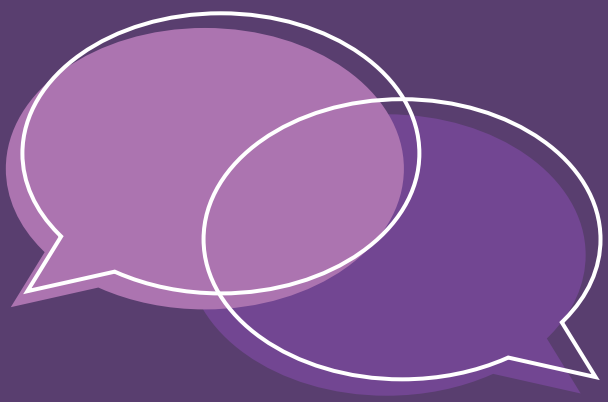
Ethics Toolkit

Consent and refusal by adults with decision-making capacity



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BMA Medical ethics and human rights

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Contents

About this toolkit

Consent is required from adult patients with capacity any time a doctor wishes to initiate any examination, treatment, or intervention. This toolkit provides practical guidance for doctors about the consent process, and the steps that should be followed in order to obtain valid consent from adult patients. It is designed to answer key questions that doctors may have and includes different sections that relate to specific aspects of consent, such as sharing information with patients, consent in emergency situations, and consent for research.

Each section is intended to stand alone, although there are some areas of overlap. The toolkit is not intended to provide definitive guidance on all issues surrounding consent. It is designed to act as a prompt to doctors to aid reflection and decision making, and to raise awareness of the ethical and legal principles that apply.

This toolkit applies to the UK, and specifies where the law differs in either England, Wales, Scotland, or Northern Ireland. It applies only to those aged 18 or over in England, Wales, and Northern Ireland and 16 and over in Scotland. For information on treatment decisions for children and young people (0-18) see our children and young people toolkit. It also only applies to adults who have the capacity to give consent. For more information on treating adults who lack capacity, including our toolkit on best interests decision making, see our separate guidance.

This Toolkit is available on the BMA's website. Individual healthcare professionals, Trusts, Health Boards and medical schools may download it and make copies.

The BMA would welcome feedback on the usefulness of the toolkit. If you have any comments, please address them to:

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1 Introduction to consent and refusal

This guidance applies across the UK, and specifies where the law differs between nations. It applies only to adults who have the capacity required to give or withhold consent - that is, those aged 18 or over in England, Wales, and Northern Ireland and 16 or over in Scotland. For information on decision making for children and young people (aged under 18, in England, Wales, and Northern Ireland, and under 16 in Scotland), and on adults who lack capacity, see our separate guidance (see key resources).

When is it necessary to seek patient consent?

Doctors must obtain consent from patients who have the capacity to give it any time they wish to initiate an examination, treatment, or any other intervention. They must also seek consent when involving patients or volunteers in teaching or research (see sections 9 and 10).

The only exceptions to this are in emergencies where it is not possible to obtain consent (see section 7), or when the law prescribes otherwise, such as when compulsory treatment for a patient's psychiatric disorder is authorised by mental health legislation (see section 8). (Mental health legislation cannot authorise non-consensual treatment for physical conditions that are not directly related to a psychiatric disorder.)

Proceeding with treatment without valid consent may put the patient at risk of harm. It also leaves the doctor who is carrying out the procedure and, where different, the doctor who sought consent at risk of criticism and, potentially, legal and/or regulatory sanctions.

What is required for consent to be considered valid?

In order for consent to be valid, patients must:

- have the capacity to make the decision;
- have been offered sufficient information to make an informed decision;
- be acting voluntarily and free from undue pressure; and
- be aware that they can refuse.

How should consent be obtained?

Consent can be explicit or implied. Explicit or express consent is when a person actively agrees, either orally or in writing. Implied consent is when consent is signalled by the behaviour of a patient, for example by opening their mouth to allow a doctor to examine their throat. This is not a lesser form of consent, provided the patient genuinely knows and understands what is being proposed and is aware that they have the option to refuse.

