Individualised consent for endoscopy: update on the 2016 BSG guidelines

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ABSTRACT

In 2016, the British Society of Gastroenterology (BSG) published comprehensive guidelines for obtaining consent for endoscopic procedures. In November 2020, the General Medical Council (GMC) introduced updated guidelines on shared decision making and consent. These guidelines followed the Montgomery ruling in 2015, which changed the legal doctrine determining what information should be given to a patient before a medical intervention. The GMC guidance and Montgomery ruling expand on the role of shared decision making between the clinician and patient, explicitly highlighting the importance of understanding the values of the patient. In November 2021, the BSG President's Bulletin highlighted the 2020 GMC guidance and the need to incorporate patient -related factors into decision making.

Here, we make formal recommendations in support of this communication, and update the 2016 BSG endoscopy consent guidelines. The BSG guideline refers to the Montgomery legislation, but this document expands on the findings and gives proposals for how to incorporate it into the consent process. The document is to accompany, not replace the recent GMC and BSG guidelines.

The recommendations are made in the understanding that there is not a single solution to the consent process, but that medical practitioners and services must work together to ensure that the principles and recommendations laid out below are deliverable at a local level. The 2020 GMC and 2016 BSG guidance had patient representatives involved throughout the process. Further patient involvement was not sought here as this update is to give practical advice on how to incorporate these guidelines into clinical practice and the consent process. This document should be read by endoscopists and referrers from primary and secondary care.

BACKGROUND

Historically, consent for medical intervention was a 'paternalistic' model where the clinician would determine the entire clinical episode from assessment, investigation and treatment. Appropriately, this has now changed to a patient-centred model where risks, benefits and alternatives including not undergoing procedures are discussed between the patient and clinician. The legal basis for this follows the Montgomery ruling in 2015 (Montgomery v Lanarkshire Health Board (2015) A.C. 1430). Here, information as to the risk of shoulder dystocia associated with vaginal delivery was not given to an expectant mother with diabetes. The consultant withheld information as she estimated the risk of serious injury to be very small and, that if the condition were mentioned, most women would ask for a Caesarean section, which was not in their interest. The delivery was complicated by dystocia and subsequent hypoxic brain injury for the child.

The Supreme Court held that the clinician has a duty of care to ensure that the patient is aware of any material risk of an intervention and of any reasonable alternative or variant treatments. A material risk is defined as whether 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.[1]

The court observed social and legal developments point away from the model of the relationship between doctor and

Summary of Recommendations

KQ1 - When seeking informed consent for an endoscopic procedure, how do we obtain individualised consent?
Recommendation
Individualised consent for endoscopy requires that specific patient-related risk factors and personal values are incorporated into the decision about whether to proceed with a given endoscopic procedure. These can only be determined through knowledge of the procedure and its alternatives as well as dialogue with the patient and, if necessary, family, friends or carers.

KQ2 - When seeking informed individualised consent for an endoscopic procedure, which patient related factors need to be taken into consideration?
Recommendation
Individualised consent for endoscopy requires that clinical factors related to the patient's symptoms, past medical history and specific patient related risk factors related to the proposed procedure, as well as the patient's personal preferences and expectations, should be explored.

KQ3 - In broad terms, which procedure related factors need to be considered in individualised consent?
Recommendation
The risks and alternatives to endoscopic procedures vary considerably. Patient information platforms such as leaflets or online resources represent a minimum and where risk is greater or treatment options vary, steps must be taken to ensure that the patient is aware of this ahead of the procedure.

KQ 4 - When considering individualising risk and patient/procedural factors, do we need to re-define who can complete the consent process?
Recommendation
The person completing the consent form needs to have adequate knowledge of the procedure, range of individual risks and alternatives to that procedure. This will depend on the specific procedure but for high-risk procedures will require either considerable personal experience in the procedure or dedicated training that should be formally approved through local governance procedures.
Recommendation
The location in which consent is confirmed on the day of the procedure should be confidential, in a different location to the endoscopy treatment room and offer sufficient privacy and dignity to allow the patient to consider their decision.

