Gastro-Intestinal Endoscopy in General Practice

Summary
Increasing emphasis on primary care in the NHS has prompted suggestions that a number of services should be provided in General Practice. This report addresses the possibility of providing gastrointestinal endoscopy in General Practice.

Commissioners of health care are responsible for ensuring access to high quality, safe, endoscopic services. Careful consideration of the safety of potential providers, as well as the capital and revenue costs is essential: duplication of services must be avoided.

For the safety of both patients and staff, the following standards must be met wherever endoscopy is performed:

1. Endoscopists must be adequately trained. Endoscopic and interpretive skills must be maintained by a sufficient workload and continuing interaction with other endoscopists and specialists.
2. Adequate equipment must be available, together with safe facilities for its cleaning and maintenance.
3. Providers must adhere to professional guidelines for sedation, monitoring and recovery.
4. There must be sufficient numbers of trained and experienced support staff.
5. A safe environment must be provided, to comply with HSE and COSHH regulations.
6. Anaesthetic and resuscitation facilities must be provided on site for the management of complications of sedation and procedures, particularly for patients at risk because of age or medical condition.

Because of the risks, therapeutic gastroscopy, colonoscopy, ERCP and endoscopy in children should be confined to hospitals, where support for the management of complications is present.

Conclusions
Providers of endoscopy must conform to standards both of safety for staff and patients and of the quality of the services. Some endoscopic procedures could be provided in General Practice if these standards are met. However, it seems likely that it would not be possible or cost-effective to provide the level of support required for anything other than routine
diagnostic gastroscopy and flexible sigmoidoscopy in fit adults and even there, the case is in doubt.

Endoscopy in General Practice
1. Introduction
This report has been prepared to present the views of the British Society of Gastroenterology on the possible developments of Gastro-intestinal Endoscopy in General Practice. It has been prepared in response to the N. H S. Management Executive Guidelines on "G.P. Fundholding Practices: The Provision of Secondary Care" (H.S.G.(93) 14) (1) which have stimulated enquiries from Members of the B.S. G., Regional Managers General Practitioners and the Medical Defence Societies. It is hoped that it will help those who have expressed interest and concern on this issue and ensure that any such development meets the required standards for the provision of Gastro-Intestinal services and is to the benefit of patients.

Fundamental changes in the National Health Service have lead to a widespread debate on the most appropriate and cost effective provision of health care. Purchasers, whether they be District Health Authorities or G.P. fundholders are seeking value for money and cost effectiveness. Endoscopy is an expensive investigation and there is a widely perceived need for greater access.

Endoscopy based in General Practice might seem to be an attractive alternative; many General Practitioners already perform regular endoscopy lists as G.P. clinical assistants in hospital Endoscopy Units.

As a result of the Government initiative on the provision of secondary care, G.P. Fundholders will now be permitted to use their own funds for providing certain non General Medical Services to their own patients. These services include upper gastro-intestinal endoscopy and sigmoidoscopy. The guidelines clearly state that "Regions must be satisfied that procedures will be carried out by suitably qualified and experienced practitioners and that the premises are suitable". The issues of training, qualifications, experience and premises are of prime concern because they are the essentials for safe practice in endoscopy.

It seems unlikely that the majority of general practitioners would wish to provide these services but if the standards of skill, staffing and facilities can be provided to enable endoscopy to be carried out efficiently and safely within general practice then there is no reason for this not to happen. Funding authorities and purchasers must however, be sure that
the capital and revenue expense is justified and that the diversion of resources into primary care does not diminish the availability and the quality of the service provided by District General Hospitals where the majority of diagnostic and all therapeutic endoscopy will continue.

The B.S.G. has taken a responsible lead in establishing standards of practice, staffing levels, patient safety and training in endoscopy.

1.1 The demand for Endoscopy
In the British Society of Gastroenterology Report "Provision of Gastro-Intestinal Endoscopy and Related Services for a District General Hospital" published in 1990, evidence was cited to show that the annual consultation rate for new episodes of dyspepsia presenting in three large general practices varied between 0.7% and 2.7% of the population (2). An endoscopic survey showed that about 1/3 had a peptic ulcer or scar and 1/3 had some other lesion; only 1-2% had carcinoma. (3) The need for accurate diagnosis in the management of upper gastrointestinal dyspepsia is greater than hitherto because specific and potent drug treatments are now available for the treatment of reflux oesophagitis, peptic ulcer and gastritis.

Units which offer open access endoscopy for general practitioners have shown that referrals for upper gastro-intestinal endoscopy now total about 1% of the population annually and it has been suggested that the demand will continue to rise until this figure is reached in most districts. (4) In a recent prospective audit of upper gastro-intestinal endoscopy in two regions of England the median endoscopy rate for the population studied was 0.66%, (range 0.12% - 1.74%). In only 6 of the 26 Districts studied did the rates exceed 1%. (5) The perceived need for greater access to diagnostic endoscopy is therefore likely to be real.

Colonoscopy has become an important investigation in the management of large bowel disease. Because of the ability to immediately obtain histological samples and because therapeutic manoeuvres such as polypectomy are safe and simple, colonoscopy is frequently undertaken in preference to barium studies as a primary investigation. While rigid sigmoidoscopy is a safe, simple, inexpensive procedure which can be performed during an ordinary physical examination it is being displaced increasingly by fibre sigmoidoscopy which enables the sigmoid colon and even the descending colon to be examined more easily. The technique is relatively easy to learn.
The demands for colonoscopy and fibre sigmoidoscopy far exceed the availability in the U.K. and these services will inevitably expand rapidly in the next few years. (6) While the Working Party consider that colonoscopy is too hazardous to be undertaken in general practice, unsedated fibre-sigmoidoscopy would be suitable in the community provided that the level of training, staffing, equipment and volume of work can ensure high quality.