The General Medical Council (GMC) at paragraph 5 of its guidance *Decision making and consent,* advises that doctors can apply their own professional judgement about the most appropriate way to seek consent which will be dependent on the specific circumstances of each decision, including:

'a. the nature and severity of the patient's condition and how quickly the decision must be made
b. the complexity of the decision, the number of available options and the level of risk or degree of uncertainty associated with any of them
c. the impact of the potential outcome on the patient's individual circumstances
d. what you already know about the patient, and what they already know about their condition and the potential options for treating or managing it
e. the nature of the consultation.'

1

The GMC also advises, at paragraph 7, that whilst it would be reasonable for a doctor to rely on a patient's non-verbal consent even for some routine, quick, minimally or non-invasive interventions, doctors should still:

'a. explain what is going to be done and why
b. make clear the patient can say no, and stop immediately if they do
c. be alert for any sign that the patient may be confused or unhappy about what you are doing.'

Can family members give consent on behalf of an adult patient with capacity?

No. Family members do not have the legal authority to give consent on behalf of an adult patient with capacity. Where the patient has appointed a family member as a health and welfare attorney to make decisions on their behalf (see section 6) this only comes into force when the patient loses capacity.

Does consent always need to be in writing?

No. Written consent is only legally required for a small number of treatments (such as some forms of fertility treatment), it is often advised in other circumstances, particularly where the procedure is very invasive or entails more than minimal risks. Doctors should familiarise themselves with the latest clinical guidance in their area of practice. Consent forms can be used to document that discussions about the procedure have taken place. However, consent forms are evidence of the consent process, rather than consent itself; a patient genuinely understanding what is being proposed is more important than how consent is recorded.

What should be recorded in a patient's medical records?

Details of the discussions that have taken place with a patient, and any other relevant people, should be recorded in the patient's medical records. This should usually include discussions about the treatment options, including potential harms and benefits of any treatment, any specific concerns the patient had and any other information that was given to them.

How long is consent valid for?

Consent should be a continuing process, rather than a one-off decision. Patients can change their mind about treatment at any time. Before beginning any treatment, doctors should check that the patient still consents. This is particularly important if:

- a significant length of time has passed since the patient agreed to the treatment;
- there is new information available;
- there have been any significant changes to the patient's condition; or
- the process of seeking consent had been delegated to a colleague.

It is important that patients are given continuing opportunities to ask further questions and to review their decisions and are kept informed about the progress of their treatment or care.

1

Can a competent patient refuse treatment?

Yes. Competent adult patients are entitled to refuse treatment, even if that will result in their death or serious harm (see section 5 and for 16 and 17 year olds see our separate guidance on children and young people - see key resources). The only exception to this is where the law prescribes otherwise, such as when compulsory treatment for the patient's psychiatric disorder is authorised by mental health legislation (see section 8).

Do I have to provide treatment which I do not think is clinically appropriate for the patient?

If a patient asks for treatment that you do not think would be clinically appropriate for them, you should discuss their reasons for requesting it with them. Any significant factors for the patient should be explored further, including non-clinical factors such as their beliefs or views. Following this, if you still consider that the treatment is not clinically appropriate, you do not have to provide it. However, the reasons for this should be explained clearly to the patient, as well as other options available to them, including seeking a second opinion.

What consent should be sought when a healthcare professional has suffered a needlestick injury or other occupational exposure to a patient's blood or bodily fluid?

If they have capacity, consent should be sought from the patient to test them, or an existing sample, for serious communicable diseases. If the patient refuses to consent no test should be carried out. For information on testing of patients who lack capacity in the event of a needlestick injury, see the BMA's separate guidance on needlestick injuries.

Key resources

BMA – Adults with incapacity Scotland toolkit
BMA – Children and young people toolkit
BMA – Mental Capacity Act toolkit
BMA – Mental capacity in Northern Ireland toolkit
Department of Health and Social Care (DHSC) – Reference guide to consent for examination or treatment
GMC – Decision making and consent

2

Capacity to consent

Are adults presumed to have capacity to consent?

