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05	16/08/2021	Aasya Mughal MCA Subject Matter Expert Edge Consultancy	Annual review and some minor ammendments



1. Introduction and Overview

The purpose of this policy is to set out Newmedica's overall approach to consent and the way in which the principles of consent will be put into practise. It is not a detailed legal or procedural resource due to the complexity and nature of the issues surrounding consent and clinicians must always follow the latest law and professional guidance.

At all times, a clinician must be satisfied that a patient with mental capacity consents to a proposed treatment or investigation. The patient must be informed of the nature, purpose, and risks of the procedure, if necessary, by the use of drawings, interpreters, videos or other means to ensure that the patient has enough information to consent'.

Patients with mental capacity have a fundamental legal and ethical right to determine what happens to their own bodies and healthcare information. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery.

"Consent" is a patient's permission for a health professional to provide care and/or treatment. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

- have capacity to take the particular decision.
- have received appropriate information to take it.
- not be acting under duress.

In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may give or refuse consent. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments.

Where an adult patient lacks the mental capacity to give or withhold consent for themselves, currently no one else can give consent on their behalf unless the patient has a Lasting Power of Attorney or deputy for personal welfare.

If a patient lacks mental capacity, treatment may be given if it is in their best interests, as long as it has not been refused:

- in a valid and applicable Advance Decision
- by a valid attorney or deputy (for personal welfare)
- by an order of the Court of Protection.

Adults are assessed as lacking the mental capacity to consent if they are unable to do any one of the following:

- Understand the information relevant to the specific decision (the nature, purpose and reasonably foreseeable consequences of the proposed procedure, including of not making the decision)
- Retain this relevant information
- Use or weigh the relevant information to arrive at a choice
- Communicate that decision (whether by talking, using sign language or by any other means).



2. Purpose

The purpose of this policy is to ensure that Newmedica complies with the statutory requirements of the Mental Capacity Act 2005, and all staff are aware of the procedures pertaining to this.

3. Scope

This Policy applies to all employees, workers, contractors, temporary, agency and locum staff, volunteers, students and people on authorised work experience ("Staff") of New Medical Systems Limited and associated Ophthalmology Joint Venture Partnerships ("Newmedica") irrespective of age, disability, race, colour, nationality, ethnic origin, religion or belief, gender, sexual orientation, pregnancy, maternity or marital status, domestic circumstances, social and employment status, HIV status, gender reassignment, political affiliation or trade union membership.

This Policy sets out the principles and procedures that Newmedica has adopted, and will work to, in order to ensure fair and effective arrangements for maintaining appropriate standards throughout. It will apply to all staff.

4. Definitions

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5. Legal and Professional Framework

Common Law

There is no statute setting out the principles of consent to medical treatment in England except for when it is medical treatment for mental disorder. Practitioners must follow case law / common law when seeking consent to examination, investigation or treatment.

The following key points highlighted in recent decisions must be noted:

- Consent must be obtained before starting treatment, physical intervention or providing personal care for a person.
- Touching a patient without valid consent may constitute the criminal offence of battery.
- Patients should be told of any possible significant adverse outcomes of a proposed treatment. This
 includes a small but well-established risk of a serious adverse outcome or other risks that may be
 considered significant or important to them as an individual. For further information please refer
 to https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-andconsent.
- The fact that a person has a mental illness does not automatically mean they lack capacity to make a decision about medical treatment.
- An individual's capacity to make particular decisions may fluctuate or be temporarily affected by factors such as pain, fear, confusion or the effects of medication. Assessment of capacity must be time and decision-specific.



- A patient with mental capacity has the right to refuse treatment and their refusal must be respected, even if it will result in their death.
- A pregnant woman with mental capacity can refuse treatment even if that refusal may result in harm to her or her unborn child.
- Patients cannot lawfully be detained and compulsorily treated for a physical condition (unless it is considered medical treatment for mental disorder) under the Mental Health Act.
- A patient's consent to a particular treatment will not be valid if it is given under pressure or duress exerted by another person.
- Doctors are under no legal or ethical obligation to agree to a patient's request for treatment if they consider the treatment is not in the patient's interests.

