**Expanded Scope of Practice**

Nurse-led consent for specific gastrointestinal endoscopic procedures carried out in the Endoscopy Department, Lymington New Forest Hospital

**Version: 1**

<table>
<thead>
<tr>
<th><strong>Summary:</strong></th>
<th>Nurse-led consent for gastroscopy, flexible sigmoidoscopy and colonoscopy procedures carried out in the Endoscopy Department, Lymington New Forest Hospital, Southern Health NHS Foundation Trust</th>
</tr>
</thead>
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<tr>
<td><strong>Keywords:</strong></td>
<td>Consent, Nurse-led, Endoscopy, Gastroscopy, Flexible sigmoidoscopy, Colonoscopy, Mental Capacity, Mental Capacity Act</td>
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<tr>
<td><strong>Target Audience:</strong></td>
<td>Lymington New Forest Hospital Endoscopy Nurses. Lymington New Forest Hospital Endoscopists who carry out Gastroscopy, Flexible Sigmoidoscopy and Colonoscopy procedures. Lymington New Forest Hospital Endoscopy Users Group/GI Meeting</td>
</tr>
<tr>
<td><strong>Next Review Date:</strong></td>
<td>November 2019</td>
</tr>
</tbody>
</table>
| **Approved & Ratified by:** | West ISD Governance Meeting  
**Date of meeting:** 14/09/2017 |
| **Date issued:** | October 2017 |
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| **Director:** | Rachel Anderson, Clinical Service Director, Lymington New Forest Hospital. |
Version Control

Change Record

<table>
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<th>Version</th>
<th>Page</th>
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<td>10/9/19</td>
<td></td>
<td></td>
<td></td>
<td>Review date extended from Sept to Nov 2019</td>
</tr>
</tbody>
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Reviewers/contributors

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Version</th>
<th>Reviewed &amp; Date</th>
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</thead>
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<tr>
<td>Dr Rachel Anderson</td>
<td>Clinical Service Director, Lymington New Forest Hospital.</td>
<td>V1 (03/08/2017)</td>
<td></td>
</tr>
<tr>
<td>Dr Michael Devane</td>
<td>Consultant Physician; Endoscopy Lead, Endoscopy Department, Lymington New Forest Hospital</td>
<td>V1 (01/06/2017)</td>
<td></td>
</tr>
<tr>
<td>Dr Chris Roseveare</td>
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<td>V1 (01/06/2017)</td>
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<tr>
<td>Endoscopy Nurses</td>
<td>Bands 5, 6 and 7; Endoscopy Department, Lymington New Forest Hospital</td>
<td>V1 (03/08/2017)</td>
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<tr>
<td>Allison Peebles,</td>
<td>Head of Nursing and Allied Health Professions</td>
<td>V1 Sept 2017</td>
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</table>
Quick Reference Guide

Valid consent is a legal and ethical requirement prior to commencing any physical investigation. With the expanding role of Registered Nurses, nurse-led consent has become an important skill extension. The following policy outlines the role of the Endoscopy Nurse in obtaining valid consent for gastroscopy, flexible sigmoidoscopy and colonoscopy procedures carried out in the Endoscopy Department, Lymington New Forest Hospital, Southern Health NHS Foundation Trust. It describes the processes in place to ensure the Endoscopy Nurse achieves skill competence and outlines how this will be achieved and monitored.
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>2.</td>
<td>Who does this policy apply to?</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>Definitions</td>
<td>5</td>
</tr>
<tr>
<td>4.</td>
<td>Duties and responsibilities</td>
<td>6</td>
</tr>
<tr>
<td>5.</td>
<td>Main policy content</td>
<td>6</td>
</tr>
<tr>
<td>6.</td>
<td>Training requirements</td>
<td>8</td>
</tr>
<tr>
<td>7.</td>
<td>Monitoring compliance</td>
<td>9</td>
</tr>
<tr>
<td>8.</td>
<td>Policy review</td>
<td>9</td>
</tr>
<tr>
<td>9.</td>
<td>Associated trust documents</td>
<td>9</td>
</tr>
<tr>
<td>10.</td>
<td>Supporting references</td>
<td>9</td>
</tr>
<tr>
<td>Appendix 1</td>
<td>Training needs analysis</td>
<td>11</td>
</tr>
<tr>
<td>Appendix 2</td>
<td>Equality Impact Assessment Tool</td>
<td>12</td>
</tr>
<tr>
<td>Appendix 3</td>
<td>Complications and side effects of GI Endoscopy</td>
<td>14</td>
</tr>
<tr>
<td>Appendix 4</td>
<td>Consent Form 1: Patient Agreement to Investigation or Treatment</td>
<td>15</td>
</tr>
<tr>
<td>Appendix 5</td>
<td>Withdrawal of Consent for GI Endoscopy</td>
<td>16</td>
</tr>
<tr>
<td>Appendix 6</td>
<td>Consent competence checklist for local induction Endoscopy Unit</td>
<td>17</td>
</tr>
<tr>
<td>Appendix 7</td>
<td>Competency workbook</td>
<td>18</td>
</tr>
</tbody>
</table>
1. Introduction

1.1 Endoscopic procedures including oesophago-gastro duodenoscopy (gastroscopy), flexible sigmoidoscopy and colonoscopy (collectively referred to as GI endoscopy) are invasive procedures of the luminal gastrointestinal tract which pose potential morbidity and mortality risks. Consequently, written consent is required by the patient except in an emergency (Everett et al, 2016). This forms a fundamental part of good clinical practice (Department of Health [DH], 2009).

