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Informed consent

Informed consent in pregnancy, labour and neonatal care.

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MS15 - Informed consent

(358)

2025-12399

Exploring Black women's experiences of consent to vaginal examination during labour. Van der Stede EW, Lanceley A, Maslowski K, et al (2025), European Journal of Obstetrics & Gynecology and Reproductive Biology vol 314, November 2025, 114719

Objectives
Consent is the foundation of all lawful, autonomy-supporting clinical practice. Yet, limited evidence indicates that women's experiences of consent in obstetric settings are often unsatisfactory, with women's voices being disregarded. Black women are particularly vulnerable to poor obstetric experiences and inequitable outcomes. Vaginal examination (VE) is commonly used to assess progress in labour so was selected as a focus for our exploratory investigation of Black women's experiences of the consent process during labour. There has been little formal exploration of women's consent experiences in this context, and none specifically in Black women.
Study design
Qualitative study using semi-structured face-to-face interviews of 15 Black women. Data were analysed using thematic analysis.
Results
Three overlapping themes were identified: unrecognised genuine choice – women were not aware that they could choose whether to have a VE; deficient information – most women were not provided with adequate information to support them in making an informed choice; distress and surprise – many women were troubled and shocked by their experience of VE. Overall, Black women did not perceive VEs as a choice, nor were they provided with adequate information to support valid consent.
Conclusions
Black women's experience of the VE consent process does not always align with current legal and professional requirements. Black women's support for choice-making was neglected and consent for VEs was not always voluntary or informed, highlighting the urgent need for healthcare professionals to address consent practices in this area.

2025-11915

O&G professionals' understanding of levator and OASI Injuries, their views on antenatal counselling and obtaining informed consent for obstetric interventions: An online survey. Stuart LG, Shek KL, Dietz HP (2025), European Journal of Obstetrics & Gynecology and Reproductive Biology vol 312, August 2025, 114088

Introduction/Hypothesis
Obstetric anal sphincter injuries (OASI) and levator ani trauma are common maternal injuries. Our aim was to explore the understanding of these injuries by O&G professionals in addition to their views on antenatal counselling and obtaining informed consent for potential maternal birth injuries.
Methods
An online survey was conducted among O&G professionals across 4 metropolitan Sydney Hospitals. It encompasses twenty-four items in four main domains consisting of a series of multiple-choice questions. These four domains are (1) Respondent characteristics; (2) Understanding/teaching of OASI and levator trauma; (3) Views on antenatal counselling; (4) Views on obtaining written informed consent for obstetric interventions.
Results
165 individuals responded (32 %), 65 % were midwives and 30 % were doctors. 99 % of them had prior knowledge of OASI, but this figure was only 62 % for levator trauma. More doctors have heard about levator trauma (94 % vs 50 % for midwives; $P < 0.001$) and more doctors considered themselves to be very well/well informed of the condition (57 % vs 20 % for midwives, $P = 0.002$). Adequacy of teaching was considered fair/poor for levator trauma by 78 % of respondents compared to 35 % for OASI. Only 26 % learned about levator trauma mainly from standard teaching. 81 % supported discussion of maternal trauma and 76 % supported obtaining written informed consent for obstetric interventions.
Conclusion
Levator trauma is much less well recognized than OASI. A lack of standard teaching may be contributory and may constitute one of the challenges in patient counselling and obtaining informed consent for obstetric interventions, supported by the majority of respondents.

Full URL: https://doi.org/10.1016/j.ejogrb.2025.114088

2025-11772

Patient Perceptions of Informed Consent for Operative Vaginal Birth: A Qualitative Analysis. Diskin L, Burcher P, Meisles D, et al (2025), Birth 25 September 2025, online

Background
Operative vaginal birth (OVB) is a potentially life-saving intervention, but as a procedure with potential risks and benefits, it must first be preceded by an informed consent discussion. Informed consent is one aspect of patient involvement in the decision to deliver with the assistance of instruments, such as forceps or vacuum. However, it is unclear whether patients undergoing operative vaginal delivery consider informed consent to be adequate; and whether the adequacy of consent impacts their birth experience.

Methods
Using open-ended, semi-structured interviews (n = 20), the purpose of this study was to characterize patient perceptions of the informed consent process for OVB and to evaluate the role pre-procedure communication might play in influencing assisted birth experiences. Patients who had undergone an operative vaginal delivery were invited to share their birth experiences and to provide suggestions for improving the consent process when relevant. Using consensus coding, three investigators independently evaluated the transcribed interviews and identified emergent codes. These codes were then compared, and any disparate ideas were discussed until consensus was reached.