Mental Capacity Act 2005

The legal framework for making treatment decisions in people who are unable to make decisions for themselves is set out in the Mental Capacity Act 2005. The fundamental test to determine whether a person lacks mental capacity to make a specific decision is:

- Is the person unable to understand the information they are being told about the decision.
- Is the person unable to retain that information for long enough to make the decision.
- Is the person unable to use or weigh that information to make a decision.
- Is the person unable to communicate their decision (by any means).

If the person cannot do any of the four stages above, the next stage is to evidence why their inability is because of an impairment or disturbance of the mind or brain such as dementia or learning disability. A patient's capacity may fluctuate, and all external conditions should be optimised to ensure that they have the best opportunity to have capacity. A patient may have capacity to make one decision (e.g. to have an eye examination) but lack capacity to make other decisions (e.g. cataract surgery).

Young People Aged 16 or 17

Section 8 of the Family Law Reform Act 1969 sets out that people age 16 or 17 are presumed capable of consenting to their own medical treatment. However, their refusal of treatment may be overridden by a court. The refusal of treatment may be overridden in cases where:

- Refusal of treatment will lead to death or severe permanent injury
- Or if there is an imminent risk that the young person will suffer grave and irreversible mental or physical harm.

The provisions of the Mental Capacity Act also apply to this age group if they lack the mental capacity to consent.

If a 16 or 17-year-old is capable of giving valid consent, there is no further legal requirement to obtain consent from a person with parental responsibility.

General Medical Council Guidance

The professional guidance published by the GMC is set out in "Consent: patients and doctors making decisions together." Doctors must follow this guidance in their practice.

Note: The above guidance has been updated and is now called Decision Making and Consent (dated Nov 2020) and link below.

https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-andconsent



https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/seeking-patient-consent-toolkit

Nursing & Midwifery Council Guidance

Section 2 of the NMC code sets out the professional standards required by Registered Nurses and Midwives in their approach to consent.

General Consent Guidelines

Implied Consent

Implied consent means that consent can be assumed if a patient has mental capacity. An example of implied consent is that a patient holds their arm out to apply a blood pressure cuff prior to taking a blood pressure measurement. Implied consent will be assumed for many routine physical contacts with patients. Where implied consent is to be assumed by the clinician, in all cases, the following will apply:

- An explanation will be given to the patient what he / she is about to do, and why.
- The explanation will be sufficient for the patient to understand the procedure.
- In all cases where the patient is under 18 years of age a verbal confirmation of consent will be obtained and briefly entered into the medical record.
- Where there is a significant risk to the patient an "Expressed Consent" will be obtained in all cases (see below).

Expressed Consent

Expressed consent (written or verbal) will be obtained for any procedure which carries a risk. A note will be made in the medical record detailing the discussion about the consent and the risks. A Consent Form may be used for the patient to express consent.

- Written consent should be sought in the following circumstances:
- Where the treatment or procedure is complex or involves significant risks
- Where the treatment or procedure requires anaesthesia or sedation
- Where providing health or social care is not the primary purpose of the procedure
- Where there may be significant consequences for the patient's employment, social or personal life

Completed written consent forms must be retained with the patient's records.

Obtaining Consent

- Consent (Implied or Expressed) will be obtained prior to the procedure, and prior to any form of sedation.
- The clinician will ensure that the patient is competent to consent (16 years or over) or has "Gillick Competence" if under 16 years. Further information about Gillick Competence and obtaining consent for children is set out below.
- Consent will include the provision of all information relevant to the treatment.
- Questions posed by the patient will be answered honestly, and information necessary for the informed decision will not be withheld unless there is a specific reason to withhold. In all cases where information is withheld then the decision will be recorded in the clinical record.
- The person obtaining consent will be fully qualified and will be knowledgeable about the procedure and the associated risks.
- The patient has a right to refuse consent, delay the consent, seek further information, limit the consent, or ask for a chaperone.
- Clinicians will use a Consent Form where procedures carry a degree of risk or where, for other reasons, they consider it appropriate to do so (e.g. malicious patients).



