Briefing Document: Themes and Important Ideas in Consent Discussions

Source: Excerpts from "12 Rob Hughes, Doug Hopkins, Mr Paul Johnson and Zoe Blackman_SRT_English.srt.pdf"

Date: 26th November 2024 [Date of presentation]

Author/Speaker: Rob Hughes, digital director at EIDO Healthcare. Doug Hopkins, deputy director of strategy at Vital Hub UK and head of partnerships. Zoe Blackman, Transformation Leader at Induction Healthcare. Paul Johnson, CEO at Redar Healthcare.

Overview:

This briefing document summarises the main themes and important ideas discussed across the provided transcripts concerning the process of obtaining informed consent within the NHS. The discussions highlight the evolving understanding of consent, the impact of landmark legal cases, practical challenges faced by clinicians, and potential solutions offered by digital platforms and revised policies.

1. The Evolution of Informed Consent and the Impact of the Montgomery Ruling:

A central theme throughout the discussions is the significant shift in the legal and ethical understanding of consent, largely driven by the *Montgomery v Lanarkshire Health Board* case. Speakers consistently refer to this ruling as a pivotal moment that moved away from a paternalistic "doctor knows best" approach (rooted in the Bolam test, later qualified by Bolitho) towards a patient-centric model emphasising individual autonomy.

- **Shift from "Doctor Knows Best" to Patient Autonomy:** Before *Montgomery*, the focus was often on whether a doctor acted in accordance with a responsible body of medical professionals. As Amelia Newbold stated, "the focus, very much historically, was on the doctor knows best. So medical paternalism and that trumped patient autonomy."
- **Material Risks and the Two-Stage Test:** *Montgomery* introduced the concept of "material risks" – risks a reasonable person in the patient's position would likely attach significance to, or risks the clinician is aware the particular patient would attach significance to. This necessitates a two-stage approach involving both objective and subjective assessment. Amelia Newbold explained: "It's a two-stage approach involving both an objective and a subjective assessment. So the objective part of this: What risks would a reasonable person in the patient's position be likely to attach significance to? And then the second part, the subjective bit: what risks should a clinician reasonably be aware that an individual patient would be likely to attach significance to?"

- **The Importance of Dialogue:** The subjective element of material risk underscores the crucial need for a meaningful dialogue between the doctor and the patient to understand what matters to the individual. Simon Parsons emphasised the importance of "that meaningful dialogue and the exchange of relevant information specific to the individual patient."
- **Causation Post-Montgomery:** Jonathan Fuggle highlighted a legal point of contention following *Montgomery* concerning causation: whether a patient, having established a failure to warn of a material risk, also needs to prove they would have made a different decision had they been properly informed. He noted that this has been debated in the Court of Appeal multiple times.
- **Consistency Across the UK:** Jonathan Webb of the Welsh Risk Pool highlighted the development of an "All Wales model consent policy" and "All Wales consent forms" to ensure consistency in consent practices across the nation, incorporating emerging case law.

2. Practical Challenges and Considerations in Obtaining Consent:

The transcripts reveal numerous practical challenges clinicians face in ensuring effective informed consent:

- **Time Constraints:** Several speakers alluded to the time pressures within the NHS making in-depth consent discussions challenging. Karen Hassell quoted a patient saying, "But they really haven't got the time, really. Your mind is not really processing yet. You know, they come up with all of these things and it's just a blur.'"
- **Patient Understanding and Information Overload:** Helena Durham, sharing her experiences as a patient, highlighted the issue of receiving large amounts of information that can be overwhelming and not always in an accessible format (e.g., font size). She also pointed out the disconnect some patients feel between the information provided and the consent form, seeing the latter as primarily for the surgeon's protection. "Nobody saw it as being really a process for them and I thought that was really sad and sort of quite concerning. But I think that was because for some of them, that link between the information and the consent almost wasn't there."
- **Consent on the Day of Surgery:** Bryony Lovett strongly argued against taking full consent 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."

- **Competence of the Clinician:** Concerns were raised about trainees performing procedures and the need for appropriate supervision and disclosure to patients about the level of involvement of senior surgeons. A vascular surgery registrar, Martin, asked, "When consenting as trainees, I mention that I may be doing part of the operation, the whole of the operation... Quite often, I won't know how much of a procedure I'm going to be doing, whether my boss will be directly in the room for all of the procedures, some of the procedure. How do you...?" Simon Parsons emphasised that consultants being "proctored by experts" for new techniques needs to be part of the consent process.
- **Changing Patient Conditions:** Simon Parsons highlighted that for patients on long waiting lists, their condition might change, necessitating a reassessment of the decision-making process on the day of surgery. "As patients have been on a waiting list, for sometimes over a year, things might change. And so we also have to be aware that when they come for their operation... their condition might have changed."
- **Dealing with Patients Who Haven't Read Information:** Charles Ranaboldo raised the common scenario of patients arriving for surgery having not read the provided information. Jonathan Webb suggested that the prior discussion still holds weight.
- **Parental Consent in Paediatrics:** Manoj Shenoy brought up the ethical challenge of situations where parents request a specific surgeon for their child.

