GUIDANCE FOR OBTAINING VALID CONSENT FOR GASTROINTESTINAL ENDOSCOPY PROCEDURES

[Replaces guideline 2008]

Authors:


Corresponding Author:

Simon Everett
Level 4, Bexley Wing, Leeds Teaching Hospitals NHS Trust, Leeds Teaching Hospitals.
Simon.everett@nhs.net
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1 INTRODUCTION AND AIDS

Since the publication of “Guidance for Obtaining a Valid Consent for Elective Endoscopic Procedures”, a report of the working party of the British Society of Gastroenterology early in 2008, General Medical Council (GMC) principles on obtaining consent were published later in 2008 and the Department of Health Reference guide to consent was updated in 2009.

Many aspects of gastrointestinal endoscopy have changed since 2008. Endoscopy is now performed in far greater numbers by a wider variety of practitioners. Therapeutic endoscopy is more commonplace and the risks of some procedures are higher with a wider range of alternatives. Large numbers of patients are referred ‘straight to test’ via practitioners who do not necessarily have sufficient knowledge of the procedure and the risks, benefits and alternatives to the proposed investigations or are being managed outside of the traditional outpatient setting through screening and surveillance pathways. It is now recognised that the patient pathway through the unit should incorporate endoscopy specific safety checks whilst the workload of acute and in-patient endoscopy is increasing and requires specific guidance.

What has not changed since 2008 is that endoscopy units are busy. Many units have to combine the pathways of screening and elective symptomatic patients with acute and emergency procedures, yet manage the pressure of offering timely investigation, rapid throughput and ensuring an individualised, safe and comfortable experience for all patients.

This document replaces the guidance of 2008. Here we offer guidance and explicit standards on obtaining valid consent for both elective and acute or emergency endoscopic procedures. The guideline is restricted to gastrointestinal endoscopy and is intended for use by all practitioners who request or perform gastrointestinal endoscopy or are involved in the patient pathway. Standards for audit, documentation and training are also included.
2 METHODS

Members of the advisory group were selected to represent key opinion leaders in general and interventional endoscopy, nurse endoscopy, training and checklists, paediatric endoscopy, general practice, medicolegal practice and from patient representation. The composition of the advisory group was reviewed initially by the BSG Endoscopy committee then further reviewed and approved by the BSG Clinical Services and Standards Committee.

The proposed structure and content of this document was drawn up by the lead author (SE) and reviewed by all members of the advisory group. Medline and Pubmed databases were searched for relevant literature and web based searches were performed for any additional relevant documentation.

The guidance was drafted by two authors (SE and HG) and reviewed over several iterations by each of the advisory group. Specifically, input from a patient representative was sought from the beginning of the project. The completed version and recommendations were reviewed for accuracy by expert legal Counsel (KA and KN) before the final version.

There is a dearth of high quality clinical research on informed consent for endoscopy. Thus, recommendations were reached through consensus and discussion. The justification for each recommendation is in the body of the text and only recommendations for which there was complete agreement from all of the group have been listed. None of the recommendations are supported by high quality evidence in the form of randomized trials. However, where specific guidance is available in the form of current legislation, GMC guidance or active case law, this was deemed as sufficient quality on which to base strong recommendations. Thus each recommendation has been scored according to the GRADE system (available at http://www.gradeworkinggroup.org/index.htm, Table 1) and these guidelines conform to AGREE II principles. [1]
### 2.1 Table 1 – Grading of evidence and recommendations

<table>
<thead>
<tr>
<th>Grade of recommendation</th>
<th>Clarity of Risk/Benefit</th>
<th>Quality of supporting evidence</th>
</tr>
</thead>
</table>
| **1A. Strong recommendation.**  
High quality evidence | Benefits clearly outweigh risk and burdens, or vice versa | Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk. |
| **1B. Strong recommendation.**  
Moderate quality evidence | Benefits clearly outweigh risk and burdens, or vice versa | Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other form. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate. |
| **1C. Strong recommendation.**  
Low quality evidence | Benefits appear to outweigh risk and burdens, or vice versa | Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain. |
| **2A. Weak recommendation.**  
High quality evidence | Benefits closely balanced with risks and burdens | Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk. |
| **2B. Weak recommendation.**  
Moderate quality evidence | Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens | Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other form. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate. |
| **2C. Weak recommendation.**  
Low quality evidence | Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens | Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain. |
3  SUMMARY OF RECOMMENDATIONS

3.1  General Principles

- Owing to the invasive nature and potential risks, all endoscopic procedures of the gastrointestinal tract require written consent, except in an emergency situation. 1B [2(49)]

- Whilst the process of consent can be delegated, the endoscopist performing the procedure is responsible for ensuring that the consent process is appropriate for the procedure being undertaken. 1B [2(26)]

3.2  Assessment of Capacity

- All those delegated to obtain consent and all endoscopists must have sufficient understanding of the Mental Capacity Act to be confident that they can comply with its requirements when assessing capacity and taking consent. 1B [2(63)], 3

- The endoscopist performing the procedure must ensure that the patient has capacity to consent for the procedure at the time that it is being performed. If capacity to consent appears to have changed since consent was first obtained then re-assessment is required. Delaying the procedure to allow further adjustments or the opportunity to regain capacity may be appropriate, but a decision to proceed based on ‘best interests’ can also be considered. 1B [3,5(43)]

- If there is concern that all practicable steps have not been taken to maximize the patient’s ability to participate in the consent process to the limit of their capacity, or if there is doubt about the patient’s capacity to consent/have consented for that procedure, then the procedure must be delayed until such time as sufficient adjustments have been made or further advice sought unless the clinical situation is of such urgency that such delays will be harmful to the patient. 1B [3]

- Further, if it seems possible that capacity may be recovered, the procedure must be delayed until such time as capacity has maximized unless the clinical situation is of such urgency that such delays will be harmful to the patient. 1B [3]

3.3  Provision of Information

- For all patients, information should be provided in a format that they can understand about the expected benefits as well as the potential burdens and
risks and alternatives of any proposed endoscopic procedure. 1B [2(18), Montgomery]

- For out-patient elective procedures, verbal and/or written information should be provided by the clinician recommending the endoscopy and this should be documented in the case notes. 1B [2(19), 5(31)]

- For out-patient procedures, written information should be provided no later than at the time of booking the procedure. 1C

- Endoscopy units must retain standard information leaflets specific to their department that pertain to all standard endoscopic procedures performed regularly within that unit. They must retain a log of these information leaflets, when last updated and by whom, and each leaflet must be reviewed annually by endoscopy staff and incorporate questions frequently asked by patients. 1C

- Information leaflets and consent forms should be available in languages common to the local population and should be reviewed by lay people. 1C

- For patients where written information is not available in an appropriate language steps must be taken to ensure that verbal information has been offered via an interpreter before the patient attends. 1C

- Where procedure specific information leaflets are not available (for example for infrequent or specialist procedures) the patient must have the opportunity to discuss that procedure before the appointment with the endoscopist (or a delegated person), either face to face or by telephone with the discussion clearly documented in the medical records. 1C

- Written information provides a minimum dataset but if an individual’s risk is higher due to frailty or co-morbidity then this must be discussed verbally and/or additional written information provided to reflect this risk and that information documented in the case notes. 1C

- For in-patients, written information must be provided in an appropriate format to the patient before they leave the ward for the procedure, leaving ample time for the information to be read and questions to be asked. Where ward staff cannot answer the questions they must ensure that the patient is given access to someone who can. 1B [2(18a), 5(31)]

- For patients who decline information, the minimum information should include the aims of the proposed investigation or treatment, the anticipated level of pain or discomfort and steps taken to minimise it. In addition, the level of risk related
to the procedure that the patient wishes to know (or not) should be ascertained and recorded. \(1B\) [2(14)]