KQ5 - For lower-risk procedures that are frequently referred "straight to test" how do we ensure that there is the opportunity to offer individual choice (without introducing unnecessary delay to the pathway)?
Recommendation
For low-risk procedures the endoscopy service should receive adequate patient-specific information from the referrer to allow safe triage. The patient should receive standardised information and have an opportunity for further discussion if required ahead of the procedure. The person completing the consent process must verify that this has occurred before the procedure occurs.

KQ6 - For high-risk/low-volume procedures what additional steps may be required to ensure individualised consent in the elective or out-patient setting?
Recommendation
In the case of complex or higher-risk endoscopic interventions, careful vetting for appropriateness is required and MDT discussion is encouraged. Referral centres should adopt systems to ensure that the patient has access to appropriate information about risks and alternatives and an opportunity to discuss this with an appropriately trained individual ahead of the procedure.

KQ7 - For high-risk procedures what additional steps may be required to ensure individualised consent in the urgent/emergency setting?
Recommendation
For high-risk urgent procedures patients should have access to an appropriately trained individual who can discuss the risks and alternatives to the patient on an individualised basis before they attend the endoscopy department for the procedure.

KQ8 - In considering all of the above, what recommendations should be made in respect of patient selection (vetting for appropriateness) ahead of the procedure?
Recommendation
Information on endoscopy requests must be sufficient to determine whether an endoscopy is appropriate. Vetting for appropriateness should be performed for all cases but is particularly central to case selection for high-risk interventions.

patient based on medical paternalism, adopting an approach to the law which:

> … instead of treating patients as placing themselves in the hands of the doctors (and then being prone to sue their doctors in the event of a disappointing outcome), treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices… (Paragraph 81. Montgomery v Lanarkshire Health Board [2015] A.C. 1430).

If a patient is to accept responsibility for the consequences of their choices, it is the duty of a doctor to make them aware of any material risk they might consider significant as well as the alternatives to the proposed procedure, adopting the seven principles of decision making set out below.

In practice, this means that the clinician must be satisfied that they understand the values of the patient before proceeding. Consent must be individualised, considering clinical and patient-related factors and assumptions should not be made. For example, the risk of perforation during endoscopy may be more significant to someone with prior bowel surgery than those without. As such, a tailored discussion with the patient outlining the pertinent facts relevant to that individual is preferred rather than merely a list of potential complications.

Updated General Medical Council guidance on consent

The updated General Medical Council (GMC) guidance on how to consent for medical procedures incorporated the Montgomery ruling and included seven principles to inform the process (table 1).

Principle 4 is key when considering individualised consent. When completing consent for endoscopy, the burden is ultimately on the professional performing the procedure to ensure that these principles are upheld, and this is explicit in the GMC guideline, which states:

> You must use your professional judgement to apply this and our other guidance to your practice. If you do this, act in good faith and in the interests of patients, you will be able to explain and justify your decisions and actions.[2]

Table 1 The seven principles of decision making and consent

Principle 1	All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able
Principle 2	Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient
Principle 3	All patients have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it
Principle 4	Doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action
Principle 5	Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements
Principle 6	The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them
Principle 7	Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible

METHODS

The authors reviewed the 2020 GMC Guidance in detail and produced a list of areas in the 2016 British Society of Gastroenterology (BSG) guideline that required development to comply with the principles laid out in that document. Key questions (KQs) were drafted that sought to divide procedures into high and low volume and high and low complexity or risk. While it was understood that this would not cover all procedures, and significant overlap would exist, it was felt that this would provide a useful lexicon on which to frame further discussion. The draft KQs were refined following circulation to all authors and specifically following input from legal counsel (AA).

After confirmation of the KQs, recommendations were drawn up and discussed by all authors. Full consensus for each recommendation was achieved. Once full agreement was achieved among all authors, the document was reviewed by the BSG Endoscopy Committee and Clinical Services and Standards Committee before final approval.

