



**GUIDELINES FOR
INFORMED CONSENT
FOR
ENDOSCOPIC
PROCEDURES**

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INFORMED CONSENT FOR ENDOSCOPIC PROCEDURES

INTRODUCTION

Informed consent is a cornerstone of good medical practice. Whenever possible patients should remain responsible for themselves. Clinicians must respect the need to maintain the autonomy and self-determination of patients. Correctly performed informed consent also acts as a shield against complaints by patients and claims of malpractice against doctors.

Gastroenterologists most often face the question of informed consent in relation to the performance of endoscopic procedures. In the USA about 1% of medical liability claims have been related to endoscopic procedures.¹ There are no satisfactory data for the UK but in a review of 31 claims against endoscopists in England and Wales it appeared that in at least 12 instances patients consented to the procedure after little or no explanation. In 6 of these cases the claimants stated, apparently with good reason, that had they known of the risk:benefit ratio they would not have undergone the procedure (or at least they would have had to be convinced that there was no reasonable alternative). It is estimated that more than half the patients would not have made claims had they received a reasonable explanation of the reason for the procedure and the risks involved.²

DEPARTMENT OF HEALTH GUIDELINES

Over the last 30 years informed consent for a medical procedure has been transformed from an ethical concept to a legal requirement. The NHS Management Executive have produced guidelines for informed consent³:-

The patient's rights

1. A patient has the right under common law to give or withhold consent prior to examination or treatment. This is one of the basic principles of health care. Subject to certain exceptions the doctor or health professional and/or health authority may face an action for damages if a patient is examined or treated without consent.
2. Patients are entitled to receive sufficient information in a way they can understand about the proposed treatments, the possible alternatives and any substantial risks, so that they can make a balanced judgement. Patients must be allowed to decide whether they will agree to the treatment and they may refuse treatment or withdraw consent at any time.
3. Care should be taken to respect the patient's wishes. This is particularly important when patients may be involved in the training of professionals in various disciplines.....An explana-

tion should be given of the need for practical experience and agreement obtained before proceeding...

The health professional's role in advising the patient and obtaining consent to treatment

Advising the patient

Where a choice of treatment might reasonably be offered the health professional may always advise the patient of his/her recommendation together with reasons for selecting a particular course of action. Enough information must normally be given to ensure that they understand the nature, consequences and any substantial risks of the treatment proposed so that they are able to take on decisions based on that information.....

Obtaining consent

Consent to treatment may be implied or express.....

Express consent is given when the patient confirms their agreement to a procedure or treatment in clear and explicit terms, whether orally or in writing.....

Oral consent may be sufficient for the vast majority of contacts with.....health professionals. Written consent should be obtained for any procedure or treatment carrying any substantial risk or substantial side-effect.

Consent form

The main purpose of written consent is to provide documentary evidence that an explanation of the proposed procedure or treatment was given and that consent was sought and obtained.....

The most important element of a consent procedure is the duty to ensure that patients understand the nature and purpose of the proposed treatment. When a patient has not been given appropriate information then consent may not always have been obtained despite the signature on the form.

GENERAL MEDICAL COUNCIL'S GUIDANCE

The GMC has recently provided guidance on informed consent⁴. Some of the guidance of relevance to obtaining consent for endoscopic procedures is reproduced here:

“Patients must be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. This right is protected in law, and you are expected to be aware of the legal principles set by relevant case law in this area.

“Effective communication is the key to enabling patients to make informed decisions. You must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Open, helpful dialogue of this kind with patients leads to clarity of objectives and understanding, and strengthens the quality of the doctor-patient relationship.

“Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary according to factors such as, the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the pa-

tient's own wishes. For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.

“The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

- details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis including options for further investigation prior to treatment;
- options for treatment or management of the condition, including the option not to treat;
- the purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects;
- for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by the treatment;
- advice about whether a proposed treatment is experimental;
- how and when the patient's condition and any side effects will be monitored or re-assessed;
- the name of the doctor who will have overall responsibility for the treatment;

- whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
- a reminder that patients can change their mind about the decision at any time;
- a reminder that patients have a right to seek a second opinion...”

“When providing information you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with patients, and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.”