Yes. It is a fundamental principle of the law in the UK that adults have the right to make decisions on their own behalf and are assumed to have the capacity to do so. This means that it is never for an adult to prove their own capacity. Where a person intends to take steps on the basis that an adult lacks capacity to make the relevant decision, that person must be able to explain why they consider that they are allowed to do so, including why the adult can be said to lack capacity.

You must not assume that a patient lacks capacity because they are suffering from a mental disorder or impairment, or any medical condition or disability, because of their age, appearance or views, or because you consider the decision to be unwise or irrational. If, however, their decision is clearly contrary to previously expressed wishes, or based on a misperception of reality, this may be indicative of a lack of capacity and should be investigated further.

You must not assume that because a patient lacks capacity to make a decision on a particular occasion, they lack the capacity to make a decision at any other time. Some patients may also have capacity to make some decisions about their healthcare but not others; the difficulty, complexity, or seriousness of the decision should be one of the factors taken into account when assessing the individual's capacity to make that decision. More information about assessing capacity can be found in our mental capacity guidance (see key resources).

It is important to note that despite the presumption of capacity from the age of 16, the situation regarding refusal of treatment is different for 16 and 17-year olds. For information about decision making by and on behalf of those aged 16 or 17, see our guidance on children and young people (see key resources).

How should I assess whether someone has the capacity to consent?

Where there are grounds to question whether the patient has the capacity to make the decision in question, an assessment is required. This is a matter for clinical judgement, guided by professional practice and subject to legal requirements.

To demonstrate capacity to consent to treatment, individuals should be able to:

- understand the information relevant to the decision;
- retain the information relevant to the decision;
- use or weigh the information; and
- communicate the decision (by any means).

In England, Wales, and Northern Ireland, a person lacks capacity if their inability to do these things is caused by an impairment or disturbance in the functioning of the mind or brain.

2

What should I do if I suspect that a patient lacks capacity?

For information on how to proceed where there are grounds to doubt a patient's capacity, healthcare professionals should refer to our guidance on mental capacity (see key resources).

Key resources

BMA – Mental Capacity Act toolkit
BMA – Adults with incapacity Scotland toolkit
BMA – Mental capacity in Northern Ireland toolkit
BMA – Children and young people toolkit

3

Sharing information with patients

What information should I share with patients to obtain their consent?

For patients to make decisions about their treatment and provide valid consent, doctors need to provide them with sufficient, clear and accurate information about any proposed course of action or treatment option. This includes information about:

- the purpose of the investigation or treatment;
- details and uncertainties of the diagnosis;
- options for treatment, including the option of no treatment;
- likely benefits and probabilities of success for each option;
- risks and potential side-effects, and adverse outcomes including the treatment not working;
- the name of the doctor with overall responsibility for their care;
- a reminder that a patient can change their mind about having the treatment at any time;
- reasons for any recommended treatment options; and
- if relevant, any foreseeable problems that could come to light while the patient is unconscious.

The discussions you have with patients should be tailored according to the nature and complexity of the proposed course of action, and the level of risk associated with it. They should also be tailored according to the individual concerns, wishes, and values of each patient and their understanding of their condition and prognosis. For example, if the proposed treatment carries a potential risk of harm that you believe the patient would consider to be serious in their circumstances, you must tell the patient, even if you think it is very unlikely to occur. You should also tell patients about less serious side-effects or complications if they occur frequently, or if you think the patient may attach particular significance to them.

In March 2015, the UK Supreme Court (*Montgomery v Lanarkshire Health Board*) clarified that doctors must '*take reasonable care to ensure that the patient is aware of any material risks involved in any treatment, and of any reasonable alternative or variant treatments*'. A 'material risk' is one in which '*a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it*'.

Although this reflects existing good practice, it is a significant judgment in that it means that doctors can no longer rely on the support of a responsible body of medical opinion ('the Bolam test') in deciding what information they should provide to patients. Instead, they must provide information about any risk to which the individual patient would attach significance.

When seeking consent, doctors therefore need to ask themselves the following questions.

- Is the patient aware of any risks relevant to their decision regarding the proposed treatment?
- Is the patient aware of any reasonable alternatives and their associated risks and benefits?
- Have I taken all reasonable measures to ensure that I have presented this information in a form the patient understands?
- Is the patient aware that they can refuse to have the treatment?