1.2 To meet both legal and ethical principles, consent must be valid. This requires the patient to;

- Have the mental capacity to make the decision – such capacity should be assumed unless proven otherwise (DH, 2007)
- Have received sufficient information - including risks, alternatives and consequences of accepting or refusing to have a GI endoscopy.
- Not be acting under duress – patients should not be put under pressure to accept or refuse a GI endoscopy by health care professionals, friends or family.

1.3 Obtaining consent for GI Endoscopy is a process which may involve various health professionals, over a period of time. The clinician requesting the procedure, outpatient clinic pre-assessment (involving 1:1 nurse-patient discussion and written procedural information) and pre-procedure consent give the patient the opportunity to ask questions regarding risks versus benefits and make an informed decision. However, it is the clinician performing the GI endoscopy that takes ultimate responsibility for ensuring the departmental consent process is appropriate for the proposed GI endoscopy procedure (Everett et al, 2016).

1.4 Nurse-led GI endoscopy consent has been shown to be more thorough than Doctor consent, with patients expressing equal comprehension of risks versus benefits across both groups of health professionals (Waloszkova et al, 2012). In light of this evidence, the British Society of Gastroenterology (BSG) has recommended that consent for GI endoscopy can be safely delegated to qualified endoscopy nurses who have been assessed as competent (Everett et al, 2016). This requires the support of their employing Trust with annual revalidation and patient satisfaction feedback.

2. Who does this policy apply to?

2.1 Band 5 and above, Registered Nurses employed by Lymington New Forest Hospital Endoscopy Department, Southern Health NHS Foundation Trust (SHFT).

3. Definitions

3.1 Nurse: Band 5 and above, Registered nurse employed by Lymington New Forest Hospital Endoscopy Department, SHFT, who has achieved the training requirements in Section 6.
3.2 **Gastroscopy**: endoscopic investigation of the oesophagus, stomach and proximal small intestine

3.3 **Flexible Sigmoidoscopy**: endoscopic investigation of the rectum, sigmoid and descending colon.

3.4 **Colonoscopy**: endoscopic investigation of the entire colon.

3.5 **Gastrointestinal Nurse Specialist (GI CNS)**: Band 8a, non-medical endoscopist, who performs gastroscopy procedures and manages outpatients with benign GI disorders at Lymington New Forest Hospital, SHFT.

3.6 **Consent**: is a patient’s agreement for a health care professional to undertake examination, provide treatment or care.

3.7 **Mental Capacity**: is the ability to make a particular decision, or take a particular action, at the time the decision or action needs to be made or taken.

4. **Duties and responsibilities**

4.1 All Registered nurses who obtain patient consent for a GI endoscopic procedure must adhere to this policy. There is no primary legislation governing consent, however under common law touching a patient without valid consent may constitute a criminal or civil offence (SHFT, 2015a).

4.2 The endoscopist carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is proposed and that the consent process is appropriate for the procedure being undertaken. It is they who will be held responsible in law if this is challenged later (BSG, 2016; SHFT, 2015a).

4.3 The Endoscopy Department manager will ensure that staff members are aware of the need to obtain valid consent (seeking guidance from the Endoscopist where a patient’s capacity to consent is in doubt), and support staff to implement this policy through appropriate training. Failure to obtain valid consent or adhere to the Mental Capacity Act (2005), where a service user subsequently suffers harm as a result, may be a factor in a claim of negligence (SHFT, 2015a).

5. **Main policy content**

5.1 On the day of admission, for their pre-booked GI endoscopy, the patient will be admitted as per the Endoscopy Unit Operational policy (Hadley and Lucas, 2015).

5.2 As part of the admission procedure, the consent process should take place before the patient enters the procedure room to avoid coercion (BSG, 2016).

5.3 The consent process will comprise the following:

5.3.1 **Explanation of the proposed procedure**: patients will have received, prior to the day of their appointment, an EIDO Healthcare information leaflet (appropriate to their GI endoscopy) explaining the procedure (SHFT 2017a, 2017b and 2017c). This offers the patient time to read, evaluate and write down any questions they may have. The Nurse will give the patient the opportunity to ask questions and express any concerns they have.
5.3.2 The consenting nurse will involve appropriate colleagues such as specialist learning disability teams and speech and language therapists if communication difficulties are encountered, unless the urgency of the patient’s situation prevents this. A pictorial interpretation of endoscopic procedures will be used as part of the consent process for patients with learning disabilities.

5.3.3 Should, from their interaction with the patient, the nurse have concerns regarding the patient’s mental capacity to make an informed consent decision this will be discussed with the endoscopist. It will be the endoscopist’s responsibility to make an assessment of capabilities and best interest decision using the Hampshire Mental Capacity Toolkit (Hampshire County Council, 2010). This may mean deferring the GI procedure until the referring clinician has been informed and this clinician has made a best interest decision necessitating the completion of SHFT Consent Form 4 (SHFT, 2015b). Should a Power of Attorney or Advance Directive be in place the nurse will inform the endoscopist. The latter will be responsible for reviewing these documents with the patient/relative/friend and respecting their contents. The nurse will ensure the patient and their carer/relative/friend, who is in attendance, are involved and kept informed of any changes to the proposed procedure and document all decisions made in the admission paperwork.

5.3.4 If the patient declines procedural information the Nurse must inform the endoscopist and document the conversation with the patient in their admission paperwork (BSG, 2016).