1.2 Therapeutic Endoscopy
The working party considers interventional procedures such as oesophageal dilatation, palliative intubation, polypectomy., are too hazardous to be considered outside fully equipped hospitals with back up facilities such as resuscitation teams, critical care, radiology and surgical services.

In any situation where endoscopic diagnosis is likely to lead to immediate intervention it would be appropriate that the patient undergoes the initial endoscopy in a hospital setting: for example the investigation and management of dysphagia and GI bleeding. Avoidable repeat endoscopy is unjustifiable.

2. Endoscopy Services and Training
2.1 Training of Endoscopists
Gastro-intestinal Endoscopy using fibre-optic instruments is a complex skill requiring a period of formal training and further experience with close supervision. Without this training the not insignificant risks to the patient are greatly increased.

It is no longer acceptable for endoscopy to be performed by untrained medical staff assisted by part-time helpers with no experience. High standards of patient care, avoidance of complications, accuracy in diagnosis, appropriate therapeutic manoeuvres and cost effective use of equipment depend on an endoscopy service being provided by skilled professionals. Formal training is essential for all endoscopy unit staff, medical, nursing and ancillary. Continuing education is also essential.

Gastro-intestinal endoscopy may be performed by different medical personnel with a special interest and training in the techniques, including physicians (usually gastroenterologists), surgeons, radiologists, hospital practitioners, staff specialists and G.Ps. Every endoscopic technique is an acquired skill which must be learnt by a combination of study, observation, apprenticeship and performance. The British Society of Gastroenterology has formalised criteria for the training of endoscopists in different areas of
diagnostic and therapeutic endoscopy. (7) An endoscopist should undergo a defined apprenticeship phase under close supervision and attend a formal teaching course, including the principles of safety and the care of instruments, before training in any aspect of GI endoscopy is regarded as complete.

It has been further recommended that doctors performing endoscopy should normally have a professional commitment to two or more endoscopy sessions weekly so as to acquire and maintain proficiency. The Endoscopy Section of the B.S.G. has already published guidelines of training in Digestive Endoscopy. (7)

Accreditation of Endoscopists is under debate although E.C directive may make registration a requirement for endoscopists in the future. Agreement has been reached by the B.S.G. and the Conference of Colleges on the principle of accredited training units although such units have yet to be identified.

It is inevitable that training in endoscopy takes place in Departments of Gastroenterology and Surgery. Close liaison with other experienced endoscopists ensures that training is a continuous process and that endoscopy remains appropriate. Endoscopy provides useful information to help in the clinical management of patients with symptoms and it is important that the endoscopist is aware of the implications of his findings within the overall spectrum of gastroenterology. Multi-disciplinary interactions between endoscopists, radiologists, pathologists, physicians and surgeons contribute to effective training.

Those who have received training have been predominantly Registrars or Senior Registrars embarking on hospital careers. Nevertheless, many trainees have left hospital practice to become general practitioners after acquiring considerable expertise. It is natural that some of these endoscopists wish to continue to exercise these skills and many do so as clinical assistants or staff grade doctors in hospital based units.

Some established general practitioners have received formal endoscope training and a period of supervision. They also contribute as clinical assistants, often providing a major diagnostic service within hospital units. It is reasonable to consider however, whether such a fully trained independent practitioner could provide an even greater service by establishing community based endoscopy. Factors in addition to training and experience will influence this decision and they are discussed in subsequent sections.
The major cause for concern is whether general practitioners can continue to refresh their interpretive and cognitive skills in such a specialist area if practising endoscopy in isolation with a relatively small workload and limited case mix.

2.2 Support staff
In a Working Party Report published in 1987 the B.S.G. established Guidelines on the staffing of endoscopy units (7). These guidelines give advice on the minimal levels of support and the training of staff. The main support to the endoscopist is given by nursing staff although added support roles can be filled by other properly trained health care workers. The specific role of the nurse in endoscopy is the care of patients before, during and after the procedure. Nurses employed in endoscopy units should undergo appropriate specialised training.

It is important to recognise that the clinical skills and technical expertise needed by nurses involved in endoscopy are above and beyond those usually required for "simple" outpatient activities. Endoscopic equipment is complex, expensive and difficult to disinfect. It is recommended that two people should assist with every endoscopy, a nurse to care for the patient and an assistant to help with the use of instruments and accessories.

Training in patient monitoring and resuscitation techniques is essential if nurses as well as endoscopists are to cope adequately with the unforeseen reactions and cardiorespiratory complications that occur more frequently than is generally acknowledged. Clearly when endoscopy is not performed regularly and frequently, staff skills may deteriorate and patients be put at risk. The medico-legal consequences could be substantial.

3. Equipment
Endoscopes and their accessories are expensive and relatively delicate. There life expectancy is considerably shortened by careless handling or incorrect maintenance. The B.S.G. has recommended that the care, maintenance and use of endoscopes and the numerous accessories involved requires a high level of technical competence amongst medical and nursing staff, comparable to that in the operating theatre. Training in instrument handling and disinfection will form an integral part of training of nurses and other endoscopy assistants and it is essential that all staff involved in endoscopy are kept up-to-date with an ever changing technology.
These considerations are applicable wherever endoscopy is practised. General practitioners and their funding bodies must recognise them when considering establishing endoscopy in the community.

