



**BRITISH SOCIETY
OF GASTROENTEROLOGY**

*Guidance for Obtaining a
Valid Consent for Elective
Endoscopic Procedures*

A Report of the Working Party of
the British Society of Gastroenterology
Replaces guideline published 1999

April 2008
<http://www.bsg.org.uk>

CONTENTS

1. Why consent is crucial
2. What is valid consent
3. Basic principles
4. Twelve key points of consent law
 - 4.1 When do health professionals need consent from patients
 - 4.2 Children
 - 4.3 Who is the right person to seek consent?
 - 4.4 What information should be provided?
 - 4.5 Reasonable information
 - 4.6 Text essentials
 - 4.7 Does it matter how the patient gives consent?
 - 4.8 Refusal of treatment
 - 4.9 Adults who lack capacity; The Mental Capacity Act
 - 4.10 The Independent Mental Capacity Advocate
5. Procedures for competent adults
 - 5.1 Single stage intervention
 - 5.2 Complex intervention
6. Direct Access Endoscopy Service and One stop Clinics
7. Refusal of Treatment
8. Tissue
9. Clinical photography and video recordings
10. Procedures for patients who lack capacity
12. Mental Health Act
13. Resolving disagreements
14. Scotland and Northern Ireland
15. Legal Annex
16. "Best Interests"

References

These guidelines have been prepared by the British Society of Gastroenterology. They represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability.

Guidance for Obtaining a Valid Consent for Elective Endoscopic Procedures

Authors:

Dr Hugh Shepherd MB, BChir, MA, FRCP

Dr David Hewett MSc., MSPHM, MBCS, CITP, MHSM

ACKNOWLEDGEMENTS:

BSG Endoscopy consent sub committee

Dr Robin Teague (chair)

Dr Miles Allison

Sister Susan Cramp

Sister Di Campbell

Dr Hugh Shepherd

Dr Anthony Mee

Dr David Hewett

Cheryl Blundell (Solicitor)

Approved by:

BSG Endoscopy Committee

Clinical services committee

BSG Council

JAG

INTRODUCTION

Endoscopic procedures are safe and practiced extensively worldwide. These techniques offer a powerful range of diagnostic and therapeutic interventions that are increasingly performed as outpatient day cases on large numbers of patients.

Procedural sessions can be very busy, often with a high volume throughput of patients who have had "direct access" to the service, having previously been seen only in primary care.

The increasing importance of patient centred practice coupled with ease of access to endoscopy services, has challenged the practical ability of endoscopic units to maintain high clinical standards. This is particularly true when obtaining valid consent for this invasive intervention.

Aspects of good consenting practice are now an important component in the Global Rating Scale (GRS) assessment of UK endoscopy units

This document sets out the standards and procedures that are appropriate for elective endoscopic procedures in adults. It is based upon current guidance from the Department of Health, the General Medical Council and other relevant sources.

1. WHY CONSENT IS CRUCIAL

Patients have a fundamental human right to determine what happens to their own bodies. Respect for this right to personal autonomy is a cornerstone of good medical practice.

Treatment without "informed valid consent" will usually imply that autonomy has been somehow overridden and will

thus constitute a breach of article 2, 3 or 8 of the Human Rights Act (1998).

Valid consent to treatment is therefore central to all forms of healthcare, from providing personal care to undertaking major surgery, and always in the patients' best interests.

Good consenting is a standard of good medical practice, an example of partnership working with patients, reflective of prevailing standards within a Trust, and is important as a source of objective evidence in cases of clinical mishap.

1.1

Standards for consenting practice must be applied to all patients. In a life threatening emergency the need to undertake treatment quickly may render full compliance impossible. Where consent cannot be obtained action taken must be the minimum consistent with the patient's best interests, in line with current good practice, and in accordance with that which a peer group would concur.

2. WHAT IS VALID CONSENT?

"Consent" is a patient's agreement to permit a health professional to provide care. Consent is freely given, based upon a consideration of the reasons why the proposed treatment or intervention is needed, and the consequences (benefits, risks and harms) that may flow from it.

Consent is a process which commences with the identification of a need to intervene in some way, and culminates with its completion. Some aspects of the concept (relating to samples and records) arising from an intervention persist long after the event. Consent may be given for a single procedure or for a series.

