



# **Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions**

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## NHS SHETLAND DOCUMENT DEVELOPMENT COVERSHEET\*

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August 2017	Consideration to adopt NHS Grampian's Consent Policy to replace the existing Informed Consent Policy due for review in September 2014
September 2017	Policy updated to reflect proposals and changes from consultant's group – Section 10 and Section 15
November 2017	CCPGC – Approval was granted subject to a minor change to the wording of the third sentence in the Introduction.
January 2018	Mr McFarlane informed of CCPGC's decision and made the necessary changes to the policy (v1.2)
March 2018	Modified the references to Vancouver style of referencing

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# Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions

## 1 Introduction

Successful relationships between clinicians and patients depend on trust. A patient must be properly informed about the risks, benefits and consequences of any proposed treatment and its possible alternatives. A fully informed patient is more likely to have realistic expectations regarding treatment outcomes; and have greater engagement in their mutually agreed healthcare plan. This would improve adherence and compliance with their ongoing treatment and management.

Consent is a process rather than a single decision. The steps in the process include discussions with patients, the giving of oral and written information and the explanation of risks and benefits. All these steps should be formally documented. Obtaining a signature on a consent form is normally the concluding part of the consent process. It is important to realise that if the patient has not been given appropriate information then consent may not be valid despite the signature on the form. Consent forms are evidence of a process not the process itself.

## 2 Objectives

By providing clear guidance to clinicians working within NHS Shetland this policy will help ensure compliance with recommendations of legislative and professional bodies and protect the autonomy and best interests of patients.

## 3 Clinical Situations

This policy is applicable to all areas of NHS Shetland and is applicable to all patients under the care of NHS Shetland unless they are undergoing treatment in hospitals not under the management of NHS Shetland. This policy is applicable to all clinical staff who perform clinical procedures and healthcare interventions on patients when they are in the employment of NHS Shetland.

## 4 Principles of Obtaining Consent

Consent is only valid if certain conditions are satisfied.<sup>1</sup> The principles derived from case law dictate that in any particular case a clinician must satisfy him/herself that the following conditions are met:

- the person giving consent is capable of doing so
- the patient has received appropriate and adequate information
- there is freedom of choice
- the person giving consent is aware that consent is an ongoing process and is able to withdraw consent.

Consent may be “expressed” (written) or “implied”.<sup>2</sup> Practitioners should be aware that implied consent is not necessarily assured by the action of the patient. For example, a patient with

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<sup>1</sup> *Scottish Executive Health Department, 2006. A Good Practice Guide on Consent for Health Professionals in NHSScotland - HDL (2006) 34.*

<sup>2</sup> *General Medical Council, 2008. Consent: patients and doctors making decisions together.*

abdominal pain who lies on a bed is probably unaware that the genital area may be exposed for hernia examination or that a rectal examination may be required. Conditions that require written consent are discussed below.

## 5 Consent and Data Protection

Whilst sharing patient information with other health professionals involved in the care of the patient is an accepted practice, sharing information beyond this can be problematic and is not without risk of regulatory action under data protection legislation. For instance, sharing patient information for teaching purposes must be with the explicit consent of the patient. If there is doubt about the legality of sharing information, advice should be obtained from the Clinical Governance and Risk Team on ext. 3689/3234.

The 'NHS Code of Practice on Protecting Patient Confidentiality' is available from the following link: <http://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>

## 6 Who obtains consent?

The health professional carrying out the procedure is responsible for ensuring that, before they start any treatment, the patient has been given sufficient time and information to make an informed decision, and has given consent to the procedure or investigation.

It is preferable that the health professional who will be carrying out the procedure obtains consent.<sup>3</sup> It is accepted however that this is not always practicable and that the process needs to be delegated; if so the delegate must be suitably competent with sufficient knowledge of the proposed investigation or treatment and alternatives including an understanding of the risks involved.

There has been much discussion with regard to Foundation Year doctors obtaining consent. The New Doctor does not preclude Foundation doctors from obtaining consent; it is therefore appropriate for Foundation doctors to obtain consent if they are deemed competent and as long as experienced help is available in case of difficulty<sup>4</sup>.

The Nursing and Midwifery Council also states that nurses should “make sure that (they) get properly informed consent and document it before carrying out any action” and the HCPC suggests practitioners “make sure that (they) have consent from service users or other appropriate authority before they) provide care, treatment or other services.”<sup>5</sup>

## 7 Timing of Consent

The timing of consent will depend on the degree of urgency of the procedure. Whilst there is no recognised absolute minimum period of time which should elapse between giving

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<sup>3</sup> *Ibid.* See also Scottish Executive Health Department, 2006: *A Good Practice Guide on Consent for Health Professionals in NHS Scotland - HDL (2006) 34*, and General Medical Council, 2009: *Guidance for doctors on using registered name and GMC reference number*.

<sup>4</sup> General Medical Council, 2009: *The New Doctor*.

<sup>5</sup> The NMC 2015. *The Code: Standards of Conduct, Performance, and Ethics for Nurses and Midwives*. London: Nursing and Midwifery Council HCPC 2016. *Standards of conduct, performance and ethics*. London: Health and Care Professions Council

information/obtaining consent/carrying out the procedure, the principles are:

- there has been adequate time to reflect on the information given
- after reflection there is adequate time and privacy to ask questions and reflect further
- if there is a significant time lapse between obtaining consent and performing the procedure, the consent should be reaffirmed
- since obtaining consent if there has been a significant change in the patient's condition, new consent should be obtained.

