CURRICULUM BASED CLINICAL REVIEWS

Consent in the endoscopy department

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ABSTRACT

The demand for endoscopic procedures continues to increase and is likely to continue to do so for the foreseeable future. Alongside elective diagnostic procedures, the number of complex and therapeutic procedures is increasing. It is therefore vital that the consent process is comprehensive, and high standards in consenting patients are maintained.

Consent is defined as a patient's agreement to treatment or an intervention proposed by a health professional. Careful patient selection is required when proposing endoscopic procedures with an appreciation of the risks and complications that are involved. This paper addresses the various components of gaining informed consent and the legal issues surrounding this process. Additionally, this article reviews legislation and focuses upon specific instances where further considerations have to be made; in a patient who lacks capacity, in children, in percutaneous endoscopic gastrostomy and in the patient who is a Jehovah's Witness.

INTRODUCTION

Consent is a legal process whereby the patient is informed of the reason why the practising clinician deems the procedure to be of benefit; is explained the potential risks or side effects of the procedure, and is offered any potential alternatives. Upon receiving this information, the patient can then make an informed decision regarding their treatment presuming they have the capacity to do this. For effective discussions with patients about complications, trainees/individuals seeking to gain consent should be familiar with commonly quoted risks associated with these procedures. The purpose of this article is to provide gastroenterologists guidance on consenting for endoscopic procedures. We have also attempted to tackle challenging situations in the endoscopy department as outlined in the Gastroenterology Curriculum 2010 (box 1), and to provide trainees with a framework to aid them when encountering these difficult situations.[1]

Box 1 Gastroenterology Curriculum 2010[1]

Competency: To establish a firm foundation of patient-centred practice in endoscopy with emphasis on consent and communication.

- Describes the components and legal aspects of informed consent
- Lists specific issues for special considerations, for example, Jehovah's Witnesses, PEG tube insertion, withdrawal of consent and The Mental Capacity and Mental Health Act

OBTAINING CONSENT

Good medical practice respects the patient's right to decide what examination/investigation happens to their body, and it is a general legal and ethical rule that consent must be obtained before any intervention goes ahead (except in exceptional circumstances). If these principles are not followed, the healthcare professional and even the employing body may be liable to legal action by the patient and professional body such as the British Society of Gastroenterologists (BSG). Consent is not a legal prerequisite for every procedure. The BSG guidelines published in 2008 state that all flexible endoscopic procedures require written consent.[3] The most commonly used consent forms are those issued by the Department of Health (box 2).[2] Ideally, the consent process for endoscopic procedures starts when the procedure is first discussed with a patient, for example, in

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Box 2 Different types of consent forms

- *Consent form 1*–This is the commonest type of consent form used, where a competent adult agrees to an investigation or treatment.
- *Consent form 2*–For seeking parental agreement to investigation or treatment for a child or young person under 16 years old.
- *Consent form 3*–Used for patients able to consent for themselves and for those with parental responsibility consenting on behalf of a child/young person. Only to be used for procedures/treatments that do not involve any impairment of consciousness.
- *Consent form 4*–For adults who lack capacity to make decisions regarding their care or treatment, or are unable to consent, and you are doing the procedure in their best interests. Ideally, this should be completed by a senior clinician (specialist registrar or consultant) from the designated team. It is then good practice for the endoscopist to countersign this form.

the outpatient setting. This allows the patient sufficient time to digest the information and come back to explore any questions or concerns they may have at a later date.

