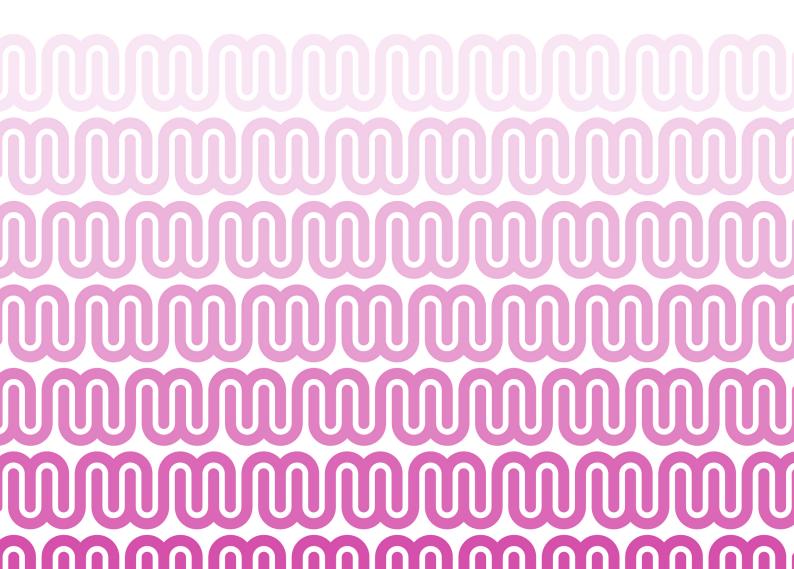


Consent to treatment

Good practice guides

July 2024



Our mission and purpose

Our Mission

To be a leading and independent voice in promoting a society where people with mental illness, learning disabilities, dementia and related conditions are treated fairly, have their rights respected, and have appropriate support to live the life of their choice.

Our Purpose

We protect and promote the human rights of people with mental illness, learning disabilities, dementia and related conditions.

Our Priorities

To achieve our mission and purpose over the next three years we have identified four strategic priorities.

- To challenge and to promote change
- Focus on the most vulnerable
- Increase our impact (in the work that we do)
- Improve our efficiency and effectiveness

Our Activity

- Influencing and empowering
- Visiting individuals
- Monitoring the law
- Investigations and casework
- Information and advice

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Introduction

This is a guide to good practice in relation to consent to treatment for mental disorder.

It is written to help mental health practitioners, but will also be of interest to service users, carers, and independent advocates. The main aim of the guide is to examine issues of consent, particularly in regard to the Mental Health (Care and Treatment) (Scotland) Act 2003 (Mental Health Act). The guide also covers treatment for mental disorder where the person is not subject to the Mental Health Act but where the Adults with Incapacity (Scotland) Act 2000 (AWI Act) applies. We hope that it will help practitioners to interpret the legal basis for treatment and to give treatment in line with best legal and ethical practice.

We are restricting the scope of this guidance to people aged 16 or over. Issues of consent and capacity for those under 16 are covered in other guidance. We do, however, refer to some of the provisions of the Mental Health Act in relation to people under the age of 18, which includes those under the age of 16.

This guidance should not be taken as legal advice. While we quote from the law and give our interpretation of best practice, we cannot produce a guide that anticipates every possible scenario.

In some circumstances, practitioners may wish to discuss difficult cases with us and may need to consult their own legal advisors.

Legislative framework

In law, adults have the right to make decisions affecting their own life. This right does not necessarily depend on any particular form of reasoning. The reasons given for decisions may be rational, irrational, unknown or, in some cases, possibly even non-existent. There is a presumption in law in favour of capacity. A general rule is that an adult is deemed to have capacity to consent to treatment, unless there is evidence to the contrary.

Mental disorder may impair capacity to consent to treatment. In general, the presumption will still be in favour of capacity. Any person subject to compulsory treatment under civil powers of the Mental Health Act (see below) will, by definition, have or be likely to have, impaired ability to make decisions about medical treatment. Therefore, in this case, the person's capacity to consent cannot be presumed. If the person is being treated under powers for mentally disordered offenders, the test for decision-making ability does not apply.

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

The Mental Health Act is based on a set of guiding principles. Anyone "discharging functions" under the Act must take into account the:

- person's past and present wishes about their care and treatment,
- care and treatment that will be of most benefit,
- range of options available for care and treatment of the individual,
- person's individual abilities and background, and
- person's age, gender, sexual orientation, religion, racial origin or membership of any ethnic group.

People giving care and treatment should also make sure that:

- any restrictions on a person's freedom are the least necessary,
- the person being treated under the Act shouldn't be treated any less favourably than anyone else being treated for a mental illness or other mental disorder,
- the needs of carers are taken into account (other than when making a decision about medical treatment),
- the person being treated is getting services that are right for them,
- when a person is no longer receiving compulsory treatment, they should continue to get care and treatment if needed.

Detailed guidance on the operation of the Mental Health Act is contained in the <u>Code of Practice</u>.

Due consideration should be given to the need to balance the various principles in the Act where there may be competing or conflicting interests and pressures.

For medical treatment, it may be that the treatment that is likely to be of most benefit may not be in line with the views of the patient. We believe that it is important for practitioners to demonstrate how they have balanced the principles when making treatment decisions where the person lacks capacity and/or refuses treatment.

Medical treatment is broadly defined under the Mental Health Act. In addition to medication, it includes nursing, care, psychological treatments, habilitation, and rehabilitation. Part 16 of the Mental Health Act deals with medical treatment. We will consider the provisions of that part of the Act in particular.

Adults with Incapacity (Scotland) Act 2000

The AWI Act also covers treatment for mental disorder. This Act is founded on clear principles.

Principle 1: The intervention must be of benefit to the individual.

Principle 2: The intervention must be the least restrictive in relation to the person's freedom in order to achieve the desired benefit.

Principle 3: Interventions should take account of the past and present wishes of the adult.

Principle 4: Interventions should take account of the views of relevant other parties.

Principle 5: Interventions should encourage the adult to use existing skills and develop new skills.

Part 5 of the AWI Act covers medical treatment. We will examine how this Act allows for treatment for mental disorder and how it interacts with the Mental Health Act. Detailed guidance on the operation of Part 5 is contained in section 2 of the <u>Adults with incapacity:</u> code of practice for medical practitioners.

The guide draws on existing guidance, codes of practice for both sets of legislation, and relevant case law. Our duty to promote best practice, in relation to the Mental Health Act, involves promoting the principles of the Act. We also recognise the importance of the principles

of the AWI Act. We have therefore examined how the principles can be applied to difficult treatment decisions, when legal interventions are being considered.

Consent to treatment

Under normal circumstances, medical treatment needs consent. If a practitioner gives medical treatment without valid consent, they could be open to allegations of assault.

The nature of consent depends on the intervention. Some simple interventions may only need implied consent. An example would be rolling a sleeve up to allow blood pressure to be checked. Verbal consent is the rule for many forms of treatment, for example taking medication. More invasive procedures, especially when carried out under anaesthetic, need written consent.

For people subject to compulsory treatment under the Mental Health Act, the Act extends the range of treatments that need their written consent (or a certificate issued by a designated medical practitioner (DMP) to authorise the treatment).

What is valid consent?

There is general agreement that a number of aspects relate to valid consent.

Consent must be:

- given freely, without duress or coercion (see section 'Refusal, persuasion and coercion')
- given by someone who is legally capable (or competent) of consenting (see section 'Capacity, competency and impaired decision-making')
- specific and cover the intervention or procedure to be performed
- informed (the person understands what is involved) (see below)
- enduring (for treatment given over a period of time)

If any of these areas are deficient then the person may not be giving valid consent to treatment.

Information-giving and consent

The General Medical Council (GMC) has produced detailed guidance on <u>Decision making and consent</u>¹. This can be referred to for more information about provision of information for patients, decision making and consent.