## **8 Emergencies**

In an emergency where the patient is unable to give or withhold their consent, it is acceptable for treatment to proceed provided treatment is a necessity and does no more than is reasonably required in the best interests of the patient.<sup>6</sup> The circumstances should be documented in the clinical record and the treatment given must be no more than the immediate situation requires.

## **9 Scope of Consent**

Following the provision of appropriate information, a patient consents to a specific investigation, procedure or treatment being carried out. When obtaining consent for this, the patient should be informed of all possible additional procedures which may be required during the process.

Additional or alternative procedures must only be carried out on anaesthetised or sedated patients where this is unequivocally a necessity, in the patient's best interests and can be fully justified. Postponement of further surgery or intervention is always the preferred option if it is possible to wait until the patient is in a position to consider consent.

It is, however, difficult to cite examples of such additional or alternative procedures that would definitely satisfy a court as being unequivocally in the patient's best interests. The desire to spare a patient a second anaesthetic is definitely not sufficient justification in itself. Procedures unconnected with that for which consent has been obtained are very unlikely to be justifiable. Patients may withdraw their consent at any time - including, if capable, during a procedure although they would need to be advised of the consequences of doing so.

### **9.1 Tissue and Pathology**

Tissue from a wide range of diagnostic procedures and surgical operations is submitted to NHS Grampian histo/cytopathology departments for diagnosis. Current consent arrangements as described in this policy allow for submission of this tissue for the purpose of obtaining a diagnosis as well as related educational and governance activities such as teaching, training, audit and quality control. Once a diagnosis is made, what remains of the tissue samples which have been processed and examined by microscopy in order to make the diagnosis must be stored in the Department of Pathology indefinitely as part of the departmental tissue archive.

In those cases where a large tissue or organ sample is submitted for diagnosis, a proportion of the tissue may be left unprocessed, since it is not required for diagnosis. This residual material is

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<sup>6</sup> *Re F (mental Patient: Sterilisation) [1990] 2 AC 1*

disposed of around six weeks after the final diagnostic report is issued. Fresh tissue from a diagnostic/surgical procedure that is surplus to diagnostic requirements and which is to be used for research requires consent using the Grampian Biorepository consent process (<http://www.biorepository.nhsgrampian.org/>). Archived tissue samples that are going to be used for research require the proposed research to be approved by the Grampian Biorepository scientific access group.<sup>7</sup>

## 9.2 Blood Transfusion

In the course of a number of clinical procedures and healthcare interventions, blood transfusion will or may be required. Like all medical treatments, transfusion should only be given when really necessary and in making the decision the clinician must balance the risk of giving the transfusion against the risk of not giving one.

Blood transfusion does have serious infectious, as well as non-infectious risks. Some risks may be considered small or remote, such as the transmission of infectious diseases, but these are risks that patients are likely to attach importance to because they may result in serious morbidity or death. It is recommended therefore that the possibility of transfusion is discussed prior to any clinical procedure or healthcare intervention. Provision of appropriate contemporary information is provided by the Scottish National Blood Transfusion Service:

<https://nhsnss.org/how-nss-works/our-structure/scottish-national-blood-transfusion-service/>

NHS Shetland Blood Transfusion Procedures Policy<sup>8</sup> applies to all staff working for NHS Shetland who are involved in the “**blood transfusion process**”. It provides users with the current procedures for the safe and appropriate administration of blood and blood components. These procedures are based on current guidelines by the British Committee for Standards in Haematology, Serious Hazards of Transfusions, EU Directives and Health Service Circulars; “Better Blood Transfusion”.

As with all aspects of consent, patients have the right to both withhold and withdraw consent.

If it is necessary to give a transfusion in emergency or unexpected circumstances, or if consent for transfusion was not previously obtained, then the reasons for the transfusion and written information supporting this decision should be provided afterwards.<sup>9</sup>

It is not necessary to discuss and/or record blood transfusion if it is not likely to be required in the course of a treatment or intervention.

## 10 Written Consent and Consent Forms

Patients can indicate their consent either orally or in writing. For most procedures written consent is not legally required – it is the process and the documentation of the process that is important. When a healthcare practitioner is gaining verbal consent for an invasive procedure (Nurse, Doctor or AHP) the gaining of consent should be clearly recorded in the patients’ healthcare record. Except in an emergency, where the patient has capacity to give consent you

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<sup>7</sup> Human Tissue Authority Code of Practice on Consent (September 2009)

<sup>8</sup> NHS Shetland Intranet Homepage →Clinical Portal →Clinical Guidelines and Policies → Blood Transfusion Procedures

<sup>9</sup> BMJ 2010; 341:c4336

must obtain written consent in cases where:

- the treatment or procedure is complex, or involves significant risks and/or side effects (this includes all procedures carried out under sedation/regional/general anaesthesia and local anaesthetic procedures with significant risk)
- providing clinical care is not the primary purpose of the procedure (e.g. clinical photography)
- there may be significant consequences for the patient's employment, social or personal life
- the treatment is part of a research programme
- there is a statutory requirement (e.g. some fertility treatments)

The **NHS Shetland Patient Consent Form** must be used for written consent (Surgical Z Drive) however a 'procedure specific' consent form is used for **Endoscopic Procedures**.

