SITUATION

Consent is formal procedure during which the patient is informed about the need for the treatment, its risks and benefits and any alternatives in order to help them make a decision about their care. Mental capacity to make informed decisions is critical to this as is good communication and information.

It is good practice to seek written consent in a number of circumstances – the most common ones being

- Where the treatment is complex or involves significant risks
- Where anaesthesia or sedation is involved

Welsh Government has now issued revised All-Wales consent forms. The forms are intended to be easier for health professionals to use, incorporate the Welsh language and provide greater assurance for UHBs that their staff are meeting the required standards.

An action plan has been prepared to roll out the new consent forms across the organisation, with full implementation planned for the end of July 2014 (see appendix two). This will be subject to agreement by the Health Services Management Board on the 19th June 2014.

The consent audit carried out by the clinical audit team at University Hospital Llandough (UHL) is presented for information. An initial audit of the consent documentation was undertaken at the University Hospital of Wales (reported to Quality and Safety Committee, June 2013). The audit tools were subsequently refined and the audit repeated at UHL. With the Chairs of the Quality and Safety Committee and the Mental Health and Capacity Legislation Committee (MHCLC) it was agreed that matters relating to consent should be brought to the MHCLC. Therefore this audit is now presented to MHCLC for information and to assist the Committee in approving a timescale for further audits (as per the UHB Annual Clinical Audit Plan) in recognition of the role out for the All Wales consent forms.

The aim of the audit was to ascertain whether the Consent forms were appropriately completed and filed as an accurate record of patients’ consent in accordance with the
policy, for patients admitted as inpatients or day cases for a proposed procedure or investigation at UHL in January 2013.

BACKGROUND

The UHB ratified an updated Consent to Examination and Treatment Policy in February 2012 –

http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/186989

In June 2012, the Medical Director wrote to the (then) Divisions, requiring them to put in place a Consent and Capacity Action Plan, based on the requirements of the Consent Policy.

It was agreed, as part of the work on Standards for Health Wales, that an audit of consent forms should be undertaken.

‘A consent form simply documents that some discussion, about the procedure or investigation, has taken place. The quality and clarity of the information given is of paramount consideration. Consent forms are evidence of a process, not the process itself. Any discussion, however, should be recorded in the patient’s medical notes.’

Extract from the British Medical Association Consent Toolkit

A list of relevant cases for the period 14/01/2013-27/01/13 was requested and obtained via IT theatre services. 5 specialty groups were identified from the data supplied - Trauma & Orthopaedics, General Surgery, Obstetrics & Gynaecology, Endoscopy Unit (Gastrointestinal) and Endoscopy Unit (Chest Medicine). The project was to include 200 sets of case-notes with a sample size of each group in proportion to the total list from IT theatre services. A final sample of 176 cases was included in the analysis.

The UHL audit sample had a mean average age of 54. The median age was 55 and age range from 17 to 87 years.

ASSESSMENT

The full report is included as appendix one. The following highlights are those deemed pertinent to this Committee. Results are being presented to relevant Clinical Boards where all elements of the audit requiring possible action will be considered.

Consent Forms

At the UHW project outset, it was believed that there were 5 different consent forms. However, at least 16 different forms were available from the Print Room. Many of these additional forms are variations on an original theme and created by individual specialties. To ensure that consent forms comply with the law, there is a need to establish a system for formally approving consent forms for use in the UHB.

Only Consent Forms 1 and 3 and a consent form specifically designed for use within Endoscopy Unit (Gastrointestinal) were found in the case notes for this UHL audit.
Consent Form 1 (n=118 including 2 inpatient endoscopies): ‘Patient agreement to investigation or treatment’.

Consent Form 3 (n=8): ‘Patient/parental agreement to investigation or treatment (procedures where consciousness is not impaired)’. It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care.

Consent Form 4 – No consent form 4 for people who lack mental capacity to give informed consent were found in this UHL audit. One was found in the UHW audit.

Special Requirements

According to the guidelines, this section should demonstrate that special requirements have been considered by the clinician taking consent. It should include any impairment (visual, hearing, language) and should reconcile with the documentation in the clinical case notes.

