Reducing risks in gastroenterological practice

Summary
Eighty five malpractice claims against gastroenterologists have been analysed. Thirty seven (44%) arose from adverse events as a result of endoscopy and 48 (56%) from clinical practice. In 31 (84%) of the endoscopy cases (including all 13 endoscopic retrograde cholangiopancreatographies) there seemed to be significant fault. In nine cases the procedure was not clearly indicated and in 10 recognition and treatment of the adverse event was delayed. In no case had the patient given adequate informed consent. Diagnostic error was responsible for most of the claims related to clinical practice (31 of 48) of which 13 were indefensible. Failure to obtain an adequate history (17 cases) and insufficient awareness of disorders of the small intestine (12 cases) were major factors. In 26 cases a key investigation was not performed. Seventeen claims were related to management or treatment but only one of these cases was difficult to defend.

Overall, there was evidence of serious fault in 50% of claims. Greater care in selecting patients for endoscopic procedures and in providing postprocedural care would have eliminated the basis of more than half the claims arising from endoscopy. There would have been few claims if properly informed consent had been obtained. Over-ready acceptance of the diagnosis of a functional disorder (for example, irritable bowel, dyspepsia) was the usual cause of delays in diagnosis.

Doctors have been slow to face up to the problem of adverse events in hospital practice. In the United Kingdom there are few published data on medical accidents but as the number of complaints and claims increases, trusts are beginning to set up risk management teams to identify and eliminate problems. At present the concept is in its infancy. Satisfactory systems for the reporting and analysis of adverse events in the United Kingdom have not been published except for surgical operations (data from the confidential enquiry into peri-operative deaths) and the reports on confidential enquiries into maternal deaths.

Over the past decade I have been asked to assess about 250 claims, of which one third have been against gastroenterologists. In this article I have attempted to classify the problems in order to try to help practising gastroenterologists avoid the daunting prospect of claims against them for medical negligence.

Materials and methods
Between 1987 and 1996, 85 successive requests for a medical opinion on a claim of medical negligence levelled against gastroenterologists have been analysed (81 cases were from England and Wales; two from Northern Ireland and two from the Republic of Ireland). One half of these cases were submitted in the past three years.

Copies of the full case notes and relevant radiographs were received together with general practitioner records, associated correspondence and statements of patients and relatives. Each case was assessed on the written evidence and a report was written describing what had happened as far as this could be determined.

In this study the cases have been classified according to the nature of the adverse event and the surrounding circumstances. The aim of the study is to formulate guidelines for reducing risks and claims of clinical negligence against gastroenterologists.

Results
Of the claims, 44% arose from adverse events as a result of endoscopic procedures and 56% from clinical practice (table 1). In about 50% of cases there was clear evidence of fault and in about one third the clinician had clearly deviated from standard medical practice.

ADVERSE EVENTS ARISING FROM ENDOCOPIC PROCEDURES
Endoscopic procedures gave rise to claims either as a result of complications (n=31) (table 2) or missed diagnoses (n=6). In 31 of the 37 cases there seemed to be significant fault and there was no evidence to show that any of the patients had given adequate informed consent for the procedure.

Thirteen cases were related to endoscopic retrograde cholangiopancreatography (ERCP) and in all but one there was a case to be answered. In seven of the cases the indication for the procedure was at best uncertain. In five cases patients underwent diagnostic ERCP early in the investigation of unexplained abdominal pain (and sphincterotomy was performed in two of these cases); in the other two instances ERCP was performed for unexplained diarrhoea (steatorrhoea had not been demonstrated and ultrasound examination of the pancreas had not shown an abnormality). Post-ERCP all seven patients had life threatening illness (acute pancreatitis in four and perforations in three) and two died. Nine of 13 claimants stated that they would not have brought a case had they received an adequate explanation of the risks of the procedure. In three

Table 1 Classification of 85 claims (53 men, 32 women) against gastroenterologists