Patients may indicate consent implicitly, that is, non-verbally (for example by presenting their arm for their pulse to be taken), orally, or explicitly in writing. Specifically, attendance does not imply consent.

There are no absolutely clear rules about when written consent is required, and when implicit consent is sufficient. Such demarcations as there are rest on custom and practice. Whilst core examples (all major surgery requires written consent whereas most venesection does not) are clear, the boundaries are fluid, and standards vary locally (e.g. cystoscopy is often performed without written consent)

As a general rule the gravity of the proposed intervention usually determines the most appropriate form of consent. Criteria such as procedures that are scheduled, invasive, complex, require sedation or anaesthetic, or are associated with significant risk, should be used to determine interventions that will require written consent.

Written consent should be a default option, to be used where circumstances indicate the presence of an unusual complicating factor.

Using this guidance all flexible endoscopic procedures require written consent.

3. BASIC PRINCIPLES

For consent to be valid, the patient must:

- Be adequately informed
- This means having received sufficient information to understand the procedure, its benefits, and the risk of harms that may arise.
- Be competent to take the particular decision
- Competency means the patient is able to understand, retain, use or weigh up the information needed to make a decision and can communicate their wishes. Failure on any one of those 4 elements of the test will render the patient incompetent.
- Not be acting under duress or be coerced (directly or indirectly) into any particular decision.
- All competent patients have the right to choose alternatives, refuse or withdraw consent at anytime.

Written consent formally confirms that an exchange of information (clinical and non clinical) has occurred between the patient and the Healthcare professional, and that on the basis of the information exchange, that the patient is content to proceed.

Where an adult patient lacks the mental capacity (either temporarily or permanently), to give or withhold consent for themselves, **no-one else can give consent on their behalf** unless there is a valid Personal Welfare Lasting Power of Attorney. (LPA). This should not be confused with a Property LPA, which has a restricted application.

4. TWELVE KEY POINTS ON CONSENT: THE LAW IN ENGLAND

In busy clinical practice it can be challenging to fully satisfy current NHS guidance and legal processes recognise these difficulties. This section applies the current guidance to endoscopic interventions.

4.1 When do health professionals need consent from patients?

Point 1.

Before you examine, treat or care for competent adult patients you must obtain their consent.

Point 2.

Adults are always assumed to be competent unless demonstrated otherwise.

If you have doubts about their competence, the question to ask is: "can this patient understand, retain and use or weigh up the information needed to make this decision and communicate his decision?"

Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation. A record of a formal assessment of competence may be necessary using Assessment Tools available from local Mental Capacity Act websites.

Point 3.

Patients may be competent to make some health care decisions, even if they are not competent to make others.

Point 4.

Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Confirmation of consent prior to the procedure is a requirement and is provided for on DOH/NHSLA compliant consent forms.

4.2 Children

Point 5.

Before examining, treating or caring for a child, you must also seek consent.

Young people aged 16 and 17 are presumed to have the competence to give consent for themselves.

Younger mature and intelligent children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved).

In other cases, some-one with parental responsibility must give consent on the child's behalf, (unless they cannot be reached in an emergency).

If a competent child consents to treatment, a parent **cannot** over-ride that consent.

Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check

4.3 Who is the right person to seek consent?

Point 6.

It is always best for the person actually treating the patient to seek the patient's consent but this may have practical difficulties.

However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, **or** if you have been specially trained to seek consent for that procedure. You must be capable of answering any reasonable question that a patient may ask, and know who to seek further advice from when unusual or novel situations arise.

Endoscopy nurses are capable of taking consent providing they have been trained to do so. It is recommended that their training is documented in their portfolio and this updated and re-assessed regularly.

The arrangements adopted locally should be recorded within the Trust Consent Policy, and be formally approved under local Governance procedures. This documentation should be readily accessible to any external inspection agency.

4.4 What information should be provided?

Point 7.

Patients need sufficient information before they can decide whether to give their consent:

- a. Information should include details about the process of the procedure (for example; the appointment, hospital, endoscopy suite, management of drugs and diabetes, arrangements on arrival and subsequent discharge, and contact numbers)
- b. The procedure itself, (including sedation) and aftercare
- c. The benefits and risks (complications and side effects) of the proposed treatment
- d. The possible alternative treatments both to the proposed intervention and in the case of treatment failure.
- e. The taking and retention of tissue samples
- f. The taking of photographic or video record

- g. The skilled supervision of and presence of any trainees
- h. The use of any experimental technique

Patients must be offered as much information as they reasonably need to make their decision. Also it must be in a form they can understand, and adequate time to read and understand the information must be given.