3. Solutions and Best Practices for Improving Consent:

The discussions also explored potential solutions and highlighted best practices:

- **Utilising Patient Information Leaflets (PILs):** EIDO leaflets were frequently mentioned as a "gold standard" for information sharing, praised for their availability in multiple languages (including Welsh) and the potential for customisation. Jonathan Webb noted the Welsh Risk Pool's long-standing support for EIDO leaflets.
- **The Importance of the Consent Process, Not Just the Form:** Ben Thomas emphasised that "a lot of clinicians equate consent with a yellow form, with a consent form, whereas actually it's about decision-making and consent." Bryony Lovett echoed this, stating, "Consent is a process. It starts with the diagnostics."
- **Digital Consent Platforms:** Several speakers, particularly Simon Parsons, Karen Hassell, and Lisa Whisker, discussed the implementation and benefits of digital consent platforms. These platforms can facilitate the provision of information earlier in the patient journey, allow patients more time to consider, enable them to ask questions electronically, and integrate with electronic patient records.

Simon Parsons highlighted the use of Isla Health's platform in Nottingham, allowing patients to answer questionnaires and raise questions before their consultation.

- **Pre-assessment and Prehabilitation:** Simon Parsons mentioned digital providers for pre-op assessment, and Bryony Lovett described incorporating prehabilitation exercises into the consent process to help patients understand and mitigate their own risks.
- **Peer Review and Audits:** Ben Thomas mentioned the importance of peer review in evaluating consent processes. Simon Parsons acknowledged that poorly performed audits are a common issue and that available resources for clinicians aren't always used effectively.
- **Using "BRAN":** Bryony Lovett highlighted the Royal College of Surgeons' emphasis on using the BRAN acronym (Benefits, Risks, Alternatives, Nothing) in the consent process.
- **Focusing on What Matters to the Patient:** Principle four of the GMC guidance, as mentioned by Simon Parsons, is that "doctors must try to find out what matters to the patient."
- **Effective Communication and Language:** Tim Johnson, drawing from his experience in financial services, emphasised the importance of explaining complex concepts in simple, understandable language, including numerical information. Omar Mulla described showing draft literature to patients for feedback.
- **Importance of Documentation:** Bryony Lovett noted the Royal College of Surgeons' emphasis on documenting the entire consent process and including it in letters to the GP. Simon Hammond also stressed the value of good documentation in defending claims and helping patients recall the conversation.
- **"No Decision About Me Without Me" in MDTs:** Bryony Lovett clarified that the multidisciplinary team (MDT) recommendation is not a final decision but facilitates the consultant's discussion with the patient. However, Helena Durham questioned the lack of patient involvement in the MDT process and whether patients should be presented with a limited set of options from the MDT.
- **Checking Understanding:** Bryony Lovett described a novel approach of asking patients what they told their friends they were having done to gauge their understanding.

4. The Cost of Litigation and the Role of Risk Pools:

Jonathan Webb and Simon Hammond highlighted the significant financial costs associated with claims related to consent.

- **High Costs of Avoidable Harm:** Jonathan Webb stated that the reserves in the Welsh Risk Pool were substantial, emphasising that the costs are driven by "avoidable harm to patients from not having that informed consent."
- **Significant Damages Payments:** Simon Hammond revealed that NHS Resolution had paid £522 million in damages and legal fees over the last five years in cases where damages were awarded for consent-related issues.
- **Damage to Patient-Doctor Relationships:** Simon Hammond also pointed out the damage to the ongoing relationship between patients and healthcare providers when consent is inadequate.

5. The Role of Regulatory Bodies and Learning from Mistakes:

Jo Clift emphasised that regulatory bodies like the GMC are keen to see evidence that clinicians are learning from mistakes and adapting their practice. She also stressed the importance of staying within one's area of expertise and seeking peer consultation when necessary.

6. Cooling-Off Periods:

The issue of cooling-off periods was raised, particularly in the context of cosmetic surgery, with a suggestion of a 14-day minimum. The applicability of such periods to time-sensitive conditions like cancer treatment was also discussed.

In conclusion, the transcripts underscore the fundamental importance of informed consent as an ongoing, patient-centred process grounded in open communication and shared decision-making. The legacy of the *Montgomery* ruling continues to shape clinical practice, driving a need for better understanding of individual patient needs and preferences regarding risk. While practical challenges remain, the adoption of digital tools, revised policies, and a renewed focus on the principles of consent offer promising avenues for improvement, ultimately aiming to reduce patient harm and litigation costs while fostering greater trust and partnership between patients and clinicians.