Results
Three primary themes emerged from patient narratives: (1) the difficulty of engaging in the consent process during the second stage of labor; (2) no perceived loss of agency; nonetheless, and (3) acceptance of limited consent discussions because OVB is preferred over a cesarean.

Conclusion
The three key themes identified in the study suggest that patients are satisfied with their birth experience following an OVB, despite significant limitations in informed consent. Findings suggest that patients are accepting a substandard consent process, and that renewed attention should be paid to improving information sharing, even during relatively urgent care encounters. Even though patients expressed satisfaction with the consent process, the adequacy of informed consent is not determined by patient satisfaction. Improving information sharing during urgent care encounters could improve the quality of informed consent for patients undergoing operative vaginal delivery. (© 2025 The Author(s))

2025-11734

Editorial - Trust and responsibility: Going with the flow. Smith A (2024), AIMS Journal vol 36, no 3, September 2024

Alex Smith considers the relationship between uncertainty, trust and responsibility, proposing the practice of truly consensual care as a form of birth activism - for parents and professionals alike. (© AIMS)

Full URL: https://www.aims.org.uk/journal/item/editorial-september-24

2025-11313

Parent and practitioner experiences of opt-out consent in neonatal intensive care: a mixed methods study within a trial. Mitchell T, Andrzejewska I, Battersby C, et al (2025), Archives of Disease in Childhood: Fetal and Neonatal Edition 31 August 2025, online

Background In neonatal trials, verbal opt-out consent has been used to reduce burden on families and make recruitment more efficient and representative. It involves information provision through posters and leaflets before randomisation, and parents can verbally ‘opt out’ of their baby being randomised to the trial. There is limited understanding of how opt-out consent is operationalised in a multicentre neonatal trial, and its acceptability to staff and parents.

Objective To explore views and experiences of verbal opt-out consent in neoGASTRIC, a neonatal randomised trial comparing routine and no routine measurements of gastric contents in preterm babies.

Methods A mixed methods (questionnaires, interviews and focus groups) process evaluation within a trial.

Setting Four UK neonatal units.

Participants 253 participants: 167 staff (149 questionnaires; 18 across two focus groups), 86 parents (85 questionnaires; 15 interviews; 14 took part in both).

Results Parents and staff supported opt-out consent in neoGASTRIC as interventions were viewed as low risk and non-invasive. Parents appreciated an appropriately timed research conversation; only 21% noticed study information banners/posters. Operationalisation of opt-out consent varied in terms of when information was provided and randomisation timing. Women approached during labour or within hours of birth reported feeling overwhelmed and lacking capacity to consider research. Some staff operationalised a modified opt-in approach.

Conclusions An appropriately timed verbal opt-out approach to consent was seen acceptable as proportionate in the neonatal context in a low-risk trial comparing different accepted clinical, non-pharmaceutical, practices. Findings informed neoGASTRIC and will guide approaches to consent in this setting. (© 2025, The Author(s). Published by BMJ Publishing Group Ltd.)

Full URL: https://doi.org/10.1136/archdischild-2025-328693

2025-10040

Legal threats to autonomy, choice, and informed consent in labor and childbirth: how the law makes pregnant and birthing people vulnerable to mistreatment and unconsented practices. Montero OF, Gretzinger F, Kilmartin Q, et al (2025), June 2025. 50 pages

Investigates how legal frameworks across twelve countries and international human rights law affect pregnant people's rights during labour and childbirth - specifically autonomy, informed consent, and choice. (MB)

Full URL: https://reproductiverights.org/wp-content/uploads/2025/06/Legal-Threats-to-Autonomy-Choice-and-Informed-Consent-FINAL.pdf

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2025-09901

Doctors' experiences on dealing with informed consent required for lifesaving interventions for pregnant women in Somalia. Aweis A, Mauma M, et al (2025), Frontiers in Global Women's Health 26 August 2025, online

Background: Informed consent is a crucial legal and ethical requirement in the physician-patient relationship for all aspects of care. Despite, patients have the right to make their own decision in health, women in the Middle East and Africa, including Somalia, often have limited autonomy in healthcare decisions due to patriarchal structures. In Somalia, male family members including husbands frequently hold the ultimate authority in women's healthcare choices, sometimes restricting access to lifesaving sexual and reproductive health services.

Purpose: To explore doctors' experiences of delay or refusal to provide consent for lifesaving interventions for pregnant women in Somalia.