These recommendations refer to the consent process in patients with capacity. It is assumed, unless otherwise stated, that a full capacity assessment has occurred as outlined in the 2016 guideline.[3] Recommendations in relation to patients without capacity are made in that guideline and are not repeated here.

Terminology around consent is important. The process of consent relates to the provision of information and all of the discussions that occur ahead of and occasionally during the procedure. The patient gives informed consent based on their understanding of the risks, benefits and alternatives that come out of this dialogue. Evidence that this process has occurred satisfactorily is provided by a signature from a suitably trained clinician and patient on the consent form.

Thus, throughout this document we have avoided the term ‘taking’ consent; instead, we refer to either obtaining or seeking consent through a process that concludes with the patient giving consent voluntarily. The term

'completing' is used to refer to the process of signing and finalising the consent form. Confirmation of consent can occur at any point in the pathway after the patient has given their consent (as can withdrawal), but does not refer to the signature or consent form per se.

KQs and recommendations

KQ1: when seeking informed consent for an endoscopic procedure, how do we obtain individualised consent?

It is not possible to be prescriptive about how to obtain consent for endoscopic procedures due to the number of procedural and patient-related factors involved. Whether the GMC principles of consent have been applied will always come to the professional judgement of the person performing the endoscopy. The principle message is to ensure that individual patient values and clinical factors have been incorporated in the consent process. Patients should have the opportunity for open dialogue with the clinical team proposing the endoscopic procedure to discuss the risks, benefits and alternatives, including the risks of not undergoing an endoscopy or the options of less invasive procedures. Where there are reasonable alternative investigations to an endoscopy such as faecal calprotectin, faecal immunochemical test (FIT), CT colonography (CTC), capsule endoscopy for lower GI investigations, or automated cell collection device (eg, Cytosponge) for Barrett's screening and surveillance, for example, they should be discussed with the patient in advance.

This relies on enough information being provided to all interested parties. The GMC recommend that the following information is included[2]:

- Recognised risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from your professional knowledge and experience.
- The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.
- Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them.
- Any risk of serious harm, however unlikely it is to occur.
- Expected harms, including common side effects and what to do if they occur.

In order to satisfy these criteria, the patient must have had information about the procedure and the endoscopist must have details from the referral pathway on their medical history and, where relevant, views of the patient. How and when that information is given to the patient and discussed with them will depend in part on the procedure being recommended. For higher-risk procedures or more complex patients, more time will need to be allocated to this discussion and for the patient to reflect on the options. This may require the input of family, friends or carers and be best in an elective out-patient setting. For diagnostic tests in low-risk patients, it may be appropriate for some of the process and completion of the form to occur on the day of the procedure, so long as adequate information has been provided and the patient given the opportunity to express their wishes or concerns in advance of this.

Table 2 Factors to consider when discussing informed consent for an endoscopic procedure in a patient with capacity

Risk evaluation (The risk of a complication occurring and the consequences if a complication should occur)	Procedure	Patient
General	General risks of the underlying endoscopic procedure (eg, colonoscopy)	Fitness for endoscopy, including comorbidities and medication use
Individualised	Factors that increase (or decrease) the risk of the specific proposed procedure (eg, polypectomy)	Patient-related risk factors for this specific procedure (eg, prior surgery)
		Patient-related preferences or concerns in relation to the procedure and outcomes

Recommendation

Individualised consent for endoscopy requires that specific patient-related risk factors and personal values are incorporated into the decision about whether to proceed with a given endoscopic procedure. These can only be determined through knowledge of the procedure and its alternatives as well as dialogue with the patient and, if necessary, family, friends or carers.

KQ2: when seeking informed individualised consent for an endoscopic procedure, which patient-related factors need to be taken into consideration?

Individualised consent requires that the circumstances specific to that patient are taken into consideration. This includes both clinical and personal factors (table 2).