- No alterations will be made to a Consent Form once it has been signed by a patient.
- Clinicians will ensure that patients consent freely and not under duress (e.g. under pressure from other present family members etc.).
- If a patient has the mental capacity to give consent but is physically unable to sign the Consent Form, the clinician should complete the Form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally. A verbatim note should be recorded of the patient's words, if possible.
- Where a procedure is a major procedure, or involves anaesthesia or sedation, the process of obtaining consent must be started either on a pre-assessment appointment, or at the appointment where a decision is made to provide this treatment to the patient. The issue of consent must not be raised for the first time on the day of the procedure where the procedure requires anaesthesia or sedation.
- Where there are concerns that a patient is being coerced into consent please raise your concerns with your line manager.

Other aspects which may be explained by the clinician include:

- Details of the diagnosis, prognosis, and implications if the condition is left untreated
- Options for treatment, including the option not to treat.
- Details of any subsidiary treatments (e.g. pain relief)
- Patient experiences during and after the treatment, including common or potential side effects and the recovery process.
- Probability of success and the possibility of further treatments.
- The option of a second opinion

Written Consent

It is rarely a legal requirement to seek written consent, but it is good practice to do so and provides evidence in the event of a claim or complaint.

The written consent must be documented on the consent form

6. Roles and Responsibilities

The health professional carrying out the procedure retains ultimate responsibility for seeking consent. If another member of the team with the appropriate skills and knowledge seeks consent, the health professional carrying out the procedure must ensure that consent has been taken properly.

For interventional procedures it is Newmedica Policy that consent will only be obtained by a qualified medical practitioner.

Specific Situations

Consent for children

Everyone aged 16 or more is presumed to have mental capacity to consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him/her to understand fully what is proposed" (known as Gillick Competence), then he/she will be competent to give consent for him/herself. Children may therefore sign a Consent Form for themselves, but may like a parent to countersign as well.

For children under 16 (except for those who have Gillick Competence as noted above), someone with parental responsibility should give consent on the child's behalf by signing accordingly on the Consent Form



7. Policy Content

Mental Capacity Act

The Mental Capacity Act 2005 (the Act) provides a statutory framework that details how vulnerable people can be empowered to make their own decisions. It rests on the following key principles:

- Presumption of capacity.
- Practical steps to help people make their own decisions.
- If they have mental capacity, individuals retain the right to make what might be seen as eccentric or unwise decisions
- Best interests (if people lack mental capacity)
- Less restrictive interventions wherever possible.

Mental capacity is specific to a particular decision at a particular time. If an individual is assessed to lack mental capacity, under the Act, everything that is be done to or for that individual must be in their best interests.

Patients Lacking Capacity

The health professional responsible for carrying out the procedure is ultimately responsible for ensuring that an assessment of capacity has been made, and that it is appropriate to carry out the treatment or procedure in the best interests of the patient – refer to appendix A. This best interests 'check-list' is set out in law and is a statutory requirement under section 4 Mental Capacity Act 2005. The health professional should seek advice from a senior colleague or a Professional Indemnity Insurer if there is any uncertainty about any of these matters.

Where a patient does not have the capacity to give or withhold consent to any intervention, this fact should be documented along within the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests following each point of the checklist in Section 4 of the Act, including the involvement of people close to the patient. The standard consent forms should never be used for adult patients unable to consent for themselves.

It should be noted than an apparent lack of capacity may in fact be due to communication difficulties. All efforts must be made to resolve these difficulties, potentially including involvement of specialist teams, such as the Learning Difficulties team or Speech and Language Therapists.

