Briefing Document: Informed Consent and Shared Decision-Making in Healthcare

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Overview:

This briefing document summarises the main themes, important ideas, and key facts presented in the provided transcripts of presentations focusing on informed consent and shared decision-making in healthcare, primarily within the context of the UK, with a specific focus on Wales.

1. Simon Parsons (Consultant Upper-GI Surgeon & Co-founder of EIDO): The Clinician's Perspective on Informed Consent

Simon Parsons' presentation provides a clinician's perspective on the importance of informed consent, grounding it in General Medical Council (GMC) guidance and legal obligations. He highlights the evolution of consent practices and the role of tools like EIDO in supporting this process.

Key Themes and Ideas:

- **GMC Guidance is Paramount:** Parsons emphasizes the updated GMC guidance on consent (2020) and its seven key principles, focusing on the first four which are crucial for the consent process itself (principles five to seven relate to capacity).
- **Principle 1:** "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."
- **Principle 2:** "Decision-making is an ongoing process focused on a meaningful dialogue and we'll come back time and again to that meaningful dialogue and the exchange of relevant information specific to the individual patient."
- **Principle 3:** Patients have the right to be listened to, receive necessary information, and be given sufficient time and support to understand it.
- **Principle 4:** "doctors must try to find out what matters to the patient." This principle is linked to the **Montgomery case**, underscoring the importance of understanding the patient's perspective.

- **Legal Obligations:** The GMC guidance carries legal weight ("where the guidance says ‘you must’, that's because it's embedded in law"). Failure to meet these obligations can lead to legal action.
- **Essential Information for Patients:** Clinicians *must* provide information on:
- Diagnosis and prognosis (including uncertainties).
- Available treatment options (including no treatment).
- The nature of each option.
- Benefits and risks of harm (including uncertainties).
- **The Role of EIDO:** Parsons, as a co-founder, explains that EIDO aims to support clinicians in providing this necessary information effectively. He acknowledges the challenges of having meaningful conversations within time constraints and avoiding medical jargon. EIDO provides information on:
- The problem and different treatment options.
- What surgery involves.
- Risks and complications.
- Benefits and post-operative expectations.
- Lifestyle changes.
- **Meaningful Dialogue is Key:** Standardised information (like EIDO leaflets) is a foundation, but it *cannot replace* a meaningful dialogue. Clinicians should focus on:
- Asking questions to understand what matters to the patient.
- Tailoring information to the individual's circumstances, hobbies, and profession.
- Assessing the risks the patient is prepared to take.
- **Supporting Patient Understanding:** Information should be provided in accessible formats, including translations, easy-read versions, large print, and digital animations. The shift to digital platforms offers significant opportunities for better information sharing.
- **Team Responsibility:** In a team setting, it's crucial that all members involved in the patient's care contribute to the consent process. Even if the consultant sees the patient on the day of surgery, the team should have already initiated the dialogue and provided information.

- **Delegated Consent:** Trainees can participate in the consent process if they are adequately trained. EIDO offers consent training packages. Trainees must work within their competency and seek support when needed.
- **Importance of Documentation:** Accurate medical record keeping is vital, including explicit reference to the information provided (e.g., mentioning the EIDO document on the consent form and in clinic letters). This serves as medico-legal evidence.
- **Considering Changes Over Time:** For patients on long waiting lists, their condition and decision-making may have changed by the time of their procedure, requiring reassessment on the day.
- **Organisational Support:** Hospitals and trusts have an obligation to support clinicians in the consent process by providing validated information. The GMC suggests raising concerns if this support is lacking.

2. Jonathan Webb (Head of the Welsh Risk Pool): The Risk Management and National Perspective in Wales

Jonathan Webb's presentation focuses on the perspective of the Welsh Risk Pool, the indemnifier for all health bodies in Wales. He highlights the increasing costs associated with claims related to consent and the proactive measures being taken in Wales to improve the consent process and reduce avoidable harm.

Key Themes and Ideas:

- **NHS Wales Context:** Provides an overview of the structure of NHS Wales, including health boards, national trusts, and the recent introduction of the NHS Wales executive.
- **Rising Claims and Costs:** The Welsh Risk Pool has seen an upward trend in claims numbers and an even greater exponential increase in the value of claims. The budget for settling claims in Wales is significant (£140 million this year).
- **Consent as a Key Area of Concern:** Approximately 20% of letters of claim received by the Welsh Risk Pool involve allegations or critiques of the consent process, making it a priority area.
- **Prevention and Learning Programs:** The Welsh Risk Pool has introduced various programs aimed at preventing harm and learning from claims, with a strong focus on consent and decision-making.
- **National Collaboration:** There is strong collaboration across NHS Wales in addressing consent issues, facilitated by technology and a shared commitment to improvement.