5.3.5 The patient’s decision to have or not to have anaesthetic throat spray and/or conscious sedation (as appropriate for the procedure) will be discussed. As applicable, the Nurse will explain how the sedation will be administered, monitored and its effects eg: short-term amnesia. If conscious sedation is preferred, the Nurse will make the patient aware that they require someone to take them home and be with them overnight. Should the Nurse have concerns that the latter cannot be met or that the patient has significant co-morbidity, contraindicated in sedation use, they will discuss this with the endoscopist.

5.3.6 **Motive or rationale for doing the procedure:** The Nurse will ask the patient to recall, in their own words, why they are having the procedure carried out. Should there be any discrepancy between the patient’s rationale and the referral form the Nurse will discuss this with the Endoscopist.

5.3.7 **Benefits of the procedure to the patient:** the Nurse will explain to the patient the importance of their GI endoscopy in eliminating any gastrointestinal cause for the symptoms for which they have been referred.

5.3.8 **Risks:** The Department of Health recommends that information on material, significant or unavoidable risks should be offered to patients prior to a procedure (DH, 2009). This includes the risks of not going ahead with the procedure. Information about risks should be given by the Nurse in a balanced manner alongside the benefits, so avoiding bias (BSG, 2016). See 5.3.7.

5.3.9 **Alternatives:** The nurse will make the patient aware of the following alternatives to GI endoscopy and the fact that alternative methods of investigation may not allow for biopsy taking.

5.3.9.1 **Gastroscopy:** gastroscopy under Propafol (unconscious sedation) at Southampton General Hospital; barium meal; no investigations.

5.3.9.2 **Flexible Sigmoidoscopy:** barium enema; CT colonoscopy; no investigations.

5.3.9.3 **Colonoscopy:** barium enema; CT colonoscopy; no investigations.
5.3.10 After being given the above information, should the patient decide not to go ahead with the proposed GI endoscopy/choose an alternative method of investigation, the Nurse will inform the Endoscopist, who will further discuss with the patient. The Nurse will document their discussion with the patient and the final outcome on the consent form and in the patient’s admission paperwork.

5.3.11 **Complications:** The Nurse should inform the patient of any likely serious adverse outcome and mention less serious side effects/complications if frequent (Appendix 3), (BSG, 2016).

5.3.12 **Effects/Side effects of the procedure:** (see 5.3.7).

5.4 **Completion of written consent form:** following the above discussion the nurse will fill out the corresponding sections of the carbonated SHFT Consent Form 1: Patient agreement to Investigation or treatment (Appendix 4). The patient will be given time to read the form and ask questions. If they are in agreement to proceed with the GI endoscopy they will complete the section entitled; “Statement of Patient”. The patient will receive the pink copy of the consent form prior to discharge. The yellow copy will be filed in their case notes and the white copy sent to the pathology laboratory with any biopsies taken during the GI Endoscopy.

5.5 **Withdrawal of consent:** the patient is at liberty to withdraw their consent at any time, including during the GI endoscopy procedure. The patient will be informed to this effect by the Nurse and withdrawal of consent for non-sedated and sedated local guidance will be followed (Appendix 5).

6. **Training requirements**

6.1 At time of departmental induction:

- Self-familiarisation with current Trust policies on Consent for examination or Treatment and Mental Capacity Act
- Completion of Consent Competence Checklist (Appendix 5)

6.2 Annual Mandatory Trust level 2 safeguarding training, which includes consent issues.

6.3 After a minimum of one year of working in the department, a discussion will take place between the Nurse, Endoscopy Manager and GI CNS as to whether the Nurse feels ready to take train in the role of nurse-led consent. Support will be given to those Nurses who feel they are not ready in the form of objective setting (using their staff nurse competency pack) and shadowing of an experienced Nurse.

6.4 If a nurse is deemed ready, using the above process, to take on consent training this will involve self-completion of an Informed Consent Workbook following which the Gastrointestinal Nurse Specialist (GI CNS) will formatively assess theory-knowledge (Appendix 7).

6.5 Minimum 3 formative DOPS (assessed and documented by GI CNS)

6.6 Minimum 3 summative DOPS (assessed and documented by GI CNS)

6.7 When competence level achieved; review of theory and practice competence and feedback from annual patient satisfaction survey at annual appraisal with Line Manager.
7. Monitoring compliance

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Lead</th>
<th>Tool</th>
<th>Frequency</th>
<th>Reporting arrangements</th>
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<td>Dates of: induction consent training; discussion surrounding ability to take on consent training; competency sign-off; annual update; discussion of consent competencies at annual appraisal; annual patient feedback</td>
<td>Shirley James GI CNS Vicky Hill, Endoscopy Manager Vanessa Lucas Endoscopy Sister</td>
<td>Electronic register</td>
<td>As occur</td>
<td>Document as part of JAG accreditation</td>
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<tr>
<td>Consent process; theory and practice (annual update)</td>
<td>Shirley James GI CNS</td>
<td>Quiz following Departmental update</td>
<td>Annually</td>
<td>Document as part of JAG accreditation</td>
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8. Policy review

8.1 This Policy will be reviewed on a two yearly basis, or following any significant changes in national policy, legislation, Joint Advisory Group for GI endoscopy or BSG guidelines.

9. Associated trust documents

9.1 SH CP 16: Consent for Examination or Treatment Version: 8.

10. Supporting references

### Appendix 1: Training Needs Analysis

If there are any training implications in your policy, please make an appointment with the LEaD department (Louise Hartland, Quality, Governance and Compliance Manager on 02380 874091) to complete the TNA **before** the policy goes through the Trust policy approval process.