Failings in any of these areas may mean that their consent is invalid. There should be provision to increase the detail of information if requested.

4.5 What is reasonable?

Generally assumptions about what people need to know should not be made. The aim is to provide information so that patients can select for themselves how much detail they want to acquaint themselves with. Information about further sources should be available so that follow up can be made when required.

Where materials are provided these should be written so that readers should be able to feel comfortable that there is a well organised and structured process involved. They should be able to derive an understanding of what is about to happen, when, where, why it will occur. To aid the decision process the benefits as well as the things that might go wrong must be clearly set out. Overall the impression that the whole process is dedicated to their best interests must be conveyed.

Encompassing information from other units, taking information guidance from the BSG professional body, and patient questionnaires (GRS standard), and use of the GRS website knowledge base, are methods of applying reasonable objectivity to individual unit practice.

Experience has shown that written information is essential with additional verbal discussion if necessary. The content and format of the information is important and inevitably will be presented in differing ways by different Trusts.

4.6 It is essential that the text includes:

- The key components to the consent process as listed above
- Information is professionally presented, written in plain language and available in languages other than English
- The risks must be discussed as well as the benefits.
- Not every possible risk needs to be detailed but as a general principle those that are considered significant, and could possibly influence the decision of a patient would be included. Examples might be common side effects with minor impact (for example, a sore throat after gastroscopy or abdominal discomfort after colonoscopy)
- Complications commencing at the 0.5-1.0% level (eg possible damage to teeth during gastroscopy)
- Any potential serious procedurally related complication, no matter how rare, likely to threaten life (for example, perforation) or produce permanent or long-term disability, long term pain or an admission to hospital (for example, ERCP related pancreatitis).

Ideally, the standardised consent form, should be an integral part of the consent pack and each customised for every individual procedure.

4.7 Does it matter how the patient gives consent for endoscopy?

Point 8.

Yes for endoscopy:

Consent for endoscopy must be given in writing, voluntarily and in a timely way: free from any form of duress or undue influence from any third party or health professional.

The issue of consent given in an endoscopy procedure room often provides cause for debate. Where an elective procedure is involved it would be difficult to defend the practice where a primary consent was involved and the patient had not encountered the endoscopist before.

There are a number of grounds upon which a challenge could subsequently be made:

- A lack of time to permit a considered decision
- An inappropriate environment for sympathetic and considerate discussion
- A perceived lack of any alternative to acquiescence on the part of the patient.
- Placing a definitive decision at the culmination of a preparation process rather than closer to the outset.

Unfortunately some patients react to the loss of autonomy and accompanying anxiety which inevitably results from entering a hospital by becoming submissive and excessively compliant.

Examples of patients coming forward when someone else's name is called are familiar to most clinics. Some have even been known to undergo procedures intended for another.

For this reason checks on identity at key stages in any procedure are essential.

The confirmation of consent is best obtained outside of the procedure room and would be reflective of an ethos of good patient centred practice with regard for timeliness and unpressured decision making.

Compliance with this guidance is currently a GRS standard.

Point 9.

A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and acknowledge the information exchange and the discussions that have taken place.

Consent can be withdrawn, without reason, at anytime and a signed consent form does not negate any patient's legal rights.

4.8 Refusal of treatment

Point 10.

Competent adult patients are entitled to refuse treatment or withdraw consent, for any reason, at anytime, no matter how perverse it might seem, even when the intervention would clearly benefit their health.

The only exception to this rule is where the treatment is specifically for a mental disorder and the patient is detained under the Mental Health Act 1983.

A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.

Procedural distress and withdrawal of consent

If an *un-sedated* patient withdraws consent during a procedure, the procedure must be immediately terminated and the event recorded in the notes.

If a *sedated* patient, characteristically, begins to struggle, and by physical and verbal act withdraws consent, the situation is entirely different. It is the responsibility of the endoscopist to act in the patient's best interests.

If this event occurs at a crucial time, which will have an impact on a successful outcome, for example, removal of a bile duct stone, then it would be wise to pause, attempt to regain co-operation and complete, perhaps with additional sedation.