3.1 Disinfection of Endoscopes and associated equipment

In 1988 the B.S.G. published interim recommendations of a Working Party on the cleaning and disinfection of equipment for gastrointestinal flexible endoscopy (8). These recommendations have been supplemented by a further report on "Aldehyde Disinfection and Health in Endoscopy Units". (9) These reports include considerable detail and firm recommendations based on the most up-to-date information available.

3.1.1 The Problem of Glutaraldehyde

Glutaraldehyde is the agent used in the majority of units for the disinfection of flexible gastrointestinal endoscopes. In common with other aldehydes, glutaraldehyde is toxic, irritant and allergenic. The problems arise from contact with liquid glutaraldehyde or its vapour. The potential hazards for staff are considerable and toxicity has been suspected in 35% of units and "harmful or potentially harmful problems" in 63% (10). For example allergic asthma may follow exposure and persist even if further exposure is avoided.

The Health and Safety at Work Act 1974 requires employers to ensure, as far as is reasonably practicable, the health, safety and welfare at work of all their employees. The act also requires employees to comply with the precautions established to ensure safe working. The Control of Substances Hazardous to Health regulations 1988 ,(COSHH) require employers to assess the risks to the health of staff by exposure to hazardous chemicals such as glutaraldehyde, to avoid such exposure where this is reasonably practicable and otherwise ensure adequate control. Failure to comply with COSHH constitutes an offence and renders the employer liable to penalties under the Health and Safety Work Act 1974. The HSE who enforce COSHH have adopted a number of standards with regard to the use and control of glutaraldehyde and these are under continual review.

There is no reasonable alternative to glutaraldehyde as a first line agent for the disinfection of endoscopes and associated equipment. Where possible disposable accessories should be used or sterilised at C.S.S.D. or in bench top autoclaves. Disinfection of flexible endoscopes should be performed within the automated washer/disinfector following thorough brushing of the channels. The use of the glutaraldehyde should be
confined to appropriate automated washers/disinfectors; the use of trays, bowls or buckets, whether lidded or not, containing activated glutaraldehyde is unacceptable.

The use of Glutaraldehyde in the disinfection of equipment should take place away from clinical areas and where suitable extraction and ventilation equipment must be incorporated.

Recommendations are made for the monitoring of atmospheric levels. This involves air sampling, filtering and analysis by high performance liquid chromatography of the eluate from the filters. Commercially available glutaraldehyde meters are less reliable. Atmospheric monitoring is a specialist operation which should be carried out by fully trained occupational hygienists.

It is not only good clinical practice but also a COSHH requirement that employees who may be exposed to glutaraldehyde undergo regular health surveillance.

This involves pre-employment health surveillance including lung function and annual reassessment by questionnaire. It is a legal requirement that records be retained for thirty years. Education of staff in these matters is essential and training in the use of personal protective equipment and spillage procedures will be an integral part of staff training. The stringent requirements of the HSE and COSHH outlined above make considerable demands in training and facilities on the providers of health care. These risks and costs must not be under estimated when considering establishing new endoscopy units which may be in use relatively infrequently compared with full-time specialist units in hospitals.

4. Procedural Safety
4.1 The hazards of Endoscopy; their prevention and management
Gastro-intestinal endoscopy is at best a simple, safe, accurate and efficient technique in the diagnosis and treatment of many intestinal conditions. It is however, not without risk. These risks reflect not only technical skill and experience but the abilities of support staff, levels of sedation, pre-operative patient care and the selection and preparation of patients.

Complications can arise merely as a result of instrumentation as well as following the administration of sedative and other drugs with or without
local anaesthetics. The problems of instrumentation include aspiration, perforation, bleeding following biopsy or polypectomy and stimulation of vaso-vagal reflexes. The problems of sedation are predominantly oversedation and subsequent cardio-pulmonary dysfunction due to hypoxia and hypotension. Local anaesthetics have been shown to put patients at particular risk of inhalation and are not without danger even when used alone. Idiosyncratic reactions to drugs are a further hazard.

A recent prospective four month audit of upper gastro-intestinal endoscopies in 36 hospitals across two regions provided data from 14,149 gastroscopies of which 1,113 procedures were therapeutic and 13,036 were diagnostic. (5)

The mortality rate from the study for diagnostic upper G.I. endoscopies was 1 in 2000 and the morbidity was 1 in 200; cardiopulmonary complications were the most prominent in this group. These surprising statistics are higher than previously reported and although the data validation was 95% these figures may still be an under-estimate. These higher than expected figures may reflect the increasing age of patients and their general medical condition but endoscopy facilities, sedation techniques, lack of monitoring and operator inexperience, were all considered to be contributing factors.

It might be argued that if G.Ps employed "risk management" strategy they would and should exclude elderly or "at risk" patients from their endoscopy service. On the results of the prospective audit this would exclude large numbers of patients from their practice.

The results of this most recent study highlight the importance of training and staffing levels of all endoscopy staff and their experience. If due regard is not paid to them the dangers to patients are obvious.

4.2 Endoscopic and recovery facilities
The B.S.G. has issued guidelines on the design of an endoscopy unit, (4) but these are aimed at a hospital based service. The need in general practice where only diagnostic endoscopy is likely are probably less demanding. Nevertheless certain broad requirements remain. Endoscopy needs to be practised in a purpose designed area with adequate space and easy accessibility. Instruments, their accessories, monitoring equipment and all the necessary drugs need to be readily to hand and staff must be able to move freely and at times quickly around a patient. Patients may need help to manoeuvre on the trolleys before, during and after endoscopy. In the event of emergency, staff need room to perform
resuscitation manoeuvres and there needs to be space for appropriate equipment. The examination needs to be performed on a "tipping" trolley so that the patient may be tilted head or feet down. Suction needs to be available to clear the mouth and pharynx of saliva and any regurgitation of gastric contents. Oxygen must be available. In general practice any endoscopy facility is likely to be used for multiple purposes but due consideration must be given to the care, storage and security of endoscopy equipment.