Clinical factors can be divided into general risk factors for endoscopy and risks that are specific to the procedure. General risk factors include comorbidities such as cardiovascular risk and medications. Individual risk factors for a given procedure include patient demographics, current symptoms (such as a history of dysphagia for upper GI procedures) and medical history (such as prior surgery, patient anatomy, prior adverse events). Often there is not a robust body of evidence to individualise risk but there should be a discussion of overall risk and whether somebody is at greater or lesser risk compared with the general

population. In some circumstances, there are useful guides such as the European Society of Gastrointestinal Endoscopy (ESGE) guidelines for adverse events associated with endoscopic retrograde cholangiopancreatography (ERCP), which can highlight those at greater risk of complications, and these should be incorporated into discussions where possible.[4]

Patient-specific clinical risk factors relate to the risk of a given complication occurring and the consequences if such a complication was to occur. A patient with significant comorbidities may be less likely to survive a given complication, such as a perforation, and this should be incorporated into an individualised consent discussion.

Personal factors will include a patient's individual preferences and fears, prior experiences and expectations or hopes in terms of clinical outcomes. An obvious example would be to differentiate the expectations of a young healthy adult compared with an elderly patient with limited life expectancy, but there will be many others, such as a greater desire to avoid surgical scars in some individuals. These should not be taken for granted and must be explored prior to recommending a given invasive procedure.

Recommendation

Individualised consent for endoscopy requires that clinical factors related to the patient's symptoms, medical history and specific patient-related risk factors related to the proposed procedure, as well as the patient's personal preferences and expectations, should be explored.

KQ3: in broad terms, which procedure-related factors need to be considered in individualised consent?

Providing information about procedure-related risk is germane to the consent process. Often this is provided in a standardised platform such as information leaflets or online resources. However, the complexity and variation of endoscopic procedures has progressed so much in recent years, and will continue to do so, such that practitioners must recognise that these platforms can only function as a general guide. The risk of colonoscopy will vary considerably depending on the clinical indication—ranging from a low-risk diagnostic test to a high-risk large polypectomy. Examples of risk variation can be found across all endoscopic procedures and need to be taken into consideration. As outlined in the 2016 BSG guideline, the consent process should include all possible outcomes and additional procedures that might be required to fulfil the primary objective of the endoscopy.[3] This may include scenarios such as resection of complex polyps found on screening or surveillance procedures where removal is appropriate. The 2016 guideline also deals with unexpected findings with explicit recommendation that the scope of the consent should not be exceeded unless failure to intervene would cause immediate harm.

Thus, while the use of standard patient information platforms is not discouraged, where the risk of a procedure exceeds that, this information must be provided in some other format, either verbally or written. Similarly, the alternatives to a given procedure will vary considerably. For example, the treatment options for a patient with common bile duct stones are very different to the treatment options for a patient with a malignant biliary stricture. These options cannot be comprehensively discussed in a single leaflet so organisations and practitioners must find a way to allow this to be discussed with a patient prior to the procedure.

Recommendation

The risks and alternatives to endoscopic procedures vary considerably. Patient information platforms such as leaflets or online resources represent a minimum and where risk is greater or treatment options vary, steps must be taken to ensure that the patient is aware of this ahead of the procedure.

KQ 4: when considering individualising risk and patient/procedural factors, do we need to redefine who can complete the consent process?

The person discussing consent and completing the consent form with the patient must have a detailed understanding of all aspects of the procedure including the risks, benefits and alternatives. This discussion may be short and simple for many low-risk diagnostic procedures, to long and complex for high-risk interventional or therapeutic procedures. Such discussions should be tailored to the specific procedure and the patient. While, in many high-volume cases, this can be via standardised processes, every opportunity must be taken to ensure that patient autonomy is preserved.