This section was left blank in 100% of cases. However, in 5 cases the admission documentation indicated that the patient had some kind of communication issues: hearing impairment (3), language barrier (2).

This section does not appear on the Endoscopy Unit (Gastrointestinal) consent forms at all.

Statement of Interpreter (n=176)

This section was left blank in 100% of cases. In 2 cases (Endoscopy Unit (Gastrointestinal)) family members were required to interpret due to language issues. UHB guidance states that it is highly inappropriate for family members to interpret.

Discussion

Standardised consent forms are used at UHL which may be a reflection of the small number of specialties. Variation can lead to uncertainty and potential mistakes. No consent form 4 for people who lack mental capacity to give informed consent was found within the sample of forms from UHL and only one was used in UHW. We cannot conclude anything from this as there is no record to indicate mental capacity on other forms.

However, given that most in-patients are elderly and that there is a high incidence of dementia, depression and delirium amongst hospital in-patients, it is surprising that only one consent form 4 was found amongst the 400 consent forms sampled from both UHW and UHL.

Good communication between healthcare professionals and patients is essential. Special requirements that may affect this were not identified. Copies of consent forms were frequently not given to patients and there was poor documentation of any written or verbal information given to the patient.

Reflecting back to the extract from the British Medical Association Consent Toolkit that consent forms document the process but are not the process itself, it is
impossible to comment from these consent audits as to how appropriate the use of the various consent forms was. There is no way of identifying whether areas of the consent form left blank equate to ‘not applicable’ or not, for example the section concerning advanced directive/living will.

Learning from this audit and the audit for UHW will provide the means to commission a repeat audit for the organisation with regard to the implementation of the All-Wales Consent form for January 2015 (six months after role-out).

RECOMMENDATION

The Committee is asked to:

- **NOTE** the current timescale for the introduction of the All-Wales Consent form subject to agreement by HSMB.

- **APPROVE** the plan for re-audit of consent forms across all the UHB sites in January 2015 (six months following implementation).

- **NOTE** the audit results for UHL.

<table>
<thead>
<tr>
<th>Financial Impact</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality, Safety and Experience</strong></td>
<td>Clinical audit is an important process that informs the quality and safety of patient care. It is an essential component of Cardiff and Vale University Health Board’s (UHB) internal controls and assurance arrangements. Clinical audit helps clinicians develop and improve the quality of the services they provide to patients. It is also a General Medical Council (GMC) requirement for doctors to participate in Clinical Audit. There are some issues highlighted in the report, particularly around communication, that potentially affect quality, safety and experience which need considering.</td>
</tr>
<tr>
<td><strong>Standards for Health Services</strong></td>
<td>Standard 6, Participate in quality improvement activities. Standard 9 – Patient Information and Consent</td>
</tr>
<tr>
<td><strong>Risks and Assurance</strong></td>
<td>Clinical Audit is a key element of the internal controls assurance of the UHB. Failure to direct Clinical Audit to support the development of clinically effective care will create a risk to the organisation. The audit focussed on the process of consent through documented evidence. No assurance can be offered where information is not documented.</td>
</tr>
<tr>
<td><strong>Equality and diversity</strong></td>
<td>Equality and diversity implications are considered when designing new clinical audits. All senior clinical auditors have attended the equality and diversity training. Random sampling is applied to clinical audits as far as possible. The sample in this audit should be</td>
</tr>
</tbody>
</table>
representative of the population participating in the consent process. The report includes information about use of family interpreters being used which is against UHB policy.
INTRODUCTION

‘A consent form simply documents that some discussion, about the procedure or investigation, has taken place. The quality and clarity of the information given is of paramount consideration. Consent forms are evidence of a process, not the process itself. Any discussion, however, should be recorded in the patient’s medical notes.’

Extract from the British Medical Association Consent Toolkit

PROJECT AIM

Written consent is a legal and formal procedure during which the patient is informed of all the risks and benefits of a specific treatment or investigation to help them make a decision about their care.

The aim of this project was to establish whether the documentation pertaining to consent was completed appropriately for patients admitted as inpatients or day cases for a proposed procedure or investigation at Llandough Hospital in January 2013.