Advance Decisions to Refuse Treatment

People who have mental capacity can state which treatment they wish to refuse in an advance decision to refuse treatment. This is only to be followed if they lack mental capacity as long as it is valid and applicable to the proposed treatment. This can be a written or verbal statement in any form such as a signed printed card, smart card, or records of a discussion in a patient's file. Additional rules apply for advance decisions refusing life-sustaining treatment.

Documentation

The following information must be documented on the relevant assessment form found in appendix A when making an assessment of capacity and decision to proceed with treatment in the patient's best interests:

- The decision to be taken
- An assessment of capacity:
 - Evidence of the impairment or disturbance in the functioning of the person's mind or brain
 - Whether the impairment or disturbance is permanent, fluctuating or temporary



- Whether the patient is unable to understand information related to the decision
- Whether they are unable to retain information related to the decision
- Whether they are unable to use or weigh information to make the decision
- Whether they are unable to communicate the decision by any means
- Practical steps taken to maximise the patient's capacity to make the decision
- Whether the decision can be delayed as the patient is likely to regain capacity in the near future
- Who has been consulted about the decision?
- Advance Decisions:
 - Is one in place?
 - Is it valid?
 - What is the treatment being refused?
 - Is the decision applicable?
- Best Interests Determination, the following must be considered
 - All relevant circumstances (ie diagnoses, prognosis history, emotional and psychological factors etc)
 - The person's beliefs, values, past and present wishes, feelings and statements and any other factors that would be important to them
 - Consult as practicable and appropriate people who have an interest in the welfare of the person.
 - Less Restrictive option; consider if there are less restrictive options in terms of the person's rights and freedoms
 - Can you wait? consider if the person will have capacity sometime in the near future in relation to the matter
 - Involve as far as reasonably practicable encourage and permit the person to participate
 - Do not discriminate; do not base the decision solely on age, appearance, behaviour or condition
 - Discussed all alternatives
- Final decision reached.
- If this information is documented on a written rather than a computer record, it must be signed, dated and timed.

Deprivation of Liberty Safeguards

The safeguards should ensure that a care home or hospital only deprives someone of their liberty when it is in the person's best interests and there is no other, less restrictive way to look after them available. The safeguards apply to people aged 18 or over who have a mental disorder (this includes dementia), who are in hospitals or care homes and do not have the mental capacity to consent to their accommodation.

A deprivation of liberty occurs when the person is under continuous supervision and control and not free to leave and the person lacks capacity to consent to these arrangements.

The key rights under the safeguards are:

- to provide the person with a representative and sometimes an Independent Mental Capacity Advocate (IMCA) as well.
- to give the person (and their representative) the right to challenge a deprivation of liberty through the Court of Protection (see 'Useful organisations').
- to provide a mechanism for deprivation of liberty to be reviewed and monitored regularly.



There have been several test cases in the European Court of Human Rights and in the UK that have clarified which situations may constitute a deprivation of liberty:

- a patient being restrained in order to admit them to hospital
- staff having complete control over a patient's care or movements for a non negligible period and the person not being allowed to discharge themselves
- staff making all decisions for a patient, including choices about assessments, treatment and discharge
- staff deciding whether a patient can be released into the care of others or to live elsewhere
- staff refusing to discharge a person into the care of others

Following application for a DOLS, the decision will be taken by a local authority as to whether to apply the DOLS or not. However, an urgent DoLS authorisation can last up to 7 days without the permission of the local authority.

Independent Mental Capacity Advocates (IMCA)

IMCAs are statutory advocates introduced by the Mental Capacity Act 2005 (the Act). The Act gives some people who lack capacity a right to receive support from an IMCA. IMCA services are provided by organisations that are independent from the NHS and local authorities.

Where eligibility criteria are met, staff have a duty under the Mental Capacity Act to instruct an IMCA. In particular, a referral should be considered where a decision is being made about serious medical treatment and there is a fine balance between risks and benefits, a choice of treatments or if the treatment proposed may involve serious consequences (such as serious and prolonged pain, distress, side effects, major consequences for the patient or serious impact on future life choices). One example of a serious medical treatment given in the Mental Capacity Act Code of Practice is a treatment which will result in permanent loss of sight (para 10.45).

