Informed Consent: Updated GMC Guidance

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The topic of consent has been increasingly contentious since the Supreme Court's decision in *Montgomery v Lanarkshire Health Board* [2015] AC 1430, which shifted the focus from *Bolam*-style clinical paternalism to patient autonomy.

On 9 November 2020, the General Medical Council ("GMC") issued updated guidance on "Decision making and consent". It is a revision of the core GMC guidance on consent, which was last updated as long ago as 2008.

This blog post provides a summary of the key parts of the guidance, which are likely to be relevant to clinical negligence practitioners when considering the issue of consent.

Obtaining Consent: The Seven Key Principles

The updated guidance provides a framework for clinical decision making, which reflects the shift in focus brought about by *Montgomery*. It provides seven key principles to which clinicians should have regard when obtaining consent from patients:

- Principle one: 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.
- Principle two: Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.
- Principle three: 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.
- Principle four: 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.
- Principle five: 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.
- Principle six: 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.
- Principle seven: 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.

The emphasis of the guidance is to involve patients in the decision making process:

> "*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.*"

The Scope of the Guidance

It is important to understand to whom, and in what circumstances, this updated guidance applies. The GMC tells us that:

- The guidance is applicable to every health and care decision made with every patient. If the patient is under 18, it should be read in conjunction with the "0-18 guidance for all doctors".
- It applies to "*treatments, procedures, interventions, investigations, screenings, examinations and referrals*".
- It is of equal application to both mental and physical health.

- It applies to all interactions about consent, regardless of the setting. This is of particular relevance in the current COVID-19 pandemic, where many interactions are held remotely.
- It does not deal with consent for disclosure of information or confidentiality, guidance on which can be found here.

Proportionality

The GMC caveats the guidance, and the seven key principles, with a necessary emphasis on proportionality. It identifies five relevant factors in assessing and implementing a proportionate approach to obtaining patient consent:

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

Depending on the nature of the procedure, it may be reasonable to rely upon a patient's verbal or non-verbal consent (i.e. for an examination). However, even for a routine procedure, a clinician should:

- explain what they are going to do and why they are going to do it;
- explain clearly that a patient is not obliged to consent and can withdraw consent at any time during the examination; and
- look out for any indications during the examination that the patient is unhappy with or confused about what they are doing.

The guidance goes on to specifically consider circumstances which are likely to affect the doctor's ability to apply this guidance, the decision making process of the patient and the doctor's ability to obtain consent.

Before the Decision to Give Consent is Made: A Dialogue

Before a doctor can be satisfied that informed consent has been obtained, it is necessary for there to be some form of dialogue between doctor and patient. The extent of this dialogue will, of course, be affected by the clinical picture at the time. The GMC give general guidance on the aim and contents of that dialogue.

The aim of this dialogue is three-fold:

1. to help the patient understand their role in the process, and their right to choose whether or not to have treatment or care;
2. to make sure the patient has the opportunity to consider relevant information that might influence their choice between the available options;
3. to try and reach a shared understanding of the expectations and limitations of the available options.

Paragraphs 10-15 of the guidance deal with the content of the discussion and information sharing. It reminds clinicians that they "*must*":

- give patients the information they want or need to make a decision;
- try to make sure the information shared with patients about their options is objective;
- explain reasons for recommending an option for treatment or care, and share information about reasonable alternatives, including the option to take no action; and

- not put pressure on a patient to accept advice.

Assumptions about the information a patient might want or need, the factors a patient might consider significant or the importance a patient might attach to different outcomes, should be disregarded in obtaining consent.

As part of the dialogue and information sharing, clinicians should be:

- Finding out what matters to a patient:
- Do they have priorities regarding aspects of their health?
- Do they have concerns about their ability to engage in activities which promote their quality of life?
- Do they have a preference about their options?
- Do they have realistic expectations about what the treatment/procedure will achieve?
- Do they understand the risks involved and the impact these may have on their life?
- Discussing the benefits and harms:
- Clear and up-to-date information, based on the best available evidence, about the potential benefits and risks of each option must be provided. This must include the option to take no action.
- A clinician is not expected to share every possible risk of harm or potential complication, but should tailor the discussion to each patient, taking into account what matters to that patient.
- As a general rule, the discussion about benefits and harm should usually include discussion about:
- Recognised risks of harm that you believe anyone in the patient's position would want to know.
- The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring.
- Risks of harm and potential benefits that the patient would consider significant for any reason.
- Any risk of serious harm, however unlikely it is to occur.
- Expected harms, including common side effects and what to do if they occur.