The project was conducted as one of the Cardiff and Vale UHBs clinical audit priorities.

METHODOLOGY

A list of relevant cases for the period 14/01/2013-27/01/13 was requested and obtained via IT theatre services.

A cohort of 687 cases was identified for the specified period. 4/687 cases were excluded as no clinical specialty was allocated on the data provided. A further 2/687 cases for Renal Transplant were excluded due to the small number represented.

5 specialty groups were identified from the data supplied - Trauma & Orthopaedics, General Surgery, Obstetrics & Gynaecology, Endoscopy Unit (Gastrointestinal) and
Endoscopy Unit (Chest Medicine). The Endoscopy Unit is utilized by both physicians and surgeons with various procedures/investigations conducted there. For the purposes of this project the Endoscopy Unit (Gastrointestinal) and the Endoscopy Unit (Chest Medicine) have been classified separately as the Endoscopy Unit (Gastrointestinal) use specifically designed consent forms (for day case patients) which differ considerably from those used elsewhere in the UHB. The Chest Medicine cases for the Endoscopy Unit have standard consent forms completed.

An approximate sample of cases was identified for each specialty dependent on the number represented in the original data. A total of 190 case notes were retrieved by the Clinical Audit Assistant. 14/190 cases were excluded as detailed below:-

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant admission missing from case note reviewed</td>
<td>7</td>
</tr>
<tr>
<td>Case notes taken before review</td>
<td>1</td>
</tr>
<tr>
<td>Patient having investigation under the Bowel Screening Wales initiative with differing consent process</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

A final sample of 176 cases were included in the analysis.

For further information regarding the final sample please refer to page 4 of the results.

Specific audit tools were designed and piloted to reflect the information documented on the consent forms currently in use. A guidance tool was prepared for reference when reviewing cases to ensure uniformity when data was collected.

A designated team of clinical audit personnel reviewed the cases and collected the data. The data was collated and analyzed by a Clinical Audit Co-ordinator. The results have been demonstrated by type of consent form rather than clinical specialty.

**RESULTS**

**Demographics (n=176)**

![Pie Chart](image)

- **FEMALE** 61%
- **MALE** 39%

Patient age (years) – mean 54, median 55, mode 51, minimum 17, maximum 87.
2/176 cases were originally booked as day cases, however their admission status changed to inpatient due to weather conditions and no overnight care being available, both patients had an overnight stay only. Both cases appear in the Day Case category in the chart above as that was the intended management.

Clinical Specialties Reviewed

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Cohort</th>
<th>Proposed Sample</th>
<th>Actual Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma &amp; Orthopaedics</td>
<td>316</td>
<td>50</td>
<td>51</td>
</tr>
<tr>
<td>General Surgery</td>
<td>154</td>
<td>30</td>
<td>31</td>
</tr>
<tr>
<td>Obstetrics &amp; Gynaecology</td>
<td>54</td>
<td>30</td>
<td>32</td>
</tr>
<tr>
<td>Endoscopy Unit (Chest Medicine)</td>
<td>12</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Endoscopy Unit (Gastrointestinal)</td>
<td>145</td>
<td>50</td>
<td>52 (inc. 2 inpatient endoscopies)</td>
</tr>
<tr>
<td>Total</td>
<td>681</td>
<td>172</td>
<td>176</td>
</tr>
</tbody>
</table>

Consent Forms

There are many consent forms in use within the UHB however, only Consent Forms 1 and 3 were identified in the case notes reviewed for this project with the exception of the Endoscopy Unit (Gastrointestinal) where consent forms specifically designed for use within the Department were used as described below:-

**Consent Form 1** (n=118 inc. 2 inpatient endoscopies): ‘Patient agreement to investigation or treatment’.

**Consent Form 3** (n=8): ‘Patient/parental agreement to investigation or treatment (procedures where consciousness is not impaired). It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care.