Any healthcare professional can, and should be, encouraged to have a conversation with a patient about a procedure up to the limit of their professional knowledge. However, the person signing the consent form is doing so to confirm that they are satisfied that the patient has received the relevant information and options and had time to consider them. This person must have a clear knowledge of the factors as laid out in table 2. For low-risk procedures, a person who does not perform the procedure can be trained in a way that will facilitate such a discussion. However, for complex or higher-risk procedures, it is anticipated that only a person with considerable knowledge of this specific procedure will have such an understanding. Usually such a person will perform the procedure themselves. Where delegated to a non-endoscopist, the person completing the consent form with the patient must be able to satisfy that they have clear knowledge of the factors as laid out in table 2, achieved through successful completion of validated training for that procedure that includes direct observation of practice. Whatever arrangements are adopted locally should be recorded within the Trust Consent Policy and be formally approved under local governance procedures.

Whoever is completing the consent process with the patient, this should occur in a confidential and non-threatening environment that offers sufficient privacy and dignity to the patient. It should be comfortable and physically separate from the endoscopy treatment room and the patient should have the option of having relatives, friends or carers present if desired. Ideally this should occur prior to the patient being cannulated and changed for the procedure. This should reduce the possibility of coercion and allow space and time for the patient to consider the test before confirming agreement to proceed.

Recommendation

The person completing the consent form needs to have adequate knowledge of the procedure, range of individual risks and alternatives to that procedure. This will depend on the specific procedure but for high-risk procedures will require either considerable personal experience in the procedure or dedicated training that should be formally approved through local governance procedures.

Recommendation

The location in which consent is confirmed on the day of the procedure should be confidential, in a different location to the endoscopy treatment room and offer sufficient privacy and dignity to allow the patient to consider their decision.

KQ5: for lower-risk procedures that are frequently referred 'straight to test' how do we ensure that there is the opportunity to offer individual choice (without introducing unnecessary delay to the pathway)?

An important consideration for the consent process is that it is proportionate and takes into account the complexity of the decision, how quickly the decision needs to be made, the impact of the potential outcome and what is already known about the patient.[2] The majority of endoscopic procedures are low-risk tests and would not mandate a lengthy and complicated consent process. For example, upper gastrointestinal (GI) endoscopy in a relatively healthy person would carry extremely low risk but is important to be performed in a timely manner. These updated guidelines are not intended to introduce delay and constraints where they are not necessary.

At a population-level harm would occur by delaying low-risk tests for suspected malignancy because of an overly burdensome consent process. Thus, each unit should find a solution for its service and population that can satisfy the requirements of these recommendations and the GMC guideline without unnecessarily impacting on service delivery.

Where systems do not employ a consultation with an endoscopist prior to the day of the procedure, the referral should contain sufficient patient-specific information, as outlined in table 2, for appropriate triage and to determine if a consultation is required. This should include confirmation that the patient has capacity to consent. Consultation should be available for patients whose indication is borderline, may lack capacity, have personal risk factors or concerns, or simply desire further discussion (accepting that such discussion may delay their procedure).

Accordingly, it may be advisable that where a referral is 'straight to test', there is confirmation that the patient has agreed to this approach and does not wish further dialogue with an endoscopist before attending on the day. Such systems require robust processes to ensure patients receive adequate information before the procedure in the form of information leaflets or online resources. Previously, this process was termed 'postal consent'. Although we endorse the provision of information to patients by post, we no longer recommend the use of this term as it implies that the consent process has been completed before the patient attends for the procedure. Further, this requires that the patient has the opportunity to access further information prior to the procedure if they wish it, for example via a preassessment team or helpline, and on the day of the procedure the endoscopist must verify that the patient is satisfied with the information already received and is happy to proceed.

Electronic consent (eConsent)

Electronic methods for seeking informed consent and 'eConsent' refer to the use of any electronic media (such as text, graphics, audio, video, podcasts or websites) to convey information related to the procedure and to seek and/or document informed consent via an electronic device such as a smartphone, tablet or computer. Such systems have become popular in clinical research trials and there are now emerging platforms for consenting for clinical procedures.

eConsent for use in clinical trials has been approved in a Joint Statement from the UK National Health Service (NHS) Health Research Authority in 2018.[5] The principles in this statement, in broad regard, are similar to those that should be adopted in clinical practice.