The Scope of Decisions

Clinicians have a duty to ensure clarity about the scope of the decisions to which a patient is consenting. Except in an emergency, the scope of the consent must not be exceeded.

If a patient has a condition that is likely to impair their capacity, the treating clinician should, where appropriate, sensitively encourage them to think about what they might want to happen if they become unable to make healthcare decisions.

Similarly, if the patient is near the end of their life this guidance should be considered alongside the "Treatment and care towards the end of life: decision making" guidance document.

A summary of the discussion with the patient about future care must be recorded.

Conflict: When the Doctor and the Patient Disagree

Even where the doctor disagrees with the patient, they must respect that decision. If it seems out of character for the patient, it may be reasonable to check their understanding. A doctor must not assume a lack of capacity just because they disagree with the patient's decision.

If the decision is not in the clinical interests of the patient, the doctor should explore the reasons for requesting it and their expectations of the likely outcome. If even after this discussion, the doctor still considers that the treatment is not in the patient's best interest, they should not provide it. Other options should, again, be outlined and a second opinion recommended.

Recording Decisions

It is important for continuity of care that a patient's medical records are up to date, but a proportionate approach to the level of detail should be taken.

There is guidance on this in the "Good medical practice" guidance document.

When recording the dialogue and information sharing around consent, the notes must include:

- the decisions made and actions agreed;
- who is making the decisions and agreeing the actions; and
- where there has been a decision to take no action.

Consent Forms

The guidance is clear that filling in a consent form is not a substitute for a meaningful dialogue tailored to the individual patient's needs.

Circumstances Affecting the Decision Making Process

There are five situations identified that may affect the decision making process, and therefore the application of this guidance:

1. Time and resource constraints

Where there are pressures of time, doctors should consider whether other members of the health care team could be delegated to obtain consent or whether there are any other sources of information available to the patient (leaflets, advocacy services, support groups etc.).

If the pressure of time or resources, which is outside the control of the doctor, "*seriously compromises*" a patient's ability to give informed consent, then the doctor should consider raising a concern.

2. Treatment in emergencies

In an emergency situation, where time is of the essence, the guidance states that the doctor must presume capacity and seek consent before providing treatment or care.

If the patient is unconscious, or otherwise concluded to lack capacity, treatment that is life-saving or preventative of serious deterioration can be administered without consent. Where there is more than one option for treatment, the one which will have the least impact on the patient's rights and freedoms should be chosen.

For as long as the patient lacks capacity, the doctor should provide ongoing care.

If capacity is regained, the doctor should explain what has been done and why. You must discuss with them, and obtain consent for ongoing treatment from that point.

3. If the patient does not want to be involved in the decision making process

Neither the doctor, or another person, is able to make decisions on behalf of an adult who has capacity.

If the patient does not wish to discuss the details of an option, having elected it, a doctor should continue to explain basic information to them before consent can be obtained.

If the patient refuses to listen to information, the doctor will have to apply their professional judgment in assessing whether they have consent to proceed. Consent is more likely to have been given in standard procedures or treatment options, unless there is reason to believe that the patient wants some different treatment or care. Taking advice from the

MDU or GMC should be considered.

4. A patient who can't make a decision freely

This applies most commonly to patients who are experiencing domestic abuse, are residents in care homes or who have carers, who have been detained, or who are subject to compulsory treatment orders (or are at risk of such an order).

The guidance should be followed by doctors in relation to providing information and supporting the patient through a decision. The doctor should attempt to speak with the patient alone and signpost to specialist support services where necessary.

If a doctor suspects that free will cannot be exercised, consent will not be obtainable, and a concern should be raised.

5. If the patient lacks capacity

There is well established law and guidance on assessment of capacity.

The key point to take from the updated guidance is that, where possible, the patient should be involved in the process, alongside consultation with the family (if there is no legal guardian).

Conclusion

The updated guidance provides a comprehensive guide for doctors in obtaining consent from patients. It clearly reflects the decision in *Montgomery* and puts patient autonomy as the number one priority in obtaining consent.

The significance of the shift in focus since *Montgomery* may become even more pronounced depending on the outcome of the decision of the Supreme Court on the appeal from *Khan v Meadows* [2019] 2 All ER 607, in which the scope of the duty of care owed by health care professionals is under scrutiny, in the context of a claim for losses suffered due to matters out with the original purpose of a patient's consultation.

It therefore remains to be seen whether the realities of clinical practice will allow compliance with the updated position, or if the guidance will simply provide a potential stumbling block for busy doctors.