Endoscopy Unit (Gastrointestinal) (n=50): Specifically designed consent forms are utilized with the consent process differing considerably from other methods in use.
within the UHB. Patients are contacted by telephone to arrange a suitable date for their procedure to take place. A telephone checklist is used to record relevant information at this point. A booklet is then forwarded to the patient prior to admission with one of the relevant Endoscopy Unit (Gastrointestinal) consent forms attached. If the patient has no further questions/queries regarding their forthcoming procedure they are asked to sign the ‘statement of patient’ section of the form prior to admission, the ‘confirmation of consent’ section is completed by a clinician on the day of the procedure. Should the patient have any queries, the form should not be signed until the day of the procedure where the patient can then discuss their procedure with a member of the clinical team and an additional ‘statement of health professional’ section is completed to reflect this.

The booklet forwarded to each patient is relevant to their procedure. For this audit the consent process for three different endoscopic procedures/investigations was reviewed: gastroscopy, sigmoidoscopy and colonoscopy. All consent forms for the Endoscopy Unit (Gastrointestinal) quote ‘Patient agreement to endoscopic investigation or treatment’. The remaining text, including the risks and benefits are pre-printed and are procedure specific.

Correct Consent Form

A consent form was present in all the case notes reviewed.

Consent Form 1 (n=118) – As far as it was possible to tell, the correct form was completed for all procedures and included 2 cases where a gastroscopy was requested and performed while the patient was an inpatient.

Consent Form 3 (n=8) – As far as it was possible to tell, the correct consent forms were used in all cases. In 2 cases (T&O) the patient had ‘left followed by right carpal tunnel’ surgery, but the procedures were performed on different dates with only one consent form completed with no confirmation of consent obtained when the second procedure was performed.

Endoscopy Unit (Gastrointestinal) (n=50) – The correct consent forms were completed in 49/50 cases. In 1 case a flexible sigmoidoscopy form was completed when the patient underwent a colonoscopy. “flexible sigmoidoscopy” was crossed out on the pre-printed form and the clinician had hand written “colonoscopy”. Other aspects of these forms are very similar in terms of text pre-printed recorded on them. A further patient had a colonoscopy and form 1 completed as there was the potential for a gastroscopy as well as the colonoscopy to be performed which was indeed the case.

Laterality

Laterality should be recorded on a consent form if any aspect of the proposed procedure(s) is “side” specific. Laterality is not relevant for procedures conducted in the Endoscopy Unit.

In 79/176 (45%) cases reviewed laterality was deemed to be relevant. 79/79 (100%) consent forms which were relevant regarding laterality had a side recorded.

Laterality - Reconciliation of Consent Form and Operation Sheet (n=79)
Consent Form 1 (n=73) – 71/73 (97%) consent forms agreed with the operation sheet regarding laterality.

T&O – Left total knee replacement where side was not recorded on the operation sheet.
General Surgery – Re-excision margins of left breast where side was not recorded on the operation sheet.

Consent Form 3 (n=6) - All consent forms agreed with the operation sheet regarding laterality.

Reconciliation of Procedure Details on Recorded Consent Form and Operation Sheet (n=176)

Consent Form 1 (n=118) – 115/118 (97%) of procedure details recorded on the consent form reconciled with the operation sheet.

T&O – Lumbar decompression L1-L4 recorded on consent form with L3-L5 recorded on the operation sheet. 2 further cases for T&O were identified where information was missing from the casenotes.

Consent Form 3 (n=8) – All procedures recorded on the consent form reconciled with operation sheet.

Endoscopy Unit (Gastrointestinal) (n=50) – 49/50 (98%) of procedures recorded on the consent form reconciled with the operation sheet.

1 case was identified where the consent form indicated that the patient would undergo a flexible sigmoidoscopy when a rigid procedure was actually performed.

Responsible Health Care Professional
This section does not appear on the Endoscopy Unit (Gastrointestinal) consent forms therefore n=126.

<table>
<thead>
<tr>
<th>Details of Responsible Health Care Professional</th>
<th>Consent Form 1 (n=118)</th>
<th>Consent Form 3 (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Name recorded</td>
<td>47/118 (40%)</td>
<td>71/118 (60%)</td>
</tr>
<tr>
<td>Name legible (n=47)</td>
<td>43/47 (91%)</td>
<td>4/47 (9%)</td>
</tr>
<tr>
<td>Job title recorded</td>
<td>35/118 (30%)</td>
<td>83/118 (70%)</td>
</tr>
<tr>
<td>Job title legible (n=35)</td>
<td>32/35 (91%)</td>
<td>3/35 (9%)</td>
</tr>
</tbody>
</table>

Addressograph (n=176)
An addressograph should be attached to the top left corner of the consent form and includes patient surname, first name, gender, date of birth, address, hospital number and in most cases the NHS number.