- It is important to ensure that the written information has been understood with particular reference to any material risks and that the patient is given the opportunity to ask questions or raise concerns and have these answered in a full, open and honest manner. Any concerns expressed by the patient, even if not in the form of questions, should also be addressed in the same way. \(1B\) (Montgomery)

3.4 The consent process

- Consent should be obtained by the endoscopist or delegated to a suitably trained individual. \(1B\) [2(26), 5(30)]

- The final signature and/or confirmation of consent for an endoscopic procedure must be obtained outside of the endoscopy procedure room in a calm and private environment. \(1C\) [5(31)]

3.5 Consent as integral part of care pathway in endoscopy

- Endoscopy units should incorporate a check within their patient pathway booklet or an adapted WHO safer surgery checklist that the patient has signed a consent form prior to entering the endoscopy room for the procedure. \(1B\) (RCTs in other patient groups)

3.6 Postal consent

- Postal consent is an established and valid approach for patients referred directly for endoscopy where a prior clinic appointment is not deemed necessary. \(1C\)

- The organisation receiving the referral must put in place pathways that ensure the referral is appropriate and the patient adequately informed. \(1C\)

- An opportunity for further discussion must always be offered in the endoscopy department and confirmation of consent recorded before the procedure begins. \(1B\) [5(43)]

- Alternative arrangements should be put in place for patients on cancer referral pathways if the post cannot be relied upon. \(1C\)

- This process is not suitable for therapeutic or high risk endoscopic procedures,
particularly (but not restricted to) endoscopic resections, PEG and ERCP procedures. 1C

3.7 Consent for surveillance procedures

- Consent should be sought in advance of all surveillance endoscopic procedures in the standard way. 1C

- If new information becomes available in relation to surveillance intervals or risk of disease, or if the patient’s condition has changed, the patient’s agreement to remain in a surveillance programme should be re-confirmed. 1B [2(52), 5(42)]

3.8 Children

- Children aged over 16 are presumed to have capacity to consent for endoscopy and related procedures. Endoscopists competent to perform the procedure in adults should apply similar principles in young people over 16. 1B [6(25)]

- Children aged < 16 years with Gillick competence can consent for endoscopy but for endoscopic procedures Gillick competence should be confirmed by practitioners trained and experienced in doing so. 1C

- Where any doubt or conflict exists in relation to consenting for endoscopy in a young person (< 18 years) or if the young patient refuses treatment it is recommended that expert legal advice is sought. 1C

3.9 Emergency Endoscopy

- In an emergency situation full compliance with written consent may not be possible under which circumstances verbal consent may be utilised but must be fully documented in the medical notes. 1B [2(50)]

- It is important to assess the extent of treatment to which a patient does or does not consent to before sedating for an endoscopy. 1B [2(40)]

- Where written or verbal consent cannot be obtained in an emergency situation action taken must be the least restrictive of the patient’s future options. 1B [3]

3.10 Patients without capacity

- Endoscopists should be familiar with the provisions of the Mental Capacity Act 2005. In particular the law in relation to Lasting Powers of Attorney (LPA),
Independent Mental Capacity Advocates (IMCA) and Advance Decisions to Refuse Treatment. 1B [2(63), 3]

- Where a patient lacks capacity and there is a proxy decision maker then the decision taken for endoscopy must be taken in the patient’s best interests. When assessing a person’s best interests the endoscopist must take into consideration the prior wishes of the patient, the views of those caring for the patient or with an interest in his welfare such as family members. Any intervention must be the least restrictive of the person’s future options and freedom. 1B [3]

- Patients lacking capacity should have Consent Form 4 completed by the team who best know the patient’s medical condition and mental capacity and should be countersigned by the endoscopist or nominated deputy. 1C

3.11 Withdrawal of consent

- Endoscopy units must have a policy relating to withdrawal of consent. 1C

- Where a person objects during an endoscopic procedure, the procedure should be stopped, and the person’s concerns and capacity to withdraw consent established. It may be possible to recommence after a suitable pause and reassurance. 1C

- If the patient appears to have capacity (whether sedated or not) and clearly indicates that he/she wishes the procedure to be discontinued then this must occur immediately unless doing so would expose the patient to risk of serious harm. 1C

- If in the endoscopist’s opinion capacity is lacking, it may be justified to continue in the person’s best interests. If stopping the procedure would put the person at risk of harm the practitioner may continue until that risk no longer applies. 1B [3]

- Any circumstances where consent is withdrawn should be noted on the endoscopy report and/or medical case notes. 1C

3.12 Photography, video and Live endoscopy events.

- Taking photos or videos during normal patient care in endoscopy does not require additional consent, but should be noted in the patient information leaflet. 1B [12(10)]
• Recordings taken at such times may be used for secondary purposes such as teaching or assessment without seeking additional consent, so long as the images are anonymised. \textit{1B [12(13)]}

• Photographic or video images must not be recorded or stored on personal mobile phones. \textit{1C}

• Video transmission, as in live endoscopy events or for presentation that does not form part of standard patient care requires additional written consent from the patient. \textit{1B [12(25), 13]}

\textbf{3.13 Nurse led consent}

• Consent can be safely delegated to endoscopy nurses who have successfully completed competency training including direct observational practice evaluation. \textit{1C}

• Annual evaluation of patient experience of the consent process and revalidation of knowledge and skills of individuals is essential. \textit{1C}
4 PRINCIPLES OF VALID CONSENT

It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care for a person. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice.

All healthcare involves decisions made by patients and those providing their care. Whatever the context in which medical decisions are made it is essential that the health care practitioner works in partnership with patients to ensure good care. This involves:

- listening to patients
- respecting their views about their health
- sharing with patients the information they want or need in order to make adequately informed decisions
- maximising their opportunities and ability to make decisions for themselves and
- respecting the decision once made.

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

- the investigation or treatment is complex or involves significant risks
- there may be significant consequences for the patient’s employment, or social or personal life
- providing clinical care is not the primary purpose of the investigation or treatment
- the treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. This will usually be the patient or someone with parental responsibility for a patient under the age of 18. The other individuals able to give consent in law are:

- A person over 16 under the Family Law Reform Act (1969) (see section 6.3.3)
- A person under 16 who is Gillick competent.
- Someone authorised to do so under a Lasting Power of Attorney (LPA) (once the person for whom the LPA exists has lost capacity).
• Someone who has the authority to make treatment decisions as a court appointed deputy.

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, the patient is content to proceed.

**Recommendations:**

• **Owing to the invasive nature and potential risks, all endoscopic procedures of the gastrointestinal tract require written consent, except in an emergency situation.**

• **Whilst the process of consent can be delegated, the endoscopist performing the procedure is ultimately responsible for ensuring that the consent process is appropriate for the procedure being undertaken.**
5 ASSESSMENT OF CAPACITY

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.[3] The Act defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary. A person lacks capacity if:

- they have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, and
- that impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.

The principle of presumed capacity means that the patient can be considered not to have capacity only if it is shown, at a particular time and regarding an intended clinical intervention, and having been given all appropriate help and support, that they are unable to:

- understand the information needed to make a decision
- remember that information long enough to make a decision
- use or weigh up that information to make a decision
- communicate their decision by whatever means (verbal, sign language or an established code such as blinking or squeezing of the hand)

The Adults with Incapacity (Scotland) Act also requires that the person is able to remember having made the decision.

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. Those involved with consenting patients for endoscopic procedures must support and engage patients to the limit of their capacity. Even where the individual lacks capacity they must be permitted and encouraged to participate as fully as possible.