If the situation deteriorates, is irretrievable, and patient safety is likely to become compromised, then termination of the procedure is recommended.

A written record must be made.

4.9 Adults who are not competent to give consent: The Mental Capacity Act of 2005

Point 11.

This situation is now covered by the Mental Capacity Act 2005, (MCA enacted 2007), and not only represents a departure from previous practice but provides a new structure for managing the care of temporarily or permanently incapacitated patients.

There is a both a legal and a professional duty to comply with the new Act, but there are no specific sanctions for failure to do so. However, failure to comply can be used as evidence in criminal proceedings.

No-one can give consent on behalf of an incompetent adult unless nominated within a valid Personal Welfare Lasting Power of Attorney (LPA), or appointed a deputy by the Court or as a named person (in care proceedings), in which case you must consult with them.

In these cases it is the attorney or advocate who must, in giving or withholding consent, act in the best interests of the patient.

In the absence of a Personal Welfare LPA, but where there are legal family or guardians, you may treat an incompetent patient if the treatment would be in the patient's best interests. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

Remember that 'best interests' is a concept that goes wider than "best medical interests". It includes factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors.

4.10. The Independent Mental Capacity Advocate (IMCA)

In situations where an incompetent patient has no identified relatives or, significant friends other than paid carers, an IMCA must be engaged to represent and support them when important or potentially life saving decisions are to be made.

The IMCA will not make a decision for the patient, but clinicians have a legal and professional duty to take full account of the information and advice given by the IMCA.

Point 12.

If a currently incompetent patient has clearly indicated in the past, while competent, an intention to refuse treatment in certain circumstances (an 'advance decision' also called an advance directive'), and those circumstances arise, you must abide by that decision if it is valid and applicable.

Advance directives about life-sustaining treatment must be made in writing and contain a specific statement which specifically confirms that the advance decision applies even if their life is at risk.

The decision must be signed by the patient, (or by someone else appointed by them), in the presence of a witness, who must also sign the document.

This summary cannot cover all situations. For more detail, consult the Reference guide to consent for examination or treatment, available from the NHS Response Line 08701 555 455 and at www.doh.gov.uk/consent

For further details on LPAs see the Public Guardian website <http://www.publicguardian.gov.uk/index.htm> and advance directives see <http://www.publicguardian.gov.uk/docs/making-decisions-opg603-1207.pdf> as well as the Department of Health's Reference guide to consent for examination or treatment (chapter 1, paragraph 19). A copy can be accessed at www.doh.gov.uk/consent

5. PROCEDURES TO FOLLOW WHEN OBTAINING CONSENT FROM COMPETENT ADULTS

5.1 Single stage interventions

In the case of diagnostic endoscopy, it might reasonably be anticipated that the intervention will be an event containing the actions of intubation and inspection.

If during the procedure it is anticipated that an additional intervention (for example taking a biopsy sample) will be required, then the consent, which is to be obtained, must in advance, reflect the possibility of additional activity.

Therefore, even common interventions such as mucosal biopsy and polypectomy must be specifically consented. The consent obtained must also explicitly cover the retention of any tissue.

Should an unexpected pathology be discovered, which incidentally will require endoscopic treatment, and the patient has not been fully consented, then it is recommended not to proceed at once. Additional consent should be sought and the procedure performed at a later time.

An example of this might be: the later dilatation of an oesophageal stricture coincidentally found at the time of a diagnostic gastroscopy.

However if the chance discovery, was considered to be life threatening, for example, a distended varix that suddenly began bleeding during diagnostic gastroscopy, then active intervention would clearly be necessary in the patient's immediate best interests.

5.2 Complex interventions

Complex interventions are those which contain multiple activities within a single event, or are comprised of a series of events spread over time.

Consent for all of the components of the entire intervention must be sought at the outset. Both the provision of written information, and one to one discussion are wise steps to take.

Accurate and detailed recording of the information exchange should be made in the medical records. However, this is less important if there are specific consenting information packs available for such complex procedures.

An example would be therapeutic gastroscopy with the intention of relieving malignant oesophageal obstruction involving both dilatation and the insertion of a prosthesis.

While administrative arrangements will vary locally, a designated member of the team must check that the appropriate consent form has been signed. This is particularly important if a series of events is planned, as it must be done, and confirmed with the patient on each occasion.