A separate properly equipped cleaning and disinfection area will be required to fulfil the COSHH requirements.

A separate and perhaps shared, appropriately staffed patient preparation and recovery area will be required and depending on the workload and patient turnover, space will be needed for one or more trolleys. Monitoring facilities and supplemental oxygen will need to be available in this area also. From time to time patients require overnight admission for observation during unexpectedly prolonged recovery.

4.3 Sedation
The recent prospective audit of upper gastrointestinal endoscopy has highlighted problems that arise from sedation in endoscopy. The BSG has long recognised this problem and issued guidelines in 1991 recommending standards for sedation and patient monitoring during endoscopy (11). The problems of sedation for non-anaesthetists has been recognised for many years by the dental profession and two reports have been issued by expert working parties (12,13). Recently a further working party of the Royal College of Surgeons of England have prepared guidelines for sedation by nonanaesthetists. (14)

4.3.1 Sedation Techniques
Endoscopy may be performed successfully and satisfactorily without sedation by skilful and experienced endoscopists. This would probably further reduce the risk to patients but it is not common practice. Even in the best hands a patients response may be unpredictable and unplanned sedation required. At present over 90% of all upper GI endoscopies in the U.K. are conducted under intravenous sedation, usually with a benzodiazepine. Despite recent advances there is no tradition of formal training in techniques of sedating patients for endoscopic procedures. All practitioners need proper instruction in sedation techniques and refresher courses are indicated.
Cardiorespiratory complications which are responsible for the majority of deaths following endoscopy can be reduced by keeping the dosage of all drugs to the minimum, permitting patient comfort and successful performance of the procedure. There is rarely any need to exceed the manufacturers recommended dose. Particular attention should be given to the dose limits for elderly patients and those with coexisting medical disease, such as cardiac, renal or hepatic failure.

Specific antagonists for benzodiazepines (flumazenil) and opioids (naloxone) must be available for immediate use. Endoscopists and support staff must be familiar with their action and use.

A cannula should be placed in a vein during endoscopy on all patients receiving intravenous sedation.

Intravenous sedation of children for endoscopy is a specialist skill and rigorous standards have been recommended. Endoscopy for children should not be carried out in general practice.

4.3.2 The Role of the Endoscopist and Assistants
Where intravenous sedation techniques are employed, experienced endoscopists assume responsibility for both sedating the patient and performing the endoscopic procedure, provided adequate assistance is available. When response to verbal command by the patient is lost an anaesthetic has been administered with all the responsibilities that this entails. The patients' clinical condition will be observed throughout by both the endoscopist and the qualified nurse.

The B.S.G. recommendations on the staffing of endoscopy units, state that two endoscopy assistants, one of whom must be a qualified nurse, are required at each endoscopy irrespective of whether the patient is sedated.

4.4 Monitoring
Clinical monitoring based on careful observation of patients and their responses remains the principle contributing factor to patient welfare. However, clinical observation alone is unreliable in the detection of early respiratory depression and it is recommended that continuous pulse oximetry becomes standard practice for all patients undergoing endoscopy having received intravenous sedation. (14)

Routine E.C.G. monitoring is not thought necessary for all patients but may be helpful as an adjunct in patients with cardiovascular risks.
4.5 Recovery
Clinical monitoring of patients should continue until recovery is complete. Staff must be immediately available to attend the observation and needs of such patients. They should not, for example, be assisting with subsequent endoscopies. The facilities required for such recovery have already been addressed.

4.6 Resuscitation
The greatest risk to patients undergoing endoscopy is cardiorespiratory arrest; other life threatening emergencies such as haemorrhage and anaphylaxis also occur. Rapid resuscitation may be necessary from time to time and it is essential that the drugs and equipment for dealing with such emergencies are immediately available and checked. Clinical staff should be trained and familiar with the techniques employed in cardiopulmonary resuscitation. Regular "refresher courses" and unpredicted "crash drill" of these procedures should be part of maintaining quality assurance.

4.7 Staff safety
Endoscopy Staff, especially those who clean instruments, may develop sensitivity to the disinfectant used. Closed systems for disinfection, adequate ventilation and appropriate change/showering facilities are important. Staff as well as patients are also at risk of infection such as tuberculosis, viral hepatitis or HIV. All endoscopy staff should be offered hepatitis B vaccination. To avoid contact with blood or body fluid, staff should wear disposable outer garments and gloves: goggles or glasses should be worn where eyesplashes are likely. Routine precautions should be adopted for the handling of sharp instruments or accessories and for the disposal of suction waste, contaminated linen and needles. The hazards from patients infected with tuberculosis remain a problem in certain parts of the country and all staff need proper training in these risks.

5. The Cost of Endoscopy
The cost of endoscopy reflects a number of factors and these include the cost of capital investment, staffing, disposables, accessories and the number of procedures undertaken. The capital expenditure required to establish an endoscopy unit is high even when only relatively simple diagnostic procedures are planned. The estimated outlay for such a unit based on current costs of instruments (1993) are shown in figure 1. In addition to the quoted sums, a 10% annual service charge will be necessary in order to guarantee maintenance. Due regard must be paid to
the life expectancy of the equipment which will need replacement over a
five to ten year period. Constant improvements to technology are taking
place and equipment may become obsolete before the end of its natural
life. If the equipment is under-utilised there will be inevitable waste.