Making a Referral

IMCA services are commissioned locally. In order to identify the correct IMCA service, visit the following web page:

http://www.scie.org.uk/mca/imca/dotp://www.voiceability.org/support-for-you/independentmental-capacity-advocacy

This web page has a search facility that enables identification of the correct local service. The service should be contacted by telephone to arrange the referral, and full documentation of the process must be kept.

Specific Situations

Minor Procedures

Prior to a minor procedure taking place, a consent form for minor procedures/invasive procedures must be completed.



8. Monitoring Compliance

How implementation and ongoing compliance is to be monitored, including standards and key indicators

Aspects of compliance or effectiveness being monitored	Monitoring Method	Responsibility for Monitoring	Frequency of Monitoring	Group/Committee to review findings and monitor completion of action plan
Training compliance	Review of clinicians training records	Human Resources	Monthly	QMC
Consent documentation	Audit	Service Manager/ Theatre Lead – quality assured by Governance Leads	Monthly	QMC



9. Equality Impact Assessment

		Yes/No	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
а	• Gender.	No	
b	• Marital Status (including Civil Partnership),	No	
С	 Gender Reassignment, 	No	
d	 Disability including Learning Disabilities, Physical Disabilities, Sensory Impairment, Mental Health Problems, 	No	
е	Race, Nationality or Culture,	No	
f	• Age,	No	
g	 Sexual Orientation (including Lesbian Gay or Bisexual People), 	No	
h	Religion or Belief,	No	
i	Trade Union Membership,	No	
j	 Pregnancy or Maternity, 	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	



Appendix I – Capacity Assessment and Part B: Best Interests Check List Consent decision for an interventional procedure.

(Mental Capacity Act 2005)

The Mental Capacity Assessment (Part A) is to be used to record the mental capacity assessment when there is a concern a patient may not be able to make a decision. It must be completed by the relevant Decision Maker. If it is assessed that the person lacks capacity, the Decision Maker should then use the Best Interests Check List (Part B). The Best Interests Check List can only be used once it has been established that a person lacks the mental capacity to consent. If as a result of a Mental Capacity Assessment, the decision is made that the patient HAS mental capacity, the Best Interests Check List does not apply and cannot be completed. Instead, the patient will give or refuse consent.

The Decision Maker is responsible for assessing the capacity of the relevant person and then for making the decision in his/her best interests, following consultation and discussions with the relevant people (see below). In determining best interests, the Decision Maker must not make assumptions based on the person's age, appearance, condition or behaviour.

Name o	of the patient:				Name of the decision maker:	
Date of	birth:				NHS number:	
Has the	person given consent to th	e assessme	ent:		Yes 🗆 No 🗆	
If the ar	nswer is no please do not cor	ntinue and	refer p	atient	back to their GP	
Decision	n required to consent to a tr	reatment/	proced	ure:	Who is concerne person lacks capa make the decisio the reason for th concern?	acity to n, what is
	PART A: MENTAL CAPAC ASSESSMENT Impairment test	ITY	YES/N	0	Information/evic	lence obtained
1	Does the person have an impairment of or disturb the functioning of their n brain?	ance in	Yes □ No □		If yes, what is the they have a form	e evidence for this? Do al diagnosis?
2	Т	uctuating emporary ermanent		No □	better to delay th	uctuating, would it be ne mental capacity n their condition
3	Does the person understa relevant information abou decision to be made?		Yes □		What was that inf and how was it co	ormation you provided– nveyed?