The GMC says in the introduction:

"Consent is a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. The exchange of information between doctor and patient is essential to good decision making. Serious harm can result if patients are not listened to, or if they are not given the information they need - and time and support to understand it - so they can make informed decisions about their care.

Doctors must be satisfied that they have a patient's consent or other valid authority before providing treatment or care."

¹ General Medical Council, Decision making and consent guidance [online] available at https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/decision-making-and-consent [accessed 15 March 2024]

<u>Good medical practice</u>² is the GMC's core guidance on professional standards for doctors and sets out the principles, values, and standards of care and professional behaviour expected of all registered medical professionals.

The professional standards for sharing information with patients include the following:

- The exchange of information between medical professionals and patients is central to good decision making. You must give patients the information they want or need in a way they can understand. This includes information about:
 - (a) their condition(s), likely progression, and any uncertainties about diagnosis and prognosis
 - (b) the options for treating or managing the condition(s), including the option to take no action,
 - (c) the potential benefits, risks of harm, uncertainties about, and likelihood of success for each option.
- You must listen to patients and encourage an open dialogue about their health, asking
 questions to allow them to express what matters to them, and responding honestly to their
 questions.
- You must make sure that the information you give patients is clear, accurate and up to date, and based on the best available evidence.
- You should check patients' understanding of the information they've been given and do
 your best to make sure they have the time and support they need to make informed
 decisions if they are able to.
- You must take steps to meet patients' language and communication needs, so you can support them to engage in meaningful dialogue and make informed decisions about their care. The steps you take should be proportionate to the circumstances, including the patient's needs and the seriousness of their condition(s), the urgency of the situation, and the availability of resources.
- You must consider and respond to the needs of patients with impairments or disabilities.
 Not all impairments and disabilities are easy to identify so you should ask patients what support they need and offer reasonable adjustments that are proportionate to the circumstances.
- You must treat each patient as an individual. You must not rely on assumptions about the treatment options or outcomes a patient will prefer, or the factors they will consider significant.

The GMC's <u>Decision making and consent</u> guidance specifies the seven principles of decision making and consent:

- 1. All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.
- 2. Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.

² General Medical Council, Good medical practice [online] available at https://www.gmc-uk.org/professional-standards-for-doctors/good-medical-practice [accessed 15 March 2024]

- 3. All patients have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it.
- 4. Doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.
- 5. Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.
- 6. The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.
- 7. Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible.

Information must be sufficiently specific and detailed to give the person as full an understanding as possible on the nature, purpose, and likely effects of the treatment. This must include:

- What the treatment consists of. The explanation will vary depending on the person's
 ability and wish to understand. For drug treatment, this includes the type of drug, its
 main effects on the person and any additional monitoring that is needed.
 For electro-convulsive therapy (ECT), this includes a full description of the procedure,
 the way ECT is thought to act, and the fact that it is a series of treatments.
- The main beneficial effects of the treatment. This includes an estimation of the likelihood of benefit, what effects the person might experience, and how long it will take for the treatment to have effect.
- Risks and unwanted effects. The person must be warned of common side effects and any uncommon but serious adverse effects.

Clinicians must give an honest and sensitive explanation of potential serious adverse effects of treatment. In doing so, they are more likely to gain the trust of people they treat. Here are examples of how to do this.

ECT and memory loss: "You may well find that your memory is not as good as usual during a course of ECT. It might be difficult to remember things that have happened recently. Some people find gaps in their memory for the time they had the treatment. ECT should not cause any lasting damage to your memory. However, if you find that there are personal memories of the past that are more difficult to recall, please let us know straight away. We would need to stop the treatment or make a major change to the way we give it."

Antipsychotic drugs and movement disorders: "Sometimes these drugs can make it difficult for you to control your movements or make you feel restless. We think that newer drugs make this less likely, but it may still happen for a few people who take the drugs. If you feel restless and have trouble sitting still or if you, or anyone else, notice that your mouth and tongue are restless in a way they weren't before, let us know straight away. We would need to change your treatment."

Withholding information and deception

Information should not be withheld unless it is judged that the disclosure of that information would cause a patient significant harm. It has been argued that it is irresponsible to share certain information with the patient if it may have a detrimental effect³. However, withholding an essential piece of information can reduce a patient's understanding of their circumstances⁴. In situations where a medical practitioner is considering withholding information from a patient, they should refer to the GMC's guidance in Decision making and consent on "Exceptional circumstances in which you may decide not to share all relevant information".

Education tools

Using additional educational tools and support can enhance a person's capacity to consent. Lapid et al⁵ found that using video and greater time for discussion on the use of ECT enhanced people's capacity. The authors suggest that for those with a limited understanding of a treatment being recommended, educational interventions can be helpful.

Reviewing consent

It is also important to recognise that consent is not a 'one-off' procedure but something which may need to be reviewed. Most mental health treatment is an ongoing process, not a single event. There is a responsibility on the mental health team to ensure that consent is always current. For example, the GMC recommends in Decision making and consent that consent should be reviewed particularly if:

- significant time has passed since the decision was made
- the patient's condition has changed
- you have reason to believe the patient might have changed their mind
- any aspect of the chosen treatment or care has changed
- new information has become available about the potential benefits or risks of harm of any of the options that might make the patient choose differently

It is important to keep the person informed about the progress of their treatment and let them know that they can change their mind at any time.

When does the Mental Health Act require consent for treatment?

Part 16 (sections 235-248) of the Act set out the conditions under which treatment may be given to patients who are either capable or incapable of consenting to specific treatments.

For treatments that do not need special safeguards, section 242 of the Act requires either written consent from the person or, if the person does not consent or consents other than in writing, a statement as to why the treatment is in that person's best interests. The responsible medical officer (RMO) should make a clear record of the reasons for any such decision.

³ Kitamura, T. (2000) Assessment of psychiatric patients' competency to give informed consent: Legal safeguard of civil right to autonomous decision-making, *Psychiatry and Clinical Neurosciences*, 4:515-522

⁴ Peay, J. (2003) *Decisions and Dilemmas: Working with Mental Health Law*, Hart: Oxford.

⁵ Lapid, M.I., Rummans, T.A., Pankratz, V.S., & Applebaum, P.S. (2004) Decisional capacity of depressed elderly patients to consent to electroconvulsive therapy, *Journal of Geriatric Psychiatry and Neurology*, 17(1):42-46.

Where the person consents, the RMO must be satisfied that consent is valid and informed. While consent in writing is important, a signature on a consent form does not, in itself, mean that the person is giving valid and informed consent. The practitioner must be able to demonstrate how consent was obtained. It would be best practice to record this process in writing. Some treatments are subject to special safeguards. In all cases, the same basic principles governing consent apply where the person is regarded as consenting to treatment. Some of these treatments may be administered in the absence of consent. The Act and associated codes of practice cover the law in detail. Figure 1 sets out the safeguards for particular treatments.

When a person consents to treatment provided under the Act, there needs to be a clear plan of treatment. This should be discussed with the person and recorded in writing. <u>Appendix 1</u> gives guidance on treatment plans.

Mental Health Act – additional safeguards for informal children

<u>Section 244 of the Mental Health Act</u> provides additional safeguards for informal children (aged under 16) for certain treatments specified in regulations - ECT, vagus nerve stimulation, and transcranial electromagnetic stimulation. Use of these provisions is very rare. A T5 certificate is required with the patient's consent or, if they are incapable of consenting, parental consent and a certificate by a DMP. If the patient is capable of making a decision about the treatment and does not consent, it cannot be given.