“You should raise with patients the possibility of additional problems coming to light during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought to before you proceed. You must abide by patients' decisions on these issues. If, in exceptional circumstances you decide, while the patient is unconscious, to treat a condition which falls outside the scope of the patient's consent, your decision may

be challenged in the courts, or be the subject of a complaint to your employing authority or the GMC. You must therefore be prepared to explain and justify your decision. You must tell the patient what you have done and why as soon as the patient is sufficiently recovered to understand.”

“Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between you and your patients which keeps them abreast of changes in their condition and the treatment or investigation you propose. Whenever possible, you should discuss treatment options at a time when the patient is best able to understand and retain the information. To be sure that your patient understands, you should give clear explanations and give the patient time to ask questions. In particular, you should:

- use up to date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment; and make arrangements, wherever possible, to meet particular language and communication needs, for example through translations, independent interpreters, signers, or the patient’s representative. Where appropriate, discuss with patients the possibility of bringing a relative or friend, or making a tape recording of the consultation;
- explain the probabilities of success or the risk of failure of, or harm associated with options for treatment, using accurate data;
- ensure that information which the patient may find distressing is given to them in a considerate way. Provide patients with information about counselling services

and patient support groups, where appropriate;

- allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of the risks is great. Where patients have difficulty understanding information, or there is a lot of information to absorb, it may be appropriate to provide it in manageable amounts, with appropriate written or other back-up material, over a period of time, or to repeat it;
- involve nursing or other members of the health care team in discussions with the patient, where appropriate. They may have valuable knowledge of the patient’s background or particular concerns, for example in identifying what risks the patient should be told about;
- ensure that, where treatment is not to start until some time after consent has been obtained, the patient is given a clear route for reviewing their decision with the person providing the treatment.”

“If you are the doctor providing a treatment or undertaking an investigation, it is your responsibility to discuss it with the patient and obtain their consent, as you will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. Where this is not practicable, you may delegate these tasks provided you ensure that the person to whom you delegate: is suitably trained and qualified; has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved; acts in accordance with this guidance.”

“You will remain responsible for ensuring that, before you start any treatment, the patient has been given sufficient time and information to make an informed decision, and has given consent to the procedure or investigation.”

explaining

- the procedure and alternatives to the patient
- the role of trainees

ensuring that

- the procedure is performed with appropriate skill
- the after-care is adequate
- the follow-up is well-defined (eg it is clear who is to take responsibility for acting on the histology report)

LEGAL ASPECTS OF INFORMED CONSENT

The nature of the legal process

The question of negligence is based in tort law. A tort is a civil wrong.

The basic principles are simple:-

1. Does the defendant owe a duty to the plaintiff?
2. Was there a breach of that duty? (this constitutes liability)
3. Did the accident cause damage? (causation)
4. What was the nature of the damage and its effect? (condition and prognosis)
5. What are the damages in financial terms? (quantum)

The nature of duty

The clinician-patient relationship implies a duty to be exercised by the doctor

1. The relationship may be created without the clinician actually meeting the patient ie a relationship exists as soon as a clinician receives a request for an endoscopic examination.
2. The limits of that relationship must be clearly defined. The endoscopist is responsible for:-

determining

- the degree of urgency of the appointment
- the need for any associated procedure

The nature of informed consent

Disclosure is the crux of informed consent. The essential elements are ensuring that the patient understands:-

1. The nature of the proposed procedure
2. The reason for the procedure
3. The benefits of the procedure
4. The risks and complications of the procedure
5. Alternatives to the procedure (including an assessment of the relative risk : benefit ratios)
6. The nature of the anaesthetic or sedation to be employed. It is advised that sedation should follow the recommendations of the BSG⁵.

The relationship between guidelines and the law

In busy clinical practice it is not possible to satisfy NHS guidelines meticulously and those in charge of the legal process recognise the difficulties. The document produced by the NHS Executive states the two key examples of case law which are used to provide practical help:

“The standard of care required of the doctor concerned in all cases is laid down in *Bolam v Friern Hospital Management Committee* (1957) 1 WLR 582, namely, that he or she must act in accordance with a responsible body of relevant professional opinion.”