	PART A: MENTAL CAPACITY ASSESSMENT Impairment test	YES/I	NO	Information/evidence obtained
4	Can the person retain the relevant information long enough to make the decision?	Yes 🗆	No 🗆	
5	Can the person use or weigh the information as part of the decision- making process?		No 🗆	Please make comments to support your answer:
6	Can the person communicate their decision by any means?	Yes 🗆	No 🗆	Can the person use gestures, writing etc other than verbal, to express their wishes?
7	If the answer is no to one of the questions 4,5,6, or 7 this must be because of an impairment of, or a disturbance in the functioning of, the mind or brain.			Explain the causal link between the person being unable to do 4, 5, 6 or 7 and the impairment or disturbance identified in box 1
	Outcome of Assessment			
9	Have there been any additional actions taken to help with communication?	Yes 🗆	No 🗆	Examples such as video, interpreters, sign language
10	Details of any specialist support sought in making this assessment e.g. GP, elderly care consultants, psychiatrists etc	Yes 🗆	No 🗆	
11	Does the assessment indicate that the person lacks capacity to make the decision to have the interventional procedure in question at the relevant time?	Yes 🗆	No 🗆	If the person lacks capacity to make the decision to have the interventional procedure, then a BEST INTERESTS ASSESSMENT is required – complete section B
Date of assessment:				cation of sessment:
Signatu Decisior	re of n Maker:		Pri	nt name:
Job title	::			ntact tails:



PART B: BEST INTERESTS ASSESSMENT

The following people should be consulted when determining best interests:

- Anyone named by the person as someone to be consulted on the matter in question
- Anyone engaged in caring for the person
- Anyone with an interest in the person's welfare including close relatives
- Anyone who has been given a Lasting Power of Attorney by the person
- A deputy appointed for the person by the Court of Protection

(NB A deputy or Lasting Power of Attorney for finance must be consulted but do not have the authority over the decision for treatment. A Lasting Power of Attorney or deputy for Health and Welfare may have authority over the decision for treatment). Check it is valid and registered by using form OPG100 (available from <u>www.gov.uk</u>) to undertake a free search of the official register.

	PART B	YES/NO	Information/evidence obtained
1	Does the person have a valid Lasting Power of Attorney or deputy for Health and Welfare who has the authority to make the decision?	Yes 🗆 No 🗆	If yes, the person holding the LPA or Deputy is the decision maker. They must give permission for the treatment/intervention. You must record that you have seen the document and that it has been validated.
2	If the decision is for medical treatment, has the person made an Advance Decision to refuse this treatment?	Yes 🗆 No 🗆	Assess and document validity and applicability to this treatment.
3	Is it likely that the person will regain capacity in relation to the decision to have the interventional procedure/ examination?	Yes □ No □	If YES, can the decision wait until the person regains capacity? Yes D NO D If YES, and it is reasonable to wait, you must do so. If NO, proceed to Questions 4 onwards
4	How has the person been helped to participate in the decision- making process as fully as is possible?	Yes 🗆 No 🗆	
5	 With regard to this decision, please ascertain (as far as possible) the patient's: Past & present wishes & feelings including written statements Beliefs and values Other factors which they may wish to be considered 	Include a describe	any records of statements made, wishes d etc.
6	 Have you consulted with: Those named by the person or interested in their welfare such as family or friends Carers Attorney/Deputy Others interested in their welfare i.e. GP 	Yes 🗆 No 🗆	Give details as to who has been consulted and what was said.



	PART B	YES/NO	Information/evidence obtained			
7	Serious Medical Treatment case only- If the person has no appropriate person (i.e., family/friend) for you to consult with have you involved the IMCA service?	Yes □ No □	Date of initial contact: Name of IMCA advocate:			
8		Yes □ No □				
9	Have you avoided discrimination and not made assumptions on the basis of the patient's age, appearance, condition or behaviour?	Yes □ No □				
10	Have you discussed any less restrictive alternatives? If not, why not?	Yes □ No □	If yes please document alternative			
Please do	Please document conclusion of the Best Interest Assessment					
Date of assessme	nt:		Location of assessment:			
Signature Decision I			Print name:			
Job title:			Contact details:			