Good practice points

- Ensure that you have given the person information about the treatment in a way that is appropriate to their needs and abilities.
- Consider appropriate educational media to enhance the person's understanding of the treatment.
- Allow the person appropriate time and support from others, including independent advocacy.
- Follow the GMC guidance on giving information.
- Document consent and the way in which it was obtained.
- Document any concerns the person has and any disagreement about treatment; if the
 person is not giving full informed consent to treatment, ensure that the treatment is
 properly authorised if it is given.

Capacity, competency, and impaired decision-making

Definitions of capacity

This section will focus on capacity to make treatment decisions in line with the law and not other aspects of capacity (for a full discussion on capacity see Atkinson et al⁶).

Capacity in the UK is a medico-legal term and competency is used more widely to describe general or specific areas of functioning.

Unlike capacity, which is decided legally, competency is usually a clinical decision. In the United States, however, competency is more usually the legal term, although in some places capacity is used.

There is no presumption, either in common law or in mental health legislation in Scotland, that the presence of a mental disorder automatically indicates the absence of capacity. However, capacity can be impaired by poor memory, lack of ability to process information, or poor judgement because of disorders of mood and thinking.

Capacity and "significantly impaired decision-making ability"

The Mental Health Act introduced significantly impaired decision-making ability (SIDMA). The grounds for use of civil mental health provisions of the Mental Health Act include that the person has, or it is likely that they have, SIDMA in relation to decisions about medical treatment for their mental health condition. This criterion applies to people subject to civil orders. Criteria for mentally disordered offenders differ.

SIDMA is not further defined in the Mental Health Act. It is important to remember that SIDMA refers to decisions about medical treatment in general, whereas capacity is decision specific. The individual might be capable of making decisions about some medical treatments but not others.

We advise assessment of capacity to consent to each individual treatment. For example, a person may have the capacity to decide to take a certain medication for mental disorder but may lack the capacity to decide on the level of nursing care and observation necessary for their safety.

The AWI Act defines incapacity as:

- being incapable of acting; or
- making decisions; or
- understanding decisions; or
- · communicating decisions; or
- retaining the memory of decisions.

In relation to medical treatment, the guidance on assessing capacity in this section will help to determine whether a person is incapable in accordance with this definition.

⁶ Atkinson, J.M., Garner, H.C., Patrick, H., & Stuart, S. (2003a) Issues in the development of advance directives in medical health care, *Journal of Mental Health*, 12:575-584.

There are a number of approaches to capacity but the Law Commission⁷ has recommended using a 'functional approach' in determining whether a person has the capacity to make a decision. What this approach focuses on is 'whether an individual is able to make a decision at the time when that decision has to be made.' This means that an individual may be deemed incapable of making a decision at one specific point in time but capable at another point in time. There will be situations where an individual is capable of making some decisions while being incapable of making some others.

Assessment of capacity

Just because a person's decision is regarded as unwise, does not in itself mean they lack capacity. To demonstrate capacity individuals should be able to:

- understand broadly what the treatment is, its purpose and nature, and why it is being proposed,
- understand its principal benefits, risks and alternatives, and be able to make a choice,
- understand in broad terms what the consequences will be of not receiving the proposed treatment,
- retain the information long enough to use it and weigh it in the balance in order to arrive at a decision, and
- communicate that decision.

A problem for this definition, and the definition in the AWI Act, is the issue of memory. Our view is that the person must be able to retain information for long enough to make a decision. In addition, we believe they must:

- remember the decision, and/or
- make the same decision consistently given the same information, and/or
- agree with a record of that decision when presented with a record of it.

Although the Mental Health (Scotland) Act 1984 did not specifically mention capacity it could be seen, in practice, to treat capacity as 'all or nothing'. Under that Act, by virtue of having a mental disorder, the person could have their decisions over-ruled by use of the Act. The Mental Health Act requires an assessment of impairment in decision-making in addition to a diagnosis of mental disorder. Most definitions, and thus assessments of capacity, emphasise understanding and reasoning skills.

The concept of emotional decision-making may also be relevant and important. Practitioners should recognise that there is a need to understand a patient's experience of illness and treatment and decisions based on these experiences. This may lead to decisions being made which, for example, might be based on fear. Information and education may help if this is the case.

Alternatively, some people may have legitimate reasons for making an emotionally based decision which may tie in with philosophical, religious, or cultural beliefs. It is important to remember that just because a person's decision is regarded by others as unwise, this in itself does not mean they lack capacity. Under section 328 of the Mental Health Act it is stated that

⁷ Law Commission (1995) *Mental Capacity, Consultation paper No 231*, The Stationery Office: London.

'a person is not mentally disordered by reason only of ...acting as no prudent person would act.' (see also section <u>Refusal, persuasion and coercion</u>).

Being able to consider and compare the benefits and risks of a proposed treatment is regarded as an important part of being competent to make treatment decisions.¹¹ Capacity can also be seen on a sliding scale, where the threshold takes account of the complexity of the decision, the risk involved, significance of and consequences of that decision.

Clinicians may need to judge whether a decision that is made on an emotional basis is merely unwise and imprudent or based on lack of understanding of, or inability to process, the information and more likely to indicate incapacity.

Compliance and capacity

Compliance or adherence, that is, accepting treatment if it is offered, does not in itself constitute consent. A person may take treatment because it is given. Accepting treatment without knowledge of its nature, purpose, and likely effects does not indicate informed consent. Likewise, a signature on a consent form does not, in itself, mean that the person is giving informed consent. The clinician must be able to demonstrate that the person has made the decision to opt into treatment knowing the nature of the treatment and its likely benefits and risks to them. A person who accepts treatment but does not meet the tests for capacity should be treated under an appropriate legal framework. The roles of the AWI and Mental Health Acts are outlined in the section <u>Treatment without consent</u>.

Fluctuating capacity

If an individual has difficulty retaining information, or is only intermittently capable of making a decision, assistance should be provided, to make an informed decision.

Decisions made should be recorded while the person is capable. Decisions made while capable should be reviewed at appropriate intervals to establish that the person's views are consistently held and can be relied upon.

Good practice points

- Use a functional approach to capacity, based on the process by which the person makes a decision, rather than whether you think their decision is the right one.
- If treatment is ongoing, or if there has been a gap between the person giving consent and the treatment starting, ensure that the person still consents and still has the capacity to do so.
- Capacity can fluctuate. Consult those who are in regular contact with the person and get another opinion from a colleague, if in doubt.

Refusal, persuasion, and coercion: what is a valid refusal?

Refusal of treatment must be one of a patient's options, if the process of seeking consent is to be meaningful. A competent person can refuse consent to treatment for a good reason, for an irrational reason or, indeed, for no reason at all. The Law Commission recommended a 'presumption against lack of capacity' and suggested that the resulting decision should not be regarded as invalid just because it 'would not be made by a person with ordinary prudence'.⁸

If a patient refuses treatment the practitioner should document the informed refusal in the patient's medical notes and include the following information:

- a. the patient's refusal of treatment,
- b. documentation that the need for the treatment has been explained, and
- c. a statement that the consequences of the refusal, including possible jeopardy to health or life, have been discussed.

Where a person suffers from a mental health condition, it is important to consider whether they have the capacity to refuse. This can be a difficult clinical judgement. The tests for capacity on page 13 may give some guidance. Particular difficulties occur where:

- The patient is suffering side effects of treatment and judges these to be so severe that it would be better to risk staying, or becoming, ill.
 - **Example**: person with schizophrenia who knows that medication stops distressing hallucinations but who refuses continued treatment because of sedation or weight gain. This may well be a valid refusal. It is important to consider the range of options and examine other treatments.
- The patient distrusts the explanation of the treatment or of the need for it. **Example:** "I understand that you think I am ill, I understand your proposed treatment and potential consequences of my taking or not taking the treatment, but I am not ill." While this person understands the nature and purpose of the treatment, it may be that they do not understand why it is being proposed.
- The patient objects to the treatment on religious or moral grounds. **Example:** Member of the Scientology movement who refuses any medication on the basis of religious belief. Respect for diversity is an important principle of the Mental Health Act. It would be very important to take into account the person's beliefs.
- The patient understands the treatment and the need for it but decides to refuse because
 the burden of ongoing treatment would be too great and they would rather die.
 Example: person with an eating disorder who feels so tortured by the illness that they
 would rather die than struggle on with treatment. Faced with this situation, clinicians
 should listen to the views of others who know the person well and would be best advised
 to get another professional opinion.
- The patient is making an imprudent decision but not because of mental disorder. **Example:** A patient understands the need for treatment but has always disliked taking medication and prefers to "soldier on" despite attempts to persuade them of the benefits.