The health professional carrying out the procedure is still ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held accountable if this is challenged later. A robust consenting process, perhaps aided by an appropriate checklist, will mitigate against this happening.

6. DIRECT ACCESS ENDOSCOPY SERVICE AND ONE-STOP CLINICS.

An open access clinic is defined as, one which offers General Practitioners the opportunity to refer patients for an investigation or treatment directly, without the need for patients to be seen in outpatients before it is undertaken.

Endoscopy is often included in the treatment protocols of one-stop clinics.

Some Trusts have adopted a combined approach to providing advance information and obtaining valid consent for possible interventions.

The consent form (usually signed at home), is integrated within the information pack, which is posted to the patient and brought by the patient to the clinic.

An opportunity for further discussion must always be offered, and confirmation of consent is recorded, before the procedure begins.

This remote or postal consenting process has been successfully piloted over many years and now, when it has been implemented through appropriate local clinical governance procedures has not impeded accreditation for CNST (Clinical Negligence Scheme for Trusts) by the NHSLA (NHS Litigation Authority).

Each endoscopic procedure pack has accompanying unique consent literature, which contains an integrated model consent form. If used, and with local customisation changes only being permitted, will be recognised and accepted by the NHSLA.

These documents have been designed for the sole and exclusive use of the clinic and endoscopic service concerned and for no other purpose.

It is suggested that endoscopic procedures which can be considered for this type of remote and advanced consenting are: diagnostic gastroscopy, therapeutic gastroscopy (oesophageal dilatation for peptic stricture and achalasia, oesophageal stenting, variceal treatment, Botox injection therapy, flexible sigmoidoscopy, colonoscopy with polypectomy or endoscopic mucosal resection, combined gastroscopy and colonoscopy, and endoscopic ultrasound.

The quality of this methodology is further strengthened by Trusts using a standardised process, where possible, using material that can be downloaded from the BSG website.

Procedures such as PEG insertion and ERCP, although sometimes performed as day cases, are recognised as being more complex both technically and clinically.

It is recommended that the advance consent process is inappropriate here, and that more conventional methodology should be employed where the patient is consented within the hospital environment, with informational material having been made available in advance, but with timely consenting within the hospital environment; usually using DOH model consent forms 1 or 4.

Trusts are committed to ensuring that patients whose first language is not English receive the written and verbal information they need and are able to communicate appropriately with healthcare staff.

Remember, it is not appropriate to use children to interpret for family members who do not speak English.

Trusts can subscribe to 'Language Line' a telephone interpreting service. This is a 24hour service which enables you to communicate quickly and easily with non-English speaking people in their own language.

Other helpful guidance is found in the toolkit, *Bridging the Gap*, produced by Sheffield Health Authority and the Commission for Racial Equality.

7. REFUSAL OF TREATMENT

1. If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment. A competent patient's decision to refuse treatment (on grounds of religious or other personal belief or any other reason) must be respected even if it will result in harm or death, except in circumstances governed by the *Mental Health Act 1983*. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail. The following paragraphs apply primarily to adults.
2. If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, you

(and where possible the patient) should note this on the form.

3. Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.
4. If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care.

Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

8. TISSUE

1. The legal position regarding the retention, storage and later use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all.

At present, Trusts require that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be retained and used for education or research purposes.

The retention of tissue samples requires specific consent (Human Tissue Act 2004). The Act established the Human Tissue Authority (HTA) as the regulatory body for all matters concerning the removal, retention and use of human tissue. The HTA publishes Codes of Practice on consent, donation of organs, tissue and cells for transplantation, post-mortem examination, anatomical examination and the removal, storage and disposal of human organs.

2. The Department of Health believes that tissue samples may be used for quality assurance purposes *without* requiring specific patient consent *provided* there is an active policy of informing patients of such use. This is essential to assure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised.

Human Tissue Authority website – Codes of Practice www.hta.gov.uk/guidance/codes_of_practice.cfm

9. CLINICAL PHOTOGRAPHY AND CONVENTIONAL OR DIGITAL VIDEO RECORDINGS

1. Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.
2. Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient.

The one exception to this principle is set out in paragraph 3 below.

If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

3. Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.
4. If you wish to make an external photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are sedated or unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.