It should not be assumed that a person with a mental disability (learning, dementia, mental health, brain injury) does not have the capacity to consent simply in order to expedite the procedure. If it is identified using the four point capacity test that they may have capacity, then reasonable adjustments to the consent process and timing need to be made to ensure that the individual is able to communicate their consent.
Patients may have capacity to consent to some procedures but not to others, or may have capacity at some times but not others. Under the Mental Capacity Act, a person must be assumed to have capacity unless it is established that they lack capacity.

Practical adjustments to aid the consent process may include:

- Discussing treatment options at a time and in a place when the patient is best able to understand and retain the information
- Speaking to the patient or to their carers, close family members and other health care staff about the best ways of communicating with them, using information in a format appropriate to their circumstances including photos, signs and symbols
- 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 or involvement of the local community disability teams as a single point of contact.
- Where there is a lot of information to remember, or the decision will have a significant effect on their life or care, endoscopists might offer patients a record of the discussion and any decisions made during a consultation (including relevant information about why the decision was made).

Where there is doubt about a patient’s capacity to consent, the procedure should be delayed, unless unsafe to do so, and advice sought from other colleagues including a psychiatric team when necessary.

5.1 Further information

- The Mental Capacity Act Code of Practice (2007), available at https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice, explains how the Act will operate on a day-to-day basis and offers examples of best practice to carers and practitioners. There are also a number of assessment tool kits available to guide health professionals through the assessment process:

- The British Medical Association (BMA) Mental Capacity Toolkit covers issues such as how to assess capacity, the basic principles of the Act, advance refusals of treatment, research and Lasting Powers of Attorney (LPAs); available at: http://bma.org.uk/practical-support-at-work/ethics/mental-capacity-tool-kit

- Guidance from the GMC is available at: http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_accessing_capacity.asp
• The Assessment of Mental Capacity Audit Tool (AMCAT) is an online tool provided by the Mental Health Foundation and Foundation for People with Learning Difficulties to help staff and others evaluate, reflect and learn about an assessment of mental capacity they have done, available at http://www.amcat.org.uk/


Recommendations:

• All those delegated to obtain consent and all endoscopists must have sufficient understanding of the Mental Capacity Act to be confident that they can comply with its requirements when assessing capacity and taking consent.

• The endoscopist performing the procedure must ensure that the patient has capacity to consent for the procedure at the time that it is being performed. If capacity to consent appears to have changed since consent was first obtained then re-assessment is required. Delaying the procedure to allow further adjustments or the opportunity to regain capacity may be appropriate, but a decision to proceed based on ‘best interests’ can also be considered.

• If there is concern that all practicable steps have not been taken to maximize the patient’s ability to participate in the consent process to the limit of their capacity, or if there is doubt about the patient’s capacity to consent/have consented for that procedure, then the procedure must be delayed until such time as sufficient adjustments have been made or further advice sought unless the clinical situation is of such urgency that such delays will be harmful to the patient

• Further, if it seems possible that capacity may be recovered, the procedure must be delayed until such time as capacity has maximized unless the clinical situation is of such urgency that such delays will be harmful to the patient.
6 PATIENTS CONSIDERED TO HAVE CAPACITY

6.1 Provision of information

6.1.1 General principles - out-patients

Clear, accurate information about any proposed investigation or treatment including alternative available treatments and the option of having no treatment, presented in a way that patients can understand, can help them make informed decisions. The amount of information that should be shared with patients will depend on the procedure, the individual patient and what they want or need to know. Information about risk must be given in a balanced way. Bias should be avoided, and the expected benefits as well as the potential burdens and risks of any proposed procedure should be explained.

The aim is to provide information so that patients can select for themselves how much detail they want to acquaint themselves with. The patient should be able to derive an understanding of what is about to happen, when, where and why it will occur.

As part of the consent process and to allow the patient to make an informed decision, written information should be provided in advance of the procedure. Written information should be provided no later than at the time of booking the procedure.

Information about the procedure should be in plain language that the patient can understand, in a font they can read, and available in languages other than English. Whilst it may not be possible to provide written information in all languages, local communities should be contacted to identify those languages that are common and information leaflets should be proof read by lay persons or patient representatives to ensure that they meet the needs of the local population.

It is important to emphasise that written information is only part of the consent process and all clinicians involved in the patient pathway have a responsibility to provide verbal information and answer questions regardless of the provision of written leaflets. At a minimum, verbal information should be provided at the time of recommending the procedure with the opportunity to ask further questions once the patient has had the chance to read the written information provided at the time of booking the procedure.

In patients for whom written information is not available in an appropriate language it is essential to ensure that steps are taken to ensure that verbal information has been offered via an interpreter before the patient attends the endoscopy unit as well as on the day of the procedure. Usually this would be at the time of an out-patient appointment.
6.1.2 General principles - In-patients

The principles in relation to provision of information relating to in-patients requiring urgent or emergency endoscopy are the same as for out-patients. However, patients in hospital for other reasons may be referred by teams throughout the hospital who are not generally familiar with the risks, benefits or alternatives to endoscopy. There is usually a greater urgency to perform the procedure, both for clinical and efficiency reasons. As a rule, patients will be at higher risk, with greater degrees of co-morbidity than out patients. Finally, in-patient procedures are usually more complex and interventional. This combination of factors makes for a high risk situation that must be reflected in the consent process and provision of information.

All in-patients referred for endoscopy, whether diagnostic or therapeutic, must have the referral reviewed for appropriateness by a clinician trained in the indications for that procedure. All patients who have an in-patient endoscopy must have written information provided to them in a format they can read and understand before they leave the ward for the procedure and an opportunity to discuss that information with an appropriately trained individual.

In this context, “appropriately trained” refers to an individual who is trained in performing the procedure or an individual who is suitably trained and qualified, has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved, to whom this task has been delegated.[2]

Best practice is that all patients referred for endoscopy should be consented on the ward. Whilst this may not always be practicable, and clinical urgency should be taken into consideration, information must be provided on the ward no later than the time the decision was taken to proceed with the procedure. Ample time must be given for the patient to read, assimilate the information and ask questions. Outside of clinical emergencies, it is not acceptable for a patient to attend an endoscopy unit without first having been provided with written information, and time to read and ask questions about it.

Where appropriate written information cannot be provided due to language barriers or the unique nature of the procedure, verbal information must be provided by clinicians appropriately trained to provide information for that procedure before the patient leaves the ward.

As with out-patient procedures, it is particularly important to stress that all clinical staff involved in that patient’s care have a duty to provide information and support the consent process to the level of their training, even if they are not specifically trained to obtain consent in that procedure. This may involve simply providing written information or answering questions but where the clinician is unable to answer a patient’s query
they are duty bound to ensure that the patient is given access to someone who can.

6.1.3 What information should be provided?

Written information for the patient prior to attending for an endoscopic procedure 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).
- The procedure itself and necessary aftercare.
- Options and expectations in relation to sedation and analgesia.
- The benefits and risks (complications and side effects) of the proposed procedure, material to that patient and the proposed procedure.
- The possible alternative treatments both to the proposed intervention and in the case of treatment failure, including the benefits and risks of these alternative treatments.
- The taking and retention of tissue samples.
- The taking of photographic or video record and possible secondary uses of anonymised records such as for teaching or assessment of health professionals.
- The skilled supervision of and presence of any trainees and the right of the patient to refuse having a trainee perform the procedure without prejudice to their treatment.
- The use of any experimental technique.
- Contact details in case further information is required by the patient.