<table>
<thead>
<tr>
<th>Claim</th>
<th>Number (%)</th>
<th>M/F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arising from endoscopic procedures</td>
<td>37 (44)</td>
<td>22/15</td>
</tr>
<tr>
<td>Arising from clinical practice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missed diagnoses</td>
<td>31 (36)</td>
<td>17/14</td>
</tr>
<tr>
<td>Problems in management</td>
<td>9 (11)</td>
<td>7/2</td>
</tr>
<tr>
<td>Drug reactions</td>
<td>6 (7)</td>
<td>5/1</td>
</tr>
<tr>
<td>As a result of a procedure</td>
<td>2 (2)</td>
<td>2/0</td>
</tr>
</tbody>
</table>

Table 2 Claims arising from complications of endoscopic procedures (31 cases)

<table>
<thead>
<tr>
<th>Complication associated with:-</th>
<th>Poor indication</th>
<th>Technical problem</th>
<th>Poor aftercare</th>
</tr>
</thead>
<tbody>
<tr>
<td>OGD</td>
<td>-</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Dilatation of the oesophagus</td>
<td>-</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Diagnostic ERCP</td>
<td>5</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Operative ERCP</td>
<td>2</td>
<td>4*</td>
<td>2</td>
</tr>
<tr>
<td>Sigmoidoscopy</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Polypectomy</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>9</td>
<td>14</td>
</tr>
</tbody>
</table>

*Including one problem with sedation.
cases neither the operator nor a member of the unit team saw the patient before the procedure. These patients were accepted for ERCP on the basis of requests from other clinical teams.

Technical problems were identified in three cases. In two of these the operators seemed not to have had replacements for defective sphincterotomes and in the third case the operator failed to recognise that failure to cannulate the common bile duct was due to an impacted stone. Rather surprisingly only one claim was related to sedation. In this case the operator struggled for 40 minutes to remove a stone from the common bile duct in a patient habituated to alcohol. The patient developed extreme surgical emphysema.

In five of the 13 ERCPs which led to adverse events there was significant delay in diagnosis and in the provision of adequate aftercare. Three of the patients were managed in general wards in which the medical and nursing staff were inexperienced and two of these patients died.

Oesophago-gastro-duodenoscopy (OGD) led to 10 claims and, although for the most part these seem to have been precipitated by one-off events, analysis reveals some important points. Three technical problems were identified. Firstly, it may be difficult to intubate the oesophagus in an elderly person and thereby perforate the pharynx. Secondly, it is possible to perforate an apparently normal duodenum when taking biopsy samples with standard endoscopic forceps. Finally, ulcer sclerotherapy is not without risk. In an attempt to stop bleeding from a duodenal ulcer an endoscopist injected both adrenaline and sodium tetradecylsulphate around the crater. Subsequently, the first part of the duodenum necrosed and another with unrecognised toxic dilatation. Delayed recognition of infection hampered the recovery of the other two patients.

Six other claims against endoscopists were related to failure to diagnose existing pathology. Three cancers in the stomach were missed: one pre-pyloric cancer was misdiagnosed as a circumferential duodenal ulcer and no biopsy samples were taken; one cancer was inadequately biopsied; and a third was an ulcer thought to be malignant but the histologist missed the carcinomatous cells on two separate occasions and the reports were accepted at face value by the endoscopist. Two duodenal ulcers were missed by experienced endoscopists. One of these was a chronic ulcer 1 cm in diameter from which the patient bled and died at home a week later. Coeliac disease was missed in one patient because the endoscopist reported the appearance of the stomach and duodenum as normal and neither the endoscopist nor the referring clinician took note of the histological report on the duodenal biopsy.

Accidents associated with dilatation of the oesophagus led to six claims. In all six cases the patients claimed that the risks had not been explained adequately. In three cases patients with persisting discomfort were discharged from hospital and in one case the patient was admitted to the ward but inadequately reviewed over a weekend and died without intervention.

Only seven claims arose from perforations associated with sigmoidoscopy or colonoscopy. Two of these cases were clearly high risk (one with acute colitis and the other with a non-functional shrunken colon) and the information required could have been obtained from radiological studies.