Validity of consent is not determined by the form in which it is given. It can be expressed verbally and non-verbally as long as the patient still understands what the intervention is and why it is needed. Written consent will only provide evidence of consent. Capacity must be determined before a patient is asked to sign. If there is a physical restriction to the patient signing the consent form, but they have the capacity, this must be clearly documented in the patient's notes. Similarly, if an individual has the capacity but is unable to read and write, they can make their mark on the consent form. Ideally it should be witnessed by another individual not conducting the procedure.[2]

As the General Medical Council (GMC) states, "a duty of a doctor is to make the patient your first concern". If there is an emergency situation in the clinical setting, when it is not possible to ascertain the person's wishes or obtain consent, the patient can be treated without consent. Treatment must be necessary to maintain the patient's life or prevent them from immediate deterioration, acting in their best interests. The treatment that is chosen must be the least restrictive to the patient's future choices. As soon as the patient has recovered sufficiently, it should be explained what action was taken and why.[4]

If valid consent is given, it remains valid for an indefinite duration unless the patient withdraws it. However, the GMC states that if more information about the procedure becomes available between time of consent and proposed date of the procedure, the healthcare professional should relay this to the patient and reconfirm their consent. If a long time has elapsed between gaining consent and the procedure, despite no new information needing to be given, it is again good practice to reconfirm consent.[2]

Postal consent, the so-called 'remote consent' was approved by the endoscopy committee of the BSG in 2006 as another option for consent to cope with the demands and increasing pressures put on endoscopy units.[5] This allows a consent form to be sent out to the patient in the post with the relevant information leaflets. Patients can then read through the information at their leisure before signing the consent form at home or on arrival to the endoscopy unit, which is then countersigned by the doctor on the day of the procedure. Guidelines including example booklets and customisable consent forms are available on the BSG website.[6]

The use of audiovisual (AV) information aids, such as DVDs, computer software programmes, audio recordings and videos can also be implemented to improve information provision in the consent process. A systematic review of AV aids on informed consent in clinical practice showed an improvement in recall at all time points in most of the studies that were included in the review, with no adverse effects on levels of satisfaction and anxiety during the consent process.[7] These results suggest that clinicians should aim to provide more than just verbal information to optimise information provision in the consent process.

In summary, the following should be covered during the consent process:

1. Clarifying the physician who is responsible for the procedure, and whether any training will be taking place during the procedure.
2. The rationale for choosing this procedure, and its potential benefits.
3. Explanation to the patient of the nature of the proposed procedure; a summary of the procedure itself, including preparation, what happens on the day of the procedure and after, care complemented by the provision of an information leaflet for the patient.
4. A description of reasonable alternatives to the procedure/treatment, with their benefits and disadvantages.
5. The risks and complications of the proposed test or treatment, including quoting the relevant complication rates, allowing the patient to make an informed decision.
6. An opportunity for the patient to ask questions or voice their concerns, and time allowed for these questions to be answered.
7. The physician should test the patient's understanding by asking them to recall the information they have been given about the procedure.
8. Information should be provided to the patient about the lasting effects of the sedative used, and they should be advised not to drive, operate heavy machinery or sign legal documents for 24 hours postprocedure. For this reason, a chaperone should accompany them home after the procedure if you are planning to give them sedation.

The Report of the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in 2004 focussed on interventional gastrointestinal endoscopy in which a total of 252 NHS hospitals and 11 non-NHS hospitals took part. Cases numbering 1818 were included in this questionnaire-based study. When asked whether written consent had been sought prior to an endoscopic procedure, in 32% of the cases, the clinician had not responded to this question raising the possibility that consent beforehand may not have been taken in these cases. On further exploration of the case notes, there did not seem to be any obvious reason why written consent had not been obtained beforehand.[8]

Of course, in some cases it may not be possible to obtain written consent from the patient, for example, in an emergency situation where the patient may need the procedure or treatment to relieve pain or distress. In this situation, a Consent Form 4 should be completed, but verbal consent may suffice along with detailed documentation in the medical notes. If the patient is not able to provide verbal consent then the medical notes should also reflect this, and that the decision to go ahead by medical staff in the patient's best interest.[3]

Careful patient selection is required when proposing endoscopic procedures, with an appreciation of the risks and complications that are involved, by the endoscopist and the requesting clinician.

RESPONSIBILITY FOR OBTAINING CONSENT

The Department of Health specifies that the doctor who is undertaking an investigation or providing treatment has the responsibility to discuss this with the patient and obtain consent. If this is not possible, the task can be delegated to someone else as long as that person satisfies the following criteria.