“.....in the case of Sidaway v Governors of Bethlem Royal Hospital (1985) AC871 Lord Bridge indicated that a decision on what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgement.....(however) a judge might.... come to the conclusion that the disclosure of a particular risk was so obviously necessary to an informed choice that no reasonably prudent medical man would fail to make it.....(Lord Bridge further stated that) it is the obligation of the doctor to have regard to the best interests of the patient but at the same time to make available to the patient sufficient information to enable the patient to reach a balanced judgement if he chooses to do so.”³

Although these statements beg important questions (such as: what is a substantial risk? what is a body of responsible medical opinion? and what is a particular risk that no prudent medical man would fail to mention?) they are helpful in determining legal outcome.

It has been suggested that the patient should be told of adverse events of a minor and temporary nature which have an incidence of more than 10% and serious events with an incidence of more than 0.5%. A senior legal opinion emphasised that these are no more than guidelines and that the law will judge every case on its merits.⁶ Certainly it is necessary for the doctor to answer all questions put to him by the patient fully and truthfully.

In the practice of gastrointestinal endoscopy it would seem that patients should be provided with written information warning of the risks of

- Dilatation of a stricture - perforation.
- ERCP - acute pancreatitis, cholangitis, perforation and bleeding

- PEG - perforation, infection and aspiration
- Colonoscopy and flexible sigmoidoscopy (especially with polypectomy) - perforation of the colon or bleeding

It must be emphasised that ALL endoscopic procedures (even simple OGD) carry a risk (all be it extremely small) of producing bleeding or perforation to the lining of the part of the alimentary tract being examined. For upper gastro-intestinal endoscopy, although special care is taken to protect the dentition, the patient should tell the endoscopist if he has a loose tooth, a dental crown or dental bridgework. The state of any loose teeth, dental crowns etc should be in the nurse checklist and recorded.

INFORMED CONSENT IN PRACTICE

It is undesirable that all units should work to an identical protocol. Each unit should develop a code of practice suitable to its mode of operation. Arranging for a patient to sign a consent form immediately before the procedure does not constitute informed consent. The patient should be fully informed by the endoscopist, ideally at least 24 hours before the procedure, and then be asked to sign a consent form. For busy units these are impossible standards.

Nevertheless there are means of approaching the ideal. The following guidelines are suggested:-

- 1 The clinician proposing an endoscopic procedure should explain why this needs to be performed and should describe its essential elements
- 2 The patient should receive an appropriately written pamphlet along with the appointment. This pamphlet should cover the issues described

above in the section on disclosure and explain the arrangements for follow-up. If the patient is given an appointment for an endoscopy session during which trainees will be present this should be mentioned.

- 3 The patient should complete 2 checklists: one to cover important aspects of general health and the other to indicate that he has read the pamphlet and has been given the opportunity to ask questions. For some units it may be appropriate to ask the patient to sign the consent form at home if he is satisfied that he has been given all the information he would like.⁷
- 4 On arrival at the Endoscopy Unit the patient should be welcomed and interviewed by a qualified endoscopy nurse who should check the level of understanding, provide further explanation and re-assurance, deal with any residual concerns and convey such concerns to the endoscopist.⁸
- 5 The endoscopist should then deal with any last minute questions. If the consent form has not been signed previously the endoscopist should now ask for a signature. (Appendix B)

These suggestions provide for reasonable informed consent but it is important to treat each patient as an individual (who is scared!). No protocol can replace friendly careful discussion with the patient both before and after the procedure.

FURTHER ISSUES

1 *How best to give the patient a real opportunity to understand the nature of the procedure before signing the consent form*

- 1.1 The purpose and nature of the procedure should be explained verbally by the clinician requesting the test. The patient should be given an explanatory leaflet and, if in agreement with the proposed procedure may sign the consent form at home possibly in the presence of a relative.⁹
- 1.2 If the patient has minor queries these may be discussed by telephone with a qualified endoscopy nurse or by an appropriately experienced GP.
- 1.3 The patient may prefer not to sign until after further discussion with a qualified nurse on the day of the procedure.
- 1.4 The patient may prefer to delay signing until he/she has had more detailed discussion with the endoscopist just before the procedure is to be performed.

2 *How best to obtain informed consent from hospital in-patients*

Sick patients may require time and simple explanation before they are in a position to give consent. There should be greater emphasis on (a) patient autonomy respecting the right of a patient to withhold consent and (b) close liaison with the referring medical team so that the gastroenterologist acts as a clinician with the patient's overall interests at heart rather than simply a technical expert. If a patient is truly incompetent to give consent, then the doctor is expected to act in his/her best interests - it must be very rare (see below) that application is needed to a court.