### ADVERSE EVENTS ARISING FROM GASTROENTEROLOGICAL PRACTICE

Forty eight claims arose from what claimants perceived to be negligence in clinical practice (table 3). There were 31 claims for missed diagnoses, of which 13 were difficult to defend. In the other 18 the diagnoses were not readily apparent and it was possible to explain to the plaintiffs why the clinician had been misled. The failure to make a diagnosis usually stemmed from the taking of inadequate case histories, especially in the cases of gastric and small intestinal pathology. Forty per cent of the missed diagnoses related to diseases of the small intestine. In eight of these cases appropriate radiological examination had not been requested or had not been interpreted correctly.

In the cases of large bowel disease there were four cases of colitis which were inadequately diagnosed. Two of these patients died: one with a delayed diagnosis of perforation and another with unrecognised toxic dilatation. Delayed recognition of infection hampered the recovery of the other two patients.

Suspected liver and gall bladder disease provided only three cases. One of these was a serious miss. A man from the Caribbean presented with persistent pyrexia and progressive ascites. He was in hospital for a month before
he died of tuberculous peritonitis superimposed on compensated cirrhosis. The medical registrar prescribed anti-tuberculosis chemotherapy but after five days this treatment was discontinued on the grounds of insufficient evidence for the presumed diagnosis.

Finally, in this group there were two patients in whom the primary pathology was outside the gastrointestinal tract. One presented with headache and a small haematomatous. He was diagnosed as Mallory-Weiss syndrome. Four weeks later he was shown to have a cerebral tumour. The other had epigastric discomfort which in retrospect was due to secondary hepatic cancer. A chest x-ray three months later revealed cancer of the lung.

Nine claims arose from alleged mismanagement of known pathology (one duodenal ulcer; three coeliac disease; three ulcerative colitis; and two functional disorders). In these cases there was no clinical fault other than poor communication in two cases and failure to obtain a second opinion in a patient with what appeared to be coeliac disease resistant to treatment.

Six claims arose from drug induced disease (table 4). Four of these cases were rare side effects of treatment with salazopyrine and it is difficult to see how they could have been avoided. One patient had a normocytic normochromic anaemia for several months which was not investigated. When the patient was admitted to hospital for an infusion of iron she found to have renal failure secondary to interstitial nephritis.

Two claims were made because of an adverse event occurring as a result of a side-room procedure. One patient developed a large haematoma as a result of an attempt at transternal biopsy of the liver performed by a very experienced clinician. The other suffered perforation of the gall bladder during a third unsuccessful attempt at liver biopsy by a junior house officer who was being taught by a registrar with limited experience.

**Discussion**

Risks in life may be reduced by analysing the nature of accidents and trying to set up fail-safe situations. In clinical practice this may seem difficult because of the infinite variability of patients and their diseases and because it is not possible to control doctor–patient interactions in the way in which one can control machines. In this article no attempt has been made to analyse the psychology of making errors. The interested reader should refer to appropriate sources.²⁻⁸

The development of endoscopic procedures has probably increased the risk of claims against gastroenterologists by about 50% (the data in this article do not allow an accurate assessment because the numbers are small and because they do not include claims of negligence arising from the general physician component of the work of gastroenterologists). The importance of endoscopy is emphasised for two reasons. A prospective audit in 1991 revealed a rate of 0.05% for perforation during OGD and 2.6% as a result of dilatation of the oesophagus.¹¹ These figures suggest that each year in the United Kingdom there are probably several hundred iatrogenic perforations of the oesophagus. It is impossible to estimate what percentage are due to malpractice but a patient who has not been warned of the risk will naturally assume that the perforation should not have occurred. Also, in this survey it would seem that over one third of the adverse events arising from endoscopy could have been prevented and that most of the resulting claims would never have been made had the patients been provided with sufficient information to give adequate informed consent.

