. If the records matched on hospital plus three other dates from birth, admission, death and procedure they were granted as matching. Figure 27 provides an overview of the results.

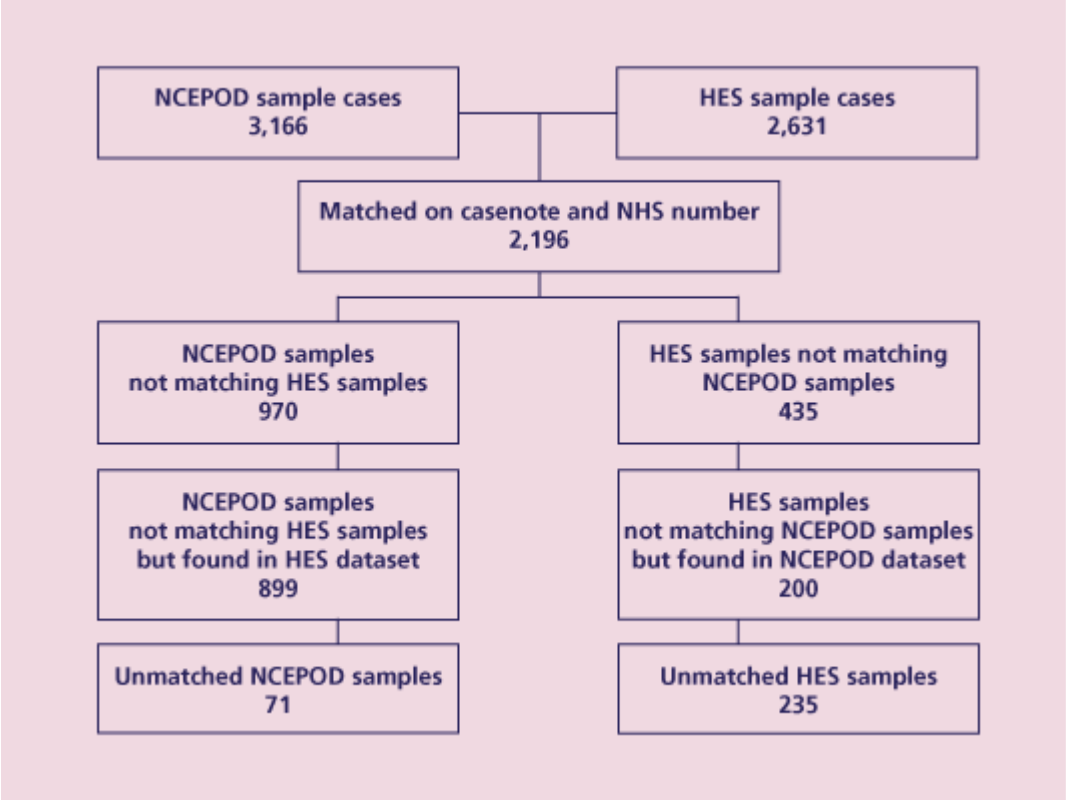


Figure 27. Overview of the samples obtained from comparing the NCEPOD and HES datasets

Of the 2,196 samples that matched, only 30 did not have the same type of endoscopy for the final endoscopic procedure e.g. one was upper GI and one was lower GI. Only 61 did not have identical codes but were the same type of procedure e.g. PEG instead of upper GI, which was a common difference in coding.

Whilst an acceptable level of matching was found, the most common reasons for cases not matching were due to simple, yet important differences in the datasets. Often casenote numbers/NHS numbers were supplied in one dataset and not the other. More worryingly was that when the NHS number was not supplied, matching often failed because the casenote number was completely different, even though the cases were from the same hospital and were identical in every other way.

The most important points of concern to highlight from this analysis are that firstly, in 899 of the 970 unmatched NCEPOD samples the cases had been reported to HES but endoscopy procedure codes had not been provided. This may indicate that hospitals had been more diligent in ensuring that endoscopic cases were reported to NCEPOD; to check this, the analysis will need to be repeated using an unrelated sample group. However, it may also indicate that the HES data were cleaner. The data in HES are updated regularly throughout the year, which may mean that incorrect procedure codes had been removed. Secondly, in 235 of 435 cases reported to HES, the death was not reported to NCEPOD at all. These cases will need to be analysed in more detail to identify why this discrepancy occurred and relay this information back to Trusts so that we can help ensure the robustness of future datasets.