7 cases had no addressograph on the consent form. Of these, all had the patient’s name and date of birth recorded, 4 also had the hospital number recorded and 1 also had the patient’s gender recorded.

Special Requirements

This section does not appear on the Endoscopy Unit (Gastrointestinal) consent forms therefore n=126.

According to the guidelines, this section should demonstrate that special requirements have been considered by the clinician taking consent. It should include any impairment (visual, hearing, language) and should reconcile with the documentation in the clinical casenotes.

This section was left blank in 100% of cases. However, in 5 cases the admission documentation indicated that the patient had some kind of communication issues: hearing impairment (3), language barrier (2).

Details of Proposed Procedure (n=176)

In 100% of cases the proposed procedure/investigation was recorded on the consent form. Legibility for this section was also 100%. It was noted that at times abbreviations were used when describing the procedure/investigation. In some cases the procedure details are pre-printed on the consent form including the Endoscopy Unit (Gastrointestinal) forms where all procedure details are pre-printed.

Statement of Health Professional (n=176)

A. Intended Benefits
In 10 cases this section was not completed (9 T&O and 1 Endoscopy Unit (Chest Medicine)).

### INTENDED BENEFITS RECORDED (n=176)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Form 1 (n=118)</td>
<td>112 (95%)</td>
<td>6 (5%)</td>
</tr>
<tr>
<td>Consent Form 3 (n=8)</td>
<td>4 (50%)</td>
<td>4 (50%)</td>
</tr>
<tr>
<td>Endoscopy Unit (GI) (n=50)</td>
<td>50 (100%)</td>
<td>-</td>
</tr>
</tbody>
</table>

NOTE: The intended benefits of the procedure/investigation are pre-printed on all Endoscopy Unit (Gastrointestinal) consent forms.

### B. Leaflet/tape Provided

### LEAFLET/TAPE PROVIDED (n=176)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Form 1 (n=118)</td>
<td>1 (1%)</td>
<td>117 (99%)</td>
</tr>
<tr>
<td>Consent Form 3 (n=8)</td>
<td>-</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Endoscopy Unit (GI) (n=50)</td>
<td>50 (100%)</td>
<td>-</td>
</tr>
</tbody>
</table>

NOTE: A booklet providing details of the procedure/investigation is forwarded to all patients prior to their visit to the Endoscopy Unit (Gastrointestinal).

With regard to Consent Forms 1 and 3, in only 1 case (Gynaecological Oncology) was an entry made to indicate that a leaflet had been given.

### C. Serious/Frequently Occurring Risks Including Death

### FREQUENTLY OCCURRING RISKS RECORDED (n=176)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Form 1 (n=118)</td>
<td>117 (99%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Consent Form 3 (n=8)</td>
<td>4 (50%)</td>
<td>4 (50%)</td>
</tr>
<tr>
<td>Endoscopy Unit (GI) (n=50)</td>
<td>50 (100%)</td>
<td>-</td>
</tr>
</tbody>
</table>

NOTE: The risks associated with the procedure/investigation are pre-printed on all Endoscopy Unit (Gastrointestinal) consent forms.
**Consent Form 1** - In 1 T&O case, risks were not recorded with 1 further case where risks were recorded but on the wrong section of the consent form.

**Consent Form 3** – In 4 T&O cases risks were not recorded.

NOTE: For some T&O cases a ‘stamp’ was used to list the possible risks. O&G use printed stickers which quote the risks associated with various procedures, clinicians cross out those not applicable to a specific case.

<table>
<thead>
<tr>
<th>RISK OF DEATH RECORDED (n=176)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Consent Form 1 (n=118)</td>
</tr>
<tr>
<td>Consent Form 3 (n=8)</td>
</tr>
<tr>
<td>Endoscopy Unit (GI) (n=50)</td>
</tr>
</tbody>
</table>

If death is a possibility, then the patient should be informed.