1. Is suitably trained and qualified.
2. Has sufficient knowledge of the proposed investigation or treatment.
3. Understands and agrees to act in accordance with GMC consent guidelines.

Of note, if the responsibility is delegated, the individual performing the procedure or giving the treatment is still responsible for ensuring that the patient has been given enough time and information to make an informed decision, and has given their consent, before the procedure is begun.[2] Consent should be gained before sedation is administered, as this may impair decision making.

The policy for foundation doctors may vary between trusts, however, the foundation programme specifies that junior doctors must follow the GMC consent policy, and they may only seek consent when they themselves and their supervisor are confident that they understand the proposed intervention and its risks, and are prepared to answer any questions the patient asks.[9]

RISKS AND COMPLICATIONS FOR ENDOSCOPIC PROCEDURES

As mentioned above, the person seeking consent from the patient should be suitably trained and qualified and must have sufficient knowledge of the proposed investigation or treatment with awareness of potential risks or complications that may be encountered.[2]

The BSG suggests that minor complications with a frequency of >10%, or serious complications of >0.5%, should be discussed with the patient and documented on the consent form.[3] The GMC states that doctors must keep up to date with developments in their area of practice as this may impact on the knowledge and understanding of the risk associated with the investigations or therapy they may be offering.[10] The majority of complication rates and quoted risks for all endoscopic procedures are based on data obtained from multicentred studies, often involving specialist centres, which are summarised in table 1.

WITHDRAWAL OF CONSENT

The issue of withdrawal of consent during endoscopy can be a contentious issue. A patient who is not under the influence of sedation can withdraw consent at any time. However, the issue arises when a patient is sedated and decides to withdraw their consent during the procedure. The BSG states that in this situation 'it is the responsibility of the endoscopist to act in the patient's best interests.' Opinion is still divided on this, as highlighted by survey carried out in which BSG members were asked whether they would abandon a colonoscopy on a sedated patient who withdrew consent during the procedure. Only 1 out of the 59 consultants who replied said they would stop the procedure after a single request and a further 51 would stop only if repeatedly asked to do so. The remaining 7 would complete the procedure.[17]

The decision to stop mid-procedure will be at the endoscopist's discretion, and will depend on the nature and stage of the procedure. It may do more harm than good to stop a procedure during a crucial stage such as a balloon trawl of the common bile duct at endoscopic retrograde cholangiopancreatography (ERCP). In these situations, it may be more advisable to pause, reassure the patient, withdraw and unloop the endoscope (for instance at colonoscopy) and to also consider giving more analgesia or sedation before carrying on to completion. It would also be good practice to seek a consensus from the nurses in the room prior to proceeding or cessation of the procedure. With regards to withdrawal of consent, ultimately the endoscopist should keep patient safety as paramount while doing the best they can for their patient.[3]

DETERMINING CAPACITY TO CONSENT FOR PROCEDURES

Patients must be presumed to have the capacity to make decisions about their care, to consent to or to

Table 1 Endoscopic complications and perforation rates[11–16]

Diagnostic procedures	General complications	Perforation risk (%)
Oesphagogastroduodenoscopy (OGD)	Bleeding	0.01
Flexible sigmoidoscopy	Pain	0.08
Diagnostic colonoscopy	Risks of sedation (1%): hypotension, desaturation, bradycardia, hypertension, arrhythmia and aspiration	0.1–0.3
Small bowel enteroscopy	Perforation	0.3
Therapeutic procedures	Specific complications	Perforation risk
Oesophageal stenting		5–25 Mainly dependent on nature of stricture benign versus malignant, length of the stricture and the type of stent employed.
Oesophageal dilatation		3
▶ Benign strictures		0.5
▶ Malignant strictures		2–6
Polypectomy		0.3–1
Balloon dilatation for colonic strictures		4
Colonic stenting		6
Endoscopic retrograde cholangiopancreatography (ERCP)	Pancreatitis (3–5%) Cholangitis (2%)	Retroperitoneal perforation occurs in <1% of sphincterotomies
Percutaneous endoscopic fastrostomy (PEG)	Overall complication rate (5–10%) Serious complications (1.5–5%): aspiration, bleeding, Damage to internal organs, perforation, buried bumper syndrome, wound infections. Minor complications (6%): feeding tube occlusion, peristomal pain	
Endoscopic mucosal resection (EMR)	Bleeding 1–45% (usually observed during procedure or during the first 24 h postprocedure) Delayed bleeding reported in up to 13.9% Stricture formation	0.3–0.4
Endoscopic submucosal dissection (ESD)		4–10