<table>
<thead>
<tr>
<th>Training Programme</th>
<th>Frequency</th>
<th>Course Length</th>
<th>Delivery Method</th>
<th>Facilitators</th>
<th>Recording Attendance</th>
<th>Strategic &amp; Operational Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent to examination or treatment principles are covered in Mental Capacity Act training as part of organisational induction and level 2 integrated Safeguarding training days.</td>
<td>At induction, then three-yearly in line with Safeguarding training requirement</td>
<td>Part of Safeguarding Level 2 training – one day in duration.</td>
<td>Various subject experts from Corporate Safeguarding Team</td>
<td>Corporate Safeguarding</td>
<td>VLE; On-line automated record</td>
<td>Corporate Safeguarding</td>
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<td></td>
</tr>
<tr>
<td>Specialised Services</td>
<td>Learning Disabilities</td>
<td></td>
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<td>Learning Disabilities</td>
<td>TQtwentyone</td>
<td></td>
</tr>
<tr>
<td>ISD’s</td>
<td>Older Persons Mental Health</td>
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</table>
| ISD’s | Adults | **Registered Nurses, band 5 and above, working in the Endoscopy Unit, Lymington New Forest Hospital, will:**
  - Familiarise themselves with Trust Policy: SH CP 16: Consent for Examination or Treatment.
  - Receive information on the principles in practice of gaining consent at their initial Trust endoscopy unit induction and complete checklist (Appendix 5).
  - Attend mandatory level 2 safeguarding training which includes consent issues.
  - Following minimum of one year in post (assessed on individual Nurse basis), complete an informed consent GI endoscopy workbook and have their competency assessed and documented (through Directly Observed Procedural Skills [DOPS]) by the GI Nurse Specialist Lymington New Forest Hospital.
  - Partake in revalidation of consent knowledge and skills at annual Trust appraisal |
| ISD’s | Childrens Services | |
| Corporate | All | |
Appendix 2: Equality Impact Assessment

The Equality Analysis is a written record that demonstrates that you have shown due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations with respect to the characteristics protected by the Equality Act 2010.

Stage 1: Screening

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<tr>
<td>Name of person completing the assessment:</td>
<td>Shirley James</td>
</tr>
<tr>
<td>Job title:</td>
<td>Gastrointestinal Nurse Specialist</td>
</tr>
<tr>
<td>Responsible department:</td>
<td>Lymington New Forest Endoscopy</td>
</tr>
<tr>
<td>Intended equality outcomes:</td>
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</table>

Who was involved in the consultation of this document?

| Shirley James, Gastrointestinal Nurse Specialist |
| Vicky Hill, Lymington New Forest Hospital Endoscopy Manager |
| Vanessa Lucas, Lymington New Forest Hospital Endoscopy Sister |
| Band 5 Registered Nurses, Endoscopy Department, Lymington New Forest Hospital |

Please describe the positive and any potential negative impact of the policy on service users or staff.

In the case of negative impact, please indicate any measures planned to mitigate against this by completing stage 2. Supporting Information can be found be following the link: www.legislation.gov.uk/ukpga/2010/15/contents

<table>
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<th>Protected Characteristic</th>
<th>Positive impact</th>
<th>Negative impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>The consenting nurse will obtain standard departmental procedural consent. Lymington New Forest Hospital offers a GI endoscopy referral service for adults ≥18 years of age.</td>
<td>No negative impacts anticipated.</td>
</tr>
<tr>
<td>Disability</td>
<td>The consenting nurse will involve appropriate colleagues such as specialist learning disability teams and speech and language therapists in making assessments of capacity where communication difficulties are suspected unless the urgency of the patient’s situation prevents this. A pictorial interpretation of endoscopic procedures will be used as part of the consent process for patients with learning disabilities.</td>
<td>No negative impacts anticipated.</td>
</tr>
<tr>
<td>Gender reassignment</td>
<td>The consenting nurse will obtain standard departmental procedural consent.</td>
<td>No negative impacts anticipated.</td>
</tr>
<tr>
<td>Marriage &amp; civil partnership</td>
<td>The consenting nurse will obtain standard departmental procedural consent.</td>
<td>No negative impacts anticipated.</td>
</tr>
<tr>
<td>Stage 2: Full impact assessment</td>
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<tr>
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<td><strong>What is the impact?</strong></td>
<td><strong>Mitigating actions</strong></td>
<td><strong>Monitoring of actions</strong></td>
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</tbody>
</table>

| Pregnancy & maternity | The consenting nurse will obtain standard departmental procedural consent. | No negative impacts anticipated. |
| Race | For those whose first language is not English, the referring clinician will be responsible for highlighting on the referral form the patient’s language/dialect. The endoscopy booking team will arrange an interpreter to be present for the duration of the patient’s appointment, including the consent process. In line with SHFT policy, family members will not be used as interpreters (SHFT, 2015a) | No negative impacts anticipated. |
| Religion | The consenting nurse will obtain standard departmental procedural consent respecting individual religion/cultural preferences. The latter will be documented on the consent form/nursing documentation as appropriate. | No negative impacts anticipated. |
| Sex | The consenting nurse will obtain standard departmental procedural consent. In line with JAG requirements, the Endoscopy department provides same-sex endoscopy lists. | No negative impacts anticipated. |
| Sexual orientation | The consenting nurse will obtain standard departmental procedural consent. | No negative impacts anticipated. |
Appendix 3 – Complications and side effects of GI Endoscopy (EIDO, 2017a, b, c)