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⁸ Law Commission (1995) *Mental Capacity, Consultation paper No 231*, The Stationery Office: London.

The clinician may consider this unwise but that would not be sufficient to constitute incapacity and may well be a valid refusal.

In situations where there is doubt and the person has the capacity to make a valid refusal, the practitioner responsible for treatment should consult the multidisciplinary team, others who know the person well and the named person. It is wise to ask a colleague for a second opinion.

Coercion

'Coercion' can refer to formal or legal measures such as compulsory treatment in a hospital or within the community, but also other actions such as persuasion, interpersonal leverage, or threats. The Scottish Mental Health Law Review (SMHLR) extensively considered what constitutes 'coercion' and published their views on their understanding of coercion in their final report. The SMHLR made recommendations for the reduction of coercion.

Perceptions of coercion are subjective. The relevant questions that need to be asked are whether the person knew that treatment could be refused or felt pressured to have it. Studies have highlighted that how a particular treatment option is brought up is important in determining whether someone has felt coerced. For example, for a professional to say: "I want you to have ECT. You're not sectioned at the moment, but I will section you if you refuse" highlights the imbalance of the power relationship between professional and patient.

In seeking to avoid detention or compulsory treatment, professionals may use what they believe are persuasive techniques to convince a person to go into hospital or accept treatment voluntarily. These techniques may still be experienced by the patient as coercive. An example of this may be spending several hours 'persuading' which may be experienced by the individual as a 'wearing down' process. Perceptions of coercion may differ between professionals and patients.

Good practice points

- Check that the person has all the information necessary to make the decision and remind them if necessary.
- Discuss the range of options with the person. If one option clearly offers the greatest benefit, it is important to emphasise this. There may be other treatment options that the person finds more acceptable.
- Consider carefully the reasons why the person is reluctant to proceed. Be very careful about attempting to persuade a person who objects on religious or moral grounds.
- If you intend to use the Act to overcome an objection to treatment, it is important to tell the person. If the person agrees to treatment solely on the basis that they would otherwise be treated compulsorily, it is very doubtful that this is valid consent. We would advise any practitioner proceeding with treatment in these circumstances, on the basis that they consider that the patient has consented, to seek an opinion from a colleague before doing so. The person should also have the support of an independent advocate.

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⁹ Rose, D.S., Wykes, T.H., Bindman, J.P., & Fleishmann, P.S. (2005) Information, consent and perceived coercion: patients' perspectives on electroconvulsive therapy, *British Journal of Psychiatry*, 186:54-59.

Treatment without consent

This section outlines good practice in giving treatment for mental disorder without the person's consent.

General considerations

Treatment in the absence of consent can be a distressing experience. Whichever piece of legislation is being used, principles should guide best practice. If a person is being treated in the absence of consent, this does not remove the duties of the practitioner to:

- Give the person as much information as possible about the treatment in a way the person can understand.
- Take the person's views about the treatment into account.
- Take account of any previously expressed wishes, including an advance statement (see section <u>Advance statements</u>).
- Take account of the views of others.
- Ensure that any treatment will benefit the person. Maximising benefit is an important principle of the Mental Health Act, but this may need to be balanced against the person's wishes and the views of relevant others.
- Respect the person's religious and cultural beliefs, where these beliefs impact on decisions about treatment.
- Think about the range of options available for the person. It may be that they would find some treatments more acceptable than others. Again, this must be balanced with the principle of maximising benefit.

Treating a person who lacks capacity to consent

It is appropriate to use the AWI Act when:

- the person is not subject to compulsory treatment under the Mental Health Act, and
- the person lacks capacity to consent to treatment for mental disorder, and
- there is no requirement for force or detention (except as an emergency measure).

Therefore, it is not necessary to use the Mental Health Act to treat a person for mental disorder where the above conditions exist. We do however advise using the Mental Health Act if it is necessary to give treatment for mental disorder and the person resists or objects to that treatment.

Treatment should be given with regard to the principles of the AWI Act. Part 5 of the Act requires a certificate of incapacity (under section 47). Appending a treatment plan to a patient's section 47 certificate is the best way to provide complex and detailed plans of treatment (the treatment plan should be referred to on the section 47 certificate: "see attached treatment plan"). The Commission's good practice guide on treatment under section 47 contains more information about use of treatment plans.

Remember that under the AWI Act, some treatments carry special safeguards. These safeguards apply, for example, to drug treatment to reduce sex drive and to electroconvulsive therapy for a mental health condition. These treatments need an independent opinion from a second opinion doctor, arranged by the Mental Welfare Commission.

Figure 1: Requirements of the Mental Health Act for consent to treatment

Treatment	Person is	Person is	Person is	Person is
	capable and	capable and	incapable but	incapable and
	consents	refuses	does not resist	resists or
			or object	objects
Neurosurgery and	Needs DMP	Cannot be	Needs DMP	Cannot be
deep brain	opinion and	given	opinion and lay	given
stimulation in	lay opinions		opinions from	
Scotland	from the		the	
	Commission		Commission.	
			Must then be	
			authorised by	
			Court of	
			Session	
Electroconvulsive	Written	Cannot be	Needs DMP	Needs DMP
therapy	consent and	given	opinion on	opinion on
 Vagus nerve 	certification		form T3A and	form T3A and
stimulation	on form T2A		can be given if	can be given to
 Transcranial 			in the person's	save life,
electromagnetic			best interests	prevent
stimulation				serious
				deterioration
				or alleviate
				serious
				suffering
 Drug treatment 	Written	DMP opinion on	Needs DMP	Needs DMP
(for more than	consent and	form T3B with	opinion on	opinion on
two months)	certification	statement as to	form T3B and	form T3B and
 Medication to 	on form T2B	why treatment	can be given if	can be given if
reduce sex drive	(T2C for	should be given	in the person's	in the person's
 Artificial nutrition 	artificial		best interests	best interests
	nutrition)			
Other treatments	Written	Best interests	Best interests	Best interests
(section 242), for	consent	test - RMO	test - RMO	test - RMO
example:		records	records	records
Medication		reasons for	reasons for	reasons for
within first two		treatment in	treatment in	treatment in
months		writing, with	writing	writing
 Psychological 		reasons for		
therapies		giving		
		treatment in		
		spite of refusal		

Treatment under the Mental Health Act

A person subject to compulsory treatment under this Act can be treated without consent if they:

- are incapable of consenting; or
- · refuse to consent.

There are safeguards for some treatments, and some require an independent opinion from a DMP appointed by the Mental Welfare Commission. Readers should consult the Act and <u>Code of Practice</u> for a detailed description of the Act's requirements. The Commission has published <u>good practice guidance on medical treatment under Part 16</u>. A brief synopsis is shown in Figure 1.

For medication that requires to be authorised on a T2B or T3B certificate, some people may have both a T2B and a T3B form - a T2B for medication that they consent to and a T3B for other medication that they are incapable of consenting to or do not consent to. This should be done - it is not correct to include medication that they consent to on a T3B form. They should only have one T2B and one T3B for medication (other than where the person is prescribed medication to reduce sex drive and other medication - medication to reduce sex drive can be authorised on a second T2B or T3B).