refuse endoscopic treatment. Decisions about capacity are made according to the criteria and framework set out by the Mental Capacity Act (MCA) 2005 in England and Wales, and the Adults with Incapacity (Scotland) Act 2000 in Scotland.[18 19] It is a two-stage process. First of all, it must be decided whether there is an impairment of, or disturbance in, the person's mind or brain. Second, is the impairment or disturbance sufficient that the person lacks the capacity to make that particular decision? The patient is only deemed to lack the capacity, when, despite all appropriate help and support, they have been unable to:

1. Understand the information given to them.
2. Retain, weigh up the relevant information.
3. Make an informed decision, or communicate their wish.[18]

Assessment of capacity is 'task specific': it must be time and decision specific (see online supplementary appendix 1). In the circumstance of fluctuating capacity, it is good practice that while the patient does have the capacity, efforts should be made to obtain the patient's view of any intended intervention that may be needed during a time of incapacity and documenting this. Similarly, if the patient currently has incapacity, any decision regarding treatment, ideally, should be delayed where possible until their capacity returns. Where this is not possible, often difficult judgements may need to be made under the MCA that states that any decision that a person lacks capacity 'must be based on a 'reasonable belief' backed by objective reasons.'[20 21]

The final responsibility for determining whether a procedure is in an incapacitated person's best interests lies with the healthcare professional performing the procedure.

If there is any doubt about the patient's capacity, additional help should be sought, that is, nursing staff who are involved in the regular care of the patient, or staff with additional specialist knowledge, like psychiatrist, neurologists or speech and language therapist. If there is still uncertainty, legal advice should be sought, as a court order may be required.[22]

In a patient who lacks capacity, consent can only be given on a patient's behalf, if there is evidence of a Health and Welfare Lasting Power of Attorney (LPA). An LPA is someone appointed to make decisions regarding an individual's medical care when they are unable to make their own decisions.[23] It is good practice to consult the patient's relatives or friends who may be aware of the patient's wishes by holding a best interests meeting. If the patient has no friends or family, consultation with an Independent Mental Capacity Advocate (IMCA) must be sought. An IMCA safeguards the rights of people who are facing difficult decisions about medical treatment, who lack capacity to make a specific decision. The IMCA will check that

decisions have been made in the best interests of the patient, that the patient's feelings and wishes have been taken into consideration and if they feel necessary, the IMCA will seek a second medical opinion.[24] When a best-interests decision in made for someone who lacks capacity, a consent form should not be signed by anyone else unless they have a LPA or, alternatively, if they are a court appointed deputy with similar authority.

SPECIFIC CONSIDERATIONS SURROUNDING CONSENT IN ENDOSCOPY

Consent in patients under 16 years of age

The GMC gives guidance on consent in children that states medical treatment to a child or young person can be provided with their consent if they are competent to give it, or with the consent of a parent or the court. In a life-threatening case, or to prevent serious deterioration in the patient's health, emergency treatment can be given without the consent of the child or the young person, however, the child or young person should be involved in the decision making as much as is possible.[25]

Capacity assessment may be facilitated by parents, members of the MDT team, an independent advocate or a named or designated doctor for child protection. Age is not the only determinant of having capacity.