Diagnostic Upper GI endoscopy

- Perforation: 1 in 2000
- Infection: low (sterile/single use equipment)
- Haemorrhage: rare (usually stops on own following biopsy taking)
- Sore throat 24-48 hrs
- Damage to teeth or bridge work
- Abdominal bloating/discomfort
- Belching
- Sensation of inability to swallow following Lignocaine throat spray
- Temporary amnesia and risk of hypotension, tachycardia and respiratory depression following IV Midazolam
- Incomplete procedure

Flexible sigmoidoscopy

- Perforation: 1 in 1500 (Diagnostic)
- Perforation: 1 in 500 (Therapeutic)
- Infection: low (sterile/single use equipment)
- Haemorrhage: <1 in 1000 (Diagnostic)
- Haemorrhage: 2 in 100 (Therapeutic)
- Abdominal bloating/discomfort
- Flatulence
- Temporary amnesia and risk of hypotension, tachycardia and respiratory depression following IV Midazolam
- Incomplete procedure

Colonoscopy

- Perforation: 1 in 1500 (Diagnostic)
- Perforation: 1 in 500 (Therapeutic)
- Infection: low (sterile/single use equipment)
- Haemorrhage: <1 in 1000 (Diagnostic)
- Haemorrhage: 2 in 100 (Therapeutic)
- Abdominal bloating/discomfort
- Flatulence
- Temporary amnesia and risk of hypotension, tachycardia and respiratory depression following IV Midazolam
- Risk of nausea, vomiting and dry mouth following IV Opioid
- Temporary blurred eyesight with IV Buscopan (resolves one hour)
- Incomplete procedure
Appendix 4 – Consent Form 1: Patient Agreement to Investigation or Treatment

Consent Form 1

Patient agreement to investigation or treatment

Name: ____________________________ Date: ____________

Special patient requirements: ____________________________ Responsible healthcare professional: ____________________________

Name of procedure or course of treatment: ____________________________ Side/site: ____________________________

(name of the procedure, if applicable)

Statement of Health Professional

(To be filled in by a health professional with appropriate knowledge of the proposed procedure)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefit of the procedure
- Any serious or frequently occurring risks from the procedure
- Any alternative procedures which may be necessary during the procedure

I have discussed what the treatment procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of the patient.

I have informed the patient of the following information:

- The procedure will involve: ______
- The procedure may involve major trauma ______
- The procedure may involve discomfort ______
- The procedure may involve risk ______
- The procedure may result in death ______

Patient’s signature: ____________________________ Date: ____________

Consent Form 1 – Page 1 of 2

Statement of Patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copies. It describes the benefits and risks of the proposed treatment. If not, you will be able to discuss it with your doctor. If you have any further questions, we are here to help you. Please read this form carefully. You have the right to change your mind at any time before the procedure or investigation is undertaken. If you have any concerns about the treatment, you or a relative to be present while the procedure is being explained and consent is obtained.

The statement of consent and other health professionals is essential to the continuation of the health service and ensuring the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this affecting your care and treatment.

Please (if so) list the boxes that you have understood and agree to the statements below:

- I agree to the procedure or course of treatment described on this form.
- I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person who, however, has appropriate experience.
- I understand that any other person involved in the procedure or treatment will be used for diagnostic and therapeutic purposes as part of my care and may subsequently be stored as part of my medical records and be used for the benefit of the subsequent care management.
- I understand that any data which may be used for confidentially monitoring and/or public health surveillance purposes, where the point of use will be to the benefit of the patient, may be used for such purposes. You are being asked to consent to the use of photographs to record the purpose of diagnosis and treatment.
- I understand that I will have the opportunity to discuss the details of the treatment with an anesthetist before the procedure, unless the urgency of the situation prevents this. This only applies to patients having general or regional anesthesia.
- Female patient(s) when applicable: I understand my care may involve X-rays and that radiation should be limited during pregnancy. Her treatment may involve radiation. Yes ___ No ___
- I understand that if any procedure in addition to those described on this form will be carried out, not it is necessary to save my life or to prevent serious harm to my health.
- I have been told about additional procedures, which may become necessary during my treatment.
- I have listed before any procedures that I do not wish to be carried out, without discussion with me.

Patient’s own signature: ____________________________ Date: ____________

Name (PRINT): ____________________________

If the patient is unable to sign, the patient’s consent must be given by a witness.

Signature: ____________________________ Date: ____________

Name (PRINT): ____________________________

Confirmation of Consent: To be completed by a health professional when the patient has signed the form in advance.

On behalf of the team caring for the patient, I have confirmed with the patient that she has no further questions and wishes the procedure to go ahead.

Signed: ____________________________ Date: ____________

Name (PRINT): ____________________________

Important notes (If applicable):

- The patient has withdrawn consent (ask patient to sign here)
- See also Advance Directives/Living Will (by Almasha’s Witness Form)

Page 1 of 2
Appendix 5: Withdrawal of Consent for Gl Endoscopy

Endoscopy Unit, Lymington New Forest Hospital
Withdrawal of Consent for Endoscopic procedures

Withdrawal of Consent for Non-Sedated Endoscopy Procedures.