Patients and methods: an exploratory, qualitative design. Purposive sampling was used to select doctors working in maternity wards in the five selected hospitals. A total of 22 medical doctors were interviewed using a semi structured interview guide, and the data were analyzed using thematic analysis.

Results: An overarching theme emerged: "The disconnect between healthcare system and patriarchy system" with five sub-themes namely: (1) Consent is given only by paternal male family members (2) Paternal and male witnesses signatures required for the consent form (3) Paternal male conflicts and other reasons for delaying or refusing consent (4) Potential consequences for the doctors without the consent of paternal male (5) Changing the consent guidelines from paternal male dependency. Consent of the pregnant women is given by paternal male family members since they are responsible for her life (blood/Diya) according to cultural practices. The husband's consent is sufficient only in the case of post-abortion care, as this also involves the fetus. Misconceptions that cesarean sections can damage the uterus, limit future pregnancies, or impair a woman's ability to perform daily activities also contribute to delayed or refusal of consent.

Conclusion: This study revealed that doctors require protection when performing their duties. All doctors who participated in the study were ready to save the lives of their patients, but were assured of their safety. Patients seem to cooperate with doctors, but the cultural practices of providing consent from male members remain a challenge to the intervention. A national health policy should be drafted and approved by the cabinet that grant women the sole right to consent to life-saving medical interventions. Additionally, community mobilization is needed to educate community leaders about the negative impact of delaying or denying women informed consent to essential

healthcare due to the patriarchal norms. (© 2025 Aweis, Mauma, Aweis, Afrah, Guled and Kulane. This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY).)

Full URL: https://doi.org/10.3389/fgwh.2025.1584113

2025-09686

Normalising Choice: An Observational Study of Australian Clinicians' Perspectives on Written Informed Consent for Vaginal Birth. Ananthram H, Vangaveti V, Wooley T, et al (2025), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) 1 August 2025, online

Background
The NSW Birth Trauma Report identified flawed consent processes and poor calibre antenatal information to have harmed birthing women. Written informed consent for vaginal birth may improve carer accountability and is currently applied in limited circumstances, for example, vaginal birth after caesarean section (VBAC).

Aims
This study explores how informed women are about birth, as perceived by clinicians, and perspectives on the implications of written informed consent for vaginal birth.

Materials and Methods
This study uses survey-based research for quantitative data and inductive content analysis for open-ended questions. Main outcome measures include carer perceptions on consent to the mode and/or location of birth and arguments against/in favour of written informed consent.

Results
One thousand two hundred and seventy-one responses were analysed for the final results, with 851 (67%) obstetric (Obs) and 420 (33%) midwifery (MW) respondents. Obs were eight times likelier to believe that women are never/rarely fully informed regarding vaginal birth ($p < 0.001$). The majority in both cohorts agreed women are frequently/always fully informed about VBAC. However, only 49 (6.6%) Obs and 20 (6%) MW were aware of written informed consent forms in use for vaginal birth. Themes developed include—'helpless clinicians' facing impediments to consent, flawed understanding of consent, rejection of consent requirements, juxtaposing consent with normality, disruption to collaboration and antenatal information undermining consent.

Conclusions
Maternity carers in this Australian survey agree women are not fully informed regarding the risks and benefits of birth. Written informed consent alongside adjuncts like birth plans or technology-based platforms may offer a way ahead for the future.

Full URL: https://doi.org/10.1111/ajo.70061

2025-09464

Informed consent: An essential key to promoting and protecting autonomy and preventing obstetric violence. Pickles C, Odada K (2025), International Journal of Birth and Parent Education vol 12, no 3, April 2025, pp 3-5

In this editorial the authors discuss about informed consent during pregnancy and childbirth and argue that stripping women's autonomy is a form of obstetric violence. (AS)

2025-09388

Birth Options After Having a Cesarean. Anon (2025), Journal of Midwifery & Women's Health vol 70, no 3, May/June 2025, pp 531-532

This column answers frequently asked questions regarding vaginal birth after caesarean section (VBAC), including risks and benefits of VBAC. (AS)

Full URL: https://doi.org/10.1111/jmwh.13774

2025-09216

Abortion [written answer]. House of Lords (2025), Hansard Written question HL9469, 15 July 2025

To ask His Majesty's Government whether they have made an assessment of potential impacts of the decriminalisation

of abortion on (1) clinical safeguards, (2) informed consent procedures, (3) access to alternative support services, and (4) the protection of vulnerable women. (© UK Parliament 2025)