For emergency endoscopy, especially where there is a risk that the patient may have to proceed to an open operation, it may be better to use the standard NHS Shetland Patient Consent form.

All writing on the consent form must be:

- Legible
- Unambiguous
- In black ink
- If abbreviations are used they must be recognised and standard (for example the use of 'ERCP' for Endoscopic Retrograde Cholangio-pancreatography)
- In language which can be understood by the patient/parent/guardian.
- Signed and dated by the patient and the clinician (including GMC number if medical).

Any alteration should be initialled, dated and timed using the 24 hour clock by both the original signing clinician, in line with GMC guidance, and initialled and dated by the patient. If the procedure has laterality this should be clearly stated in full - right, left or bilateral; abbreviations such as 'L' or 'R' are not acceptable in this instance.

Alongside this policy, NHS Shetland has adopted the use of Nationally Approved EIDO patient information leaflets to compliment the consent process. Other leaflets may also be used from recognised organisations such as the Royal College of Anaesthetists.

## 11 Withholding Consent

People with capacity over the age of 16 have the right to withhold consent.<sup>10</sup> If it is decided that a patient has the capacity to provide consent then it is considered they will also have the capacity to withhold consent. A patient's decision to withhold consent, along with the reasons for this decision, must be fully documented in the patient's notes. It should be remembered that withholding agreement to examination or treatment may be due to insufficient provision of information or a mental disorder.

In some cases it may be appropriate to consider the use of the Mental Health (Care and Treatment) (Scotland) Act 2003 (MH(C&T) (S) A 2003) for the treatment of mental disorders and the Adults with Incapacity (Scotland) Act 2000 (AWISA) for the treatment of physical illnesses. However, a capable patient's right to withhold consent must be respected, irrespective of whether it is felt that the decision is rational, irrational or otherwise. In the event of withholding consent, clinicians should consider asking the patient to talk to a colleague. This allows the time for further consideration and discussion. It also allows another clinician to confirm capacity and/or witness this. For information on children and consent, and the mature minor, see section 15, page 16.

The Adults with Incapacity (Scotland) Act 2000 (AWISA) can be used to provide essential medical treatment in patients who lack capacity to make decisions regarding that medical treatment.

The Mental Health (Care and Treatment)(Scotland) Act 2003 (MH(C&T) (S) A 2003) can only be used to legally provide treatment for physical disorder where there is evidence that that physical disorder occurred as a consequence of psychiatric disorder (e.g. treatment of drug overdose in a depressed patient, antibiotics for infection in delirium, etc.)

It should be noted that the MH(C&T) (S) A 2003 cannot be used if the patient is deemed capable of providing consent. A capable patient's right to withhold consent must be respected, irrespective of whether it is felt that the decision is rational, irrational or otherwise.

## 12 Withdrawal of Consent

Competent adult patients are entitled to withdraw consent, for any reason, at any time, even when the intervention would clearly benefit their health. This includes a competent pregnant woman, even if this would be detrimental to the foetus. The only exception to this rule is where the treatment is specifically for a mental disorder and the patient is detained under the MH(C&T) (S) A 2003.

The British Society of Gastroenterology (BSG) provides a good example of guidance on consent during a procedure as relating to endoscopy:-

“If an *un-sedated* patient withdraws consent during a procedure, the procedure must be immediately terminated and the event recorded in the notes. If a *sedated* patient, characteristically, begins to struggle, and by physical and verbal act withdraws consent, the situation is entirely different. It is the responsibility of the clinician to act in the patient's best interests. If this event occurs at a crucial time, which will have an impact on a successful

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<sup>10</sup> Scottish Executive Health Department, 2006: *A Good Practice Guide on Consent for Health Professionals in NHSScotland - HDL (2006) 34.*

outcome, for example, removal of a bile duct stone, then it would be wise to pause, attempt to regain co-operation and complete, perhaps with additional sedation. If the situation deteriorates, is irretrievable, and patient safety is likely to become compromised, then termination of the procedure is recommended. A written record must be made.”<sup>11</sup>

The essence of this guidance should be noted and applied in relevant circumstances in all specialties.

### **13 Information – Provision and Documentation**

People should receive enough information, supplied in a way they can understand for them to make an informed decision.<sup>12</sup> In order to help people understand, the clinician should ensure that, if appropriate, all reasonable aids have been used (e.g. translation, audio-visual aids, extra time and the simplification of language used for patients with learning disabilities). The booklet “Consent, it’s your Decision” (Health Rights Information Scotland, August 2010) is available for information for patients and can be downloaded from NHS inform:

<https://www.nhsinform.scot/publications/consent-its-your-decision-leaflet>

The amount of information provided to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure and the patient’s own wishes. A careful balance needs to be struck between listening to what the patient wants and providing enough information in order that the patient’s decisions are informed.