3

In July 2023, the Supreme Court in McCulloch v Forth Valley Health Board clarified the meaning of the words '*reasonable alternative or variant treatments*' in *Montgomery v Lanarkshire Health Board*. The Court was asked to determine whether a particular treatment is a '*reasonable alternative*' is a matter of professional skill and judgement to be assessed by applying the professional practice test, in other words, the '*Bolam test*', or whether it is a matter to be determined by reference to the circumstances, objectives, and values of the individual patient.

The Court unanimously held that whether a treatment is a reasonable alternative is to be determined by the application of the Bolam test.

The Court confirmed that:

- a doctor cannot simply inform a patient about the treatment option or options that they prefer;
- once a range of reasonable treatments have been identified, absent any indication from the patient to the contrary, the doctor must explain all of those alternatives (and the risks involved) to the patient. However, a doctor is not obliged to tell a patient about treatments which the doctor does not consider to be reasonable - to be judged by applying the Bolam test; and
- a doctor is not obliged to tell a patient about treatments that the doctor does not consider reasonable (applying the Bolam test) even where the doctor is aware of an alternative body of opinion which considers the treatment to be reasonable.

Should I withhold any information?

No. You should not withhold any information the patient needs to make a decision, including when a relative or carer asks you to. Failure to provide sufficient relevant information could be challenged in law.

There is some limited scope for doctors to withhold information where they have a reasonable belief that providing the information would cause the patient serious harm. In the case of Montgomery, the Supreme Court made clear, however, that this exception should not be abused; it is designed to protect patients from serious harm, not to prevent them from making a choice the doctor considers to be contrary to their best interests.

In some circumstances it may be appropriate to provide relevant information over a period of time, rather than providing it all at the same time. In such cases it should be clear from the medical record what information has already been shared, what information still needs to be shared, why some information was withheld and when and how the patient will be provided with it.

How should I share information with patients?

The GMC emphasises the importance of listening to patients and a shared decision-making process. In this process, the information your patients share with you, is as important as the information you give them.

3

Patients should be involved as much as possible in decisions about their own health and care, and should be given information about their treatment options in a way that they can understand. Doctors should take all reasonable steps to maximise patients' ability to understand, consider options and make a decision. This includes:

- taking time to understand the patient's values, wishes, preferences, and knowledge of their own condition;
- using clear and consistent language when discussing risks of harm and potential benefits;
- encouraging patients to ask questions;
- supporting patients with additional needs to have the time and any reasonable adjustments to make a decision;
- offering a record of your discussions if the patient may have difficulty retaining information;
- giving the patient time to reflect, before and after they make a decision;
- where appropriate, involving other members of the healthcare team in discussions;
- giving information that the patient may find distressing in a considerate way;
- sharing information at a time and place when you think the patient is most likely to be able to understand and retain it;
- supporting discussions with accurate written material, or visual or other aids;
- providing the opportunity for patients to discuss their options with others; and
- considering whether the patient might need more time with you or the healthcare team.

Before making a decision, you must check that your patients have understood the information they have been given and the language that you have used, or whether they need any more support to make a decision. You should ensure the patient is aware of any time limit on making their decision.

How should I answer any questions my patients may have?

Doctors should respond honestly and accurately to any questions patients may ask them. This includes discussing the nature and extent of any uncertainty regarding the clinical effect of a particular intervention.

If you are unable to answer a question, where possible you should find out the answer by consulting another professional or resource – or explain to the patient if there is an inherent uncertainty.

What if a patient does not want to know the information?

If a competent patient does not want to know the information, or make a decision, about their treatment, you should try to find out why and whether you can do anything to support them. Ultimately, however, patients retain the right not to be informed of the risks of a procedure – if a patient does not want to know, doctors are under no obligation to tell them.

Nevertheless, a minimum amount of basic information may need to be given in order for consent to be considered valid. Without basic information, patients may be unable to make a valid choice to delegate responsibility for treatment decisions to doctors. The amount of basic information needed depends upon the individual circumstances, the severity of the condition and the risks associated with the treatment.