**Consent Form 1** - In only 3 cases (2 T&O, 1 Gynaecology) was risk of death recorded on the consent form.

Endoscopy Unit (GI) – The Eido Healthcare patient leaflet on flexible sigmoidoscopy indicates that the risk of death is 1:15000.

**D. Documentation of Blood Transfusion**

This section does not appear on Consent Form 3 or the Endoscopy Unit (Gastrointestinal) consent forms therefore n=118.

When completing Consent Form 1, if there is a potential for the patient to require a blood transfusion during the procedure, the blood transfusion box should be ticked. In 43/118 cases the box was ticked to indicate that a blood transfusion may be required however only 2/43 patients actually received a transfusion both post-operatively. 72/114 (63%) boxes were not ticked, none of these patients received a blood transfusion.

**E. Documentation of Other Procedures**

This section is not applicable for Consent Form 3 or the Endoscopy Unit (Gastrointestinal) therefore n=118.

When completing Consent Form 1, any potential additional procedures should be recorded under the ‘other procedures’ section of the consent form. 26/118 (24 Gynaecology, 1 in-patient Endoscopy, 1 Endoscopy Unit (Chest Medicine)) indicated that other procedures may be required and in all cases specific details were recorded.
Documentation of Anaesthesia

Documenting anaesthesia does not apply to Consent Form 3 or Endoscopy Unit (Gastrointestinal) forms for sigmoidoscopy or colonoscopy but does apply for gastroscopies therefore n=131 (118 cases for Consent Form 1 and 13 cases for gastroscopy).

Consent Form 1 (n=118) – Anaesthesia recorded on the consent forms were general/regional 93, local 2, local and sedation 9, sedation 1 and for 13 cases the proposed method of anaesthesia was not recorded. In cases where proposed anaesthetic management was not recorded 11 received general/regional anaesthesia, 1 local throat spray and sedation and 1 local throat spray only.

Endoscopy Unit (Gastrointestinal) (n=13) - Patients attending the Endoscopy Unit for a gastroscopy are asked for their preferred anaesthetic choice (local throat spray and/or sedation) prior to their procedure which should then be recorded on the consent form.

13 gastroscopies – 7 local throat spray only, 3 local throat spray with sedation if required, 1 sedation only and 2 had nothing recorded on the consent form (both received sedation).

Statement by Clinician (n=176)

Once consent has been obtained the clinician taking consent should record the date, their signature, printed name, contact details and their job title. The job title and printed name should be legible. Contact details do not appear on Consent form 3 or the Endoscopy Unit (Gastrointestinal) consent forms.

In the case of the Endoscopy Unit (Gastrointestinal) this section is a separate page (page 3) and should only be completed for cases where the patient wanted further discussion about their procedure and had not signed the consent form prior to admission (as detailed on page 4). This section was present in 5/50 cases but all forms were blank so no conclusions could be drawn regarding their relevance.

<table>
<thead>
<tr>
<th></th>
<th>Consent Form 1 (n=118)</th>
<th>Consent Form 3 (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed</td>
<td>118 (100%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Dated</td>
<td>117 (99%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Job title recorded</td>
<td>111 (94%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Job title legible</td>
<td>106/111 (95%)</td>
<td>5/8 (63%)</td>
</tr>
<tr>
<td>Printed name</td>
<td>114 (97%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Printed name legible</td>
<td>78/114 (68%)</td>
<td>5/8 (63%)</td>
</tr>
<tr>
<td>Contact details</td>
<td>3 (3%)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Statement of Interpreter (n=176)
This section was left blank in 100% of cases. In 2 cases (Endoscopy Unit (Gastrointestinal)) family members were required to interpret due to language issues. UHB guidance states that it is highly inappropriate for family members to interpret.

**Statement of Patient (n=176)**

Once consent has been obtained the patient should record the date, their signature and printed name. The printed name should be legible.

