Briefing Document: Informed Consent in Medical Practice

Source: Excerpts from " 04 Amelia Newbold and Jonathan Fuggle_SRT_English.pdf"

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Overview:

This briefing document synthesises the key themes and important ideas discussed in the provided transcripts regarding informed consent in medical practice. The sources include perspectives from a consultant surgeon (Simon Parsons), representatives from the Welsh Risk Pool (Jonathan Webb) and the All Wales peer review for decision-making and consent (Dr. Ben Thomas), and medico-legal experts (Amelia Newbold and Jonathan Fuggle).

1. The Foundational Principles of Informed Consent:

All speakers emphasise that informed consent is not merely a form-filling exercise but a dynamic and ongoing process centred around a **meaningful dialogue** between the clinician and the patient. This dialogue aims to ensure the patient is **appropriately informed** and can make a **voluntary decision** about their treatment.

- **GMC Guidance:** Simon Parsons highlights the GMC's updated guidance on consent (2020), particularly the first four key principles:
- "'all patients have a right to be involved in decisions about their treatment and care and to be supported to make informed decisions if they're able.'"
- "Decision-making is an ongoing process focused on a meaningful dialogue and the exchange of relevant information specific to the individual patient."
- "all patients have the right to be listened to and to be given information that they need to make a decision and the time and support that they need to understand it."
- "'doctors must try to find out what matters to the patient.'" This last principle is linked to the **Montgomery case**.
- **Legal Obligation:** Parsons stresses that the GMC guidance, where it says "you must," is often embedded in law, and failure to comply can lead to legal repercussions.
- **Shared Decision-Making:** The overarching goal of proper informed consent is to promote shared decision-making, as summarised by Parsons: "informed

consent is a process which, if performed properly, promotes shared decision-making, and that's key for what we're all about."

2. The Content and Delivery of Information:

Clinicians have a duty to provide patients with comprehensive and understandable information.

- **Essential Information:** Parsons outlines the key information that must be shared, including: diagnosis, treatment options (including alternatives), what the surgery involves, risks and complications, benefits, post-operative expectations, and relevant lifestyle changes.
- **Tailoring Information:** The information should be "relevant information specific to the individual patient." Clinicians should actively seek to understand "what matters to the patient," including their hobbies, profession, and the risks they are prepared to take, to tailor the information accordingly.
- **Support for Understanding:** Providing information quickly is ineffective. Support is needed to do it properly, which is where resources like EIDO come in. This includes offering information in various formats (translations, easy read, large print, animations) to cater to different needs and improve accessibility. Parsons notes that "moving to digital opens up a whole new opportunity" to provide clearer and more accessible information.
- **Checking Understanding:** It is crucial to "check back that understanding" to ensure the patient has actually grasped the information provided. Amelia Newbold emphasises, "Have they have they actually understood, not assuming a level of understanding?"

3. The Role of Documentation:

Thorough and accurate documentation is vital for medico-legal protection and demonstrating that a meaningful dialogue has occurred.

- **Beyond the Consent Form:** While consent forms are important as evidence of signature, they are not a detailed account of the discussions. Newbold states, "a consent form is important, but it really just demonstrates that a patient can write their name. It isn't a detailed account of the discussions that you've been having."
- **Documenting the Dialogue:** Lawyers look for evidence of a "meaningful dialogue" in the medical notes, showing discussions about risks and benefits. Newbold asserts that this documentation "is going to protect you in terms of showing what discussions you've had about risks and benefits with a particular patient."

- **Referencing Information Leaflets:** Parsons advises trainees to "refer to the information that you've given on the consent form so that we have medico-legal evidence that the patient has received an EIDO document." He also includes this in his clinic letters. Newbold highlights the importance of documenting when patient information leaflets are provided, even referencing the *Biggadike* case where mentioning "EIDO leaflets given" with a tick box served as evidence.

4. The Evolution of the Legal Test for Consent:

The legal standard for informed consent has shifted from a paternalistic "doctor knows best" approach to one that prioritises patient autonomy.