The GMC states:

1. At 16 a young person can be presumed to have the capacity to consent
2. A young person under 16 may have the capacity to consent, depending on their maturity and ability to understand what is involved.[25]

If a young person lacks capacity, then consent for endoscopy can be gained from the patient's parents; one parent's consent is usually sufficient. Mothers and married fathers have parental responsibility. This is not lost if the parents divorce. In recent years, unmarried fathers are also now deemed to have parental responsibility as long as they are named on the child's birth certificate. If the child's birth was registered before this date (variable according to location in the UK) then the father does not automatically have parental responsibility. Legal advice should be sought if the parents disagree or appear not to be acting in the patient's best interests.[25] A parent cannot override a child who has the capacity who decides to accept treatment; however, when a child lacks capacity the parent can consent for the young person. Guidelines differ depending on your location in the UK for consent in children, therefore, it is advisable to seek legal advice.[26–28]

Consent for percutaneous endoscopic gastrostomy

Percutaneous endoscopic gastrostomy (PEG) feeding has been available since the 1980s and is indicated for any patient who is unable to meet his/her nutritional requirements and is envisaged as likely to require enteral feeding for at least four to six weeks.[29] The benefits of enteral feeding are to provide micro and macro nutrients, and to also aid in maintaining immunological integrity, wound healing and recovery.

Table 2 Commonest indications for PEG placement.

Indications for PEG feeding[3]	
Neurological disorders of swallowing	For example, cerebrovascular accident (CVA), multiple sclerosis, motor neuron disease, Parkinson's disease, cerebral palsy
Cognitive impairment and depressed consciousness	Head injury
Mechanical obstruction to swallowing	Oropharyngeal or oesophageal cancer, radiation enteropathy
Long-term partial failure of intestinal function requiring supplemental intake	Short bowel, fistulae, cystic fibrosis

PEG, percutaneous endoscopic gastrostomy.

The commonest indications for PEG placement are for impaired swallowing associated with neurological disorders, or as a consequence of vascular or neoplastic diseases (table 2).[30]

The decision for commencing a patient on supportive nutrition remains complex with ethical and legal aspects that need to be considered, so it is important to be familiar with these. Much of this guidance comes from the BMA and BAPEN.[31 32] Essentially, a patient should be provided with fluid and nutrients if they express the wish to be fed unless there are medical contraindications. This is considered a basic duty of care. If a patient is unable to consume nutrients orally then fluid and feeding should be considered by alternative methods including nasogastric tube and PEG. Legally, this method is considered a medical treatment and does not come under the remit of basic medical care.

The situation differs if the patient is in the terminal phases of an incurable disease. Here, careful ethical consideration should be made to the purpose of commencing nutritional support as this may be appropriate for palliation but not always if the aim is to prolong survival.

The NCEPOD advises that all patients for whom PEG feeding is proposed should be reviewed by a multidisciplinary team. Most trusts now have a dedicated nutritional team consisting of a consultant gastroenterologist with an interest in nutrition, a dietician and a pharmacist who are involved in making decisions, such as enteral and para-enteral feeding.[8]

Jehovah's witnesses and consent

In Jehovah's Witnesses undergoing endoscopic procedures, consideration has to be taken regarding anaemia and blood loss. Jehovah's Witnesses may have objections to the use of blood or blood products, even if their life is at risk.[33] The matter must be addressed with sensitivity, and it is essential to

establish the views held by the individual patient, as certain forms of autologous transfusion may be acceptable.[34 35] In these situations, the local Hospital Jehovah's Witness liaison committee can aid Jehovah's Witnesses patients making decisions about medical treatment and the use of blood products. Most Trusts also have a dedicated policy for use of blood products in this situation.

Any refusal for blood or blood products in the case of procedure-related complications must be clearly stated by the patient and documented beforehand. If the patient is unable to articulate their wishes due to their current condition, and if there is any suggestion they are a Jehovah's Witness, transfusion should be postponed for as long as possible. Advanced directives are often lodged with the patients' general practitioner, and every effort should be made to obtain them. When treating children whose parents are Jehovah's Witnesses, legal advice should be sought. Specific Issue Orders can be issued to sanction the use of blood products without removing all parental responsibility.[36]

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