The type of information the clinician should discuss will include:

- the purpose of the investigation or treatment, details and uncertainties of the diagnosis
- options for treatment including the option not to treat
- explanation of the likely benefits and probabilities of success for each option
- the likely outcome if not treated
- known side effects and risks as identified below
- the name of the consultant who has responsibility for the treatment proposed
- if appropriate, a discussion of the role of staff other than the consultant being involved in the procedure
- if appropriate, that the patient will have a chance to discuss their anaesthetic with an anaesthetist prior to the procedure
- a reminder that the patient can change his or her mind after signing the consent form
- the possibility of problems occurring during the procedure and the requirement for additional procedures.

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<sup>11</sup> *British Society of Gastroenterology, 2008: Guidance for Obtaining a Valid Consent for Elective Endoscopic Procedures.*

<sup>12</sup> *Ibid 10*

- A discussion of what is going to happen and what a patient is likely to experience during a procedure may be helpful, particularly if not under anaesthetic.

In relation to risk, the clinician should include:

1. The nature of the risk
2. The effect on the life of the patient
3. The importance to the patient of the benefits of the treatment
4. Any possible alternatives
5. The risk of those alternatives

The recent case of *Montgomery vs Lanarkshire Health Board* (2015) UKSC 11<sup>13</sup> has changed the way the law in the UK will now interpret information provided to patients by clinicians during consent processes, and this legal judgement has replaced *Sidaway* (1985) as the legal test.<sup>14</sup> The onus is now on the Doctor to find out what their patients want to know in relation to treatment choices and to warn the patient of material risks in treatment that a reasonably prudent patient would think significant. The only 'therapeutic exception' to this is where a Doctor reasonably considers that disclosure of such information would be seriously detrimental to the patient's health. In the *Montgomery* case of 2015 the Supreme Court applied the standards of the GMC to the consent process at the time to the facts of the case in 1999; they did not consider this retrospective judgement and therefore the *Montgomery* judgement may also apply to other past treatments.

Information must be given to the patient in a way that can be readily understood. The information must be provided orally (written or pictorially or through a BSL interpreter for deaf patients) and where possible be supported by written or audio-visual material. The clinician must record in the case records (either on the consent form, in the handwritten section of the notes or in a letter) details of the information, including any key points of discussion, provided.

Written or audio-visual material may be departmental, Board specific or externally produced. Written or audio-visual material is additional to the oral process. It must be remembered that different versions of written or audio-visual material may be used. When the material has been given to the patient it should be clearly documented which version has been given. Consideration should also be given to including a copy of the material in the case record to avoid future legal debate over what information was given.

Appendix 2, page 26, provides a flowchart outlining the process for obtaining consent.

## 14 Incapacity

The Adults with Incapacity (Scotland) Act 2000 (AWSIA) covers issues relating to property, financial and personal welfare of adults incapable by reason of physical or mental disorder. Part 5

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<sup>13</sup> *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

<sup>14</sup> *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1985] AC 87.

of this act covers issues relating to medical treatment. The clinician primarily responsible for the care of an adult (defined as persons age 16 or over) is required to assess and document the adult's capacity to consent to any proposed medical treatment.

Any planned intervention will be expected to adhere to the following core principles:

- beneficial to the adult
- take account of the adult's present and past wishes and feelings
- minimise restriction to the adult's freedom while achieving the desired benefit
- when appropriate, take into account the wishes of relevant others e.g. relatives and carers (if reasonable and practicable to do so)
- encourage the adult to exercise residual capacity (by the use of aids or prolonged/ repeated explanation)

Incapable in the AWISA means incapable of –

- acting; or
- making decisions; or
- communicating decisions; or
- understanding decisions; or
- retaining memory of decisions

In law there is a presumption in favour of capacity. This does not mean that a person is assumed to have capacity unless there is a certificate that states otherwise. In practical terms to demonstrate capacity an adult should be able to:

- understand in simple language what the medical or surgical treatment is, its purpose and nature and why it is being proposed
- understand its principal risks, benefits and alternatives
- understand, in broad terms, what will be the consequences of not receiving the proposed treatment
- retain the information
- make the choice freely

In the event of the adult being deemed incapable the clinician primarily responsible shall be expected to issue a Certificate of Incapacity prior to treatment, which should be kept in the patient's clinical record. It is best practice to draw up a treatment plan to accompany the Section

47, see Appendix 3, page 27. The condition of the patient should be considered when deciding whether a second opinion is required. Where a concern persists, another clinician should consider the patient's ability or inability to consent and record this within the clinical record. For treatments which would require a consent form otherwise, a separate Section 47 form should be drawn up.

There are provisions in the AWISA for the appointment of Welfare/Financial Attorneys and Welfare/Financial Guardians. A person can nominate an Attorney whilst they have capacity to do so. A Guardian is appointed once the person has lost capacity. These orders can authorise actions to be taken in relation to the property, financial affairs or personal welfare of the adult. Personal welfare is inclusive of physical and mental health matters. Regarding health matters, a doctor should obtain consent from the Attorney or Guardian, where it is "reasonable and practicable to do so".<sup>15</sup> The Attorney or Guardian is comparable to the capacious patient.