- **The Bolam Test (Historical):** Historically, the *Bolam* test allowed clinicians to rely on the practice of a responsible body of medical professionals to determine the duty to provide information.
- **The Montgomery Case (Current Law):** The landmark *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 case significantly changed the law, aligning it with the GMC guidance. Newbold explains that following *Montgomery*, "Clinicians have a duty to take reasonable care to ensure that patients are aware of…a material risk involved in a recommended treatment and of any reasonable alternative or variant treatments."
- **Material Risks (Objective and Subjective):** Material risks are determined by a two-stage approach:
- **Objective:** What risks would a reasonable person in the patient's position likely attach significance to?
- **Subjective:** What risks should the clinician reasonably be aware that the individual patient would likely attach significance to? This necessitates understanding the patient's "lifestyle, their characteristics and their future aspirations."
- **Reasonable Alternative Treatments:** The *Bailey* (2017) and *McCulloch* (2022) cases clarified the extent to which alternative treatments must be discussed. While all possible options (including experimental ones outside the UK) do not necessarily need to be covered, clinicians must discuss "reasonable" alternatives. *McCulloch* suggests a return of expert evidence in determining what is "reasonable" in this context.

5. Causation in Consent Claims:

Establishing a breach of duty (failure to adequately inform) is not sufficient for a successful claim. The patient must also demonstrate **causation**.

- **Not a Standalone Right to Damages:** Failing to warn of a risk does not automatically entitle a patient to damages.
- **Demonstrating Different Action:** The claimant must prove that if they had been properly informed of the risks or alternative options, they would have made a different decision that would have avoided the harm suffered. This often relies on the claimant's factual witness evidence.

6. Practical Implications and Risk Mitigation:

The presentations offer several practical takeaways for clinicians to improve their consent practices and mitigate litigation risk.

- **Focus on Dialogue:** Prioritise genuine and meaningful dialogue with patients over simply obtaining a signature on a form.
- **Understand Patient Perspectives:** Actively seek to understand what is important to each individual patient.
- **Provide Accessible Information:** Utilise available resources (like EIDO) and adapt information formats to meet individual patient needs.
- **Check for Understanding:** Don't assume understanding; actively check that patients have comprehended the information.
- **Document Thoroughly:** Record the discussions about risks, benefits, and alternatives in the medical notes, beyond just noting that leaflets were provided.
- **Keep Updated:** Stay informed about current GMC guidance and developments in consent law.
- **Team Communication:** Involve the wider team in the consent process, ensuring information is shared and discussed with the patient consistently, even if the consultant's first interaction is on the day of surgery.
- **Address Waiting Lists:** Be aware that patients' circumstances may change while on waiting lists and revisit the consent process on the day of the procedure.
- **Trust Support:** Hospitals have an obligation to support clinicians in the consent process by providing validated information and resources. Concerns should be raised if this support is lacking.
- **Peer Review:** The All Wales model highlights the value of peer review in assessing the quality of the consent dialogue and process, focusing on shared decision-making and identifying areas for improvement. This moves beyond simple consent form audits.

- **Training and Competency:** For delegated consent (e.g., to trainees), ensure the individual is properly trained and competent to conduct the consent discussion, with access to consultant support for complex questions. Trainees should act within their area of competency and seek help when needed.
- **Addressing Patient Concerns:** Actively listen to and address patient concerns, including preferences about who performs the procedure. While patients cannot always dictate who operates, their concerns should be understood and discussed.
- **Handling Lack of Engagement on the Day:** If a patient on the day of surgery indicates they haven't read or understood the provided information, it is crucial to revisit the discussion and ensure they have the necessary understanding before proceeding. Amelia Newbold advises that if there are concerns about the patient's understanding, the procedure should not go ahead until this is addressed.

7. Innovations and Future Directions:

- **Digital Platforms:** Digital platforms offer opportunities for more accessible and understandable patient information, moving away from outdated paper-based resources.
- **Locally Produced Leaflets:** Initiatives are underway to allow the uploading of locally produced information leaflets into centralised systems, providing clinicians with a single resource.
- **Standardised Consent Forms:** There is a move towards developing standardised consent forms with new principles and guidance through collaboration between various medical and patient organisations.
- **E-learning:** E-learning modules on consent are being developed and implemented to improve clinician understanding and application of consent principles. The Welsh experience highlights the positive reception and impact of such resources when tailored to the local context.

In conclusion, the sources collectively underscore the critical importance of informed consent as a patient right and a fundamental aspect of good medical practice. The emphasis has shifted towards a patient-centred approach, prioritising meaningful dialogue, shared decision-making, and ensuring patients are genuinely informed and understand the proposed treatment and its alternatives and risks. Continuous learning, robust documentation, and a supportive organisational environment are essential for navigating the complexities of informed consent and mitigating potential legal challenges.