For people aged under 18 who are subject to compulsory treatment under the Mental Health Act, Part 16 applies as it does for those over 18. However, if a T2A, T2B, or T2C certificate is completed, the approved medical practitioner who completes it must be a child specialist. If a T3A or T3B is completed, either the patient's RMO or the DMP who completes the certificate must be a child specialist.

Force

The Mental Health Act only authorises force where the person is in hospital. See below for guidance where the person is not in hospital. Force should only be used if:

- Administration is necessary and cannot be achieved in other ways.
- The person persistently resists treatment. It is best practice to wait and try again at a later point in time, unless the situation is urgent.
- The principles of the Act are applied. In particular, there must be careful consideration
 of alternatives, consultation with appropriate others and minimum restriction of the
 person's freedom. Any force should be the minimum necessary and only for as long
 as necessary.

Emergencies

In emergencies, treatment may be given if it is in a patient's 'best interests' and follows the requirements of the Act. Under Part 16 (section 243) of the Act, urgent medical treatment may be given to a patient who is detained in hospital and who does not consent, or is incapable of consenting, if the purposes of the treatment are to:

- a. save the patient's life,
- b. prevent serious deterioration in the patient's condition,
- c. alleviate serious suffering on the part of the patient, and
- d. prevent the patient from behaving violently or being a danger to the patient or others.

Emergency treatment should only be given if it is unlikely to entail 'unfavourable, and irreversible, physical or psychological consequences' (except to save life) or 'significant physical hazard to the patient' (except to save life or prevent serious deterioration).

NB. ECT cannot be given to a patient who is capable of consenting and who refuse ECT as urgent treatment or otherwise. Part 16 of the Act does not authorise the giving of ECT to a person who is capable of consenting and who refuses.

Emergency treatment under the Mental Health Act should be recorded on form T4 which the RMO should send to the Commission within seven days. This will include treatment that is urgently necessary but is:

- not covered by a best interests' statement under section 242, or
- subject to special safeguards, but urgently necessary before DMP opinion can be arranged, or
- not covered by an existing T3A or T3B certificate authorising the treatment.

NB. the T4 form is completed retrospectively and is used by the RMO to notify the Commission of treatment given under section 243. The Act requires the RMO to notify the Commission within seven days, so treatments within seven days might be included on one T4 form.

There are some problem situations where the provision of emergency treatment is uncertain:

a) Advance authorisation of IM "if required" psychotropic medication (this should usually not be included on a T2B form)

The Commission has concerns about intramuscular (IM) "as required" psychotropic medication being included on T2B forms in most cases. This is because any advance consent the individual has given is invalid if they have withdrawn their consent at a later time when the medication is given or if restraint is involved.

It is our view that IM medication prescribed "as required" in hospital should be authorised on a T3B form. If it is prescribed, the medical practitioner must be considering that it could be needed at some point. We have considered whether or not it is acceptable to prescribe IM "if required" medication where there is neither a T2B nor a T3B form in place and then to notify the Commission if it is administered as an emergency. We do not consider this to be good practice. Medication should be prescribed according to individual need.

Unforeseen situations arise in all forms of care. It would be more acceptable for the ward to have a general guideline on medication to be used in urgent situations and for the on-call medical practitioner to prescribe on a "one-off" basis, with advice from the person's RMO or a senior colleague (as urgent treatment under section 243). This should be reported to the Commission on a T4 form. If the situation is likely to recur, the RMO should reassess the person and consider whether to request a visit from a DMP to consider authorising future IM "if required" psychotropic medication on a T3B form.

b) Emergency detentions

The Act only authorises urgent medical treatment under section 243 when a person's detention is authorised by an emergency detention certificate. It does not authorise treatment without consent during the time between the signing of the certificate and admission to

hospital. In this situation, any treatment can only be given under the general principle of necessity. The prescribing practitioner should record the reasons for administering treatment.

c) Emergency treatment when treatment is authorised, but the person is not in hospital.

The Mental Health Act does not authorise the use of force in administering treatment where the person is not in hospital.

In emergency situations, it may still be necessary to administer treatment by force. Again, practitioners should record the reasons for this.

In some instances, it may be possible to foresee a need for forcible treatment in the future. For example, a person with severe learning disability, in his own tenancy with support, may need sedation to allow personal care tasks. In an emergency this would be acceptable, under duty of care. Practitioners should, of course, still take good practice in the use of force into account. Even if the person is subject to compulsory treatment under the Mental Health Act, this provides no authority for treatment with force in the community.

Section 47 of the AWI Act does not authorise the use of force unless it is "immediately necessary and only for so long as is necessary in the circumstances". If a person who is not in hospital requires use of force to administer treatment as part of their care plan, we would recommend that consideration is given to applying for a welfare guardianship with powers to authorise this.

Regaining capacity to consent or refuse

Practitioners may decide to embark on a course of treatment when a person lacks capacity to consent. However, the ability of the person to consent is not static but may fluctuate. As treatment takes effect, it may be that the person regains capacity to consent. Practitioners need to reassess the situation if this is the case.

Points to consider are:

- Has the person recovered enduring capacity to consent? Sometimes, the person's condition improves temporarily, only to slip back. Practitioners must be satisfied that the person has regained the ability to consent for long enough to accept their decision on treatment.
- Sometimes, this may result in the person deciding to refuse treatment before its completion. Remember that, in order to be capable of refusing treatment, the person must be able to understand the likely consequences of that refusal. There may be a delicate balance between continuing an effective treatment, where the person dislikes the treatment or experiences adverse effects, and risking a relapse by stopping the treatment. Practitioners need to judge whether the person is capable of making that choice. Again, independent advocacy and an opinion from a colleague may be helpful.
- When a person regains capacity and agrees to continued treatment, it would not be appropriate to continue as if the person lacks capacity. It would be best practice to document consent and to proceed on that basis. This may necessitate a review of the care plan.

 A person receiving treatment under a T3A or T3B certificate who then becomes capable of consenting to that treatment (and does so) should have a T2A or T3B completed by the RMO to authorise the treatment.

In addition, any person being treated under the AWI Act who regains capacity to consent should be treated accordingly. Any certificate given under section 47 should be revoked.

Certificates of independent opinion under section 48 will then no longer be valid. Any treatment may only proceed on the basis of informed consent.

Figure 2: Procedure to follow for person who regains capacity to consent

Treatment	Regains capacity and	Regains capacity and
	consents	refuses
Neurosurgery and deep brain	If decision was made in the	Cannot proceed
stimulation in Scotland	absence of capacity, a full	
	reassessment is needed	
Electroconvulsive therapy	Document consent on form	Cannot proceed if
 Vagus nerve stimulation 	T2A and proceed on that	person continues to
 Transcranial 	basis	have capacity to make
electromagnetic stimulation		a decision about the
		treatment and refuses
Drug treatment (for more	Document consent on form	Will need new DMP
than two months)	T2B and proceed on that	opinion to include
 Medication to reduce sex 	basis (T2C form for artificial	reasons on T3B for
drive	nutrition)	continuing to give
 Artificial nutrition 		treatment to capable
		person who refuses
Other treatments (section 242),	Proceed on basis of signed	RMO records reasons
for example:	consent	for continuing
 Medication within first two 		treatment to capable
months		person who refuses
 Psychological therapies 		

Good practice points

- Follow the principles of legislation when providing treatment in the absence of consent.
- Review the person's ability to consent on a regular basis. It is not appropriate to continue to treat a person who regains capacity as if that person was incapable.
- Keep the care plan under review as the person's ability to consent changes.
- Consult the Acts and their Codes of Practice to ensure that legal requirements are obeyed. The forms also act as a guide.
- Use force as little as possible and only for as long as necessary.
- Carefully document any emergency treatment that is given on the principle of necessity but is outwith the authority of the Act(s).