If there is a disagreement on the part of the Welfare Guardian or Welfare Attorney, the medical practitioner can request a second opinion from a medical practitioner nominated by the Mental Welfare Commission. Treatment to save life or prevent serious deterioration can be given unless there is an injunction against it as per s.50 of the AWISA.

In the event of incapacity, it is expected that relatives and carers as well as other professionals will be involved in decisions about the incapable patient. Guidance for carers regarding their involvement in the consent process and their right to be involved in decisions is available from Health Rights Information Scotland leaflet "Caring and Consent" which is available to download from the NHS Inform site:

<https://www.nhsinform.scot/publications/caring-and-consent-leaflet>

The situation of an incapable patient presenting as an emergency is unchanged by the AWISA. Treatment necessary to save life or prevent serious harm to the patient should be given unless consent is withheld by the person authorised within the AWISA. This however does not preclude the use of it.

Within prescribed requirements, health professionals other than a medical practitioner can issue a Certificate of Incapacity covering treatment within their own area of practice. Such professionals include: dentist, ophthalmic optician, registered nurse or healthcare practitioner. Dependent on the nature of the illness the patient is suffering, a Certificate of Incapacity can be issued for a period of up to three years. It should be noted that for all health professionals the certificate relates to the specified treatment which should be clearly stated on the form.

Authority to treat under the AWISA is limited. Firstly, it does not authorise the use of force unless immediately necessary and only for as long as necessary. Secondly, it does not authorise transport of the adult to a place of safety, this would require a warrant from the court.

There are exceptions to the AWISA. Section 47 of the act cannot be used where Part 16 of the (MH(C&T) (S) A 2003) applies. In such circumstances, additional criteria as defined by the MH(C&T) (S) A 2003 must be satisfied before electro-convulsive therapy (ECT), sterilisation,

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<sup>15</sup> *Adults with Incapacity (Scotland) Act 2000, s.52(c)*

termination of pregnancy or treatment to reduce sexual drive can be carried out. Appendix 3, page 27 provides a flowchart outlining the process detailed above.

Where an incapable patient resists intervention of a non-emergency physical healthcare intervention, the AWISA Part 5, Code of Practice, directs the clinician to the use of an Intervention Order with specific power to use reasonable force or Welfare Guardianship with a Compliance Order. Further guidance on this issue can be found at the Mental Welfare for Scotland website:

[www.mwscot.org.uk/media/51242/Adults\\_who\\_lack\\_Capacity\[1\].pdf](http://www.mwscot.org.uk/media/51242/Adults_who_lack_Capacity[1].pdf)

#### **14.1 Consent and Mental Disorder**

The MH(C&T) (S) A 2003 allows for the compulsory treatment of mental disorder. Mental disorder is defined as mental illness, learning disability and personality disorder. Within this, the act allows for: lifesaving treatments e.g. ECT for severe depression; prevention of deterioration e.g. depot medication for the treatment of psychosis; prevention of suffering e.g. the prescription of anti-depressants in postnatal depression; and preventing a patient from behaving as a danger to him/herself or others e.g. 24 hour nursing care for a patient suffering from mania.

The majority of those who suffer from mental disorder have the capacity to decide on their treatment options. For those who have significantly impaired decision making regarding their mental disorder, detention and treatment under the MH(C&T) (S) A 2003 should be considered. Obtaining psychiatric guidance is advised, as there are other criteria to be met for a patient to be detained under MH (C&T) (S) A 2003.

If a patient is thought to require detention, where possible the opinion of an Approved Medical Practitioner (AMP) should be sought so that a Short Term Certificate can be considered and granted, which can last up to 28 days.

In circumstances where this is not possible, such as the necessity to proceed quickly with treatment, geographical isolation, or inability within the community due to it being out with daytime working hours any *registered* medical practitioner can consider the criteria for an Emergency Detention Certificate through discussion with a Mental Health Officer. An Emergency Detention Certificate can last up to 72 hours. The necessity of such a Certificate must be reviewed as soon as practical by an AMP within 24 hours of the detention. Psychiatric advice is available 24 hours a day via Royal Cornhill Hospital, Aberdeen and can be contacted via switchboard.

An example where the treatment of mental disorder and physical illness overlaps is in the presentation of self-harm through overdose of alcohol and paracetamol at Accident & Emergency (A&E), where the patient requires treatment with Parvolex to prevent irreversible liver damage and potentially death. If the patient is willing for treatment, then this should go ahead. If the patient is unconscious and requiring life-saving treatment, then treatment of the physical illness should proceed in the patients best interests. When the patient is refusing to be treated, the doctor must consider the following:

1. Do they have capacity to consent to treatment with Parvolex?

If not, and the treatment is required as an emergency then proceed in the patient's best interests under common law.

For any non-emergency treatment, if the patient lacks capacity to consent to treatment, it is important to remember to complete a Certificate of Incapacity for the treatment.