Patients must be offered as much information as they reasonably need to make their decision. It must be open and honest and be in a form they can understand, with adequate time to read and understand the information given. It is important to ensure that the written information has been understood with particular reference to any material risks and that the patient is given the opportunity to ask questions or raise concerns and have these answered in a full, open and honest manner. Any concerns expressed by the patient, even if not in the form of questions, should also be addressed in the same way.

The adverse outcomes that may result from the proposed procedures must be presented, including the potential outcome of not performing the procedure and the risk of failure of the procedure to achieve the desired aim.

DoH guidance is that a person should be advised of any material, significant or unavoidable risks in the proposed treatment even if small; any alternatives to it; and the risks incurred by doing nothing to reflect the Chester vs. Afshar judgement. A Court of Appeal judgment stated that it will normally be the responsibility of the doctor to
inform a patient of ‘a significant risk which would affect the judgment of a reasonable patient’. Further clarity has been provided recently from the Court of Appeal in Montgomery vs. Lanarkshire Health Board (UKSC_2013_0136_Judgment) in which it is stated:

“The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it” ([87] Montgomery)

You must tell patients if the procedure might result in a serious adverse outcome, even if the likelihood is very small as well as less serious side effects or complications if they occur frequently. Any risk that is likely to influence the decision of a patient should be included. It is important that in meeting these requirements, the patient is not overwhelmed with excessive information, such that they are unable to evaluate the material risks and benefits. This judgment must be patient-centred, in that the risk that can influence a patient’s decision can vary from one patient to the next and requires careful judgement and dialogue on an individual basis.

Notwithstanding these comments, diagnostic endoscopy remains overall a safe procedure. Written information leaflets provide a minimum dataset that we pass onto patients, but if an individual’s risk is higher due to frailty or co-morbidity then this must be discussed verbally and/or additional written information provided to reflect this risk and that information documented in the case notes.

As a final point, if a clinician decides that it would, in the reasonable exercise of medical judgment, be detrimental to the health of the patient to make a particular disclosure then that disclosure need not be made. However, this ‘therapeutic exception’ should not be abused, it is a limited, narrow exception to the general principle. It is not intended to subvert it by enabling a doctor to prevent the patient from making an informed choice where a clinician considers a patient liable to make a choice contrary to her best interests ([91] Montgomery).

6.1.4 Patients who decline information:

No one else can make a decision on behalf of an adult who has capacity. If a patient asks you to make decisions on their behalf or wants to leave decisions to a relative, partner, friend, carer or another person close to them, you should explain that it is still important that they understand the options open to them, and what the treatment will involve. If
they do not want this information, you should try to find out why.

If, after discussion, a patient still does not want to know in detail about their condition or the treatment, you should respect their wishes, as far as possible. But you must still give them the information they need in order to give their consent to a proposed investigation or treatment. This is likely to include what the investigation or treatment aims to achieve and what it will involve, for example: whether the procedure is invasive; what level of pain or discomfort they might experience, and what can be done to minimise it; anything they should do to prepare for the investigation or treatment; and if it involves any significant risks.

If a patient insists that they do not want even this basic information, you must explain the potential consequences of them not having it, particularly if it might mean that their consent is not valid. You must record the fact that the patient has declined this information. You must also make it clear that they can change their mind and have more information at any time.

**Recommendations:**

- For all patients, information should be provided in a format that they can understand about the expected benefits as well as the potential burdens and risks and alternatives of any proposed endoscopic procedure.

- For out-patient elective procedures, verbal and/or written information should be provided by the clinician recommending the endoscopy and this should be documented in the case notes.

- For out-patient procedures, written information should be provided no later than at the time of booking the procedure.

- Endoscopy units must retain standard information leaflets specific to their department that pertain to all standard endoscopic procedures performed regularly within that unit. They must retain a log of these information leaflets, when last updated and by whom, and each leaflet must be reviewed annually by endoscopy staff and incorporate questions frequently asked by patients.

- Information leaflets and consent forms should be available in languages common to the local population and should be reviewed by lay people.

- For patients where written information is not available in an appropriate language steps must be taken to ensure that verbal information has been offered via an interpreter before the patient attends.
• Where procedure specific information leaflets are not available (for example for infrequent or specialist procedures) the patient must have the opportunity to discuss that procedure before the appointment with the endoscopist (or a delegated person), either face to face or by telephone with the discussion clearly documented in the medical records.

• Written information provides a minimum dataset but if an individual’s risk is higher due to frailty or co-morbidity then this must be discussed verbally and/or additional written information provided to reflect this risk and that information documented in the case notes.

• For in-patients, written information must be provided in an appropriate format to the patient before they leave the ward for the procedure, leaving ample time for the information to be read and questions to be asked. Where ward staff cannot answer the questions they must ensure that the patient is given access to someone who can.

• For patients who decline information, the minimum information should include the aims of the proposed investigation or treatment, the anticipated level of pain or discomfort and steps taken to minimise it. In addition, the level of risk related to the procedure that the patient wishes to know (or not) should be ascertained and recorded.

• It is important to ensure that the written information has been understood with particular reference to any material risks and that the patient is given the opportunity to ask questions or raise concerns and have these answered in a full, open and honest manner. Any concerns expressed by the patient, even if not in the form of questions, should also be addressed in the same way.
6.2 Confirmation of consent.

6.2.1 Who can seek consent?

The General Medical Council states that “if you are the doctor undertaking an investigation or providing treatment, it is your responsibility to discuss it with the patient. If this is not practical, you can delegate the responsibility to someone else, provided you make sure that the person you delegate to:

- is suitably trained and qualified
- has sufficient knowledge of the proposed investigation or treatment and understands the risks involved
- understands, and agrees to act in accordance with this booklet.

If you delegate, you are still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before you start any investigation or treatment.” [2 – para 26]

In endoscopy units, this means that the endoscopist performing the procedure must:

- verify that the patient has the capacity to make the decision in question and either,
- obtain consent themselves or
- verify and document that the consent has been legitimately obtained by someone who is capable of doing so.
- Reassess capacity if it appears that the status has changed

This means that the ultimate responsibility to ensure that appropriate consent has been obtained for the procedure being undertaken is with the endoscopist, who should confirm this before the patient enters the room. If the procedure is being performed by a trainee under supervision, the responsibility to obtain consent can be delegated to the trainee, but the ultimate responsibility remains with the supervising endoscopist.

Endoscopy nurses are capable of taking consent (“nurse-led consent”) providing they have been trained to do so (see training below). It is recommended that their training is documented in their portfolio and is updated and re-validated annually as part of the appraisal process.

In practice, it is likely that delegation of consent to non-endoscopists (either junior doctors or nurses) may be possible for high volume, low risk procedures such as diagnostic upper endoscopy or flexible sigmoidoscopy but is unlikely to be appropriate for procedures that may or will involve more complex therapeutic interventions such as dilatation, polypectomy or ERCP.
Whatever arrangements are 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.

6.2.2 The consent process

The seeking and giving of consent should be a process, rather than a one-off event. It is good practice where possible to seek the person’s consent to the proposed procedure well in advance, when there is time to respond to the person’s questions and provide adequate information. Endoscopists should then check, before the procedure starts that the person still consents. This is particularly relevant to in-patients for the reasons alluded to above.

Whilst consent is not necessarily time-limited, if consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

Department of Health guidance is that if a person is not asked to signify their consent until just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, there may be real doubt as to its validity. Whilst this does not specifically state that consent for an endoscopic procedure should be sought prior to entering the endoscopy procedure room, the principles of this guidance means that such practice would be difficult to defend should it be called into question.

Thus, the final signature confirming consent, or verification of a previously signed consent form (as in postal-consent, or for ward in-patients) must be taken outside of the endoscopy room, in a calm and private environment where the patient does not feel coerced into making a decision by the immediacy of their surroundings.