Full URL: https://questions-statements.parliament.uk/written-questions/detail/2025-07-15/HL9469

2025-09194

Is Active Third Stage Becoming an Intervention of Habit?. Amor J (2024), The Student Midwife vol 7, no 4, October 2024, pp 10-13

The third stage of labour (the birth of the placenta) is often an afterthought for many birthing people and their families, and the formality of informed consent can easily be overshadowed by the arrival of a new baby. The current preference of midwives for active management of placental delivery has become the norm within hospitals across the country, due to the risk-averse culture of the medical system. But is this always the best approach? This article delves into the nuances of this critical stage, examining the potential benefits and drawbacks of both active and physiological management, while emphasising the paramount importance of informed consent and shared decision-making. (© Copyright 2025 All4Maternity)

2025-09185

NMC Series – Challenges To Supporting Choice. Williams J (2024), The Student Midwife vol 7, no 3, July 2024, p 19

An overview on Standards of Proficiency for Midwives, focused on women's choice and how midwives can understand and support women's rights. (AS)

2025-09033

"I didn't feel I could say no": A qualitative study of pregnant women's experiences of consent to vaginal examinations. Parmar A, Lanceley A, Maslowski K, et al (2025), European Journal of Obstetrics & Gynecology and Reproductive Biology vol 311, July 2025, 114065

Objective
A vaginal examination (VE) using digital cervical assessment is routinely offered to women to assess whether labour is established and to monitor its progress. Informed consent is always required but anecdotal evidence suggests these requirements are often ignored. This study investigates women's experiences of being asked for their consent to VE(s).
Study Design
Qualitative study using semi-structured face-to-face interviews with 17 women who had recently undergone a VE during labour at an urban inner-city hospital. Data were analysed using thematic analysis.
Results
Two overarching, inter-related themes captured women's experiences of the consent process. 1: Perceived absence of choice – women felt they had no option but to undergo VE(s) presented as 'routine' practice; they were not made aware of alternatives including the right to decline. 2: Unsupported decision-making − scant information was provided and women were not informed of the risks or procedural detail.
Conclusion
Consent to VE(s) is not fully informed or voluntary and often takes the form of presumed compliance rather than genuine choice-making. There is an urgent need for healthcare professionals to amend their practice to ensure that the legal and professional requirements of a valid consent process are met. (© 2025 The Authors. Published by Elsevier B.V.)

Full URL: https://doi.org/10.1016/j.ejogrb.2025.114065

2025-08181

Lost in translation. Various (2025), Midwives vol 28, July 2025, pp 28-31

Translation services need to be seen as a critical part of maternity care. If English isn't the first language of the woman in front of you (and for five million people in the UK, that could well be the case), how do you put her at ease, understand her needs, give her medical information and reach informed consent? As the 2024 MBRRACE-UK perinatal confidential enquiry into the experiences of 25 women whose babies died found, not being able to communicate can make a critical difference in care. (© Author)

2025-08088

Empowering women during childbirth. The Lancet (2025), The Lancet vol 406, no 10498, July 2025, p 1

This editorial highlights the urgent need for evidence-based and respectful maternity care. It calls for better communication, informed consent, and listening to women to improve childbirth experiences and outcomes. (AS)

Full URL: https://doi.org/10.1016/S0140-6736(25)01382-0

2025-06868

Ethics, maternal-fetal interventions, and the technological imperative. Carter BS, Cummings CL (2025), Seminars in Perinatology vol 49, no 6, October 2025, 152095

In medicine, the technological imperative presupposes the inevitable and essential adoption of technologies for the benefit of patients and society. Recent advances in maternal-fetal interventions have followed technological advances in prenatal diagnostic imaging and genetic testing, anesthesiology, and fetal surgical capabilities. Applied here, the technological imperative raises important ethical questions regarding maternal autonomy, informed consent, and decision-making. The ethical or moral arguments for employing such technology rest with the clinician(s) who offer, use, and state that it is the correct thing to do, and who must also be cognizant of the limits of technology and the assumptions represented by other imperatives. There is a need for the education of ethicists and clinicians about the implications and limitations of the technological imperative in this field. Fetal health centers should collaborate with bioethicists at the patient, committee, and program development levels as the field continues to advance.