2. Do they suffer from a mental disorder?

If Yes and the mental disorder has resulted in significant impairment of their decision making capacity and there is clearly a significant harm to the patient in not treating their mental disorder, then the patient may require detention under the MHA 2003 to allow their detention within A&E for assessment and treatment of the mental disorder. Treatment of the physical disorder can be carried out under MHA 2003 where this is a consequence of the mental disorder. Treatment of other physical co-morbidities must be considered based on whether they have capacity to offer or withhold consent and proceed accordingly.<sup>16</sup> (It is possible to have a mental disorder, meet the criteria for detention under the MHA 2003 and still have the capacity to withhold consent to treatment for a physical disorder. An example would be a patient suffering from chronic schizophrenia, with grandiose delusional beliefs that he is God and can communicate with the masses via telepathy, yet can fully understand that he has a gangrenous foot due to smoking, and is fully aware that he may die due to sepsis if it is not amputated, yet chooses to withhold consent for the amputation).

## 14.2 People with Learning Disabilities

Because someone has a diagnosis of a learning disability, this must not undermine the presumption that he/she has decision-making capacity. Characteristics associated with specific syndromes cannot be presumed to be evidence of incapacity e.g. Down's syndrome, as there is an extensive range of ability. Similarly, difficulties in communication should not be confused with incapacity. Often individuals will comply with the consent process and provide the assessor with the expected response yet not understand the treatment proposed. It is not necessarily the case that they cannot understand, rather the need for the health professional to take the time to consider the information with them, in an accessible format to the individual.

For people with learning disabilities, it is important to use simple, non-technical language. Other communication aids can be used like Makaton, pictures and talking mats. It is important to discuss only one idea or question at a time and give plenty of time for the individual to consider their response. You should question their understanding of the information you have provided to ensure comprehension, retention and an ability to come to a decision based on this information. People with learning disabilities are at times keen to please, or appear more socially able than they are. They do so by answering questions based on what they think you want to hear by interpreting body language and non-verbal cues. This should not be confused with informed consent. Support with gaining consent from people with a learning disability is available from the

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<sup>16</sup> Mental disorder cannot be used to justify physical treatment under common law if the patient is capable of giving or withholding their consent to it, see *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290. The MHA 2003 does allow for the treatment of physical disorder but ONLY where the physical disorder is a direct cause or consequence of the mental disorder e.g. mania secondary to hyperthyroidism, delirium secondary to a chest infection or psychosis secondary to porphyria.

Learning Disability Nurse who can be contacted via switchboard.

## 15 Children

Under Scots law, a patient aged 16 and over, unless they lack the appropriate capacity, is presumed to have the competence to give consent for themselves. Individuals under the age of 16 years, who understand fully what is involved in the proposed procedure, can also give consent (although their parents/guardian will ideally be involved). In other cases, a person with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. Those under 16 years of age who are not deemed to be competent cannot give consent in any circumstances, including emergencies.

The Age of Legal Capacity (Scotland) Act 1991 requires that if a competent child consents to or refuses treatment; a parent responsible/guardian cannot over-ride that decision<sup>17</sup>. If a child who has been deemed to be capable refuses treatment, consideration should be given to whether the child fully understands the implications of refusal or if the illness is interfering with their capacity. If there is doubt then legal advice should be sought via the medical director's office and in the interim, if required, emergency treatment should be given. The booklet "A guide for young people under 16 – Consent, your rights" (Health Rights Information Scotland, August 2010) is available for information for children and young people under 16 and can be downloaded from the Health Rights Information Scotland website:

<https://www.nhsinform.scot/publications/consent-your-rights-leaflet>

It must be remembered that consent is required before any examination, treatment or procedure – this consent is often "implied" by the behaviour of the patient - e.g. complying with physical examination or phlebotomy. When a baby or a young child is admitted to hospital, the clinician should discuss with the parents what routine procedures will be necessary and ensure that they have given their consent for these interventions in advance. If parents specify that they wish to be asked prior to particular procedures being initiated, this must be adhered to unless any delay involved in contacting them would put the child's health at risk.

In the case of emergency life-saving treatment or where treatment is required to prevent significant deterioration, the child cannot consent and the person with parental responsibilities or alternative is not available, then emergency treatment should be given.

Only people with "parental responsibility" are entitled to give consent on behalf of their child. It is essential to establish who has responsibility for the child if the parents are not available, i.e. if the child is in the care of the local authority social services. It is important to remember that not all parents have parental responsibility for their children.

A "responsible parent" as defined by The Parental Responsibilities and Parental Rights Agreement (Scotland) Amendment Regulations is<sup>18</sup>:

- The mother (unless her rights have been removed by court order)

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<sup>17</sup> *Mental Health (Care and Treatment) (Scotland) Act 2003, and The Age of Legal Capacity (Scotland) Act 1991.*

<sup>18</sup> *The Parental Responsibilities and Parental Rights Agreement (Scotland) Amendment Regulations 2006*

➤ The father but only if:

- he was married to the mother at the time of conception or at any time after; or
- he was given them by court order; or
- together with the mother he has made and registered a “Parental Responsibilities and Parental Rights Agreement”; or
- he is registered on the birth certificate as the father of the child on or after 4<sup>th</sup> May 2006.

If a responsible parent is not available, the procedure cannot be delayed and the child cannot give consent, then it is acceptable for the person who has care of the child to provide consent as long as it is not within their knowledge that the responsible parent would refuse. This includes relatives (including a parent without parental responsibilities) and child-minders<sup>19</sup>. It does not apply to teachers or others having care and control of a child in school. If a parent or parents refuse to give consent for treatment thought to be appropriate by clinical staff, consideration can be given to legal action to allow treatment. If two parents with equal parental responsibility disagree on consent legal action may need to be sought.