5. If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of someone close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

10. PROCEDURES TO FOLLOW WHEN PATIENTS LACK CAPACITY TO GIVE OR WITHHOLD CONSENT

The Mental Capacity Act 2005 requires a presumption that every adult patient has the capacity to make decisions about their care and treatment and to decide whether to agree to, or refuse, any proposed medical intervention.

Fortunately, perhaps with the exception of decisions surrounding PEG insertion, the endoscopist will normally be involved in decisions which have a only a short term impact on the patient's life.

Presumed competence means that only if it is shown that, at a particular time surrounding intended clinical intervention, the patient, (after either formal assessment, or having been given all appropriate help and support), cannot under-

stand, retain, use and weigh up the information needed to make a decision and so cannot communicate their wishes, can an adult patient be regarded as lacking capacity.

When patients may be able to make simple decisions, but not complex ones there is an added responsibility to assess their capabilities with great care. Clinicians must support and engage patients to the limit of their capacity.

There are assessment tool kits available to guide clinicians through an assessment process (eg www.hants.gov.uk/mental-capacity-tool-kit.pdf), and of course help can be sought from more experienced colleagues including a psychiatrist when necessary.

10.1 This process will involve:

- Discussing treatment options at a time and in a place when the patient is best able to understand and retain the information.
- Discussing with patients the possibility of bringing a relative, carer or friend, or making a recording of the consultation, to help them remember the information discussed.
- Speak to patient's carers, close family members and other health care staff about the best ways of communicating with the patient, where the patient agrees.

Where there is a lot of information to remember, or the decision will have a significant effect on their life or care, you should offer patients a record of the discussion and any decisions made during a consultation (including relevant information about why the decision was made).

Standard model consent form 4, which requires the additional signature of a doctor who knows the patient and confirm that the treatment is in their best interests should be used for this type of consent.

Typical examples where there may be a lack of mental capacity and the Act will apply are:

Stroke or brain injury

Mental health problem (patients not subject to a section order)

Dementia

Learning disability

Altered level of consciousness because of illness or treatment

Substance misuse

10.2 Making decisions with patients who lack capacity

1. Make the care of your patient your first concern. Decisions made must always be in the patient's best interests.
2. Treat patients as individuals and respect their dignity
3. Encourage and support patients to be involved in decisions about their treatment and care.
4. Treat patients with respect and not allow your personal views or assumptions about patients' lifestyle, beliefs, views or quality of life to adversely affect the decisions you make about their treatment and care.
5. Anything done for or on behalf of people without capacity should be the least restrictive of their basic rights and freedoms.

In reaching a decision about any proposed investigation or treatment, you must also consider:

1. Whether the patient's loss of capacity is temporary or permanent; allow for fluctuations.

2. What options for treatment are clinically indicated.
3. Which option (including the option not to treat) would be least restrictive of the patient's future choices.
4. What you and the rest of the health care team know about the patient's wishes and feelings, beliefs and values.
5. Any evidence of the patient's previously expressed preferences, such as an advance statement or decision.
6. The views of the patient's partner, family, carer or other person who has an interest in the patient's welfare.
7. The views of anyone that the patient asks you to consult, or in the absence of friends or relatives the IMCA service
8. What information is relevant to the decision that has to be taken and follow the guidance in DOH "Confidentiality: Code of Practice"

It is recommended that you refer to the document, "Booklet 3: "Making decisions: a guide for people who work in health and social care"" www.doh.gov.uk/consent

11. MENTAL HEALTH ACT 1983

This Act provides for and sets out the circumstances in which people with mental disorders can be legally required undergo treatment without their consent. This will primarily be for their mental disorder but other medical intervention is included where it has a bearing on the mental illness concerned.

An example might be for endoscopy to be performed to retrieve swallowed objects hazardous to health.

The Mental Health Act has been under review, and a draft bill has been laid before Parliament.

12. RESOLVING DISAGREEMENTS

You should aim to reach a consensus about a patient's care and treatment, by giving adequate time for discussions between the parties. Where differences of opinion cannot be resolved satisfactorily, you should consult more experienced colleagues. In complex cases where it is difficult to reach agreement, you may also find it helpful to seek multi-disciplinary clinical, ethical review, independent of the healthcare team. As a last resort a judicial review resulting in a binding declaration can be carried out by a Judge in the Court of Protection (in England and Wales) Further information is available on www.doh.gov.uk/consent

13. ADDITIONAL INFORMATION

Scotland: Adults with Incapacity (Scotland) Act 2000

This Act provides ways to help safeguard the welfare of people (aged over 16yrs) who lack the capacity to take some or all conditions themselves.