<table>
<thead>
<tr>
<th></th>
<th>Consent Form 1 (n=118)</th>
<th>Consent Form 3 (n=8)</th>
<th>Endoscopy Unit (GI) (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed</td>
<td>117 (99%)</td>
<td>8</td>
<td>47</td>
</tr>
<tr>
<td>Dated</td>
<td>107 (91%)</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td>Printed name</td>
<td>70 (59%)</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Printed name legible</td>
<td>70 (n=70) (100%)</td>
<td>3 (n=3) (100%)</td>
<td>27 (n=27) (100%)</td>
</tr>
</tbody>
</table>

Consent Form 1 has a section 'Procedures not to be carried out', this section was left blank in 100% of cases. It is therefore unclear whether there actually were any ‘Procedures not to be carried out’ as it cannot be assumed that although left blank this section was not applicable.

**Witness Details**

This section is only relevant for Consent Form 1 and was left blank in 100% of cases. It is therefore unclear whether any witnesses were involved in the consent process as it cannot be assumed that although left blank this section was not applicable.

**Confirmation of Consent**

For Consent Forms 1 and 3 consent should be confirmed if the consent form was completed prior to this specific episode of care when the procedure took place e.g. consent form completed at a pre-admission clinic or during a previous admission.

Confirmation of consent at the Endoscopy Unit (Gastrointestinal) should always be completed when the patient is admitted for their procedure.

**Consent Form 1 (n=118) – Confirmation was required in 44/118 (37%) of cases.** In 2/44 cases the consent form was signed the day before admission and procedure but fell outside the specific episode of care and therefore should have had a confirmation completed but did not. In 1 case (T&O) the date that the consent form was completed was not recorded, it was therefore not possible to establish if confirmation was required. 7/44 (16%) had the confirmation section of the consent form completed, however for 2/7 cases the confirmation was signed on the same day as the original consent form was signed and in both cases this was 7 days prior to the admission and procedure (2 T&O). Therefore only 5/44 (9%) had an appropriate confirmation recorded.

**Consent Form 3 (n=8) – Confirmation was required in 5/8 (62.5%) of cases.** 0/5 (5 T&O) had a confirmation completed.
Endoscopy Unit (Gastrointestinal) (n=50) – All cases required confirmation on admission. 48/50 (96%) had confirmation of consent recorded.

Advanced Directive/Living Will

This section was only applicable for Consent Form 1 therefore n=118.

Consent Form 1 (n=118) - In all cases, the section for information relating to advanced directives/living wills was left blank. No evidence was found in the 118 cases audited of an advanced directive/living will being relevant.

Consent Withdrawn

This section was only applicable for Consent Form 1 therefore n=118.

Consent Form 1 (n=118) - In all cases, the section provided for any information related to ‘consent withdrawn’ was left blank.

Copy Accepted by Patient (n=176)

Consent Form 1 (n=118) - In 109/118 (92%) cases, it was not recorded on the consent form whether the patient was given the white copy of the form. In the 41/109 (38%) cases, the white copy was missing from the casenote and it could be assumed that the patient was given the copy even though it was not recorded as such by the health professional. In the remaining 9/118 (8%) cases, it was recorded on the consent form that the patient had been given the white copy and recorded accordingly.

Consent Form 3 (n=8) - In all 8 cases, it was not recorded whether the patient was given the white copy of the consent form. In 6/8 (75%) cases, the white copy was still in the casenotes. In the remaining 2/8 cases, the white copy was missing from the casenote and it could be assumed that the patient was given the white copy even though it was not recorded as such by the health professional.

Endoscopy Unit (Gastrointestinal) (n=50) – There is no tick box present on these forms to indicate whether the patient has been given the white copy of the consent form. In 48/50 (96%) cases the white copy was missing from the case-note and it could be assumed that the patient was given the copy.

CONCLUSIONS

- A consent form was present in all the cases reviewed with all but 1 using the correct form, as far as it was possible to tell.

- Procedure details recorded on the consent form reconciled with the operation sheet in 97% of cases. Where there was a difference a smaller procedure had been carried out (e.g. L1-4 on consent L3-5 operation).

- Details relating to the proposed procedure were recorded in 100% of cases.