**Figure 1:**
**Capital Costs of Endoscopy**
Illustrative list of major equipment needed to provide a diagnostic upper GI
diagnostic upper GI endoscopy and fibre sigmoidoscopy service. The cost is approximate at
1993 rates and excludes VAT.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper GI Endoscopes x 2</td>
<td>£26,000</td>
</tr>
<tr>
<td>Fibre sigmoidoscope x 1</td>
<td>£10,000</td>
</tr>
<tr>
<td>Light source x 1</td>
<td>£4000</td>
</tr>
<tr>
<td>Procedure trolley</td>
<td>£1500</td>
</tr>
<tr>
<td>Endoscopy trolley</td>
<td>£1300</td>
</tr>
<tr>
<td>Suction machine x 3</td>
<td>£3000</td>
</tr>
<tr>
<td>Automated washing machine</td>
<td>£18,000</td>
</tr>
<tr>
<td>Pulse oximeters x 3</td>
<td>£4500</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£68,300 + VAT</strong></td>
</tr>
</tbody>
</table>

In addition to the costs listed there will be likely building costs either for
erecting new accommodation or adapting existing buildings. The costs of
installing fume extraction equipment will depend on local requirements.

The quoted unit cost for an endoscopy across the country is extremely
variable and this variation reflects a number of factors. The "cost" itself
may be the "bid price" by purchasers to providers and many endoscopists
have discovered that the figure is wildly inaccurate and based on incorrect
assumptions.

The most accurate published figures which are supported by many
unpublished data were presented in the B.S.G. report on "Provision of
Gastrointestinal Endoscopy and Related Services for a District General
Hospital". (Fig 2 & 3) These figures are based on 1990 costs. (4)

Clearly one sensitive variable would be the instrument cost per
examination and this itself would be largely determined by the numbers of
endoscopies performed.

It is unlikely that G.Ps would require the same staffing overheads but a
minimum of two trained endoscopy assistants would be required to fulfil
the recommended safety standards. When considering the establishment of an endoscopic service within their own practice, G.Ps and their funding bodies must consider whether such a high capital outlay is justified and whether it is cost effective to provide a service to their own and their colleagues’ patients. Local market forces will influence this and hospitals will need to ensure that their costings are accurate and that no profiteering based on monopolistic assumptions is contemplated.

6. Discussion
A clear change of emphasis is developing in the delivery of health care and greater responsibility will fall on G.Ps as acute accommodation is reduced, short stay care develops and work is reallocated between the acute hospitals and the community. It is likely that G.Ps will take a greater responsibility than at present for longer term management of patients and decisions pre and post intervention. In future, selection for endoscopy in most patients will be made by G.Ps. Fundholders will welcome this, as will endoscopists dependent on finances following the patient. There is increasing support for "open access" endoscopy in hospital units. (4)

Nevertheless, access to endoscopy remains under-provided and alternatives to hospital based units have been considered. In some instances G.Ps have bought endoscopes or had them purchased by Regional Health Authorities, pharmaceutical companies or charities. These piecemeal developments, while showing commendable enthusiasm and entrepreneurship, have failed to consider all the implications and in some instances have ignored even the legal requirements of COSHH and HSE regulations. As far as can be ascertained little consideration has been given to the local strategic planning of endoscopic services or the numerous complicated interactions discussed in this report. There is no evidence of structured pilot studies of effectiveness, safety or outcome, nor indeed are there any published audits of established services. Consumer preference has been sited as a major incentive but it is unlikely that this preference has been made with the full knowledge and appreciation of the risks, precautions and the importance of staff training and experience which go towards ensuring safe endoscopy. Patient preference should only be of paramount consideration when appropriate clinical standards can be achieved; these standards are the cornerstone of quality care.

**Figure 2:**
Example of Staff Costs/Procedure
(Based on data from Freeman Hospital, Newcastle 1990) (4)
These have been calculated from the average time/procedure plus 10 minutes between procedures.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time (min)</th>
<th>Interval (min)</th>
<th>Staff Cost £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic OGD*</td>
<td>15</td>
<td>10</td>
<td>22.22</td>
</tr>
<tr>
<td>OGD + biopsy</td>
<td>20</td>
<td>10</td>
<td>26.66</td>
</tr>
<tr>
<td>Fibresigmoidoscopy</td>
<td>15</td>
<td>10</td>
<td>22.22</td>
</tr>
</tbody>
</table>

*Calculated on the basis of the following minimum staff required to carry out a procedure.
Consultant/Clinical Assistant
Sister, Grade G
Staff Nurse, Grade E  £53.33 per hour
Orderly, Grade D
Porter
Recovery costs are not included

Hospital based endoscopy depends largely on highly trained specialists who may be perceived monopolistic and protectionist. However, there may be advantages in such specialists providing endoscopic services since they will have acquired a wider clinical knowledge of gastroenterology over and above simple endoscopic interpretation, on which to base their clinical management decisions. The conflicts of access and perceived vested interest will be best resolved by improving communication between G.Ps, specialists, patient groups, purchasers and provider units so that coordinated services are developed providing high quality, safe, cost effective and appropriate endoscopy to those who need it.