In relation to Religious Circumcision, where parents are requesting circumcision for their child on religious grounds, it is recommended that written consent is obtained from both parents.

## 16 Civil Partnerships

When discussing with relatives and carers, it should be remembered that the Civil Partnership Act 2004 came into effect in 2005 and the Marriage and Civil Partnership (Scotland) Act 2014, came into effect in December 2014. These two pieces of legislation enable same sex couples to have their relationship given formal legal recognition, either as a civil partnership, or as a same sex marriage<sup>20</sup>. Within this policy the same rights will apply to those in civil partnerships and marriage (whether same sex or opposite sex).

Civil partnerships and same sex marriages are something that all healthcare staff need to be aware of, especially when dealing with incapable patients. It is possible that a patient may have entered into a civil partnership or same sex marriage, of which neither partner’s family is aware. In extreme circumstances, this may lead to families taking important decisions about the patient, while the civil partner/same sex marriage partner is excluded, because they do not wish to disclose their relationship. If this situation is suspected, staff should act with tact and diplomacy. They should seek the first opportunity to speak to the possible civil partner/same sex marriage partner and ask if they have entered into either a civil partnership or same sex marriage with the patient. The response received will then help to guide future decision making.

## 17 Local Ethnic Communities in Shetland

The European Economic Area (EEA) was expanded on the 1<sup>st</sup> April 2004 and again in 2007. This gave EEA nationals the right to live and work in any part of the EEA. It is important to ensure that

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<sup>19</sup> *Ibid*

<sup>20</sup> *Civil Partnership Act 2004, and Marriage and Civil Partnership (Scotland) Act 2014.*

these patients/parents/guardians receive information in a language they can understand. This can be achieved by the use of:

“Language Line” telephone interpretation service. This gives access, on the telephone, to professional linguists for 170 different languages, in 60-90 seconds. This service is available 24 hours per day, 7 days per week. The telephone number is 0845 310 9900. There are staff in each area trained in its use.

Please note that you will need the correct customer account number and departmental code when you call Language line. The codes are held at the Gilbert Bain Reception, in the Senior Nurse Folder and on the Senior Nurse Drive.

To request the translation of any written material please contact Corporate Services on extension 3064 or 3069, or email [shet-hb.corporateservices@nhs.net](mailto:shet-hb.corporateservices@nhs.net).

### **18 Patients who are Hearing Impaired, Profoundly Deaf or Blind**

It is important to ensure that all patients fully understand the information which is being conveyed to them, including those who are hearing impaired or profoundly deaf.

For patients/parents/guardians who are hearing impaired, it is important to have the discussion, in an environment where there is as little background noise as possible. If a person is lip reading, ensure that there is good light and that the person conveying the information speaks slowly and clearly, stopping periodically to check that the information is being effectively communicated.

For patients/parents/guardians who use a hearing aid there is a portable induction loop system available in the Out-Patient Department. In an urgent situation, information can also be written.

For British Sign Language (BSL) users the following resource is available to support clinical conversations: <http://contactscotland-bsl.org>. This is available seven days a week from 8am to 12 midnight. In an urgent situation, information can also be written.

### **19 Advance Directives and Advance Statements**

In Scotland, an advance directive is an oral or written expression of what treatment of physical disorder a patient does not want, at a time when they are incompetent to do so, e.g. a card carried by a Jehovah’s Witness to ensure he does not receive a blood transfusion, even when unconscious and incompetent to say so. The directive can be withdrawn at any time by a competent patient either verbally or in written form.<sup>21</sup>

An advance statement as defined by the MH(C&T) (S) A 2003, is a signed and witnessed written expression of what treatment of mental disorder a patient does and does not want, at a time when they are incompetent to do so, e.g. an expressed wish to be detained in hospital if he is severely depressed, to be given medication and cared for to prevent self-harm but not to receive ECT.

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<sup>21</sup> *Re T (Adult: Refusal of Treatment)*[1992] 3 WLR 782

Such a statement can be overridden by the compulsory powers of the Act. The statement can be withdrawn at any time by a competent patient only in a signed and witnessed written form.<sup>22</sup>

Prior to treating a patient as directed by an advance directive or statement, the doctor must ensure validity as far as this is possible: was the patient competent at the time of making the directive or statement;<sup>23</sup> whether the patient had the necessary information disclosed to them to reach a decision;<sup>24</sup> that the decision was a voluntary one, i.e. not subject to family pressure;<sup>25</sup> applicable to the current circumstance, i.e. was the wish relevant to elective procedures or only life-saving situations;<sup>26</sup> and finally, whether the directive or statement remains applicable over time,<sup>27</sup> i.e. had the patient considered recent medical advancements. When it is not possible to ensure validity, e.g. in emergency situations the principles outlined in Section 8 should apply.