- Patient wishes procedure to be stopped and endoscope removed.
  - Endoscopist halts procedure and assesses the situation
    - Endoscopist clarifies with patient if they wish to continue or stop; considering patient’s best interest
      - Consider top-up doses of sedation or analgesia
        - Patient agrees to continue – procedure recommenced
          - Nurse continues to assess comfort levels with patient
        - Patient states they want the procedure to stop
          - Endoscopist or nurse ask patient again if they wish procedure to continue
            - Patient states 3 times that they wish procedure to stop
              - Endoscope removed and withdrawal of consent recorded on consent form, clinical notes and nursing assessment form
              - Endoscopist continues with procedure in "best interests" of patient and reasons documented in clinical notes and nursing assessment form

Withdrawal of Consent for Sedated Endoscopy Procedures.
If the nurse has any concerns about the endoscopist actioning the withdrawal of consent this will be reported to the Unit Manager and an Incident report completed. All discussions and actions taken will be recorded on the HICSS report and the nursing documentation.
Appendix 6: Consent competence checklist for local induction Endoscopy Unit:

Date Undertaken:
Name and signature of Nurse:
Name and signature of Assessor:

1. Able to express a clear understanding of consent and can access the Trust Consent Policy

2. Understands why consent is crucial and when to obtain it

3. Able to name three methods of gaining consent

4. When to document consent

5. Clear understanding of the Mental Capacity Act (MCA) and how this relates to consent. Can access the Trust MCA Policy, and the MCA Code of Practice.

6. Understands duty of care

7. Consent in an Emergency

8. Provision of Information (patients are fully informed)

9. Who is responsible for gaining consent

10. Refusal of treatment

11. Where to obtain more information should you need it
Current Guidance and Practice on obtaining informed consent

Contents

- Aims
- Learning Outcomes
- Defining consent
- ‘EMBRACE’
- Why do we need a record of consent?
- How do we record consent?
- When is consent valid?
- When is consent invalid?
- The knowledge and skills of consent
- English Consent Law – FAQs
- The Mental Capacity Act
- Further reading
This workbook is designed as a guide to the theory and knowledge behind the acquisition of informed consent for individuals undergoing GI endoscopic procedures and how this role can be included in the pre-procedure interview as part of the assessment process.

You should record your notes and comments within the appropriate part of the document with specific relation to;

1. Your own role and practice
2. The healthcare setting in which you work

The document will then be used to guide a discussion with your assessor to determine your level of understanding and competence to undertake the role of contributing to the consent process.

The aim of this learning pathway is to enable you to;

- Understand the principles of informed consent
- Apply a structured model to the provision of information
- Understand the legal and ethical issues relating to consent

Learning Outcomes

Upon completion of this learning pathway and review of the related literature you should be able to;

1. Understand the requirement for consent
2. Demonstrate the information required by individuals to enable them to make an informed decision
3. Answer questions which may be asked by individuals during the consent process
4. Describe the modalities of providing information
5. Utilise the ‘EMBRACE’ acronym in practice
6. Describe the role of the nurse in the consent process in the practice setting
7. Identify resources and guidelines which relate to the consent process

Definition of consent

Consent n agreement, permission v 2 (foll By to) permit, agree to

Dictionary and Thesaurus 2004 Harper Collins Glasgow

Consent

‘Patients are legally required to consent to treatment, surgery and any intervention that requires physical contact. Consent may be verbal, written or implied. However where there is a possibility of risk or dispute a written record is advisable. It is the responsibility of the healthcare professional undertaking the procedure to provide a full explanation to the patient prior to treatment or surgery about what is involved and any additional measures that may be required and to obtain written consent.'
In the past this would have been the doctor responsible for the proposed procedure but increasingly other healthcare professionals are undertaking treatment and investigations or contributing to the process of providing information to the patient.’


**Informed consent**

‘In the United Kingdom a written record or consent form must be signed by the doctor or appropriately trained healthcare professional stating that he / she has explained the nature and purpose of the operation, investigation or treatment in terms which can be understood. Any questions the patient may have during this process should be referred to the doctor or other healthcare professional prior to the form being signed.’


**TASK**

Give an example from your own practice of implied consent

**TASK**

List the methods used within your department to inform individuals about their treatment

**‘EMBRACE’**

The ‘EMBRACE’ acronym is useful tool which provides a model or structure to the provision of information to make the consent process informed.

It is utilised by GI Joint Advisory Group (JAG) as a learning aid.

- E  Explanation of the proposed procedure
- M  Motive or rationale doing the procedure
- B  Benefits of the procedure to the patient
- R  Risks
- A  Alternatives
- C  Complications
- E  Effects/Side effects of the procedure
It is important for any health professional involved in the consent process to understand the evidence basis which informs practice. Each stage of the ‘EMBRACE’ model is informed by evidence, research and guidance.

For example, M = Motivation or the rationale for undertaking the procedure. In most cases this means the clinical indication for the investigation which will have a basis in research.

**TASK**

What are the clinical indications for upper GI endoscopy?

**TASK**

What are the differences between the clinical indications for flexible sigmoidoscopy and colonoscopy?

**TASK**

Using an example from practice – OGD, Flexible sigmoidoscopy, colonoscopy – complete the following “EMBRACE” model and identify the source/evidence to the information you include:

**EXPLANATION**

Define the procedure and consider the experience/sensations of the patient.

**MOTIVATION**

Identify the rationale/clinical indications for the following –

Upper GI Endoscopy

Flexible Sigmoidoscopy

Colonoscopy

**BENEFITS**

Explain how the patient may gain from undergoing the proposed procedure.
For example: identify the cause of unpleasant symptoms, treat the cause of symptoms.

RISKS

What are the identified risks of the following -

Upper GI Endoscopy

Flexible Sigmoidoscopy

Colonoscopy

Do some procedures carry more risk than others? For example does therapy carry a greater risk?

Identify the source of the information you provide?

ALTERNATIVES

List the alternatives to:

Upper GI Endoscopy

Flexible Sigmoidoscopy

Colonoscopy

COMPLICATIONS

Equate the risks you identified earlier – how often do they occur? Which patients are at higher risk of complications?