It allows other people to make decisions on their behalf.

Section 1 sets out the general principles that are to be followed by anyone acting under the provisions of the Act to make decisions or intervene in the affairs of an adult. The Act is supported by codes of practice setting out guidance for those acting under the legislation.

Part 5 covers decisions about medical treatment and research.

www.opsi.gov.uk/legislation/scotland/acts/2000/20002004.htm

Northern Ireland

There is currently no primary legislation, and decisions about medical care when patients lack capacity must be made in accordance with common law, which requires decisions to be made in the patient's best interests.

14. LEGAL ANNEX

Four leading cases in English law have set precedents and serve to highlight some of the driving principles surrounding the application of practice guidance.

1. *In the opinion of your peers; would a significant number (not necessarily a majority, see below**) of them have acted in a similar way?*

Bolam v Friern Hospital Management Committee (1957) 1 WLR 582

"He or she must act in accordance with a responsible body of professional opinion"

2. *Declaration of risk, especially the magnitude of risk.*

Sidaway v Governors of Bethlem Hospital (1985) AC871

The case involved a risk of spinal cord damage of less than 1%. Lord Bridge indicated that the degree of disclosure to assist a patient in deciding whether or not to undergo a procedure was a matter of clinical judgement. However, if the disclosure of a particular risk was such an obviously necessary component to an informed choice; no reasonably prudent medical man would fail to make it.

Chester v Afshar (2004) UKHL 41 Pt2

Mrs Chester was left partially paralysed after surgery for a lumbar disc protrusion. Dr Afshar had failed to warn Mrs Chester that the risk of this complication was unavoidable (1-2% for routine cases).

The House of Lords ruled that the failure to disclose the risk was a breach of duty. Furthermore, the rationale behind the duty to consent is to enable adult patients of sound mind to make their own decisions affecting their lives and bodies.

3. *Responsibility and duty of care, opinion of your peers and logical analysis of your actions.*

****Bolitho v City of Hackney Healthcare Trust (1998) AC 232**

A doctor failed to attend a call to see a patient, Patrick Bolitho, who subsequently sustained severe brain damage. This was a breach of duty. It was also alleged that on attending him the doctor should have intubated him.

However, the ruling indicated on this occasion that the breach of duty had not caused the injury as the claimant had failed to prove, on balance of probabilities, that the doctor should have intubated Master Bolitho.

The House of Lords held that where the breach of duty is an omission it had to decide what course of events would have transpired if the duty had been fulfilled.

Bolitho suggests that the "reasonable body of medical opinion" established in Bolam must be able to withstand logical analysis, and in this case the outcome was that the patient's progress was unaffected. The case therefore failed the test of causation.

This is an important case to consider principles when responsible for, and supervising trainees, who, when left unsupervised, call for assistance.

15. "BEST INTERESTS"

- It is important not to make assumptions about someone's best interests merely on the basis of person's age or appearance, condition or any aspect of their behaviour.
- The decision-maker must consider involve all the relevant circumstances relating to the decision in question.
- The decision-maker must consider whether the person is likely to regain capacity (eg. after receiving medical treatment). If so, can the decision wait until then?
- The decision-maker must involve the person as fully as possible in the decision that is being made on their behalf.

- If the decision concerns the provision or withdrawal of life sustaining treatment the decision-maker must not be motivated by a desire to bring about the person's death.
- Consideration must be made of previous wishes and beliefs
- Consultation with other people, named, relatives and close friends, an advocate or Court appointed person

REFERENCES

1. General Medical Council (2007) Consent: patients and doctors making decisions together. A draft for consultation. May-August 2007
2. Mental Capacity Act (2005)
3. Human Rights Act (1998)
4. Department of Health (2001) Reference guide to consent for examination or treatment
5. Department of Health (2003) Families and post mortems: a code of practice
6. Department of Health (2003) Confidentiality: NHS Code of practice
7. Human Tissue Act (2004)
8. Making decisions: A guide for people who work in health and social care (2007)
9. Journal Royal College of Physicians, Feb 2008

Designed, Typeset and Printed by
Q3 Digital/Litho
Loughborough, Leicestershire
01509 213456