- 2.1 Ideally, if a ward doctor thinks that an endoscopic procedure is indicated then he should request an opinion from the appropriate specialist who should see and assess the patient on the ward. This is particularly true for ERCP, PEG and other interventional procedures and for patients in high-risk categories (eg those bleeding from the gut). If the specialist agrees with the request then he should explain the procedure and the risks to the patient before obtaining consent.
- 2.2 In practice this may be impossible. Each ward should have appropriate leaflets so that the patient may read about the procedure or have it explained to him by a competent person. Close liaison with wards and endoscopy staff can help the exchange of relevant information both verbal and written. Immediately before the procedure the endoscopist should take care to clear up any residual worries.

3 *What to do if a patient refuses essential treatment*

- 3.1 In practice this is an exceptionally rare occurrence. Every effort should be made by the consultant, backed up by the GP to arrive at a sensible decision.
- 3.2 If there are doubts about the validity of refusal to undergo essential treatment for a life-threatening situation (eg the patient's capacity is diminished by illness, medications, false assumptions or misinformation) then an application may be made to a court.

4 *Endoscopic Procedures involving insertion of a long-term prosthesis*

Three endoscopic procedures differ from all others because they have both short and long-term consequences.

These are insertion of a stent through an oesophageal or other stricture, insertion of a biliary stent and insertion of a gastrostomy tube. The explanation of these procedures needs to include not only details of the procedure and possible early complications, but also details of long-term management and potential problems. (Appendix A).

These procedures are often carried out for sick patients in hospital. Another doctor and health care team may be involved. It is important that the appropriateness of the procedure in the patient's overall management should be agreed with them. Since the endoscopist has specialist knowledge of the technique proposed, his/her opinion may make an important contribution in this regard.

Many patients for whom per-cutaneous insertion of a gastrostomy is considered suffer from cerebral handicap or dysfunction. Such patients often have difficulty in comprehension and/or communication. Capacity to give consent may vary from time to time, and limited capacity may make it essential that explanation is given simply, slowly and on more than one occasion. Consent may only be possible orally or by gesture but, since gastrostomy is an invasive procedure, a reasonable degree of certainty that the patient has consented plus discussion with relatives, is needed in every case. In such circumstances, previously declared wishes, especially if written as an advance directive, are helpful in assessing a person's response.

Joint guidance issued by the British Medical Association and the Law Society warns against therapeutic over-enthusiasm when the doctor's opinion of the patient's best interests conflicts

with what the patient wants. 'In this situation it is tempting, but ethically and legally wrong, for the doctor to underestimate the capacity of the patient in order to achieve what the doctor believes to be in the patient's best interests'.

For a mentally incompetent adult, the doctor makes a decision after discussion with all concerned on the basis of the patient's best interest.

5 Who is responsible for informed consent from an individual patient?

5.1 The law takes the view that the responsibility for obtaining informed consent lies with the endoscopist who is to perform the procedure. The endoscopist cannot delegate this responsibility except to a person who has been fully instructed for the specific case. The endoscopist should ensure consent has been obtained.

5.1.1 Although a nurse may not take delegated responsibility for obtaining informed consent, if it is her opinion that the patient is not adequately informed then she has a duty to inform the endoscopist and to record that she has done so.¹⁰

6 Who takes responsibility for minors?

6.1 If the parents are married at the time of birth of the child both have parental responsibility. An unmarried mother has sole responsibility unless the father has acquired responsibility by Court Order or a Parent Responsibility Agreement.

6.2 Parents or guardians consent on behalf of a child up to the age of 16 years. Children of less than 16 years

who fully understand the issues may consent for themselves, even in the face of parental refusal. (Note: Parents cannot over-ride a child's consent but can over-ride a refusal).

6.3 Parents or guardians should consent on behalf of a mentally-impaired adolescent up to the age of 18 years.

6.4 If parents refuse essential treatment or if there is conflict between the parents then it may be necessary to ask the Court for permission to treat.