**Figure 3:**

Calculated Procedure Costs For Freeman Hospital (1990) (4)
(note: these do not include "recovery" and "radiology" costs)

**Diagnostic OGD**
- Instrument Cost: 5.05
- Light source etc: 0.80
- Staff cost: 22.22
- Disposable costs: 2.70
- Overheads
  - Fixed: 19.01
  - Variable: 15.01
  - Total: 64.79

**OGD + Biopsy**
- Instrument cost: 5.05
- Light source etc: 0.80
- Staff Cost: 26.66
- Biopsy forceps (1/20): 0.10
- Brush cytology: 10.30
- Total: 127.85
Histology cost 31.39
Other disposables 2.70
Overheads Fixed 22.84
Variable 18.01

Sigmoidoscopy
Instrument cost 4.72
Light source etc 0.60
Staff cost 22.22 £63.76
Disposable costs 2.20
Overheads Fixed 19.01
Variable 15.01

The failure of hospitals to fulfil the need for diagnostic endoscopy and the cost of investigations has led to this superficially attractive option of G.Ps providing their own endoscopic service. The N.H. S. Management Executive Guidelines on "G.P. Fundholding Practices: The Provision of Secondary Care" (HSG (493) 14) specifically propose that intestinal endoscopy be included in the those services for which G.P's may retain funding for the procedures rather than purchase the services from hospital providers.

Clearly such services could be provided by G.Ps in a variety of environments, ranging from District General Hospitals, through small G.P. managed community hospitals which might or might not have consultant backup, to the practice surgery. The G.P. might provide a service for several of his colleagues. Alternative proposals to a G.P. based community service include greater access to hospital facilities by G.P. endoscopists and "outreach" clinics performed by hospital based consultants in Community Hospitals or individual/group practices. It has also been suggested that mobile units could provide a peripatetic service in much the same way as mass miniature radiography or breast screening. The standards of care outlined in this report must influence a decision to implement any of these alternatives.

The single most important factor is patients' safety and this depends on the environment in which the endoscopy is performed and the expertise of the endoscopist and his/her support staff. This expertise results from detailed and prolonged formal training, experience and interaction with other endoscopists. Continuing education is essential in order to maintain standards and to adapt to new technology. The training which leads to safe practice inevitably leads to quality practice and will ensure appropriate patient selection, correct endoscopic interpretation and thereafter sound clinical management. Appropriately trained support staff may be difficult to
recruit in the community where nurses are likely to have broadly based responsibilities which will not usually be highly technical; the care of semi conscious patients will not be part of their daily routine.

If endoscopy is practised without due regard to the issues of training, expertise, staffing, instrument handling and particularly HSE and COSHH requirements, endoscopists and their staff put themselves at very serious medico-legal risks. In the event of a medical accident it would be hard to defend allegations of negligence. There is also medico-legal responsibility to refer patients only to units where minimum standards are achievable.

Endoscopy must remain cost effective and consideration should be given by all concerned to the overall health care resources, so that duplication and waste do not proliferate as a result of rivalry, vested interest and short term budgetary advantages.

It is essential that established specialists support and encourage their G.P. colleagues where development of endoscopy in the community seems appropriate. They should assist with training, continued education, advice on equipment and help to provide access to supporting medical services. Strategic planning of endoscopic services must involve close communication between all providers and purchasers.

References


Appendix 1

General Recommendations on Training in Digestive Endoscopy.
1. Any practitioner who is to have a sessional commitment to Endoscopy should receive formal training.
2. Wherever endoscopy is taught it should be provided as part of an overall gastroenterology service with cooperation between physician, surgeon, radiologist and pathologist. Joint ward rounds, clinics and clinical meetings are desirable to achieve high standards of patient care.
3. In-service experience should be supplemented by attendance at courses approved or organised by the Endoscopy Committee of the B.S.G. The purpose of this is to update endoscopists about newer equipment, techniques and management.

Recommendations for Training in O.G.D.

Facilities

i. Training should be in a unit carrying out a minimum of 1,000 OGD examinations per year so that a full range of conditions is observed and diagnostic and therapeutic measures encountered.
ii. The training unit should be furnished with modern endoscopy equipment. Fluoroscopy, not necessarily in the Endoscopy Unit, should be available for selected cases such as endoscopic intubation. At least one teaching attachment (training arm) or video system is essential.

3. Endoscopic Experience

i. Trainee endoscopists should attend regular weekly sessions (or more often) for at least six months.
ii. At least 150 to 200 examinations should be completed with some degree of supervision.
iii. Therapeutic endoscopy should be taught only after the basic training for OGD has been completed. It should include attendance at sessions for a further period of 6 to 12 months. Procedures should be carried out initially under supervision and subsequently independently.
iv. A written record of the number and variety of procedures carried out under supervisions and subsequently independently should be kept for inspection.

4. Courses in Diagnostic and Therapeutic OGD.

i. These courses should be approved by the Endoscopy Section Committee of the British Society of Gastroenterology and be provided on a Regional or National basis.
ii. Trainee endoscopists should attend courses on basic endoscopy and therapeutic endoscopy. These should include such topics as patient care, maintenance, cleaning and disinfection of endoscopes and
equipment, electrical hazards, recognition and management of the complications of endoscopy, and sessions on therapeutic endoscopy such as oesophageal stricture dilatation, prosthetic tube placement, polypectomy, variceal injection, and electrocoagulation. The general administration of an endoscopy unit should also be covered.

Training in Colonoscopy and Polypectomy.
As with OGD in-service training is most important.

Recommendations:
1. Training Units should undertake at least 200 procedures per year and to allow time for training there should be at least two colonoscopy lists per week.
2. The role of histology, combined x-ray and surgical meetings with review of operative findings are stressed.
3. Modern colonoscopic equipment is essential and fluoroscopy should be available.
4. Apart from the acquisition of technical expertise the trainee should understand the mechanics of the procedure as well as the indications for colonoscopy, its limitations and the complications which may occur. Techniques of patient preparation should be understood. Trainees should attend a course on colonoscopy covering these topics.
5. Although the performance of a specific number of techniques does not imply competence, each trainee should observe and assist at 50 colonoscopic examinations and subsequently complete 50 successful colonoscopies on his/her own with supervision. The trainee should have acquired experience in polypectomy.
6. Courses in colonoscopy should be approved by or be carried out under the aegis of the Endoscopy Section Committee.