3

You should explain why it is important for them to make an informed decision, and the potential consequences of them choosing not to receive information including, in some circumstances, being unable to proceed with the treatment.

Patients who refuse information should be advised that information can be provided at any time, should they change their mind, and a note should be made on the medical record that the patient has refused information.

What if I am not able to share information sufficiently, due to time and resource constraints?

If you are not able to share information sufficiently with your patients, because of pressures on your time or limited resources, you should consider the role of other members of the healthcare team in assisting you (see section 4). This might involve them gathering information and answering questions on your behalf. You should also consider other sources of information that are available such as patient information leaflets or support groups.

If there are factors outside your control which are compromising your patients' ability to make informed decisions, you should raise these concerns with your employer. Patients need to be given sufficient information for their consent to be valid.

Key resources

DHSC – Reference guide to consent
GMC – Decision making and consent

4 Who is responsible for seeking consent?

Whose responsibility is it to seek consent?

Clinical, legal and professional responsibility for ensuring that valid consent has been obtained before treatment is provided rests with the person carrying out the procedure. In some circumstances this may be delegated to a colleague, provided that person has the necessary knowledge, skills, and experience.

The GMC is clear that the doctor undertaking an investigation or providing treatment, is responsible for ensuring they have valid consent or other authority before commencing the procedure or treatment.

Part of the consent process may be delegated to other members of the team, but the doctor carrying out the treatment must be sure the person they are delegating to:

- is suitably trained and qualified;
- has sufficient knowledge and skills; and
- feels competent to carry out the tasks requested.

Your decision about whether delegating is appropriate should depend on the complexity of the intervention, the level of uncertainty surrounding the outcome, your relationship to the patient and any concerns the patient may have. If you are the doctor being delegated to, you must make sure you have sufficient knowledge and expertise to obtain consent from the patient.

What if I am asked to seek consent but do not feel competent to do so?

It is your responsibility to ensure you have sufficient knowledge and expertise to provide information, answer questions, and seek consent for common procedures in the specialty within which you are working. If, in a particular case however, you do not feel that you have sufficient information or expertise to comply with the request, you should inform the person who will be carrying out the procedure. You should not comply with a request to seek consent if, having raised these concerns, appropriate support is not provided.

What if the person I ask to seek consent raises concerns about doing so?

If you are informed by the individual tasked with seeking consent that they do not have the necessary knowledge or skills to comply with the request, you must ensure that support is provided, or make alternative arrangements, to ensure that valid consent is obtained.

If you delegate responsibility for seeking consent to someone who does not have the necessary knowledge and skills, you must accept overall responsibility for any failings in the consent process.

Key resources

DHSC – Reference guide to consent
GMC – Decision making and consent

5

Refusal of consent

Can patients refuse to consent to treatment?

Yes. Competent adult patients can refuse to consent to any treatment except where compulsory treatment for the patient's psychiatric disorder is authorised by mental health legislation (see section 8). The situation is different for patients under the age of 18; for more information on this see the BMA's guidance on children and young people (see key resources).

Doctors must respect a patient's decision to refuse treatment, even if they do not agree with it or when it could lead to permanent injury or death. For example, a Jehovah's Witness can refuse a blood transfusion even where this is essential for survival. Providing treatment without valid consent, and in the face of a competent refusal, would leave the doctor open to legal and professional sanctions.

A refusal of treatment should not be interpreted as a refusal of all treatment or care. It is essential that steps are taken to keep the patient comfortable and that any symptoms or distress are appropriately managed.

Can patients refuse food and fluids?

Yes. Competent adult patients can refuse food and fluids – whether provided orally or by tube (clinically-assisted) – and such refusals must be respected. It should be made clear to such patients, however, that they can change their minds and accept food and/or fluids at any time.

Whilst a valid and applicable advance decision to refuse clinically-assisted nutrition and hydration will be legally binding once a patient loses capacity (see section 6), an advance refusal of oral feeding (which forms part of 'basic care') will not be. Oral feeding should continue to be offered to, but not forced upon, all patients who are capable of swallowing safely.

Do patients need to justify their decision to refuse consent?