7 Who takes responsibility for mentally-impaired adults?

7.1 For a mentally-impaired adult the clinician takes responsibility "to do his best for the patient". Of course the clinician should discuss the issues in detail with parents and carers but a third party should not be asked to sign a consent form. The clinician should write in the case record what he has done and why, especially if parents or carers express misgivings. For difficult cases it is prudent to get the support of an appropriately-trained clinical colleague and this is especially so if the opinion of a parent/carer is to be over-ridden. Normally this should be the responsibility of a consultant.

7.2 Treatment can be lawfully withheld from a patient in a persistent vegetative state where there is no hope of recovery and the patient would die shortly provided that responsible medical opinion felt that continuing treatment was futile (this is a result of the ruling regarding Tony Bland who was crushed in the Hillsborough Stadium disaster). It is not certain whether or not the same ruling would hold for cases of severe cerebral palsy. It has been suggested that if the circumstances are clear, doctors do not

even need to apply to Court for a declaration (Frenchay Healthcare Trust - v- S [1994] 2 AER 403) but if there is any doubt a legal ruling should be sought. (This is important for an endoscopist asked to provide a feeding line via a PEG).

- 7.3 In an emergency the endoscopist takes responsibility and no consent is necessary.

8 *Jehovah's Witnesses*

- 8.1 Refusal to receive a transfusion of blood or blood products by a competent Jehovah's witness must be accepted as irrefutable. Specific guidelines prepared by the Jehovah's Witnesses are available to aid decision making.

- 8.2 If it is deemed that the child of a Jehovah's Witness requires transfusion of blood or blood products in relation to an endoscopic procedure a Court order should be sought.

9 *What are the responsibilities of the endoscopist in respect of sedation?*

- 9.1 In giving advice to patients about the procedure it is necessary to explain how best to minimise discomfort. The patient should be offered the choice to have sedation or not.

- 9.2 If sedation is to be used it is important to advise patients of special precautions to be taken after leaving the hospital with respect to the consumption of alcohol, the driving of vehicles and the operation of machinery. Patients must be advised to avoid potentially dangerous activities for 24 hours. This advice should be given in written form as well as verbally. Most endoscopic procedures of the gastro-intestinal tract are carried out

under simple sedation using drugs which depress the central nervous system but allow the patient to respond to command throughout the period of sedation. The technique should carry a margin of safety sufficient to avoid unintended loss of consciousness. If the level of sedation exceeds these limits then problems such as depression of vital centres and aspiration become likely.¹¹ The law and defence organisations are seldom, if ever, prepared to defend an operator/anaesthetist who has an accident with sedation. It is usual for an experienced endoscopist to take responsibility for sedating the patient as well as undertaking the procedure but it should be a minimal requirement that a second appropriately-trained person is present throughout the procedure. Such a person may be a nurse who is qualified as an endoscopy assistant and who is capable of monitoring the clinical condition of the patient throughout the procedure. Should the occasion arise he or she must be capable of assisting the doctor in the case of an emergency. If intravenous access is used to administer drugs the needle should be left in place until recovery is complete.¹²

10 *What should be done if the patient withdraws consent half-way through the procedure?*

- 10.1 Almost always withdrawal of consent comes from a struggling patient who is under the influence of drugs. The endoscopist then has the responsibility of doing what he considers to be in the patient's best interests. For example if a stone is about to be released from the lower end of the common bile duct then, after a pause for explanation and perhaps further sedation, the best course of action may be to continue.

10.2 If the patient is struggling and the procedure is likely to take more than an extra few minutes then it is prudent to withdraw the endoscope, allow the patient time to recover and then to discuss with him/her how best to proceed. For example, the endoscopic procedure could be performed at a later date under a general anaesthetic, or an alternative investigation such as contrast radiography may be considered more appropriate.

11 *Figures for complication rates for different endoscopic procedures*

It is likely that many tertiary centres of excellence will have lower complication rates for therapeutic endoscopy than some smaller units. Where possible it is best to quote complication rates for the unit where the procedure is to be performed.

Endpiece

This paper deals solely with informed consent which is only one of the items of information needed by patients before they undergo an endoscopic procedure (Appendix C). In an audit of 16 out of 18 Endoscopy units in Northern region it was found that adequate written information about risks; about procedures for consent; and about aftercare was provided to patients in only four instances. Re-assessment of the quality of information given in pamphlets, after advice had been given, satisfied the standards of audit in only 12 of the 18 units.¹³ Thus in the country as a whole it seems likely that many endoscopists fail in their duty to patients to provide adequate information. (Appendix D). As a result they leave themselves open to unnecessary and painful litigation. It is prudent to remember the aphorism provided by an experienced barrister dealing in this area who said, "People who are talked to seldom sue".⁶

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APPENDIX A

An example of a patient information leaflet on PEG tube insertion*.