Electronic signatures can vary in complexity and are classified as 'simple,' 'advanced' or 'qualified'. In research practice, it is recommended that the choice will depend on study type and complexity. In clinical practice, it is essential to be sure that the person signing the form is the same person that is potentially undergoing the procedure (and being able to demonstrate this if required). It is also important to understand that such methods may unintentionally discriminate against people who are not comfortable with or who cannot use such technology. Accordingly, alternative methods for the provision of information and/or documentation of consent should be available for those unable or unwilling to use electronic methods.

The Joint Statement stresses that 'while a consent form provides an important audit trail and assurance

that the consent process was conducted appropriately; a signature on a consent form (regardless of whether it is wet-ink or electronic) does not determine that the consent given has been sufficiently informed and is legally valid'. Further, eConsent does not absolve those engaged in studies of the responsibility to communicate adequately with participants. The statement concludes that in Clinical Trials of Investigational Medicinal Products, an interview (however conducted) is mandatory. This must be facilitated through an interactive communication that allows participants to ask questions and receive answers. A similar approach should be adopted for clinical practice.

It should be noted that while eConsent is subject to a Joint Statement and is in widespread use in clinical research, such platforms have not been validated or approved for clinical practice and we recommend caution until such time as they are. While eConsent platforms may offer advantages for low-risk high volume procedures, we recommend against their use in high-risk or complex procedures. Further, any service or individual considering using such platforms should ensure that they meet all of the criteria for individualised informed consent laid out in this section and the remainder of this document and we would advise that they be checked by organisational legal teams before implementation.

Recommendation

For low-risk procedures, the endoscopy service should receive adequate patient-specific information from the referrer to allow safe triage. The patient should receive standardised information and have an opportunity for further discussion if required ahead of the procedure. The person completing the consent process must verify that this has occurred before the procedure occurs.

KQ6: for high-risk/low-volume procedures what additional steps may be required to ensure individualised consent in the elective or outpatient setting?

For higher-risk cases such as ERCP, percutaneous endoscopic gastrostomy (PEG), complex endoscopic resections and enteroscopies, the endoscopy service needs to have a robust system to ensure the consent process is completed in line with the GMC principles. This was emphasised in the 2016 guideline:

> However, where such a process is implemented for higher-risk or more complex procedures, an opportunity to discuss the procedure either by telephone or face to face should be made available in advance of the day as a minimum standard[3]

Such cases are more likely to lead to complications, might have a number of alternatives and risk evaluation may well be complex. Such issues recently emerged in a Coroner's enquiry into post-ERCP deaths. (https://www.judiciary.uk/publications/william-doleman-anita-burkey-peter-sellars-and-carol-cole-prevention-of-future-deaths-report/). These cases are often referred from other specialties within the same hospital and, increasingly, from referral hospitals separate to the treating Trust. In many situations, the referrers do not have the necessary expertise to fully counsel their patients as to risks and alternatives. Accordingly, it is essential that the receiving team implement robust systems to review appropriateness for the procedure (vetting) ahead of the appointment so that inappropriate referrals can be intercepted, or necessary additional information obtained well in advance of the procedure. The involvement of multidisciplinary teams (MDTs), with appropriate administrative support, is encouraged for complex cases.[6]

Such 'vetting for appropriateness' is an important element of informed consent in so far as it prevents the need for complex discussions about appropriateness on the day of the procedure when the patient has attended and is expecting the procedure to go ahead. Every attempt must be made to prevent this from occurring. However, should a patient attend for a procedure that the endoscopist feels may not be indicated, or that the indication or appropriateness has changed since referral, the endoscopist is responsible for informing the patient and cancelling or deferring the procedure.

Further, while it is beholden on the referrer to initiate counselling of the patient about the procedure, the receiving organisation cannot entirely rely on this. Thus, although this may create logistical difficulties, it is essential that solutions are found to facilitate access for the patient to detailed discussion with an individual who is familiar with the risks and options and to allow individualised consent according to the principles laid out above. Video and telephone consultations may be an appropriate solution in this circumstance, but units should develop their own models.

