Briefing Document: Review of Informed Consent in Healthcare

Source: Excerpts from " 5. Informed Consent in Healthcare Key Themes and Legal Landscape.pdf"

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Overview:

This briefing document summarises the main themes and crucial insights discussed in the provided transcripts of presentations focusing on informed consent in healthcare. The presentations cover legal obligations, practical challenges, the role of information resources, and the ongoing evolution of best practices.

1. The Foundational Principles of Informed Consent:

All speakers emphasised that informed consent is not merely a form to be signed but an ongoing process centred on a "meaningful dialogue" between the clinician and the patient. Simon Parsons highlighted the **General Medical Council (GMC) guidance on consent**, specifically the first four key principles:

- **Patient Involvement:** "'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.'"
- **Ongoing Process:** "Decision-making is an ongoing process focused on a meaningful dialogue and the exchange of relevant information specific to the individual patient."
- **Right to Information and Understanding:** "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."
- **Understanding What Matters to the Patient:** "'doctors must try to find out what matters to the patient.'" This principle is directly linked to the **Montgomery case**.

Parsons stressed that these principles are often embedded in law, stating, "where the guidance says ‘you must’, that's because it's embedded in law. The law says you must. And if you don't fulfil those obligations, there is a chance that you will end up in court as a result."

2. The Importance of Providing Comprehensive and Understandable Information:

Several speakers addressed the crucial aspect of the information provided to patients. Parsons outlined the key elements of information that "you must give to your patients," including:

- Diagnosis
- Prognosis
- Available options (including alternatives)
- What the treatment involves
- Risks and complications
- Benefits
- Post-operative expectations
- Lifestyle changes to aid success

He emphasised the need for support in delivering this information effectively, highlighting the role of **EIDO information** in providing a baseline of standardised information. He advocated for using consultation time to "spend my time asking the questions, finding out what's important to the patients... and the risks they're prepared to take so that I can tailor my information for them."

3. The Impact of the Montgomery Ruling:

Amelia Newbold and Jonathan Fuggle provided a detailed overview of the legal landscape of consent, with a significant focus on the landmark **Montgomery v Lanarkshire Health Board** case. They explained how this ruling shifted the legal test for the duty to provide information away from the **Bolam test** (peer review) towards a **patient-centric approach** based on "material risks."

- **Material Risk Defined:** A risk is material if "'a reasonable person in the patient's position would be likely to attach significance to it', or the doctor knows or should reasonably know that the particular patient would be likely to attach significance to it."
- **Objective and Subjective Assessment:** This involves considering what a reasonable person would find significant and what the individual patient's circumstances and concerns are. "'doctors must try to find out what matters to the patient.'"
- **Meaningful Dialogue:** Montgomery necessitates a "meaningful dialogue" to understand what is significant to the patient, considering their "lifestyle, their characteristics and their future aspirations."

4. Reasonable Alternative Treatment Options:

Following Montgomery, the discussion has extended to the extent of the duty to discuss alternative treatment options. Fuggle referenced the cases of **Bailey (2017)** and **McCulloch (latest Supreme Court case)**, which provide further clarity:

- **Limits to Alternatives:** Clinicians are not necessarily obligated to discuss all possible options, especially those experimental or unavailable within the standard healthcare system (Bailey).
- **Reasonable Clinical Judgement:** Clinicians can exercise "reasonable clinical judgment" in deciding which options to offer (McCulloch), suggesting a partial return of expert evidence in determining reasonable options.

5. Causation and the Link Between Breach of Duty and Harm:

Fuggle also addressed the issue of causation, explaining that even if there is a breach of duty in failing to warn of risks, the patient must also establish that "if they had been warned of the risks that they weren't warned of or were given alternative options that they weren't, would they then have gone on and done something different?" This remains a crucial element for a successful claim.

6. Practical Implications and Challenges:

Several practical challenges and implications were discussed:

- **Documentation:** Thorough and accurate documentation of consent discussions is paramount for medico-legal protection. Simply ticking a box indicating "EIDO leaflets given" (as in the **Biggadike case**) may not be sufficient evidence of a meaningful discussion.
- **Patient Understanding:** It is crucial to check the patient's understanding of the information provided, not just assume it. Language barriers and differing levels of health literacy must be considered (as highlighted in the **Mordel case**).
- **Delegated Consent:** While permitted, delegated consent to trainees requires proper training and access to consultant support. Trainees must "act within your area of competency."
- **Changes in Patient Condition:** Clinicians must be aware that a patient's condition and preferences may change, especially if they have been on a waiting list for a long time, requiring a reassessment of consent on the day of the procedure.
- **Competence and New Techniques:** Consenting for procedures performed by trainees or involving new techniques requires transparency with the patient about the level of supervision and the consultant's role. Consultants introducing new techniques should also undergo appropriate proctoring.

- **Patient Refusal on the Day of Surgery:** If a patient expresses doubt or indicates they haven't understood the information on the day of surgery, even if prior discussions have occurred, the procedure should likely be deferred to allow for further reflection and understanding.
- **Addressing Specific Patient Concerns:** Clinicians must actively listen to and address specific concerns raised by patients or their representatives (e.g., parents of child patients regarding trainee involvement).

7. The Role of Collaboration and Patient Information Resources:

Julie Smith, Omar Mulla, Rachel Power, and Tim Johnson discussed the collaborative efforts involved in creating high-quality patient information.

- **EIDO's Collaborative Approach:** EIDO works with clinicians, patient information experts, and patient organisations to develop and update their library of leaflets and resources.
- **Importance of Patient Input:** Omar Mulla highlighted the value of seeking feedback directly from patients on the clarity and understandability of information. Rachel Power emphasised the need for information to be inclusive and representative of diverse patient populations.
- **Plain Language and Numeracy:** Tim Johnson stressed the importance of communicating complex medical information, including numerical risks, in plain language that is easily understandable for individuals with varying levels of numeracy and health literacy.
- **Addressing Epistemic Injustice:** Rachel Power raised the concept of "epistemic injustice," where a patient's knowledge and experience are disregarded by healthcare professionals, underscoring the importance of truly listening to and respecting patient perspectives.

8. Digital Consent: Benefits and Pitfalls:

The panel briefly discussed the increasing role of digital consent.

- **Benefits:** Digital platforms offer advantages such as patient choice in how they consume information (e.g., screen readers, font size adjustment) and potential for multimedia resources (animations, videos).
- **Pitfalls:** Concerns were raised about equitable access, as not all patients have smartphones, Wi-Fi, or even basic mobile phones. Digital solutions should complement, not replace, traditional methods to avoid excluding certain patient groups. The human interaction and meaningful dialogue remain central.

Key Takeaways:

- Informed consent is a continuous, patient-centred process built on meaningful dialogue and shared decision-making.
- The Montgomery ruling has fundamentally shifted the legal duty to inform patients based on what a reasonable person or the specific patient would consider material.
- Clinicians must provide comprehensive, clear, and understandable information about diagnoses, treatment options (including reasonable alternatives), risks, benefits, and expected outcomes.
- Actively assessing and documenting patient understanding is crucial.
- Collaboration with patients, patient organisations, and information providers is essential for developing effective and accessible resources.
- While digital tools offer benefits, equitable access and the importance of human interaction must be considered in the consent process.
- Thorough documentation of the consent discussion is vital for medico-legal protection.
- Clinicians must be mindful of delegated consent, changes in patient circumstances, and the specific concerns of individual patients.

This briefing highlights the critical aspects of informed consent discussed in the presentations. It underscores the evolving legal and ethical landscape and the ongoing efforts to improve communication and shared decision-making between clinicians and patients.