After the procedure, patients should be offered a copy of the signed consent form or it should be documented if they decline.

For in-patients ideally the consent form will be signed by the patient and countersigned by an appropriately trained individual as per section 6.2.1 on the ward prior to attending the endoscopy department. However, it is recognised that this may not always be possible for complex interventional procedures. Under which circumstances, so long as the requirements for adequate provision of information (section 6.1.2), and for signing the form in a calm and private environment are met as above, then it is acceptable that the consent form for an in-patient procedure be signed in the endoscopy unit but outside of the procedure room.
Recommendations

- Consent should be obtained by the endoscopist or delegated to a suitably trained individual.

- The final signature and/or confirmation of consent for an endoscopic procedure must be obtained outside of the endoscopy procedure room in a calm and private environment.

6.2.3 The consent form

The contents of consent forms are a matter for local Trusts to determine. Each Trust will have developed forms that correspond to now archived Department of Health Guidance. Updated guidance exists on how to amend these forms in the light of recent legislative changes at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138297/dh_103652.pdf

As a general principle, it is advisable for Trusts to retain consent forms for patients with capacity that are specific to high volume procedures such as diagnostic endoscopy and colonoscopy. However, where such forms do not correspond to the specific procedure being undertaken, the form must be amended before the patient signs it, or a blank form completed.

Consent forms should name the procedure in clear terms understandable to the patient, avoid abbreviations and complex medical jargon and describe the material risks and benefits and alternative procedures as well as any additional procedures (such as biopsies) and procedures the patient would not want. The name and grade of the consenting practitioner(s) should be legible and any trainees that may be involved, and there should be a space for an interpreter to sign the form where appropriate.

6.2.4 Consent as integral part of care pathway in endoscopy

Given the high volume and increasing therapeutic nature of endoscopy in many units, the complexity and risk of endoscopic procedures and the implications to the patient and endoscopist of an incomplete or inappropriate consent process, endoscopy departments must put in place measures to ensure consent is appropriate and complete (relevant to the clinical circumstances) for all patients attending for a procedure.

Ample evidence now exists in surgery that adoption of the WHO safer surgery checklist in the operating theatre reduces the opportunity for error. Adaptations of such checklists are being proactively adopted by many endoscopy units. [4] Whilst there is
no proof of similar efficacy in endoscopy to the theatre environment nor of the ideal format, early adopters have confirmed that such adapted checklists reduce the opportunity for error, facilitate whole team communication and allow patient involvement e.g. through reconfirmation of consent. Examples of endoscopy specific checklists include elements such as positive patient identification and procedure and equipment related checks. As part of this process endoscopy units should also include in the checklist final confirmation that the consent form has been completed (except in emergency circumstances) for the correct patient and procedure.

**Recommendation**

- **Endoscopy units should incorporate a check within their patient pathway booklet or an adapted WHO safer surgery checklist that the patient has signed a consent form prior to entering the endoscopy room for the procedure.**

### 6.3 Special circumstances.

#### 6.3.1 Postal consent.

Patients may be referred by their general practitioners (GP) directly for endoscopic investigation. Whilst general practitioners referring patients can be expected to understand the nature of the investigation, it cannot be assumed that they are sufficiently trained to discuss the risks and benefits of the procedure with the patient. Thus, the organisation receiving the referral must put in place pathways that ensure that the referral is appropriate and the patient adequately informed.

Referrals may be for “direct access” investigation in which the GP is referring for the test only, on a suspected cancer pathway (“straight to test”) or prior to an out-patient appointment (“test first”). These pathways and terminology will vary between hospitals but usually refer only to diagnostic procedures, most commonly upper GI endoscopy or flexible sigmoidoscopy and sometimes colonoscopy.

Postal consent refers to the provision of information leaflets and consent forms (packs) to patients in the post before attending the unit. Once the patient has read the information, and if they have no further questions, they can sign the consent form before attending for the procedure. Postal consent alone is not suitable for high risk or complex interventional procedures such as (but not restricted to) endoscopic resections, PEG insertions or ERCP.

The GMC states that before beginning treatment, you or a member of the healthcare team should check that the patient still wants to go ahead; and you must respond to any new or repeated concerns or questions they raise. This is particularly relevant to postal consent where the information may have been sent some weeks in advance of the
procedure and the patient may not yet have had a chance to discuss the procedure with a trained practitioner.

Furthermore, for patients on suspected cancer pathways the tight timescales may mean that the post cannot be relied upon to provide the information before the appointment date. Under which circumstances, alternative arrangements must be made. This might include giving patients the opportunity to discuss the procedure on the phone with a trained practitioner, collect the information leaflet in person before attending for the procedure, emailing information or providing information “on-line”.

**Recommendations**

- **Postal consent is an established and valid approach for patients referred directly for endoscopy where a prior clinic appointment is not deemed necessary.**

- **The organisation receiving the referral must put in place pathways that ensure the referral is appropriate and the patient adequately informed.**

- **An opportunity for further discussion must always be offered in the endoscopy department and confirmation of consent recorded before the procedure begins.**

- **Alternative arrangements should be put in place for patients on cancer referral pathways if the post cannot be relied upon.**

- **This process is not suitable for therapeutic or high risk endoscopic procedures, particularly (but not restricted to) endoscopic resections, PEG and ERCP procedures.**

**6.3.2 Consent for surveillance procedures**

Many patients have surveillance endoscopic procedures planned some months or years in advance without need for medical review in between. Examples would be follow up for Barrett’s oesophagus or colonic adenomas. Many hospitals now put patients on a system whereby they are automatically recalled for endoscopy or colonoscopy some years after the previous examination.

It is possible for the patient to consent in advance for such procedures. The Department of Health states that when a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person.[5] However, the fact that the patient has agreed to a surveillance programme
does not imply that their consent is valid for all subsequent procedures and consent should be sought in advance of all procedures in the standard way.

Furthermore, if new information becomes available regarding the proposed procedure between the times the patient agreed to surveillance and when the procedure is planned to be undertaken, a member of the healthcare team should inform the patient and reconfirm their agreement to surveillance. Specifically if the guidelines in relation to surveillance intervals or risk of disease change between procedures, a patient should be informed of these changes so that they can consent (or not) in light of this new information.

Similarly, if the patient’s condition has changed significantly in the intervening time it will be necessary to discuss the pros and cons of surveillance again, on the basis that the likely benefits and/or risks of the intervention may also have changed.

Whilst consent can be obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

**Recommendations**

- Consent should be sought in advance of all surveillance endoscopic procedures in the standard way.
- If new information becomes available in relation to surveillance intervals or risk of disease, or if the patient’s condition has changed, the patient’s agreement to remain in a surveillance programme should be re-confirmed.

6.3.3 Children.

Guidance in relation to consent for children (aged < 18 years) is provided by the General Medical Council both in its 2008 guidance on consent but in greater detail in its 2007 document “0-18 years: guidance for all doctors” and by the Department of Health 2009 second edition advice on consent.[5, 6] It is beyond the scope of an endoscopy related document to describe all of the complexities of child law on consent. Where any doubt or conflict exists in relation to consenting for endoscopy in a young person (< 18 years) it is recommended that expert legal advice is sought.

The capacity to consent for endoscopy depends more on the young person’s ability to understand and weigh up options than on age. By virtue of section 8 of the Family Law Reform Act 1969,[7] people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment,
such as an anaesthetic. In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. The exception to this is if the reason not to be able to make a decision is for some reason other than a disturbance in the functioning of the mind or brain, for example being overwhelmed by the magnitude of the decision, in which case legal advice should be sought. If the 16 or 17-year-old is capable of giving valid consent then it is not legally necessary to obtain the authority of a person with parental responsibility for that person, though the young person would commonly welcome the involvement of family in decision making.