Advance statements

The Mental Health Act contains provisions for a person to make an 'advance statement'. This is a statement written by the person specifying the ways in which they wish to be treated for a mental health condition, or not treated, if they become unwell in the future.

Section 275 says that an advance statement specifies wishes about treatment in the event that the person becomes "mentally disordered" and their ability to make decisions about those treatment matters becomes significantly impaired.

The writer must be capable of making these wishes at the time they write their advance statement. The Act requires that the statement is signed by a witness who confirms this. This is necessary for the advance statement to be valid.

The Act requires mental health professionals to have regard for the advance statement if the individual is being treated under the Act (section 276 contains these provisions).

When a patient has lost capacity to consent or refuse treatment, there should be a check to see if that patient has made an advance statement.

Where an advance statement is not available, the patient's known wishes should still be taken into account.

Making an advance statement

In making an advance statement the person is making a competent, informed choice about treatment which will apply in the future, when they have lost the capacity to make that decision.

Our <u>advance statement guidance</u> provides information on the process of making an advance statement.

Opt-out decisions

Patients who intend to refuse certain treatments might be encouraged to consider what limitations they would put on this.

For example, a person wants to refuse ECT. They could consider whether to refuse ECT completely or to accept in certain circumstances, e.g. if other treatments had failed or if their life is at risk.

If a person wants to refuse medication, they should consider:

- Whether to refuse all medication or accept some. If so, they should state which. It is also helpful to give reasons why a medication is refused and another preferred.
- For how long they would refuse medication. The person could consider stating that
 medication would be acceptable after a certain time if there was no improvement
 without it.

The person making an advance statement should also consider the consequences of their decisions and the management techniques which might be necessary if they refuse all treatment. In some circumstances this might include restraint or seclusion.

Discussing consequences of decisions, and alternative treatments, will be especially important if a person is refusing treatment they have not experienced.

Opt-in decisions

People may decide to specify in advance, treatment that they would like to receive. Giving such treatment takes account of the person's previous wishes. However, if the person lacks capacity to consent at the time treatment is proposed, the advance statement cannot be regarded legally as "consent".

Clinicians must still follow proper legal procedures. An advance statement cannot be used to demand any particular treatment.

Changing advance statements

The same requirements for competency, witnesses and so forth apply to changing or revoking an advance statement as to making one. Advance statements should be updated regularly, or the decision reaffirmed, so that they are seen as current.

Where advance statements are kept; the advance statement register

The Mental Health Act requires health boards to place an advance statement, or a document withdrawing an advance statement, with the person's medical records. The Mental Welfare Commission must be notified by the health board of the making or withdrawing of an advance statement and will maintain a register of all advance statements.

The person who made the advance statement, or someone acting on their behalf (such as their RMO, named person or advocacy worker) may 'inspect' the information on the register that is relevant to them.

Treatment that conflicts with an advance statement - advance statement override

Any decision to override an advance statement needs to be justified by reference to the principles of the Act. A difficult decision would be where an incapable person, with an advance refusal of treatment, changes their mind and agrees to treatment. Those providing treatment will need to judge whether a present acceptance of treatment is more valid than an advance refusal. Given that they were capable when refusing and incapable when agreeing, it would not be appropriate to accept this as "consent".

However, a decision to give treatment that conflicts with an advance statement might be in line with the principle of taking the person's present views into account.

Advance statement override (ASO) notifications

If anyone gives or authorises treatment that is in conflict with an advance statement, then section 276(8) of the Act requires them to give the reasons for this in writing.

This record should be kept in the person's case record and also given to:

- the person who made the statement,
- that person's named person,
- that person's welfare attorney,
- that person's guardian, and
- the Commission.

If the person's RMO or a DMP is making a notification of an ASO, we advise that it is good practice for them to do this in the form of a letter of explanation to the person, copied to other

people who need to receive it, including the Commission. We consider that this is a good, person-centred way to do this. The letter should be individualised and written in the most appropriate way for the individual's information.

Good practice points

- The person making the advance statement should indicate that they have has considered the consequences of their treatment wishes.
- Practitioners should, when a person is well, suggest making an advance statement and give them every assistance to do so.
- When giving treatment that conflicts with an advance statement, the practitioner should ensure that this is justified by referring to the principles of the Act and pay attention to the need to make ASO notifications to the person themselves, the Commission, and others.
- The Commission undertakes monitoring of ASO notifications during planned periods and may undertake proportionate review of individual ASOs as it determines is necessary both within and outwith the planned monitoring periods.

Special situations

Covert treatment

The practice of administering medication covertly is controversial. In mentally capable patients it is a breach of autonomy and likely to constitute assault. For people who lack capacity (either permanently or temporarily), the question is whether the best interest of the individual is justification enough for covert practices. Studies show that the practice does seem to be used commonly for people with dementia who routinely receive their medication in their food or drinks.¹⁰¹¹ The main concern raised is that if the practice is condoned in a few exceptional cases, as in an emergency, this could lead to a rise in the abuse of the practice.¹²

A balance has to be struck between the potential harm to a patient of not having the medication, versus the breach of patient autonomy and the potential side-effects of any medication.¹³

Clear policies on when it might be appropriate to use covert medication should be in place because, without them, awareness, and frank discussion of 'underground' practices, surreptitious practices will continue in secrecy.¹⁴

Guidelines should be provided to medical professionals and carers of adults with incapacity about how to act if the use of covert medication is considered. The UK Central Council for Nursing Midwifery and Health Visiting (UKCC) has issued guidelines which say that 'disguising medication in food or drink can be justified in the best interests of patients who actively refuse medication but who lack the capacity to refuse treatment. As such 'covert medication' may be considered to prevent a patient from missing out on essential treatment where the patient is incapable of consent'.¹⁵

The Commission has separate guidance on the use of covert medication, including a covert medication care pathway that we recommend should be completed when medication is given covertly.

Treatment of physical health problems in people with mental disorder

The Mental Health Act does not usually apply to treatment for physical illness. Where a person is being treated under the Mental Health Act and lacks capacity in relation to treatment for physical illness, treatment can be given under the AWI Act. This requires a certificate of incapacity under section 47 and adherence to the principles of the Act. If there is a welfare proxy (welfare attorney, welfare guardian, or holder of an intervention order) with the power to

¹⁰ Munro, W. (2004) *Coercion, persuasion and communication: Exploring aspects of Mental Health Officer practice in the process of hospital admission,* Thesis for Master of Community Care Degree, University of Glasgow.

¹¹ Treloar, A., Beats, B., Philpot, M. (2000) A pill in the sandwich: covert medication in food and drink, *Journal of Social Medicine*, 93:408-11.

¹² Kirkevold, O., Engedal, K. (2005) Concealment of drugs in food and beverages in nursing homes: cross sectional study, *British Journal of Psychiatry*, 330:20-24.

¹³ Scott, J., Williams, E.R.L. (1997) Concealed administration of drug treatment may represent thin end of the wedge, *British Journal of Psychiatry*, 314:299-300.

¹⁴ Lamnari, A (2001) Point-counterpoint: is it ethical to give drugs to people with dementia? Yes: It is ethical if it is in their best interests, *Western Journal of Medicine*, 174:228.

¹⁵ Ramsay, S (2001) UK nurses receive guidance on covert medication of patients, *Lancet*, 358:900.

consent to the treatment, their consent should be sought. In fact, the AWI Act says that a s47 certificate does not confer authority to treat if there is a welfare proxy, the person issuing the certificate is aware of that, and they do not consult the proxy. The exception to this is where it would not be reasonable or practicable for them to do so.

Force can only be used to provide medical treatment under section 47 of the AWI Act if this is immediately necessary. Section 47 does not authorise the use of force unless it is "immediately necessary and only for so long as is necessary in the circumstances".