It can be seen from these data that neither reporting system is perfect. However, more deaths were reported to HES than to NCEPOD and only 71 records in the NCEPOD dataset could not be found in the HES data, which is an encouraging finding that will hopefully be consistent when the analysis is repeated with a different sample group.

If NCEPOD had used the HES dataset as the sample pool then a significant sample would have been identified and could have been used for the study. The major concern is that of obtaining the data from HES. The data used in this exercise were not available until eight months after the end of the 2002-03 financial year. It would have been hard to expect a clinician to complete a questionnaire on a patient that they may have seen up to 20 months previously. However, with the advent of the new National Programme for Information Technology (NPfIT) system for hospitals it is hoped that in time data transfer will become quicker and more easily available and identification of problems in the datasets now can only work to aid that process.

FUTURE COLLECTION OF DATA ON ALL INPATIENT DEATHS

All data held by NCEPOD is done so with a firm respect and compliance with confidentiality laws, even though regulations such as the Data Protection Act (DPA) 1998[1] do not apply to data from deceased patients, NCEPOD applies the same policy to all patient data held. As the third principle of the DPA 1998 states that 'data collected should be relevant to the purpose for which it is being collected and the quantity collected should be appropriate' it has been decided that collection of data on all inpatient deaths should cease. NCEPOD will utilise alternative sampling methods for future studies. One method, and the initial approach, will be to request that hospitals sample directly from their patient administration system (PAS) and identify information relevant only to a particular study. A second option will be for NCEPOD to continue to work with the Department of Health's Hospital Episode Statistics (HES) to identify what and why discrepancies between the two datasets occur so that in future NCEPOD may sample directly from HES. Due to the changing nature of NCEPOD studies it is no longer appropriate to routinely collect data on deaths occurring in hospitals and therefore on 1 April 2004 NCEPOD ceased collection of this dataset.

[1] *Data Protection Act 1998* – Principles. Information Commissioner's Office, 1998.
http://www.hmso.gov.uk/acts/acts1998/80029--l.htm#sch1ptI

APPENDIX E. ADVISORS

A C Bateman Consultant Histopathologist	Southampton University Hospitals NHS Trust
I D Botterill Consultant in General Surgery & Coloproctology	The Leeds Teaching Hospitals NHS Trust
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Consultant Anaesthetist	Hospitals NHS Trust
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Consultant Histopathologist	Hospitals NHS Trust
R McMahon	Central Manchester and Manchester
Consultant Histopathologist	Children's University Hospitals NHS Trust
A Mee	Royal Berkshire and Battle
Consultant Physician/Gastroenterologist	Hospitals NHS Trust
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Consultant Gastroenterologist	Edinburgh
A B Price	North West London
Consultant Histopathologist	Hospitals NHS Trust
M H Robinson	Queen's Medical Centre Nottingham
Consultant Colorectal Surgeon	Hospitals NHS Trust
R M Slater	Central Manchester and Manchester
Consultant Anaesthetist	Children's University Hospitals NHS Trust
E T Swarbrick	The Royal Wolverhampton
Consultant Physician/Gastroenterologist	Hospitals NHS Trust
J Tillett	Cardiff and Vale
Endoscopy Unit Manager	NHS Trust
A Wyman	Sheffield Teaching
Consultant Surgeon	Hospitals NHS Trust

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- The local reporters in each hospital who work tirelessly to ensure full participation by their organisation
- All those clinicians who contributed to the study by completing questionnaires
- The advisors whose names are listed in ' Appendix E Advisors ' in the appendices section
- The organisations who provide the funding to cover the cost of the Enquiry who are listed here:

National Institute for Clinical Excellence
Department of Health, Social Services and Public Safety (Northern Ireland)
States of Guernsey Board of Health
Department of Health and Social Security, Isle of Man Government
Aspen Healthcare
Benenden Hospital
BMI Healthcare
BUPA
Capio Health Care UK
Covenant Healthcare Ltd
Cromwell Hospital
Fairfield Independent Hospital
HCA International Ltd
Hospital of St John & St Elizabeth
King Edward VII Hospital
King Edward VII's Hospital Sister Agnes
McIndoe Surgical Centre
Mount Alvernia Hospital
North Wales Medical Centre
Nuffield Hospitals
St Anthony's Hospital
St Joseph's Hospital
The Foscote Private Hospital
The Heart Hospital
The Horder Centre
The Hospital Management Trust
The London Clinic
The New Victoria Hospital
The Orchard Hospital
The Spencer Wing

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