Briefing Document: Key Themes and Ideas from Consent in Healthcare Discussions

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Overview:

This briefing document summarises the main themes and important ideas discussed across a series of presentations and discussions regarding informed consent in healthcare. The focus is on understanding the evolving legal landscape, practical challenges, and the importance of patient-centred approaches to consent.

Key Themes and Ideas:

1. The Evolving Legal Landscape and the Impact of Montgomery:

- Shift from Paternalism to Patient Autonomy: The discussions repeatedly highlight the significant shift in legal precedent regarding consent, moving away from the "doctor knows best" (Bolam test) towards a focus on patient autonomy and what a reasonable person in the patient's position would want to know (Montgomery ruling). As Amelia Newbold states, "the focus, very much historically, was on the doctor knows best. So medical paternalism and that trumped patient autonomy. That continued until a case called Sidaway, which did not change the law, but Montgomery certainly did."
- Material Risks and the Two-Stage Test: The concept of "material risks" as defined by the Montgomery case is central. This involves a two-stage approach:
- **Objective:** What risks would a reasonable person in the patient's position be likely to attach significance to?
- **Subjective:** What risks should a clinician reasonably be aware that an individual patient would be likely to attach significance to? Amelia Newbold emphasises, "This is the dialogue point. This is the part where you need to understand what is significant to your individual patient in front of you."
- Causation: Following a breach of duty (failure to warn of appropriate risks), patients also need to establish causation that if they had been warned, they would have made a different decision. Jonathan Fuggle notes the legal complexities around this: "does the patient then have to go on and 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? So what lawyers always referred to as causation."

 Ongoing Evolution: Simon Hammond from NHS Resolution suggests that the legal landscape around consent is not yet fully settled: "I think the answer, it's no, probably not. Because I think as you have already seen, even though we've had those seminal cases which have occurred and reference that one there in McCulloch, things are still going to get tested."

2. The Importance of Shared Decision-Making and Meaningful Dialogue:

- **Beyond the Consent Form:** Multiple speakers stress that consent is a process, not just the signing of a form. Dr Ben Thomas notes that "a lot of clinicians equate consent with a yellow form, with a consent form, whereas actually it's about decision-making."
- Individualised Information: Providing information tailored to the individual patient's needs, understanding, and what matters to them is crucial. Simon Parsons highlights the principle that "doctors must try to find out what matters to the patient."
- **Active Listening:** Clinicians must actively listen to patients, understand their concerns, and provide the time and support needed to make informed decisions.
- Addressing Patient Perspectives: Helena Durham, representing the patient
 perspective, poignantly points out that patients often perceive the consent
 process as being "for the surgeon so that I don't sue them" rather than a genuine
 shared decision-making process for their benefit. She emphasises the need to
 bridge the gap between information provision and feeling genuinely involved in
 the decision.

3. Practical Challenges and Solutions in Obtaining Informed Consent:

- Time Pressures: The conflict between the need for thorough consent discussions and pressures to reduce waiting lists and increase efficiency is acknowledged. Dr Ben Thomas raises this, asking about the priority between "a good conversation with the doctor about the decision-making process... but also the imperative of the waiting list time and the time to treatment."
- Information Overload and Accessibility: Providing information in an understandable and accessible format is vital. Helena Durham's experience highlights the challenges of receiving leaflets that are not in a readable format for individuals with visual impairments. Julie Smith from EIDO discusses efforts to provide translations, easy-reads, and animations.
- The Role of Information Leaflets (EIDO): EIDO leaflets are frequently
 mentioned as a valuable tool for providing standardised information. Jonathan
 Webb notes that the Welsh Risk Pool has supported EIDO leaflets for 15 years,
 seeing them as the "gold standard information sharing for procedures." However,

it's emphasised that these are a starting point and should be supplemented by individualised discussion. A case mentioned by Jonathan Fuggle highlights the importance of documenting the provision of leaflets.

- **Electronic Consent (E-Consent):** Bryony Lovett discusses the implementation of electronic consent in her trust, aiming for a paper-free system while accommodating patients with varying digital literacy. This system includes opportunities for patients to review information, ask questions, and confirm consent at different stages.
- Peer Review and Audit: Dr Ben Thomas discusses the importance of peer review in assessing the consent process, focusing on the decision-making undertaken with the patient. Simon Parsons acknowledges that audits of consent processes are often "performed pretty badly" and that available resources are not always used effectively.
- Consent on the Day of Surgery: Bryony Lovett strongly argues against taking consent solely on the day of surgery, stating, "Consenting on the day of surgery is a complete waste of time. The patient's completely terrified. They've turned up, which is effectively implied consent. They do sign a form, but that is not consent, consent is the process that went on before that."

4. Specific Considerations and Best Practices:

- Documentation: Meticulous record-keeping of the consent discussion, including reference to information provided (e.g., EIDO leaflets), is crucial for medico-legal protection. Simon 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." Jo Clift reinforces this with "no notes, no defence. Poor notes, poor defence."
- Competency and Delegation: Clinicians must act within their area of competency and seek help when needed. When delegating procedures to trainees, it must be ensured that they are appropriately trained and supervised, and this should be reflected in the consent process.
- Changes in Patient Condition: Clinicians must be aware that a patient's
 condition or circumstances may have changed, especially if they have been on a
 long waiting list, and revisit the decision-making process accordingly.
- Bedside Manner and Building Trust: Francis Brooks and Jo Clift emphasise the
 importance of bedside manner and emotional intelligence in building trust with
 patients. They suggest that "patients don't sue people they like, or they try not
 to." A good rapport facilitates better communication and a more informed
 consent process.

- Identifying "Red Flag" Patient Profiles: Brooks and Clift also discuss identifying patient profiles that might indicate a higher risk of complaints or litigation, such as "serial patients," "secretive patients," and "unrealistic patients."
- **Learning from Mistakes:** Regulators, such as the GMC, are keen to see evidence that clinicians learn from mistakes and adapt their practice accordingly.
- Addressing Situations Where Patients Haven't Read Information: Charles
 Ranaboldo raises the common scenario where patients on the day of surgery
 admit they haven't read the provided information. The response suggests
 revisiting the prior discussions and ensuring the patient still wishes to proceed
 having had those conversations.
- Considering Patient Language Preferences: Jonathan Webb highlights that in Wales, consent information is available in Welsh, and research shows patients prefer to be consented in their language of choice.

5. Financial Implications of Consent-Related Claims:

- Simon Hammond from NHS Resolution reveals that a significant amount of money is paid out in damages and legal fees for consent-related claims. He stated the figure as £522 million over the last five years. This underscores the financial importance of ensuring robust consent processes.
- Bryony Lovett highlights that a significant percentage of complaints to NHS
 Resolutions relate to consent, although the number of complaints against
 surgeons has decreased. The cost of litigation remains a substantial burden on
 the NHS.

Conclusion:

The discussions presented underscore the multifaceted nature of obtaining valid informed consent in contemporary healthcare. The legal framework established by the Montgomery ruling necessitates a patient-centred approach that prioritises meaningful dialogue, individualised information, and a genuine understanding of what matters to each patient. While tools like EIDO leaflets and electronic consent systems can aid the process, they must be implemented thoughtfully and complement, rather than replace, thorough and empathetic clinician-patient interactions. Addressing practical challenges such as time pressures and information accessibility, alongside meticulous documentation and a commitment to continuous learning, are essential for improving the consent process and mitigating the risks of legal challenges and, most importantly, ensuring patients feel truly informed and empowered in their healthcare decisions.