No. Patients are not required to justify their decision to refuse consent, but healthcare professionals should seek to ensure that patients base their decisions on accurate information and that they have corrected any misunderstandings. Patients also need to know if refusing treatment now will limit their future options.

Doctors must not put pressure on patients to decide in a particular way, but should allow them time to consider a decision with potentially serious consequences.

Key resources

BMA – Children and young people toolkit

6

Advance care planning

Can a patient plan for future treatment once capacity is lost?

Yes. It is a good idea to encourage patients to think about what they would want to happen in the future if they are unable to express views about treatment for themselves. This is particularly important where loss of capacity is a foreseeable possibility, or where the patient may find it difficult to make decisions in the future. It is also useful for patients to consider these issues in circumstances where decisions may need to be made quickly at a later stage, or when they have a condition that will affect the length or quality of their life.

Doctors should take all reasonable steps to plan for foreseeable changes in a patient's capacity to make a decision, and help patients to make decisions at a time when they are able to do so. They should encourage patients to think about what they might want in the event of different outcomes, and to discuss this with the healthcare team and those close to them. These discussions should cover:

- the patient's wishes, concerns or personal beliefs in relation to their future care;
- any treatments they would want provided, or to refuse, and under what circumstances; and
- any interventions that might become necessary during an emergency.

Doctors must record the discussions in the patient's medical record and document any views or decisions the patient expresses.

Can patients request treatment in advance?

Advance requests for treatment are not legally binding, but they should be taken into account in assessing whether the treatment would be in the patient's best interests. It is, however, part of a doctor's duty of care to take reasonable steps to keep a patient alive where that is the patient's known wish (*R (on the application of Burke) v General Medical Council* (2005)).

Can patients refuse treatment in advance?

Yes. If a patient has clear views about treatments they would want to refuse, and the circumstances in which they would want to refuse them, they should be informed of the possibility of making a formal advance decision to refuse treatment (ADRT), known as an advance statement in Scotland. For more information see our mental capacity guidance (see key resources).

Can patients appoint someone to make decisions on their behalf?

Another option for patients who wish to plan for a future loss of capacity is to formally appoint someone as an attorney with the power to make health and care decisions on their behalf (in England and Wales these are called lasting powers of attorney or LPAs and in Scotland they are called welfare attorneys). In England, Wales, and Scotland, where the appropriate process has been followed, the attorney will be the lawful decision maker. Currently, in Northern Ireland, nobody can give consent on behalf of an adult who lacks capacity.

6

More information is available in our separate guidance on mental capacity (see key resources).

Key resources

BMA – Adults with incapacity Scotland toolkit
BMA – Mental Capacity Act toolkit
BMA – Mental capacity in Northern Ireland toolkit
DHNI – For now and the future. An advance care planning policy for adults in Northern Ireland
NHS England – Universal principles for advance care planning
NHS Wales – Advance and future care plans
Scottish Government – Anticipatory care planning

7

Consent for emergency treatment

Does consent need to be sought for emergency treatment?

Yes, if the patient has the capacity to give consent.

If the patient is unable to give consent, can treatment be provided in an emergency situation?

In an emergency, where consent cannot be obtained, doctors should provide treatment that is immediately necessary either to preserve life or to prevent a serious deterioration in the patient's condition. The only exception to this is where there is clear evidence of a valid and applicable advance decision to refuse the treatment in question.

In England, Wales, and Northern Ireland, emergency treatment does not have to be restricted to what is immediately necessary. It can also include steps that are in the patient's best interests to prevent deterioration in order to ensure that recovery is an option. It is unclear, however, how far the principle of necessity applies in Scotland and so a section 47 certificate of incapacity should be issued as soon as possible. For more information, see the BMA's guidance on mental capacity (see key resources).

Where decisions can reasonably be delayed until such time as the adult is likely to regain capacity, or to permit an assessment of capacity and discussion with those close to the patient, then they should be.

Key resources

BMA – Mental Capacity Act toolkit
BMA – Adults with incapacity Scotland toolkit
BMA – Mental capacity in Northern Ireland toolkit
GMC – Decision making and consent

8

Compulsory treatment under mental health legislation

Can treatment be provided to a patient without seeking consent if they are detained under mental health legislation?