The advance directive and statements do not allow for patients to demand treatment which is not seen by the treating doctor to be in their interest or force the doctor to act unlawfully.<sup>28</sup> Patients can demand the withdrawal of life prolonging treatment but not such that this would be assisting suicide.<sup>29</sup>

The making of an advance directive continues in Scotland to be defined by case law with no guidance summary available. Further information on the making or respecting of the advance statement should be sought from the patients Consultant Psychiatrist. Guidance can also be found within 'The New Mental Health Act: A Guide to Advance Statements' (<http://scotland.gov.uk/Resource/Doc/26350/0012826.pdf>).<sup>30</sup>

## 20 Information Sources for Patients

The following NHS Inform booklets are available:

- ["Consent, it's your decision"](#)
- ["Consent, your rights. A guide for young people under 16"](#)
- ["Caring and Consent – information for carers"](#)

Further information on consent to treatment is contained in some in-patient admission booklets. Patients can request a copy of this policy. An electronic version of this policy is available from the Document Search section of the intranet homepage (search keywords: consent policy).

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<sup>22</sup> MH(C&T)(S)A 2003 s.275 (3)

<sup>23</sup> *Re C* [1994] 1 WLR 290

<sup>24</sup> *Re T (Adult: Refusal of Treatment)*[1992] 3 WLR 782

<sup>25</sup> *Ibid*

<sup>26</sup> *Ibid*

<sup>27</sup> *HE v A Hospital NHS Trust* [2003] EWHC 1017

<sup>28</sup> *R (Burke) v GMC* [2005] EWCA Civ 1003

<sup>29</sup> *Re AK*(2001) 58 BMLR 151 & *Pretty v United Kingdom* (2002) 35 EHRR 1

<sup>30</sup> Scottish Executive. *The New Mental Health Act: A Guide to Advance Statements*, 2005

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## Legislation

Adults with Incapacity (Scotland) Act 2000

Age of Legal Capacity (Scotland) Act 1991

Civil Partnership Act 2004

Mental Health (Care & Treatment) (Scotland) Act 2003

Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) (contains amendments to Section 47 of the Adults with Incapacity (Scotland) Act 2000)

The Parental Responsibilities and Parental Rights Agreement (Scotland) Amendment Regulations 2006

All the above legislation is available in full from <http://www.opsi.gov.uk/legislation/revised>.

## Case Law

*HE v A Hospital NHS Trust* [2003] EWHC 1017

*Montgomery v Lanarkshire Health Board* [2015] UKSC 11

*R (Burke) v GMC* [2005] EWCA Civ 1003

*Re AK* (2001) 58 BMLR 151 & *Pretty v United Kingdom* (2002) 35 EHRR 1

*Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290

*Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1

*Re T (Adult: Refusal of Treatment)* [1992] 3 WLR 782

## Appendix 1 – Legal Advice Regarding Risk

What constitutes risk that should be discussed?

The GMC guidance on consent states at paragraph 28:

*“clear, accurate information about the risks of any proposed investigation or treatment, presented in ways a patient can understand can help them make informed decisions. The amount of information about risk that you should share with patients will depend on the individual patient and what they want or need to know. Your discussions with individual patients should focus on their individual situation and risk to them.”*

And further at paragraph 31

*“You should do your best to understand the patient's views and preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about. You must not make assumptions about a patient's understanding of risk or the importance they attach to different outcomes. You should discuss these issues with your patient.”*

### **The decision of the Supreme Court in *Montgomery v Lanarkshire Health Board***

In the 2015 case of *Montgomery v. Lanarkshire Health Board*<sup>31</sup> the UK Supreme Court significantly re-stated the law relating to consent.

The ruling has set aside the previous test, applying from the cases of *Hunter v. Hanley* and *Sidaway*. To prove a breach of duty to advise and warn, a pursuer no longer requires to prove that no doctor of ordinary skill would have failed to have given her advice, if acting with ordinary care, as supported by medical opinion.. The test now is that Doctors are under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable or variant treatments. The risks of alternative or variant treatments should be explained to the patient. The question of which alternative treatments could be available is a question of fact.

The question now therefore is not what the ordinary competent doctor would advise. What the Supreme Court has clearly stated in *Montgomery* is that this is not a question for medical experts or for the profession to decide. The test of materiality has been refined with the focus now on the patient and what the particular patient sat in front of you would want to know. The test of materiality now is whether in the circumstances of the particular case, a reasonable person in that person's position would likely attach significance to that risk, or the doctor should reasonably be aware that the particular patient would be likely to attach significance to it. What is material to one patient may not be material to another and this requires that the doctor engage with the patient in question.

It was emphasised that whether a risk is material cannot be reduced to percentages, and instead is based on a variety of factors such as: (1) nature of the risk; (2) effect on the life of the patient; (3) the importance to the patient of the benefits of the treatment; (4) any possible alternatives; and (5) the risk of those alternatives.

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<sup>31</sup> [2015] UKSC 11

Doctors are therefore required to find out what it is that is of concern to the patient. It is not for doctors or experts to decide what the reasonable patient in the patient's position would want to know. This is very much in keeping with the GMC statement in Paragraphs 28 and 31 and in essence the court has now caught up with the professional regulator. A patient may decide that she does not wish to know what her risks and options are and this should be very clearly noted and if possible witnessed.

The "therapeutic exception", which allows a doctor to withhold information from a patient only applies if its disclosure would be seriously detrimental to the patient's health, or in circumstances of necessity, such as where the patient is unconscious.

## Appendix 2 – Consent Flowchart