HAVING A GASTROSTOMY (PEG)

General Explanations

Those looking after you are concerned that you are not receiving enough nourishment because you have difficulty in eating. We are asking your agreement to introduce a small tube into your stomach through the skin and between the navel and the breast bone. By placing a tube through the skin and underlying tissues in this way it is possible to avoid the need for a tube which passes through your mouth or nose. Liquid nourishment can be introduced through the tube several times a day to replace or supplement what you take by mouth so that your body will receive a normal amount of food each day. Between the times when the fluid is introduced, the tube can be closed so that it cannot be seen beneath your clothes and visitors need not know that it is there. It is likely that you will need to receive nourishment every day through this tube for at least several weeks.

What you Should Expect

Before the Procedure

A doctor will explain what is going to be done and will ask you to sign a consent form. This is to ensure that you understand the procedure and its implications. If you have any questions or worries do not be afraid to ask.

Passage of an Instrument and Tube Through Your Mouth

You will be asked to remove false teeth and spectacles. Then you will be made comfortable on the bed resting on your left side. A nurse will stay with you throughout. The doctor will give you an injection to make you feel sleepy and relaxed. To keep your mouth open a plastic mouthguard will be put between your teeth.

A flexible instrument, thinner than your little finger with a bright light on the end, will now be gently introduced into your mouth over the back of your tongue and down into the stomach. Some air will be passed through the instrument to distend the stomach and allow the doctor a clear view.

Later this instrument with the light will be removed quickly and easily. It will be replaced by a soft plastic tube which will be drawn over your tongue and down into the stomach.

Passage of a Needle and Tube Through the Skin of the Abdomen

A local anaesthetic injection will be given at a point in the skin of the upper abdomen. A needle and small tube will then be introduced at this point through the skin and into the stomach. You may feel a sense of painless pressure while this is done.

After the Procedure

The insertion of the tube takes about half an hour. It is quite likely that the back of your throat will feel slightly sore for the rest of the day. You may also feel a little bloated if some of the air remains in your stomach. Both these discomforts will pass and will usually need no medication.

Feeding

Fluid will first be introduced through the tube on the following day. Over the next 3-4 days a regime of feeding will be established and the relevant people will learn how to manage the feeding system. It should then be possible for you to receive nourishment through the tube every day for as long as it is needed.

Care of the Tube

You or those looking after you will need to keep clean the point at which the tube passes through the skin. Once the tissues have healed it is possible for the tube to be replaced if necessary.

Potential Problems

There may be a slight risk to crowned teeth or dental bridgework, and you should tell the doctor if you have either of these.

Occasionally, a problem arises because the tube, or the instrument used to introduce it, damages the stomach or leads to a leak of stomach contents. These unusual complications can require special treatment including an operation.

An infection can occur at the point where the tube passes through the skin and an antibiotic may be given to reduce this risk or treat any infection that occurs.

* the committee are grateful to Professor John Lennard-Jones for kindly preparing this example leaflet.

APPENDIX B

An example of a possible consent form.

Endoscopy Consent Form

I
of
.....
hereby consent (or hereby consent to the submission of my child/ward)
.....to undergo endoscopy, the nature and purpose of which
have been explained to me by Dr I have understood the information that
has been given/told to me about the procedure. I have been given the opportunity to ask ques-
tions. I also give consent for any necessary biopsies, photographs or X-rays to be taken.

Warning

1. * For gastroscopy, dilatation/stent insertion in the oesophagus, PEG tube and any other endoscopic procedure.

I understand that all endoscopic procedures carry a very small risk of haemorrhage or perforation of the gut, following which surgery may be necessary. Other rare complications include aspiration pneumonia and a reaction to the IV sedative drugs used to sedate me. Upper gastrointestinal endoscopies may involve a slight risk to crowned teeth or dental bridgework.

2. * For Colonoscopy and Flexible Sigmoidoscopy

I understand that these examinations carry a small risk of damage to the lining of the large bowel which may need to be repaired by means of surgical operation. The risk of perforation or bleeding is increased if it is necessary to treat polyps with hot biopsy forceps or a polypectomy snare.