Training in Fibresigmoidoscopy.
The shorter and cheaper flexible sigmoidoscopy is used to obtain views of the rectum and distal colon. It is easier and quicker to use than a colonoscope and it is of value in outpatients or endoscopy units. The procedures should be taught under supervision until confidence is acquired. Experience in its use, however, does not imply expertise with a colonoscope.

Appendix 2
Staffing of Endoscopy Units.

1. Endoscopy Assistants.
   i. Two endoscopy assistants, at least one of whom must be a qualified nurse (SEN or SRN), are required at each endoscopy table.
   ii. A qualified nurse should be responsible for patient preparation, ensuring that the patient is given a full explanation of the procedure.
   iii. A qualified nurse should be responsible for supervising the patient's recovery.
   iv. Radiographers, theatre technicians and laboratory technicians, following a course of training, may work as endoscopy assistants under nursing direction, but should not be responsible for patient preparation or patient recovery. They should also be accompanied by at least one qualified nurse when assisting at the endoscopy table.

Training of Endoscopy Assistants.

Training Courses Available.
The English National Board course 906 lasts 10 to 13 days and is run, at present, by only three centres and caters for a total of approximately 24 nurses per year. No other group of specialised nurses appears to have such small provision by the ENB and replies to the questionnaire confirm that only a few nurses have attended this course.

A retailer of endoscopic equipment runs two day basic courses twice yearly, dealing mainly with care of equipment. The survey suggests that this is the most commonly used teaching course for endoscopy assistants.

Up-date courses are provided by the British Society of Gastroenterology and are organised by the Endoscopy Nurse/Assistants Group, both nationally and locally approximately four times per year. The commercial organisation also sponsors advanced nurses training courses for two days twice yearly. In addition, study days are arranged by various local groups.

The working party regrets the small number of courses available and considers that they are insufficient for training needs. Certain Health Authorities are reluctant to provide funding for endoscopy assistant training.

Training Requirements
In-service experience is a crucial part of training but nurses wishing to claim an expertise in endoscopy should undergo specialised training. Courses offered by commercial companies are of great value and should be encouraged but should not constitute the sole basic training offered to endoscopy assistants. All nurses working in this specialised area require a basic training with provision for an annual update. The nurse in charge of an endoscopy unit will require further training to undertake this role.

Recommendations on a Training Scheme for Endoscopy Assistants.

1. The training schemes agreed by the Endoscopy Section Committee should be regularly reviewed and amended as necessary. All training courses offered should be approved by the endoscopy section of the British Society of Gastroenterology.
2. The training scheme for endoscopy assistants should be as follows:
   
   i. They should attend a two day basic training course within one year of appointment.
   
   ii. Shortly after appointment, two weeks should be spent gaining practical experience under supervision. This should be done in an established, busy endoscopy unit carrying out at least 1,000 procedures per annum ideally within easy access of the assistant's hospital.
   
   iii. They should attend annual up-date sessions in the form of study days or advanced training courses.
   
   iv. They should be encouraged to become members of the assistants groups of the endoscopy section of the British Society of Gastroenterology and receive the information circulated by that organisation.

Appendix 3
Cleaning and Disinfection of Equipment for Gastro-intestinal Flexible Endoscopy:

Summary

1. All patients undergoing gastro-intestinal endoscopy must be considered "at risk" for HIV and appropriate cleaning/disinfection measures taken for endoscopes and accessories.
2. Thorough manual cleaning and detergent, of the instrument and its channels is the most important part of the cleaning/disinfection procedure. Without this, blood, mucus and organic material will prevent adequate penetration of disinfectant for inactivation of bacteria and viruses.

3. Aldehyde preparations (2% activated glutaraldehyde and related products) are the recommended first line antibacterial and anti-viral disinfectant. A four minute soak is recommended as sufficient for inactivation of negative bacteria and viruses (including HIV and HBV).

4. Quaternary ammonium detergents (8% Dettox for two minutes for bacterial disinfection), followed by exposure of the endoscope shaft and channels to ethyl alcohol (70% for four minutes for viral inactivation), is an acceptable second-line disinfectant routine where staff sensitisation prevents the use of an aldehyde disinfectant.

5. Accessories, including mouth guards and cleaning brushes, require similarly careful cleaning/disinfection before and after use. Disposable products (especially injection needles) may be used and appropriate items can be sterilised by autoclaving and kept in sterile packs.

6. Closed circuit endoscope washing machines have advantages in maintaining standards and avoiding staff sensitisation to disinfectants. Improved ventilation including exhaust extraction facilities may be required.

7. Endoscopy staff should receive HBV vaccination, wear gloves and appropriate protective garments, cover wounds or abrasions and avoid needlestick injuries (including spiked forceps, etc).

8. Known HIV-infected or AIDS patients are managed as immunosuppressed and require protection from atypical mycobacteria/cryptosporidia etc., by one hour aldehyde disinfection of endoscopic equipment before and after the procedure. A dedicated instrument is not required.

9. Increased funding is necessary for capital purchases of GI endoscopic equipment, including extra and immersible endoscopes with additional accessories to allow for safe practice.

10. Greater numbers of trained GI assistants are needed to ensure that cleaning/disinfection recommendations and safety precautions are followed, both during routine lists and emergency endoscopic procedures.

11. These recommendations are based on expert interpretation of current data on infectivity and disinfection: they may require future modification.