A young person under 16 may also have the capacity to consent, depending on their maturity and ability to understand what is involved. In the case of Gillick, the court held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being ‘Gillick competent’. A child of under 16 may be Gillick competent to consent to endoscopic examination or treatment.

The concept of Gillick competence is said to reflect a child’s increasing development or maturity. However, the understanding required for different procedures will vary considerably and the child’s capacity to consent should therefore be assessed carefully in relation to each decision that needs to be made. Age-appropriate material should be available to assist this process.

If, after such assessment, the child is deemed Gillick competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. The fact that Gillick competence is variable, complex and relates to the maturity of the child means that for all but the simplest situations it should be assessed only by practitioners trained and experienced to do so.

Where a child under the age of 16 lacks capacity to consent (ie is not Gillick competent), consent can be given on their behalf by any one person with parental responsibility. In this circumstance it is good practice to consider asking the child to counter-sign the form with their “assent” to undergo the procedure.

It is usually sufficient to have consent from one parent but if parents cannot agree and disputes cannot be resolved informally, you should seek legal advice about how to proceed. Those authorising treatment on behalf of children and young people must have the capacity to consent to the intervention in question, be acting voluntarily and be appropriately informed. The power to consent must be exercised according to the ‘welfare principle’: that the child’s ‘welfare’ or ‘best interests’ must be paramount.
The legal framework for the treatment of 16- and 17-year-olds who lack the capacity to consent is more complex and differs across the UK:

- In England, Wales and Northern Ireland, parents can consent to investigations and treatment that are in the young person’s best interests.
- In England and Wales, treatment can also be provided in the young person’s best interests without parental consent, although the views of parents may be important in assessing the young person’s best interests.
- In Northern Ireland, treatment can be provided in the young person’s best interests if a parent cannot be contacted, although you should seek legal advice about applying for court approval for significant (other than emergency) interventions.
- In Scotland, 16- and 17-year-olds who do not have the capacity to consent are treated as adults who lack capacity and treatment may be given to safeguard or promote their health.

Parents cannot override the consent of a young person with capacity to treatment that you consider is in their best interests, but you can rely on parental consent when a child lacks the capacity to consent.

If a young person with capacity refuses treatment, the courts have, in the past, found that parents can consent to their child being treated even where the child/young person is refusing this. However, there is no post-Human Rights Act 1998 authority for this proposition, and it would therefore be prudent to obtain a court declaration or decision if faced with a child or young person with capacity who is refusing to consent to treatment, to determine whether it is lawful to treat the child.

In summary, children and young people should be encouraged to involve their parents in all decisions. Young people aged over 16 can consent for endoscopic procedures if they have capacity. Children aged less than 16 years may give assent to a procedure and if considered Gillick competent may give consent. If not considered Gillick competent they may still give assent but parental consent should be sought. A child aged less than 16 cannot refuse consent if the guardian/parent/carer believes it to be in their best interests but in any situation where doubt exists then legal advice should be sought.

**Recommendations**

- **Children aged over 16** are presumed to have capacity to consent for endoscopy and related procedures. Endoscopists competent to perform the procedure in adults should apply similar principles in young people over 16.

- **Children aged < 16 years with Gillick competence** can consent for endoscopy but for endoscopic procedures Gillick competence should be confirmed by
practitioners trained and experienced in doing so.

- Where any doubt or conflict exists in relation to consenting for endoscopy in a young person (< 18 years) or if the young patient refuses treatment it is recommended that expert legal advice is sought.

6.3.4 Emergency endoscopy

Considerations in relation to provision of information and obtaining written consent for in-patient endoscopy procedures are outlined in sections 6.1.2 and 6.2.2 above. However, in an emergency it may not be possible to obtain written consent. Under these circumstances it is reasonable to rely on verbal consent but it is still important to give the patient the information they want or need to make a decision and this should be recorded in their medical records.

When consenting a patient for endoscopy in a life threatening situation, such as severe gastrointestinal haemorrhage, it is important to discuss with them, in advance of use of sedation, the extent of treatment to which they do or do not consent, including, for example, interventional radiology, surgery or intensive care.

When an emergency arises and it is not possible to find out a patient’s wishes, you can treat them without their consent, provided the treatment is immediately necessary to save their life or to prevent a serious deterioration of their condition and provided an advanced directive has not been provided (see later). Where written or verbal consent cannot be obtained and it is considered that endoscopy is in the patient’s best interests, the action taken must be the least restrictive of the patient’s future options but still compatible with the purpose of the intervention.

Recommendations

- In an emergency situation full compliance with written consent may not be possible under which circumstances verbal consent may be utilised but must be fully documented in the medical notes.

- It is important to assess the extent of treatment to which a patient does or does not consent to before sedating for an endoscopy.

- Where written or verbal consent cannot be obtained in an emergency situation action taken must be the least restrictive of the patient’s future options.
The Mental Capacity Act 2005 (MCA enacted 2007) covers people in England and Wales who can’t make some or all decisions for themselves.[3] In Scotland, Adults with Incapacity (Scotland) Act 2000 provides ways to help safeguard the welfare of people aged 16 and over who lack the capacity to take some or all decisions for themselves.[8] There is currently no primary legislation on capacity covering Northern Ireland. Decisions about medical treatment and care when people lack capacity must be made in accordance with the common law, which requires decisions to be made in a person’s best interests.

The general principles of the MCA (England and Wales), which are similar in the Scottish Act are:

- A person who is over the age of 18 must be assumed to have capacity unless it is established that he lacks capacity.
- A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
- A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
- An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.
- Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.

No-one can give consent on behalf of an adult lacking capacity unless nominated within a valid Personal Welfare Lasting Power of Attorney (LPA), a Court of Protection appointed deputy or as a named person (in care proceedings), in which case you must consult with them. The LPA may specify limits to the attorney’s authority, and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. It may be important to read the LPA if available to understand the extent of the attorney’s power. In these cases it is the attorney or advocate who must, in giving or withholding consent, act in the best interests of the patient. It should be noted, however, that a LPA can only consent on behalf of a patient once the patient has lost capacity to consent for that procedure at that time.

In the absence of a Personal Welfare LPA, but where there are legal family or guardians, you may treat a patient lacking capacity if the treatment would be in the patient’s best interests. However, ‘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 or all of these factors.

If an individual deemed to lack capacity has clearly indicated in the past, while competent, an intention to refuse treatment in certain circumstances (an ‘advance decision’, ‘living will’ or an ‘advance directive’), and those circumstances arise, you must abide by that decision if it is valid and applicable.

Advance decisions to refuse life-sustaining treatment must comply with specific requirements to be valid. They must be made in writing and contain a specific statement that explicitly 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.

The Mental Capacity Act 2005 protects a health professional from liability for treating or continuing to treat a person in the person’s best interests if they are not satisfied that an advance decision exists which is valid and applicable. The Act also protects healthcare professionals from liability for the consequences of withholding or withdrawing a treatment if at the time they reasonably believe that there is a valid and applicable advance decision. If there is doubt or disagreement about an advance decision’s existence, validity or applicability, the case should be referred to the Court of Protection.