The Commission has produced detailed good practice guidance right to treat? on authority for delivering physical healthcare for people who lack capacity and who resist or object to treatment. The following examples and text provide brief guidance on the use of legislation for treatment of physical health problems in people with mental health conditions. Right to treat should be referred to for more detail about this.

Example: a person with mental illness and who also suffers from diabetes refuses treatment with insulin for the latter. Without this treatment, their health would be at significant risk.

Under a section 47 certificate of incapacity, treatment may proceed. If the person resists, the clinical team may need to use force in view of the immediate necessity. If the person continues to refuse in the longer term, an order under part 6 of the AWI Act (intervention order or guardianship) may be necessary.

If a person who lacks capacity refuses treatment for physical illness and treatment that is necessary, although the situation may be less urgent, we recommend an application under part 6 of the AWI Act. For example, a person with chronic mental illness has cataracts and is blind. Surgery would help but he refuses, due to a delusional belief about his loss of vision. The Sheriff could appoint a welfare guardian with the authority to consent to treatment and, if necessary, issue an order that the person complies with the welfare guardian's decision.

Sometimes, physical illness is a cause or consequence of mental disorder. If so, the Mental Health Act can be used to administer treatment. For example, delirium can occur as a result of a chest infection. It is appropriate to treat the chest infection as the cause of the delirium under the Mental Health Act.

The Code of Practice also states that people who have deliberately self-harmed can be treated under the Mental Health Act. However, this would only be appropriate if:

- the person meets the criteria for compulsion, and
- procedures needed to use the Act will not delay the provision of treatment that is
 urgently necessary for the person's physical health. Despite all the legislation, there
 is still a place for the doctrine of necessity if a person is in serious and imminent
 danger.

Consent and research

Consent is based on the elements of information, decisional capacity and voluntarism. It has been argued that voluntarism in clinical and research consent is the least understood area of informed consent. Voluntarism 'encompasses an individual's ability to act in accordance with one's authentic sense of what is good, right, and best in light of one's situation, values, and prior history'. ¹⁶

The capacity to choose without coercion is also critical. It is suggested that voluntarism in consent can be analysed according to four areas of possible influences:

- 1. developmental factors: where capacity for voluntarism is affected by a person's development in terms of cognitive abilities, emotional maturity and moral character,
- 2. illness-related considerations: special mental symptoms and their nature, severity and temporal pattern may significantly affect an individual's capacity for voluntarism,
- psychological issues and cultural and religious values: for example, psychological issues and values may influence impressions of what is good and what choices are acceptable when facing decisions, and
- 4. external features and pressures: which may include resource limitations or legislation, which determine the fundamental nature of the consent decision by defining what choices actually exist and affect an individual's motivation for accepting a particular intervention because of a lack of alternatives.²⁶

In relation to research (including clinical trials of drugs or treatments/causes of or possible treatment for a particular condition), what should be taken into consideration is:

- that the research is not contrary to a patient's interests,
- that a patient understands that it is research,
- that a patient is given adequate information on which to make a decision,
- that information should be presented in a way that is accessible and understandable to a patient.

Information should include:

- the risks/benefits involved,
- that it has been approved by an ethics committee,
- that a patient can withdraw their consent at any time.

In relation to the request for participation:

- time should be given to allow a person to properly consider his/her potential participation,
- no pressure should be placed on a person to participate,
- the person should have enough support to make an informed choice,
- if consent is given this should be taken in writing.

¹⁶ Weiss-Roberts, L. (2002) Informed consent and the capacity for voluntarism, *American Journal of Psychiatry*, 159:705-712.

It is likely that people with dementia or learning disabilities who do not have capacity to consent to research will come under the AWI Act. This Act has a list of requirements that must be satisfied before research can proceed. The code of practice for <u>Part 5 of the AWI Act</u> provides guidance on these provisions.

The position of people who are detained/compulsorily treated under the Mental Health Act is not clear. For clinical research involving treatment the AWI Act may have to be used. For non-intervention research (for example, interviews to get patients' views on a topic) this may not be necessary.

The GMC's guidance Consent to research provides guidance about involving individuals who lack capacity to consent in research.

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Appendix 1: Treatment plans, T2 forms, consent forms

This section provides some guidance on good practice in writing a treatment plan in relation to part 16 of the Mental Health Act.

This is relevant for responsible medical officers (RMOs) and other approved medical practitioners (AMPs):

- writing plans of authorised treatment on T2A or T2B certificates,
- completing the non-statutory T2C form for artificial nutrition,
- in other situations where a plan of treatment is completed for a patient receiving treatment under part 16, for example, treatment under section 242 such as medication in the first two months before a T2B or T3B is due.

We have also provided guidance on good practice in completing patient consent forms for medication.

We recommend separate T2B forms for medication and for artificial nutrition.

Medication for mental disorder beyond two months and medication to reduce sex drive can be authorised on one T2B form or one for each. Authorising both on one T2B form may be less confusing, but these are separate treatments and there may be a reason for issuing separate T2B forms, for example, if the RMO wishes to specify different durations of authority to treat.

Electroconvulsive Therapy (ECT)

Treatment with ECT should be regarded as a course. Where the person consents, their capacity to decide about ECT and whether they are giving consent should be checked before every treatment. This is in standard 6 of the <u>Scottish standards for ECT</u>, which should be followed for ECT treatment in Scotland.

When documenting a course of ECT on a T2A certificate, we recommend that the treatment plan includes:

- whether treatment will be administered as unilateral or bilateral (or that either method is acceptable)
- the maximum number of treatments per week that the person can receive (usually two)
- the maximum number of treatments authorised by the certificate (usually no more than 12)
- the duration of the authority of the certificate
- a statement that the treatment must commence within a stated timescale after the T2A has been issued (we recommend that this should be no longer than two weeks.
 Our view is that if there is a delay in the start of a planned course of ECT, a new patient consent form and T2A should be completed.)
- the plan may include a statement on the maximum allowed intervals between treatments. This is not essential. However, we advise that a new certificate is required if the last treatment was more than 14 days ago.

Artificial nutrition

This is most likely to be used for people with eating disorders. It could be indicated for people with other forms of mental illness where the person is unwilling or unable to eat because of mental disorder. If the person needs artificial nutrition because of physical illness, it would be more appropriate to use the AWI Act. The plan should specify the form of artificial nutrition, for example, nasogastric or PEG tube. It should also specify duration of the authority to treat. Usually, this should be no more than three months. We do not think that giving fluids intravenously constitutes artificial nutrition. The Commission has issued separate guidance on nutrition by artificial means.

Medication

Only medication for mental disorder needs to be included on a T2B form. Treatment for side effects of drugs for mental disorder is not normally considered to be treatment for mental disorder authorised under the Mental Health Act. This might include treatment for drug-induced Parkinsonism or constipation. Also, it is not necessary to include drug treatment for epilepsy. Anti-convulsant drugs are often used to treat mental disorder and should be recorded on the plan if used for that or if used for both purposes.

More information about what medications should or should not be included on T2B and T3B forms is contained in the Commission's good practice guidance on medical treatment under Part 16 of the Mental Health Act.

When the patient consents to treatment

Patient consent forms for medication

Good practice when completing consent forms:

- There should be a single entry for each medication.
- Clozapine should always be individually named in a separate entry that states that the treatment includes the associated blood tests.
- The purpose of the medication should be stated.
- If the same medication or class of medication is included both regularly and "if required", there should be separate entries for each of these.
- Each entry should include the route of administration of the medication for example, oral or intramuscular injection.
 - NB. As we have covered above, the Commission's view is that IM "if required" psychotropic medication should not be included on a T2B form. This would very seldom be appropriate. Our view is that this should be authorised on a T3B form.
- If medication is to be given via a nasogastric (NG) tube, the NG route should be specified.
 - NB. the Commission's the view is that it is not appropriate to consider inserting an NG tube solely for the purpose of administering medication for mental disorder¹⁷.