Recommendation

In the case of complex or higher-risk endoscopic interventions, careful vetting for appropriateness is required and MDT discussion is encouraged. Referral centres should adopt systems to ensure that the patient has access to appropriate information about risks and alternatives and an opportunity to discuss this with an appropriately trained individual ahead of the procedure.

KQ7: for high-risk procedures what additional steps may be required to ensure individualised consent in the urgent/emergency setting?

Requests for acute interventions are often for patients admitted to hospital with emergency medical problems such as GI bleeding or cholangitis. These referrals frequently come from specialties that lack complete knowledge of the available endoscopic procedures. These are often

higher-risk procedures and high-risk patients and the consequences of intervention (or not) need to be adequately explained to satisfy the requirements for informed consent. While these cases are usually urgent, with rare exceptions, this does not reduce the need to fulfil the principles of assessment of appropriateness and fully informed and individualised consent ahead of the procedure. Thus, with the exception of clinical emergencies where detailed discussion is not possible, all inpatients referred for urgent procedures should have the same access to individualised risk evaluation and discussion about alternatives as patients in the elective setting. This may require in-reach to the ward by an appropriately trained individual ahead of the procedure but, again, Trusts must find their own solutions to satisfy these requirements. In the case of emergencies this may not be practical and clinical care should not be harmed by delay; nonetheless every attempt should be made to satisfy these principles within the constraints of the emergency setting.

Recommendation

For high-risk urgent procedures, patients should have access to an appropriately trained individual who can discuss the risks and alternatives to the patient on an individualised basis before they attend the endoscopy department for the procedure.

KQ8: in considering all of the above, what recommendations should be made in respect of patient selection (vetting for appropriateness) ahead of the procedure?

Endoscopy remains a service for which the majority of cases are performed on individuals referred in from outside specialties, different hospitals or Trusts or primary care. It is evident that a discussion about consent is invalid if the procedure per se is not required or inappropriate for the clinical indication. Increasingly triage and/or risk stratification tools are available to facilitate patient selection for interventions, such as FIT or faecal calprotectin tests prior to colonoscopy, and alternative tests may be available for the same indication (eg, CTC or colon capsule endoscopy). It is essential that such tools are used within the limits of available evidence and patients can understand the relevance of such results and the alternatives available to them. Further, the opportunity for an individualised discussion must not be lost, where required, even in high-volume low-risk referrals. Organisations must, therefore, implement systems that ensure the test is appropriate for the indication, that there is sufficient information for safe and individualised triage and, where necessary, the patient has access to discussion.

For higher-risk interventions, this need is even greater and careful vetting for appropriateness, with all of the relevant information available, ahead of the procedure by an appropriately trained individual is an essential prerequisite for a subsequent informed consent discussion. Online systems are available to facilitate vetting processes and are encouraged.

Recommendation

Information on endoscopy requests must be sufficient to determine whether an endoscopy is appropriate. Vetting for appropriateness should be performed for all cases but is particularly central to case selection for high-risk interventions.

CONCLUSIONS

Even high-volume, diagnostic endoscopic procedures are not without risk and in recent years more alternatives to endoscopy and robust triage tools have become available. In addition, there are increasingly complex endoscopic interventions that that have higher risk but offer novel therapy or may offer alternatives to more conventional surgical approaches. All of these issues place greater demand on endoscopy services and individual endoscopists to ensure that the consent process is robust, timely and patients are involved in the decision process. Here, we have provided recommendations and guidance aiming to help endoscopy services comply with recent updated GMC guidance on the consent process. It is recognised that these recommendations may place increased demands on already stretched units and it is intended that they be incorporated in a manner suited to individual units and in a way that is proportionate to the indication and procedure. Nonetheless, it is essential to adopt these in order to meet current legislation and, if implemented thoughtfully, they will improve the quality of the patient journey and may reduce the number of inappropriate procedures performed.

Correction notice This article has been corrected since it published Online First. The formatting of table 1 has been updated.

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