Standard model Consent Form 4 should be used to document a “best interest” consent. The key points to consider are that you:

- Make the care of your patient your first concern. Decisions made must always be in the patient’s best interests.
- Treat patients as individuals and respect their dignity.
- Encourage and support patients to be involved in decisions about their treatment and care.
- Treat patients with respect and do 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.
- 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:

- Whether the patient’s loss of capacity is temporary or permanent and allow for fluctuations.
- What options for treatment are clinically indicated and which option (including the option not to treat) would be least restrictive of the patient’s future choices.
- What you and the rest of the health care team know about the patient’s wishes, feelings, beliefs and values and any evidence of the patient’s previously expressed preferences, such as an advance statement or decisions.
- The views of the patient’s partner, family, carer or other person who has an interest in the patient’s welfare.
- The views of anyone else that the patient asks you to consult, or in the absence of friends or relatives the Independent Mental Capacity Advocate (IMCA) service.
- What information is relevant to the decision that has to be taken, following guidance in DoH document “Confidentiality: Code of Practice” [9]

The Mental Capacity Act has, since 2007 in England and Wales, introduced a duty on NHS bodies to instruct an Independent Mental Capacity Advocate (IMCA) in serious medical treatment decisions when a person who lacks capacity to make a decision has no one who can speak for them. The IMCA is there to support and represent that person and to ensure that decision-making for people who lack capacity is done appropriately and in accordance with the Mental Capacity Act. Whilst they are not there to make a decision for the patient, clinicians have a legal and professional duty to take full account of the information and advice given by the IMCA.

7.1 Completing Consent Form 4 for patients lacking capacity

7.1.1 Out-patients

If an out-patient attending for an elective endoscopy is identified as lacking capacity before attending for the procedure, form 4 should be completed by the referring medical team in advance of the procedure, taking into consideration principles of “best interest” as laid out above. When the patient attends the unit the form should then be countersigned by the endoscopist performing the procedure to confirm that in his/her opinion the procedure is appropriate for the patient’s condition. This is particularly relevant if the procedure is complex or has significant risk but good practice dictates that it should occur for all elective endoscopic procedures.

7.1.2 In-patients

For in-patient endoscopic procedures, the form should be completed by the medical team most knowledgeable of the patient’s mental condition and capacity in conjunction with the family and countersigned by the endoscopist before the procedure.

Where specialist advice is required in relation to the procedure (commonly but not exclusively ERCP or PEG insertion) the form should be completed by a member of the
medical team with knowledge of the patient’s medical condition and mental capacity alongside an individual with specialist knowledge of the procedure i.e. endoscopy nurse, Clinical Nurse Specialist or doctor, in conjunction with the patient and family.

In an emergency situation the endoscopist should apply the principle of ‘best interests’ as outlined in section 6.3.4.

In circumstances where a patient (either in-patient or out-patient) attends for an endoscopic procedure and the endoscopist identifies that the patient may lack capacity for the procedure, it should be delayed until a full assessment has been made by the medical team caring for the patient in conjunction with the family and form 4 is signed, unless such a delay would cause, in the endoscopist’s opinion, additional harm or risk to the patient. Under these circumstances the endoscopist must make a decision according to the principle of “best interests” and document the circumstances in the medical case notes.

7.2 Further details:


For further details on LPAs see the Public Guardian website (www.publicguardian.gov.uk). More information about LPAs is given in chapter 7 of the Code of Practice (www.publicguardian.gov.uk/mca/code-of-practice.htm) and in https://www.gov.uk/power-of-attorney.

Recommendations

- Endoscopists should be familiar with the provisions of the Mental Capacity Act 2005. In particular the law in relation to Lasting Powers of Attorney (LPA), Independent Mental Capacity Advocates (IMCA) and Advance Decisions to Refuse Treatment.

- Where a patient lacks capacity and there is a proxy decision maker then the decision taken for endoscopy must be taken in the patient’s best interests. When assessing a person’s best interests the endoscopist must take into consideration the prior wishes of the patient, the views of those caring for the patient or with an interest in his welfare such as family members. Any intervention must be the least restrictive of the person’s future options and freedom.
Patients lacking capacity should have Consent Form 4 completed by the team who best know the patient’s medical condition and mental capacity and should be countersigned by the endoscopist or nominated deputy.
8 WITHDRAWAL OF CONSENT AND REFUSAL OF TREATMENT

8.1 When consent is refused

If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment, this decision must be respected, except when the treatment relates to a mental disorder, as defined by the Mental Health Act 1983. This latter circumstance is unlikely to occur in an endoscopy unit. This is the case even where this may result in the death of the person (and/or the death of an unborn child, whatever the stage of the pregnancy).

8.2 Withdrawal of consent

A person with capacity is entitled to withdraw consent at any time, including during the performance of an endoscopic procedure. Where a person does object during the procedure the practitioner should, if at all possible, stop the procedure, establish the person’s concerns and explain the consequences of not completing the procedure.

At times, appropriate reassurance and further analgesia may enable the practitioner to continue with the person’s consent. However, if the patient is in persistent pain, consideration should be given to discontinuing the procedure for reasons of safety, regardless of the patient’s consent.

Assessing capacity during a procedure may be difficult. Factors such as prior application of sedation, pain or panic may diminish capacity to consent but the practitioner should try to establish whether at that time the person has capacity to withdraw a previously given consent. In the case of an upper endoscopy, where the patient cannot speak, communication should be established through hand or arm signals. For lower endoscopy, the pros and cons of continuing the procedure can be discussed with the patient.

If the patient appears to have capacity (whether sedated or not) and clearly indicates that he/she wishes the procedure to be discontinued then this must occur immediately unless doing so exposes the patient to significant risk of harm. In difficult or contentious circumstances, it is essential that the endoscopist takes into account the opinion of all of the health professionals present in the room at this time.

If in the endoscopist’s opinion capacity to withdraw consent is lacking or uncertain, it may sometimes be justified to continue the procedure in the person’s best interests, for example completing a polypectomy or sphincterotomy that has already begun. If stopping the procedure would genuinely put the person at risk of harm, the practitioner may be entitled to continue until that risk no longer applies. However, judgements
about capacity during a procedure can be very difficult; under these circumstances the endoscopist should work in the principle that the patient is likely to have capacity and the procedure should be discontinued as soon as it is safe to do so and the events should be documented in the case notes.

All endoscopy units must have a policy relating to withdrawal of consent. Any circumstances where consent is withdrawn should be noted on the endoscopy report and/or medical case notes.

8.3 Advance decisions to refuse treatment

See section 7 above.

Recommendations

- Endoscopy units must have a policy relating to withdrawal of consent.

- Where a person objects during an endoscopic procedure, the procedure should be stopped, and the person’s concerns and capacity to withdraw consent established. It may be possible to recommence after a suitable pause and reassurance.

- If the patient appears to have capacity (whether sedated or not) and clearly indicates that he/she wishes the procedure to be discontinued then this must occur immediately unless doing so would expose the patient to risk of serious harm.

- If in the endoscopist’s opinion capacity is lacking, it may be justified to continue in the person’s best interests. If stopping the procedure would put the person at risk of harm the practitioner may continue until that risk no longer applies.

- Any circumstances where consent is withdrawn should be noted on the endoscopy report and/or medical case notes.
9 ADDITIONAL CONSIDERATIONS

9.1 Tissue/biopsies

The Human Tissue Act 2004 (HT Act) covers England, Wales and Northern Ireland with the exception of the provisions relating to the use of DNA, which also apply to Scotland.[10] The HT Act established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006. Human tissue is referred to in the Act as ‘relevant material’ and is defined as material that has come from a human body and consists of, or includes, human cells. The Act requires that consent is obtained before a person’s organs and tissue can be stored or used for purposes such as research, post-mortem examination, and transplantation.

Subsequently, 9 codes of practice have been published that give practical guidance to professionals carrying out activities which lie within the HTA’s remit. Most relevant here is the guidance on code of practice for consent in relation to human tissue.[11]

Under the HT Act, consent from the living is needed for storage and use of tissue for:

- obtaining scientific or medical information which may be relevant to any person including a future person
- public display
- research in connection with disorders, or the functioning, of the human body
- transplantation.