What are the potential complications from diagnostic and therapeutic upper GI endoscopy?

What are the complications of flexible sigmoidoscopy and colonoscopy, including therapy?
EFFECT/SIDE EFFECTS

Side effects may include unpleasant symptoms following a procedure.

List the commonly occurring side effects following GI endoscopy.

Identify the common side-effects following sedation and explain how this informs practice.

What is variant CJD?

Why should all patients be asked about their risk of exposure to vCJD during the consent process prior to every endoscopy?

Which of the following procedures are high-risk for transmission of vCJD?

OGD with duodenal biopsy

Colonoscopy with polypectomy
ENGLISH CONSENT LAW

TASK

The following section reviews the Mental Capacity Act (2005) and considers the implications to the consent process.

Learning Outcomes

Following completion of this section you should be able to;

- Summarise the Mental Capacity Act (2005)
- Identify the relationship between the Act and the concept of informed consent
- Understand the legal definition of ‘best interests’
- Relate the Mental Capacity Act to the role of the endoscopy nurse

The Mental Capacity Act (2005);

- Aims to empower and protect people who may lack capacity to make some decisions for themselves
- Includes people with:
  - Dementia
  - Learning disabilities
  - Mental health problems
  - Stroke or head injuries
- Clarifies who can make decisions in which situations and how this should be done
- Enables people to plan ahead for a time when they might lack capacity
- Covers an individual’s major decisions about their property and affairs, healthcare treatment, personal care, where they live etc.
- Became law in October 2007
- Underpinned by five key principles:
  - Presumption of capacity
  - Support for individuals to make decisions
The Act defines the legal standing of ‘presumption of capacity’

- Every adult is presumed to have capacity unless proved otherwise
- Sets out a single clear test for assessing whether or not a person lacks capacity to make a certain decision at a certain time
  - Is there an impairment of the functioning of the person’s mind or brain?
  - If so, is the impairment or disturbance sufficient that the person lacks the capacity to make a certain decision?

Support to make decisions:

- Defines the role of the Independent Mental Capacity Advocate (IMCA) service
- Identifies which decisions have to be referred to the Court of Protection
  - For example, withdrawal of artificial nutrition and hydration from a person in a permanent vegetative state
- Individuals have the freedom to make what might be viewed as ‘unwise’ decisions
- Makes clear the formalities of safeguarding the validity and applicability of ‘advance decisions’

The Act also defines in law the concept of ‘best interests’ and the ‘least restrictive option’ with regard to treatment:

- Defines in law the process for making a decision on behalf of someone who lacks capacity under the Act
- Provides a statutory checklist that decision makers must work through to decide what is in the individual’s best interest
  - For example, can the decision be put off until the person regains capacity?
- Anything done for or on behalf of an individual should be the least restrictive option to their basic rights and freedoms
- This is particularly important when the individuals lack of capacity may be temporary

Case study one
John is suffering from oesophageal cancer. He is 77 years old and in the advanced stages of dementia.

Prior to developing dementia he told his wife that he would never want any treatment for cancer unless it would definitely cure him.

The consultant wants to place an oesophageal stent.

What issues need to be considered?

What is required for John’s advance decision to be recognised under the Mental Capacity Act?

*John may have made an advanced decision – the concept of the ‘living will’ exists in common law in England.*

The Mental Capacity Act formalises this and sets out clear arrangements for what is required for an advanced decision particularly when the decision may result in loss of life.

**Advanced decisions are valid when:**

- It is made when the person has capacity
- The person making it has not withdrawn it
- The advance decision is not overridden by a later Power of Attorney that relates to the treatment specified in the decision
- The person has acted in a way that is clearly consistent with the decision

**An advance decision is only applicable when:**

- The person who made it lacks the capacity to consent or deny consent to the treatment in question
- It refers specifically to the treatment in question
- The circumstances to which refusal of treatment refers are present

**An advance decision to refuse life-sustaining treatment is only applicable when:**

- It is in writing and recorded in the person’s medical notes
- It is signed by the individual (or on their behalf at their direction if they are unable to sign) in the presence of a witness who has also signed it
- It is clearly stated that the advance decision is to apply to the specified treatment even if life is at risk

**Case study two**

Nathan has swallowed several batteries during a prank.

He is 23 years old but has a learning disability which gives him the mental capacity equivalent to a ten year old.

The consultant would like to remove the batteries using an endoscope. His parents agree.

You are Nathan’s nurse. He tells you he does not want an endoscopy.

How will you approach this situation?
Capacity is not determined by age. Children under sixteen can consent or refuse treatment if they have capacity to understand the consequences of their decision. An adult or parent cannot overrule a competent child.

Advanced decisions require that the individual is over 18 years old.

All other individuals must be treated equally under the Act – i.e. they are assumed to have capacity unless proven otherwise

Therefore if Nathan has the capacity to make his own decisions even if they are considered unwise they cannot be overruled however if Nathan lacks capacity under the Act a decision can be made in his best interests

Case study three

Ruth collapses whilst out running. She is admitted to hospital suffering abdominal pain and haematemesis. She is transferred from A&E to endoscopy for an emergency OGD. On arrival she is semi-conscious and disorientated. Her HB is found to be 4.8. The consultant commences a blood transfusion.

Her husband arrives and says that due to her faith she would refuse blood.

Are the actions of the medical and nursing team acceptable under the Mental Capacity Act?

Under the Act the consultant and nursing team acted appropriately unless:

- Ruth had communicated to them that she did not want blood
- Ruth was carrying information stating that she would refuse blood due to her faith – for example, an alert medallion etc.