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¹⁷ The only exception to this that the Commission might condone Clozapine being authorised on a T3B to be given via NG tube in very exceptional circumstances. After much consideration and consultation, the Commission developed an IM/NG Clozapine protocol for treatment-resistant Schizophrenia, involving detailed individual assessment and a DMP assessment if NG or IM Clozapine is proposed as a last resort.

Medication is sometimes given via NG tube if one is already in situ for artificial nutrition.

- State the agreed dosage for each medication, including the maximum daily dose. It
 is important that the consent form clearly records the medication doses that the
 patient has consented to.
- If the dose of a medication or combined doses exceed the recommended British National Formulary (BNF) maximum, the consent form should include any appropriate additional monitoring for example, high dose antipsychotic monitoring in accordance with guidance from the Royal College of Psychiatrists. It is important to document clearly that the patient has been given full information about this and their consent.
- If a medication is prescribed for an indication that it is not licenced for ("off-licence"), this should be stated on the consent form. It is important to document clearly that the patient has been given full information about the treatment and that the medication is being used off-licence, and their consent.

A patient consent form should be a separate stand-alone document.

We recommend that it is good practice for the doctor to sign the consent form as well as the patient.

We have sometimes seen consent forms that state "as per T2B" and have no detail about the treatment that the patient has consented to. We do not consider this to be good practice.

We have sometimes seen T2B forms with no patient consent form attached and a note on the treatment plan page, signed by the patient, saying that they consent to the treatment. We consider that this is not good practice and that it is clear on T2A and T2B forms that the patient's written consent should be attached (as a separate document).

Appendix 2 contains an example patient consent proforma.

Treatment plans; T2B forms

Where the patient gives capable consent to treatment, good practice in recording medication on T2Bs and other treatment plans includes:

- Specify the actual medications on the treatment plan rather than give broad classes of medication.
- Doctors are best advised to have an up-to-date BNF available when completing a treatment plan. When naming a particular drug, use the British approved name.
- The treatment plan should include a single entry for each medication.
- The treatment plan entries should include the name of the medication (as above, we advise that this is good practice), or the class of drugs. A BNF chapter number alone is insufficient as staff may not be familiar with the BNF or have it to hand at the time of prescription or administration. Also, the BNF content may later change.
- If the same medication or class of medication is included both regularly and "if required", there should be separate entries for each of these on the treatment plan.
- The entries on the treatment plan should include the indication for the medication.

- Ensure that the treatment plan accurately represents the treatment that the patient
 has consented to e.g. if the patient consents to a named antidepressant, it is wrong
 to write a T2B entry to authorise "one antidepressant....". The T2B could be thought
 to authorise other antidepressant medications too, which it would not properly
 authorise.
- If the patient consents to medication from a class or group of medications, ensure that the medication entry on the treatment plan does not overstep to potentially include medications the patient has not given their full informed consent to.
- State the route of administration in the entries on the treatment plan (e.g. oral or intramuscular injection). As we have covered above, the Commission's view is that IM "if required" psychotropic medication should not be included on a T2B form. This would very seldom be appropriate. Our view that this should be authorised on a T3B form.
- If medication is given via a nasogastric (NG) tube, the NG route should be specified. This would not be covered by a T2B authorising medication via the oral route. NB the Commission's the view is that it is not appropriate to consider inserting an NG tube solely for the purpose of administering medication for mental disorder. Medication can be authorised to be given via a NG tube if one is already in situ for artificial nutrition. For the avoidance of doubt, it is good practice to state this on the treatment plan.
- State the maximum authorised dosage for the medication in each entry on the treatment plan. For medications prescribed for their licensed use, it is often appropriate to refer to BNF maximum doses and frequency of administration. If the dose(s) authorised differ from the BNF doses, or a lower dose is planned, ensure that the treatment plan includes clear information about the dose authorised (single dose, dosage interval and maximum daily dose). See below for high doses.
- For "as required" medication, be especially careful about the dosage and frequency to ensure that treatment will not exceed what the patient has consented to and what is on the treatment plan e.g. a T2B authorising oral lorazepam at doses within BNF limits would not authorise doses above 4mg per day.
- For certain treatments, the plan may state that the administration of the drug should achieve a certain serum level.
- If medication on the treatment plan exceeds the recommended BNF maximum, the plan should state a requirement for any appropriate additional monitoring, for example, high dose antipsychotic monitoring in accordance with guidance from the Royal College of Psychiatrists.
- Clozapine is a special case because of the associated blood tests and should always
 be documented by name. The entry on the treatment plan should state that it also
 includes associated blood tests. NB. this is only the case for clozapine because of its
 product licence. Other drugs, for example, lithium, also need blood tests but these are
 not part of the product licence and should not be included on T2Bs or T3Bs.
- If a medication is prescribed for an indication that it is not licenced for ("off-licence"), the treatment plan should specify the indication and that the use of the medication is unlicensed. The entry should include clear information about the dose authorised (single dose, dosage interval, and maximum daily dose). Making reference to BNF

recommended doses may not be straightforward or appropriate as there will not be information in the BNF stating doses for the unlicenced indication.

When the patient does not consent to treatment

DMP visit requests (SOP1 forms); T3B forms

If the patient does not consent, it is reasonable for the treatment plan to be broader by including classes of medication.

For medication requiring a T3B form, the RMO should request a visit by a DMP by submitting a second opinion request form (SOP1) to the Commission.

It is helpful if RMOs write proposed treatment plans on SOP1 forms in line with good practice, as a DMP would write on a well-written T3B form. The above good practice guidance for completion of treatment plans should be followed except that it is more likely that some entries will be requests for authorisation for a class of medication rather than a named individual drug.

An example of a typical treatment plan entry for a class of medication

"Any one antidepressant medication given orally on a regular basis within BNF dose and frequency guidelines."

The RMO and DMP will need to agree a plan that is broad enough to ensure that appropriate changes to treatment are possible without a further DMP visit. The plan must, however, be relevant to the individual. The plans should also only include treatment that is currently necessary, or likely to be needed, should present treatment be ineffective.

Entries for promethazine on treatment plans

We have come across situations where RMOs and DMPs have not been clear how to write entries for promethazine on T2B and T3B forms when this is authorised as treatment for agitation. We thought it would be helpful to include our advice about wording for treatment plan entries for this medication here.

Promethazine hydrochloride is licensed for "sedation (short-term use)".

The doses in the BNF¹⁸ appear to be single doses without additional information on dosage intervals or maximum daily dose.

We advise that a treatment plan entry should specify promethazine hydrochloride to distinguish from promethazine teoclate.

Example wording for SOP1 and T3B forms:

"Promethazine hydrochloride orally 'if required' for agitation, maximum single dose a mg, minimum frequency b hourly, up to maximum c mg per day (total dose combined with IM 'if required' Promethazine shall not exceed x mg per day)."

"Promethazine hydrochloride IM 'if required' for severe agitation, maximum single dose a mg, minimum frequency b hourly, up to maximum c mg per day (total dose combined with oral 'if required' Promethazine shall not exceed x mg per day).

-

¹⁸ Accessed 18 March 2024

Appendix 2

Mental Health (Care and Treatment)(Scotland) Act 2003 Consent form for medication

NAME:		D.O.B
ADDRESS:		
WARD (inpatients):		
I confirm that my responsible medical office me the nature, purpose and likely effects of		> has explained to
The medication plan is:		
Regular medication		
Discretionary medication (for as required u	se)	
I understand the medication plan and cons	ent to it.	
Signed: (patient)	Date	
Signed: (RMO)	Date	



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