- Serious/frequently occurring risks were documented well.
• Relevant signatures were recorded well.

Areas for discussion/improvement:

• Discussion regarding anaesthesia and sedation wasn’t always recorded.

• Families provided interpretation on a two occasions which is not supported by UHB policy.

• Poor legibility was observed on occasion.

• There was little evidence to demonstrate that patients had been provided with leaflets/tapes prior to their procedure where consent forms 1 and 3 were completed. The Endoscopy Unit (Gastrointestinal) routinely forward a comprehensive information leaflet to patients prior to their procedure.

• Documentation regarding confirmation of consent was poor.

• Abbreviations were used inappropriately with regard to procedures and the associated risks.

• Documentation of special requirements was poor.

• Documentation relating to the responsible health professional was poor.

RECOMMENDATIONS

• The importance of the consent process should be emphasised throughout the UHB to ensure that patients are well informed regarding the risks and benefits of their specific treatment or investigation and the supporting documentation is completed appropriately to demonstrate this.

• A focused programme of education could support and facilitate this process.

• A re-audit should be conducted in the future.

• A survey of patient experience of the consent process could be conducted to understand their perception and ensure that their views are taken into consideration.

ACKNOWLEDGMENTS

Thank you to the following people for their support during this project:

Mr Tony Robinson, Clinical Audit Assistant
Mr Mick McGeoch, Clinical Audit Co-ordinator
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Mrs Susannah Coles, Senior Clinical Audit Co-ordinator
Mrs Kathleen Morris, Senior Clinical Audit Co-ordinator
Ms Julia Barrell, Mental Capacity Act Manager
Mrs Kay Charles, Nurse Endoscopist
Mrs Nicola Morgan, Team Administrator Manager of Endoscopy Unit, Llandough
Mrs Karen Davies, Information Officer, UHW
Mr John Meredith, IT Service Manager, UHW
Mrs Judith Van Der Voort, Consultant and Clinical Lead for the Postgraduate Centre
Mrs Joshna Patel, Undergraduate Centre Manager
## DRAFT

**CONSENT FORMS – ACTION PLAN**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Detail</th>
<th>By whom</th>
<th>When</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation date to be agreed with Clinical Boards</td>
<td>Need a “cut off” date for use of old forms and use of new ones</td>
<td>Med Director</td>
<td>Monday, 21st July 2014</td>
<td>To be included in Med Director’s paper to HSMB for the Boards to agree</td>
</tr>
<tr>
<td>Information to CBs, Media Resources, etc</td>
<td>To inform staff how to purchase the forms, when to use, briefings, etc</td>
<td>Med Director/MCA Manager</td>
<td>Beginning of June 2014</td>
<td>Information must be sent out at end of May/beginning June to allow CBs time to make necessary arrangements</td>
</tr>
<tr>
<td>Information on Admin Round up</td>
<td>To inform UHB staff</td>
<td>Asst. Director of Comms/MCA Manager</td>
<td>End of May, June and July</td>
<td></td>
</tr>
<tr>
<td>Information on Home Page of Intranet</td>
<td>To inform UHB staff</td>
<td>Asst. Director of comms/MCA Manager</td>
<td>From end of May onwards</td>
<td></td>
</tr>
<tr>
<td>Information on Consent page of intranet</td>
<td>To inform UHB staff</td>
<td>MCA Manager</td>
<td>From end of May</td>
<td></td>
</tr>
<tr>
<td>Briefings to Clinical Boards</td>
<td>To inform staff</td>
<td>Grand Round organiser/MCA Manager</td>
<td>From beginning of June</td>
<td></td>
</tr>
<tr>
<td>General Briefings</td>
<td>To inform staff</td>
<td>Head of LED/MCA Manager</td>
<td>From beginning of June</td>
<td>LED to be asked to organise briefings</td>
</tr>
<tr>
<td>Written/ in person briefing to CB Q&amp;S meetings</td>
<td>To inform staff</td>
<td>MCA Manager</td>
<td>From end of May</td>
<td></td>
</tr>
</tbody>
</table>

J S BARRELL/SHORTLAND  
MCA Manager  
2nd June 2014