In this example her loss of blood had affected her capacity to make decisions and lacking any other source of information at the time the consultant acted appropriately.
English consent law – Frequently asked questions

When do health professionals need to seek consent?

- Before you examine, treat or care for patients
- Always ask ‘does this patient have the capacity to understand the information needed to make this decision?’
- Consent is an ongoing process not a one off event
- Patients can withdraw consent at any time

Where is the best place for the patient to consider their consent?

- The consent process should always take place in a non-threatening environment
- For outpatients – the consent process should begin at home
- For inpatients – the consent process should begin on the ward
- Best practice in Endoscopy setting is for the discussion about consent to take place prior to the patient entering the endoscopy room

Who is the right person to seek consent?

a) The doctor referring the patient
b) The person doing the procedure
c) Some-one who has been specially trained

- Best practice is for the person actually treating the patient to seek consent
- Another professional may seek consent on behalf of a colleague if they are capable of performing the task
- Individuals specifically trained to seek consent may also substitute

Does a patient’s consent have to be voluntary?

- Consent must be given voluntarily
- Any form of duress or undue influence from health professionals or others such as relatives or friends make the consent invalid
Does it matter how the patient gives consent?

a) Oral  
b) Signature  
c) Implied

- Consent can be written, oral or non-verbal  
- A signature does not prove the consent valid – a consent form is purely a record of the patient’s decision and may prove that a discussion has taken place  
- Always refer to local Trust policies which should define when written consent is required

Can patients refuse treatment?

- Competent adult patients can always refuse treatment – even when the proposed treatment would benefit their health  
- A competent pregnant woman may refuse treatment – even when this may be detrimental to the foetus  
- Patients detained under the Mental Health Act cannot refuse treatment for a mental disorder  
- A parent can over-ride a child’s refusal to consent only in exceptional circumstances

Who can give consent for an incompetent adult?

a) No-one  
b) A relative or friend  
c) Professionals

- No-one can give consent on behalf of someone else  
- A patient unable to consent can be treated if the proposed treatment in his or her ‘best interest’  
- ‘Best interests’ were open to interpretation until the Mental Capacity Act 2005
END2  Provide information on endoscopic procedures to individuals

About this workforce competence

This workforce competence covers the provision of information to individuals, at any time during the provision of endoscopic procedures. Individuals undergoing endoscopic procedures require different types of information at different stages of an endoscopic procedure: to help them prepare, to help them understand what is happening, and to know the results. It is important that their right to information is respected, and that they are provided with honest and accurate information. A separate workforce competence (END1) is available to cover the way information is actually communicated.

Links

This workforce competence links with the following dimensions and levels within the NHS Knowledge and Skills Framework (October 2004):

KSF Dimension Core 1: Communication level 3

Performance criteria

You need to:

1. respect the individual’s rights and wishes relating to their consent, privacy, beliefs, and dignity
2. establish the extent to which the individual requires any carers to be involved during the provision of information
3. discuss the amount and type of information which the individual requires, or has already accessed, to make informed decisions relating to the endoscopic procedure
4. provide information that is relevant to the individual’s requirements, and ensure it is as accurate as possible within the context of what is known about their condition
5. use a range of information giving methods to present information to the individual
6. answer honestly any questions raised by the individual, and refer any questions that cannot be immediately answered to the appropriate person
7. identify other sources of information and information resources that the individual can accessed to clarify their situation
8. provide sufficient opportunity for the individual to reflect on the information
9. keep accurate, legible, and complete records, and comply with all the relevant legal, professional, and organisational requirements and guidelines.
Witness statement – record of practice (for use at formative and summative DOPS)

END2 Provide information on endoscopic procedures to individuals

Nurse: _____________________ Assessor: ______________ Date: __________

Statement – Following observation of practice the following is true of the nurse being appraised:

1. The nurse demonstrates respect for the rights and wishes of the patient relating to their consent, privacy, beliefs and dignity

2. The nurse established the extent to which the patient required carers to be involved during the provision of information

3. The nurse assessed the amount and type of information required by the patient to allow them to make an informed decision regarding the endoscopic procedure

4. The nurse ensured that all shared information was accurate and relevant to the patient within the context of the reason for the referral

5. The nurse appropriately selected a range of information giving methods including verbal, written, diagrammatic etc.

6. The nurse answered all questions appropriately and referred to another professional when questions exceeded their ability to answer

7. The nurse identified the sources of information the patient may wish to access

8. The nurse identified that the patient had been given time to reflect on any decisions

9. The nurse kept accurate, legible and complete records

Signed

Nurse: _____________________ Assessor: ______________

Date: ____________________

RECORD OF ASSESSMENT
Name:

Competence code: END2

Competence title: Provide information on endoscopic procedures

Type of evidence: Practice: Witness statement

Theory: Completed workbook

Rating – Summative assessment must to a minimum of level 4 for independent practice (see below)
Assessor to date and sign appropriate assessment score box

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1. Minimal knowledge and understanding about how the competence relates to practice
2. Needs supervision to effectively carry out the range of skills within the competence
3. Performs some skills within the competence effectively without supervision
4. Confident of knowledge and ability to perform all the identified skills within the competence effectively
5. Confident and competent to perform all the identified skills and facilitate and assess others

Comments

Nurse Signature:
Assessor Name and Signature:
Date:
References and further reading


Acknowledgment: kind thanks go to Royal Devon and Exeter NHS Foundation Trust Endoscopy Department whose competency document this booklet has been modelled upon.