3. * For ERCP

I understand that ERCP is an endoscopic procedure that may damage the bile duct or produce either cholangitis (infection in the bile duct) or inflammation of the pancreas. If a sphincterotomy is necessary then the risk of haemorrhage or perforation is increased. If a stent is inserted through an area of narrowing in the bile duct or pancreas to relieve jaundice, again cholangitis and pancreatitis may occasionally occur. I understand that the stent may need to be replaced from time to time.

*** Delete where necessary**

Date: Signed:
(Patient)

I confirm that I have explained to the patient the nature and purpose of the endoscopic procedure.

Date: Signed:
(Medical Practitioner)

APPENDIX C

Suggested style and items that should be included in any information sheet provided for patients undergoing endoscopic procedures

Specific items may need omission or different emphasis depending on the intended audience - Out patient, Day case or In patient

Different pamphlets will be needed for upper gastrointestinal endoscopy, colonoscopy, ERCP and certain therapeutic procedures

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1. Information should be clear, informal and understandable to the lay person, avoiding the use of jargon. (Plain English).
 2. There should be clear directions for finding the endoscopy unit.
 3. There should be a contact telephone number for the endoscopy unit.
 4. There should be accurate and unambiguous statements regarding fasting or bowel preparation.
 5. There should be information on the taking of regular medications (or a request to contact the endoscopy unit if in any doubt).
 6. Instructions for diabetic patients should be included (perhaps just a request to contact the unit).
 7. **Procedural risks should be clearly itemised.** This might include minor problems such as a sore throat but MUST include substantive risks associated with therapeutic endoscopy where relevant.
 8. For upper gastrointestinal endoscopy, a discussion of sedation and non-sedation with throat spray should be included.
 9. **Consent procedures should be explained.** Some units may opt to undertake this task in a clinic setting, others may send the consent forms with the information sheets, but asking for them to be signed when they arrive at the unit after discussion with the endoscopist or nurse practitioner.
 10. Emphasise the value and availability of spoken clarification for the patient when they attend the endoscopy unit.
 11. Care after the procedure, including side effects, should be described.
 12. "Do's and Don'ts" on going home should be stated.
 13. **Information on getting the result of the endoscopy should be stated.** This may be the General Practitioner, a referring consultant or a member of the endoscopy staff. If this is unclear, it can be very frustrating for the patient.
 14. Follow up arrangements should be stated where applicable.
 15. A statement asking for valuables to be left at home should be included.

APPENDIX D

Suggested Audit Standards For Consent And Patient Information

1. Information leaflets are in 'Plain English'.
 2. Information leaflets for Out patients and/or Day case patients include ALL the information points outlined in Appendix C.
 3. All patients have access to the relevant information and give 'informed consent' (see 5).
 4. The correct consent procedures are used for all patients who are unable to give informed consent themselves. (This can be a particular problem for patients requiring PEG insertion).
 5. A patient survey is undertaken at least once a year to ensure:
 - information is appropriate and understood
 - 'informed consent' was given from the patient's perspective
 - opportunities for verbal clarification worked.
 6. The procedural risks for your own unit are known and accurately stated in the information sheets.
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Quality Issues

Quality Assurance

Are minimal standards for information availability and consent procedures achieved? Monitoring of patient complaints and compliments regarding the endoscopic service can help to identify areas for improvement.

Quality Monitoring

The audit suggestions above can contribute to this, especially '5'.

Quality Control

Are critical events such as serious complications and lapses in consent procedures identified, monitored and minimised by rigorous review?

Quality Improvement

No unit will be able to meet all the outlined criteria but mechanisms should be put in place to achieve an 'ideal' situation over time with the constant drive to improve procedural performance both technically and from the patient's perspective.

Clinical Risk Management

These standards should be seen as a critical element of Risk Management in endoscopic practice. Other issues would include ensuring appropriate indications for all endoscopic procedures and monitoring technical competence including complications.

We plan that this guideline will be revised from time to time. Comments or suggestions for use in subsequent editions should be sent to: The Clinical Services and Standards Committee, British Society of Gastroenterology, 3 St Andrews Place, Regent's Park, London NW1 4LB.