Mental health legislation permits doctors to treat a patient compulsorily for a mental illness, without their consent. This includes treatment for physical conditions arising directly from a psychiatric condition such as forced re-nutrition in patients with anorexia nervosa or treating wounds self-inflicted as the result of a mental disorder. However, it is still good practice to explain to the patient the treatment that will be provided, and where possible, to seek their agreement.

Compulsory treatment can only be authorised under mental health legislation if it is treatment for the mental illness and the legislation specifically excludes imposing treatments for other physical conditions. Consent is still, therefore, required for other forms of treatment, even if the patient is detained under mental health legislation.

Legislation has been passed in Northern Ireland that will remove the ability to provide compulsory treatment for mental disorders for patients who have capacity; these provisions have not yet come into force.

Are advance decisions overruled when a patient is detained under mental health legislation?

Advance decisions can be overruled if the individual is being treated compulsorily under mental health legislation, with regards to treatment for a mental illness. A valid and applicable refusal of treatment for conditions that are not covered by the mental health legislation will still be binding.

Key resources

GMC – Making decisions and consent

9

Consent for research

Is separate consent required for research procedures?

Yes. Doctors must ensure that patients asked to consider taking part in research are given clear information, presented in a way they can understand. Patients should be made aware that they are being asked to take part in a research project and that the results are not predictable. Adequate time must be given for reflection prior to the patient giving consent. Where patients do not wish to receive full information about the research, this may affect the doctor's decision to involve them.

What information should be provided to obtain valid consent to participate in research?

Information should preferably be provided in writing and should be approved in advance by a research ethics committee. It should include:

- the purpose of the research and what it involves;
- information about research-related procedures – particularly invasive procedures;
- the probability of random allocation to treatment, if appropriate;
- the fact that patients can withdraw from the research at any time, without penalty or any adverse effect on the care they receive (but that once data or samples have been anonymised, it will no longer be possible to withdraw consent for their use);
- any financial arrangements in place, such as for covering patients' expenses and compensation in the event of trial-related injury;
- information about confidentiality and the possibility of access to confidential notes by third parties (such as regulatory authorities, auditors, or ethics committees); and
- what, if any, information they can expect to receive about the research findings and conclusions.

Is consent required for the use of human tissue for research?

Under the Human Tissue Act 2004 (England, Wales, and Northern Ireland) if the samples are anonymised and the research has been approved by a research ethics committee, consent is not required. In other circumstances, consent must be obtained and documented before the storage and use of a living person's organs, tissues, or cells, for the purpose of research. In addition, where the intention is to perform DNA analysis, the Act's requirement for consent extends to Scotland.

The Human Tissue (Scotland) Act 2006 does not cover the use of tissue from living individuals. Research ethics committees may, however, require consent to be obtained where the tissue is used in identifiable form.

Key resources

GMC – Good practice in research
GMC – Consent to research

10 Consent for teaching purposes

Is it necessary to seek a patient's consent for medical students or other observers to be present during a consultation or treatment?

Yes. The doctor carrying out the consultation should explain to the patient that an observer would like to sit in on the consultation, who that person is and why they would like to observe. Patients should feel able to say no, knowing that it will not impact on their treatment in any way.

Wherever possible, patients should be given the option of considering the request before the arrival of the observers.

Is specific consent required to teach practical procedures on a patient who has been anaesthetised?

Yes. Before any anaesthetic is given, specific consent must be obtained from the patient to carry out any practical procedures on them for teaching purposes.

Is it necessary to seek consent from patients for the use of visual and audio recordings of procedures, for teaching purposes?

Yes. Doctors must obtain consent from the patient prior to a recording being made and for its subsequent use for teaching purposes.

Patients may withdraw their consent to the use of visual and audio recordings for teaching purposes at any time. If they do so, the recordings must be erased.

What type of consent is required for the use of human tissue for educational purposes?

Consent is not required for the storage and use of material from living individuals for teaching purposes, provided it is anonymised. The use of identifiable samples for teaching requires consent.

Key resources

GMC – Making and using visual and audio recordings of patients

British Medical Association
BMA House, Tavistock Square,
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BMA 20230628