Under the HT Act, consent from the living is not needed for storage and use of tissue for:

- education or training relating to human health (including training for research into disorders, or the functioning, of the human body)
- performance assessment
- public health monitoring
- quality assurance.

In practice, for endoscopy this means that consent must be sought for obtaining diagnostic tissue samples and that additional specific consent must also be sought for these samples to be stored and used for future research. Information in respect of obtaining and storing tissue samples should be provided in the standard patient information leaflets. Hospital Trusts should also have their own policies for consent in relation to storing samples for future research use.
9.2 Photography, video and video-conferencing

The Department of Health guidance (2009) states that consent should be obtained for any visual or audio recording, including photographs or other visual images.[4] The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, audit or research, people must be aware that they can refuse without their care being compromised and that when required or appropriate it can be anonymised.

Advice from the General Medical Council is provided in the 2011 document “Making and using visual and audio recordings of patients”.[12] In this it is stated that consent to make the recordings (video or photographic) of laparoscopic and endoscopic images is implicit in the consent given for the procedure and does not need to be obtained separately.

Furthermore, the GMC states that you may disclose or use any such recordings taken as part of patient care for “secondary purposes” without seeking consent provided that, before use, the recordings are anonymised. This includes purposes such as teaching, training or assessment of healthcare professionals and students, research, or other health-related uses which are not designed to benefit the patient directly.

However, when seeking consent for endoscopic investigation or treatment that involves taking such photos or videos, you should, where practicable, explain that such a recording will be made and could be used in anonymised form for secondary purposes, including in the public domain. In practice this information should be included in the patient information leaflet.

Recordings made as part of the patient’s care form part of the medical record, and should be treated in the same way as written material in terms of security. Thus, photographic or video images should not be recorded on personal mobile phones that are removed from the hospital environment.

Recordings that do not form part of patient care, for example videos of therapeutic procedures intended solely for presentation at meetings, or video-conferencing (for example as part of a live endoscopy event (LEE)) require that you follow GMC guidance in respect of making recordings for secondary purposes. Here the GMC states that you must obtain consent before such recordings and that it is good practice that consent is confirmed in writing.

The amount of information you should provide before seeking consent for LEEs or presentations will vary but should include the purpose of the meeting, who will be in the
audience, what information will be transmitted, whether it is anonymised or not and
should address the concerns of the individual patient. Before making the recording, you
should explain that patients may withhold consent, or withdraw consent during the
video conference, and this will not affect the quality of care they receive or their
relationship with those providing care.

Further advice in relation to LEEs has been provided by The European Society of
Gastrointestinal Endoscopy (ESGE).[13] For LEEs patients must be informed in advance
of the event of the proposal to include them, and that an additional separate informed
consent form must be signed. The ESGE specifically recommend the use of an
endoscopist patient advocate for consent. Patients should be informed that there is no
additional benefit expected from being treated in a LEE as compared with a routine
setting and if they do refuse their endoscopic procedures must be performed outside
the LEE without significant delay. Every attempt should be made for patients to be
unidentifiable during the event, but patients should be informed that this may be
difficult during procedures by mouth.

The situation may sometimes arise where you wish to make a recording specifically for
education, publication or research purposes during an endoscopic procedure but the
patient is temporarily unable to give or withhold consent because, for example, they are
sedated. 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 not be used for any secondary purpose and be immediately destroyed

Recommendations

- Taking photos or videos during normal patient care in endoscopy does not
  require additional consent, but should be noted in the patient information
  leaflet.

- Recordings taken at such times may be used for secondary purposes such as
  teaching or assessment without seeking additional consent, so long as the
  images are anonymised.

- Photographic or video images must not be recorded or stored on personal
  mobile phones.

- Video transmission, as in live endoscopy events or for presentation that does
  not form part of standard patient care requires additional written consent
  from the patient.
9.3 Trainees performing endoscopy

It is essential that trainees are permitted to perform endoscopy under close supervision. Supervising trainees to a level that minimises risk or discomfort to the patient requires an enhanced level of endoscopic skill by the supervisor. Regulations in relation to training and supervision are laid out by the Joint Advisory Group (JAG) for endoscopy and Trusts must follow these regulations carefully.

Patients attending for endoscopy must be informed ahead of the day of the procedure if there is a possibility that trainees may be present in the endoscopy room, or may be performing the procedure. This information should be included on the information leaflets, and patients should be made aware that they have the right to refuse to allow a trainee to perform the procedure, without prejudicing their future access to treatment, but should also be advised that this is an essential part of the training of new doctors (see sections 6.1.3 and 6.2.3).

The consent form should state clearly the grade and profession of the endoscopists performing the procedure, and all endoscopists (including named supervising consultant) involved in the procedure must be documented on the report. Responsibility for obtaining consent can be delegated to a trainee under supervision, but the ultimate responsibility to verify the validity of this consent remains with the supervising endoscopist (see section 6.2.1).

9.4 Nurse led consent.

Consent can be safely delegated to endoscopy nurses, but must be supported by the individual’s Trust and undertaken only after the successful completion of competencies that include direct observational practice evaluation and supporting evidence of learning.[14] Annual revalidation of knowledge and skills through the appraisal process and evaluation of nurse–led consent from patient satisfaction surveys are essential.

Competencies should include as a minimum a working knowledge and understanding of the following:

- The range of diagnostic and therapeutic procedures and associated risks performed within the endoscopy unit for which they will be obtaining consent.
- The patient information used to support the procedures performed.
- The ethical and legal issues in gaining informed consent.
- National legislation including the Mental Capacity Act
- The consent process including withdrawal of consent
Recommendations

- Consent can be safely delegated to endoscopy nurses who have successfully completed competency training including direct observational practice evaluation.

- Annual evaluation of patient experience of the consent process and revalidation of knowledge and skills of individuals is essential.
10 DOCUMENT LIBRARY REQUIRED BY ENDOSCOPY DEPARTMENTS, AUDIT AND RESEARCH REQUIREMENTS

10.1 Document library.

- Information leaflets specific to the unit, for all commonly performed procedures, including a log stating when they were last updated and by whom, and each leaflet must be reviewed annually by endoscopy staff.

- Information leaflets and consent forms should be available in languages common to the local population and should be reviewed by lay people.

- Standardised consent forms for all common procedures.

- Unit and/or Trust policy on consent.

- Unit and/or Trust policy on withdrawal of consent.

10.2 Mandatory unit audits for consent

We recommend that the following elements of the consent process are audited:

- KPIs for consent
  - An annual observation audit of a selection of endoscopists
  - Consent form signed outside of procedure room
  - Out-patients - Information (written or verbal) provided before attendance in endoscopy unit.
  - Checklist completion
  - Quality of consent forms: legibility, grade of endoscopists on form, presence of trainees documented
  - Copy of consent form provided to patient
  - Inpatient consent - written information before arriving in department, complex procedures discussed with patient before attending department
  - Patients who lack capacity – form completed by team caring for patient
and countersigned by endoscopist.

- Annual patient survey of quality of consent process including timeliness of provision of written and verbal information.

10.3 Recommendations for future research

- When should information best be provided, in what format and by whom to maximise retention and understanding before the procedure?
- How is information of the risk of endoscopy best presented to patients?
- Patient preferences for level of risk provided.
- Evaluation of safer endoscopy checklists.
11 ACKNOWLEDGEMENTS AND CONFLICT OF INTERESTS

Many thanks to Mr Graham Bell (titles), patient representative, for his input into this manuscript.

There are no conflicts of interest for any of the authors of this manuscript.
12 REFERENCES


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