- **All Wales Model Consent Policy and Forms:** Wales has a national, regularly updated consent policy and standardised consent forms, ensuring consistency across the nation. These forms are "live documents" and are subject to ongoing review (e.g., regarding mental capacity).
- **Challenges with Digital Implementation:** While there is a desire to utilize digital technology for consent, current implementations can sometimes lengthen the workflow for busy clinicians, requiring further work to improve accessibility.
- **Consent Standards and Assurance:** The Welsh Risk Pool has introduced standards for Consent to Examination or Treatment and provides assurance reports to health organisations to drive improvement plans.
- **Long-Standing Support for EIDO:** The Welsh Risk Pool has supported the use of EIDO consent information leaflets for 15 years, viewing them as the "gold standard" for information sharing. These are available in Welsh and English, and the importance of consenting patients in their language of choice is recognised.
- **Local Leaflet Integration:** By 2025, the EIDO platform in Wales will allow for the uploading of locally produced leaflets where EIDO leaflets do not exist, creating a single resource for clinicians.
- **Focus on Communication, Documentation, and Escalation:** The Welsh Risk Pool learning panel has identified these three areas as crucial for improvement, aligning with the principles highlighted by Simon Parsons and the GMC guidance.
- **Wales-Specific E-learning Package:** A bespoke e-learning package on consent has been developed for NHS Wales staff, with over 10,000 users. This video-based package features eminent speakers and focuses on the practical application of consent principles for "jobbing clinicians."

3. Dr. Ben Thomas (All Wales Clinical Lead for Decision-Making and Consent): The Peer Review Framework

Dr. Ben Thomas' presentation delves into the concept of peer review as a method for measuring and improving the quality of the consent dialogue and process. He argues that consent is more than just a form and emphasizes the ongoing nature of shared decision-making.

Key Themes and Ideas:

- **Consent as Decision-Making, Not Just a Form:** Thomas stresses that consent should be viewed as an implicit part of every healthcare interaction and an ongoing dialogue, with medical notes serving as a record of shared decision-making.

- **Complexity and Nuance of Medical Decision-Making:** He highlights the subjective nature of risk assessment, the individuality of patients, and the dynamic nature of decision-making, quoting William Osler and Peter Richards to illustrate this uncertainty and the potential for wrong decisions.
- **Dichotomy Between Medical and Legal Decision-Making:** Thomas contrasts the retrospective, fact-based, and certainty-driven nature of legal reasoning with the prospective, dynamic, uncertain, and often outcome-based approach sometimes seen in medicine. He points out that legal scrutiny often focuses on the *process* of decision-making.
- **Broadening the Remit to Decision-Making:** The All Wales consent group has expanded its focus to encompass all aspects of decision-making, including end-of-life decisions and mental capacity.
- **Limitations of Consent Form Audits:** Traditional consent form audits are seen as a limited "surrogate marker" of the quality of the consent process, lacking evidence of the preceding dialogue.
- **Rationale for Peer Review:** Peer review was adopted as a tool to assess the two-stage model of consent conversations and the process of shared decision-making. Its benefits include:
- Relevant expertise within the process.
- Opportunity for reflection on practice.
- Normalising review and reflection as part of professional development.
- Facilitating specialty-based discussions and consistent approaches.
- Providing assurance about delegated consent.
- Enabling organisational monitoring of trends and targeted interventions.
- **Simple Methodology:** The peer review process involves retrospective review of medical notes using a developed consent tool by specialty or clinical governance groups, coordinated by the MDT leader and typically involving a senior clinician's judgment.
- **Key Standards for Review:** The peer review looks at the consent form, the two-stage consent process, the consent dialogue, and the discussion around risks and benefits.
- **Findings from Peer Review:** Initial cycles of peer review in Wales revealed key areas for improvement:
- Procedure-specific leaflets were provided in only 40% of cases.

- The version of the leaflet provided was recorded in only 25% of cases.
- Not all appropriate and available treatment options were discussed in over 20% of cases.
- **Challenges with Engagement:** Maintaining engagement in subsequent cycles of peer review has been a challenge, potentially due to clinical capacity and other factors.
- **Positive Feedback and Educational Value:** Despite the challenges, the peer review framework has been well-received nationally and is seen as a valuable organisational and, crucially, educational tool that promotes reflective practice.

Key Discussion Points Raised During Q&A:

- **Accessibility of E-learning Module:** The Welsh Risk Pool's consent e-learning module is currently specific to NHS Wales staff, accessible via their ESR platform (and 'Learn at Wales' for primary care). It is not a UK-wide resource, although theoretically accessible on ESR in England.
- **Consideration of Patient Preferences:** The peer review audit in Wales primarily focused on the clinician's decision-making process and documentation of dialogue, rather than directly auditing patient preferences for the format of information. This was acknowledged as an important aspect of patient experience that may not be fully captured by the current audit.
- **Challenges with Implementing Best Practices:** There is a recognition that resources and best practice guidelines are not always consistently used by clinicians, highlighting a persistent gap between knowledge and implementation.

Overall Summary:

The presentations collectively underscore the critical importance of informed consent as a legal, ethical, and clinical imperative. They emphasize a shift in focus from consent as a mere form-filling exercise to a dynamic process of shared decision-making centred on meaningful dialogue with the patient. The GMC guidance provides a clear framework for clinicians' obligations, and tools like EIDO can support the provision of necessary information. However, these resources are insufficient without genuine engagement and communication tailored to the individual patient's needs and preferences.

The Welsh Risk Pool's proactive approach, including national policies, standardised forms, and the implementation of a peer review framework, demonstrates a commitment to improving consent practices and reducing avoidable harm. The findings from the peer review highlight specific areas for improvement, particularly around the discussion of treatment alternatives and the consistent provision and documentation of

patient information leaflets. While challenges remain in ensuring consistent engagement and fully incorporating patient preferences into audit processes, the overall message is one of ongoing effort and learning to enhance the quality of informed consent in healthcare.