The following key points emerge:

- Endoscopic examination should be not undertaken lightly. This is particularly true for ERCP, a procedure which carries risks equivalent to those of some open surgical operations. A careful clinical assessment is necessary. ERCP is not a reasonable initial screening test in the investigation of abdominal pain or diarrhoea. Special care should be taken with ERCP in women, particularly when there is no evidence of dilated ducts.¹² In this study eight women and four men made claims as a result of disease caused by ERCP. This the reverse of the sex ratio for all other claims (table 1).
- Patients must give properly informed consent.¹³¹⁴ This means ensuring that the patient understands the nature of the procedure; why it is proposed; the likely benefits; and the associated risks. This should be regarded as equally true for other invasive procedures.
- Ideally, the patient should be told when the procedure is to be undertaken by a trainee¹⁵ and trainees should never be left unsupervised as occurred in at least two of the cases described (OGD leading to a perforated pharynx and colonoscopy causing perforation of a severely ulcerated colon). Training should be the responsibility of the most experienced endoscopists. Again, this true for all invasive procedures (note the case of the repeated attempts at biopsy of the liver which led to perforation of the gall bladder).
- It is wiser to give up than to struggle with faulty equipment. Similarly, it is unwise to struggle with a poorly sedated patient although this clearly a matter of judgement. If necessary the effects of the sedative drugs administered should be reversed and the situation explained to the patient who may be prepared to grin and bear the procedure under topical anaesthesia. Alternatively, the endoscopist may need the help of a skilled anaesthetist.
- Incorrect endoscopic diagnoses may be prevented by obtaining adequate biopsy samples from lesions and/or material for cytological examination and by ensuring a fail-safe mechanism for the checking the results of histological reports.
- Any patient who has significant discomfort after an endoscopic procedure must be admitted for observation and appropriate investigation (for example, gastrografin swallow after dilatation of the oesophagus). All patients and their relatives should be given a clear statement what to do after leaving the endoscopy unit if their recovery does not proceed smoothly.
- The endoscopist has a direct responsibility for the aftercare of patients admitted to the ward. In this study in six of 10 cases management was left in the hands of inexperienced ward staff for more than four hours.

Diagnostic error in clinical practice provides almost all the other valid claims for negligence against gastroenterologists. This is more difficult to guard against because although most patients will accept that procedures carry risks, they expect perfection in diagnosis. Nevertheless, there are some common threads running through the cases described in this article which are important.

- An adequate case history is essential for diagnosis.¹⁶ In at least one third of cases leading to claims the recorded history was cursory. In two cases the probable diagnosis was mentioned in the referral letters and supporting evidence was available in the hospital case notes. Without
an adequate history the key investigation may be missed (table 3).

- Beware the patient with intermittent severe pain (colic). If necessary ask the patient to attend the emergency department to be assessed when in pain. Appropriate investigation, such as a straight radiograph of the abdomen for intermittent intestinal obstruction, may reveal the cause.

- Beware the diagnosis of irritable bowel syndrome, especially if the diagnosis does not fit easily. For example, it is not reasonable to diagnose an irritable bowel without investigation for a man who first has symptoms at the age of 55 years (he had non-steroidal anti-inflammatory drug gastritis) nor if the symptoms are atypical such as persistent diarrhoea with yellow stools (the patient had giardiasis). It is probably unwise to make a diagnosis of irritable bowel in a hospital outpatient clinic solely on the basis of the clinical history without investigation and without review.

- Patients with colitis who are clearly sick need inpatient care and assessment to establish whether or not there is an infective component and to guard against complications. The four cases in this study suggest that this is more than an occasional problem.

- Finally, when in doubt, it is good practice to get a second opinion. This reassures both the doctor and the patient, and also provides good protection against claims of negligence.

Claims rarely arise from problems in management unless there is an associated diagnostic problem, but it seems that some patients wish to hold doctors responsible for the side effects of drugs. It is sensible to mention these especially if the diagnosis does not fit easily. For example, it is probably unwise to make a diagnosis of irritable bowel in a hospital outpatient clinic solely on the basis of the clinical history without investigation and without review.

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