Appendix 4

Summary

1. Glutaraldehyde, used in the majority of Endoscopy Units in the United Kingdom for the disinfection of flexible gastrointestinal endoscopes, is a toxic substance being an irritant and a sensitiser; symptoms associated with glutaraldehyde exposure are common amongst staff working in Endoscopy Units.
2. COSHH obliges the employer to make a systematic assessment of risk of staff of exposure to glutaraldehyde and institute measures to deal effectively with exposure.
3. At present glutaraldehyde remains the first-line agent for the disinfection of gastrointestinal flexible endoscopes. Other agents are being developed; a standard means of assessment for flexible endoscope disinfect-ants should be devised.
4. Equipment and accessories that are heat-stable should be sterilised by auto-claving; disposable accessories should be used where ever possible.
5. Flexible endoscopes should be disinfected within automated washer/disinfectors; trays, bowls or buckets for this purpose are unacceptable.
6. Local exhaust ventilation must be used to control glutaraldehyde vapour. Extracted air may be discharged direct to the atmosphere or passed over special absorbent filters and re-circulated. Such control measures must be regularly tested and records retained.
7. Endoscope cleaning and disinfection should be carried out in a room dedicated to the purpose, equipped with control measures to maintain the concentration of glutaraldehyde vapour at a level certainly below the current Occupational Exposure Standard of 0.2 ppm and preferable below the commonly used working limit of 0.1 ppm. Sites other than the Endoscopy Unit where endoscopy is regularly performed, such as the Radiology Department, should have their own fully equipped cleaning and disinfection room.
8. COSHH limits the use of personal protective equipment to those situations where other measures cannot adequately control exposure. Such equipment includes appropriate gloves, apron, goggles and respiratory protective equipment.
9. Monitoring of atmospheric levels are glutaraldehyde should be performed by a competent person such as an Occupational Hygienist; the currently preferred method of sampling uses a filtration technique, the commercially available meters being less reliable.

10. Health surveillance of staff is mandatory; occupational health records must be retained for thirty years.

11. Endoscopy staff must be informed of the risks of exposure to glutaraldehyde and trained in safe methods of its control. Only staff who have completed such an education and training programme should be permitted to disinfect endoscopes.

12. The unsafe use of glutaraldehyde has significant health and legal consequences; the safe use of glutaraldehyde may have revenue consequences which contribute significantly to the cost of gastro-intestinal endoscopy.

**Appendix 5**

Sedation for Non-Anaesthetists


The Practice of Sedation

Summary

The objective of sedation is to help patients accept uncomfortable and distressing diagnostic and therapeutic procedures while easing technical difficulties for the operator.

During sedation communication must be maintained such that the patient will respond to command throughout.

The risks of each case should be assessed by the sedationist before the intended procedure. A pre-procedural questionnaire should be completed by the patient to provide a readily scanned list of potential risk factors for the sedationist.

Suitable premises for the safe practice of sedation must contain a table/trolley/dental chair which can be tipped head-down and have oxygen, suction, resuscitation equipment and drugs immediately available.
Benzodiazepines are the most commonly used class of drugs for intravenous sedation. When used in appropriate doses using a careful titration technique they provide a satisfactory margin of safety between sedation and the induction of anaesthesia. Their pharmacodynamic and pharmacokinetic properties vary and the preferred drug for intravenous sedation is the watery soluble shorter acting benzodiazepine, midazolam. The inhalation agent most used for sedation is nitrous oxide which is easily reversible and relatively free of risk.

There is evidence that there is a major drug interaction between benzodiazepines and opioid drugs which may be synergistic or additive depending on the opioid drug employed. Failure to modify dosage of these drugs, when used in combination may lead to life-threatening complications.

The specific antagonists for benzodiazepines (Flumazenil) and opioids (naloxone) must be available for immediate use but should not encourage sedationists to adopt a lax approach to titrating dose of the agonist against response.

An oxygen supply and equipment with compatible fittings for its delivery to the patient must be immediately to hand in any area where intravenous sedation is undertaken.

It is recommended that every patient undergoing sedation receives oxygen-enriched air. In the majority of procedures the sedationist is also likely to be the operator and as such carries the ultimate responsibility of the safety of both the sedation techniques and the procedure itself. At least one other suitably trained person, either medical/dental, nursing or technically trained must be present to provide clinical monitoring of sedated patients.

There is no published evidence that the routine use of monitoring equipment will reduce the morbidity and mortality associated with sedation but the adoption of minimal monitoring standards should increase patient safety as it has an anaesthetic practice. It is recommended that oximetry becomes standard practice for all patients receiving intravenous sedation.

It is considered mandatory that all patients undergoing intravenous sedation should have a cannula placed in a vein for reliable continuous intravenous access throughout the procedure. The cannula must be left in place until recovery is complete.
The management of children undergoing sedation in hospital is a specialised field requiring its own standards of patient care.

Resuscitation equipment available in the treatment area and the recovery area (if separate) should include the basic drugs and equipment necessary for the maintenance of airway, breathing and circulation, as well as a source of oxygen, suction and a tipping trolley/table/dental chair. Staff of all grades and disciplines, including consultant staff, should be familiar with resuscitation methods and undergo periodic re-training.

Clinical monitoring must be continued until recovery is complete.

The minimum criteria for discharge include stable vital signs, the ability to walk without support, toleration of oral fluids, the ability to void urine, minimal nausea, adequate analgesia and appropriate aftercare.

Day cases should be accompanied home by a responsible adult who should be given written instructions as to what to do and who to contact in the event of problems. No patient should be allowed to sign legally-binding agreements, drive or carry out any activity involving motor skills for 24 hours after intravenous sedation.