2025-05427

IVF: Donors [written answer]. House of Commons (2025), Hansard Written question 51679, 12 May 2025

Karin Smyth responds to a written question asked by Luke Murphy to the Secretary of State for Health and Social Care, regarding what assessment his Department has made of the consistency of informed consent practices in donor conception. (AS)

Full URL: https://questions-statements.parliament.uk/written-questions/detail/2025-05-12/51679

2025-04520

Consent to Medical Treatment UK 2023: Dream Mirage or Nemesis?. Donegan J (2023), AIMS Journal vol 35, no 3, 2023

Dr. Jayne Donegan describes how she was regarded by the General Medical Council when she helped parents make fully informed decisions. (Author)

Full URL: https://www.aims.org.uk/journal/item/fully-informed-consent

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2025-04117

Community engagement approaches and lessons learned: a case study of the PRECISE pregnancy cohort study in Kenya. Wanje O, Koech A, Kinshella MW, et al (2025), Frontiers in Public Health 11 March 2025, online

Community engagement (CE) has been recommended as an important ethical consideration for health research to enhance informed consent and exchange knowledge between researchers and community members. The purpose of this paper is to describe how CE was developed and delivered for the PRECISE prospective pregnancy cohort study in Kenya. PRECISE enrolled pregnant women in antenatal care, followed them up to the postpartum period, and collected data and biological samples to enable the study of placental disorders in sub-Saharan Africa. Initially CE was aimed at informing the community about the study, establishing community-wide acceptance of the research and addressing concerns about biological sample collection to facilitate participation in the study. CE later evolved to be a platform for mutual learning aiming to deepen the community's understanding of research principles and informed consent and providing a feedback loop to researchers. We engaged diverse stakeholders including health workers and managers, local administrators, religious and traditional leaders, older women, pregnant women, non-pregnant women and men. We utilized a variety of CE approaches and tools adapting to the specific contextual factors at the study sites. Achievements included widespread understanding of informed consent and research principles, clarification of misconceptions, and dispelling of fears regarding biological sample collection. The relationship with the community was strengthened evidenced by frequent inquiries and active participation in CE activities and the research study. For effective CE, we recommend involvement of community members in the CE team and continuous and adaptive CE throughout the study period. (Author)

Full URL: https://doi.org/10.3389/fpubh.2025.1439150

2025-01884

Fostering Informed Consent and Shared Decision-Making in Maternity Nursing With the Advancement of Artificial Intelligence. Penner SB, Mercado NR, Bernstein S, et al (2025), MCN - American Journal of Maternal/Child Nursing vol 50, no 2, March/April 2025, pp 78-85

Artificial intelligence (AI), defined as algorithms built to reproduce human behavior, has various applications in health care such as risk prediction, medical image classification, text analysis, and complex disease diagnosis. Due to the increasing availability and volume of data, especially from electronic health records, AI technology is expanding into all fields of nursing and medicine. As the health care system moves toward automation and computationally driven clinical decision-making, nurses play a vital role in bridging the gap between the technological output, the patient, and the health care team. We explore the nurses' role in translating AI-generated output to patients and identify considerations for ensuring informed consent and shared decision-making throughout the process. A brief review of AI technology and informed consent, an identification of power dynamics that underly informed consent, and descriptions of the role of the nurse in various relationships such as nurse–AI, nurse–patient, and patient–AI are covered. Ultimately, nurses and physicians bear the responsibility of upholding and safeguarding the right to informed choice, as it is a fundamental aspect of safe and ethical patient-centered health care. (Author)

2025-01846

Women's Experience of the Consent Process to Planned Caesarean Section and Its Surgical Risk: A Qualitative Study. Nithiyananthan M, Nicholls J, Whitten M, et al (2025), BJOG: An International Journal of Obstetrics and Gynaecology vol 132, no 8, July 2025, pp 1104-1113

Objective
To explore how women appreciated the risks discussed within the consent process for planned caesarean section (CS).

Design
Exploratory qualitative interview study.

Setting
NHS Teaching Hospital in Central London.

Population
Women over the age of 18, English speaking, scheduled for a planned CS.

Methods
Semi-structured interviews were conducted before and after a woman's CS. Eighteen women were recruited and interviewed prior to undergoing CS and 12 of these were interviewed following CS. Interviews were audio-recorded, transcribed and thematically analysed.

Main Outcome Measures
Themes generated from analysis of interviews exploring the experiences of women consenting to CS and specifically their awareness of postpartum haemorrhage (PPH), hysterectomy, organ damage and risk of placental abnormalities in future pregnancies.

Results
Two broad themes and four subthemes were identified (1) Untimely provision of risk information: (a) superficial risk discussions during the antenatal period and full risk disclosure on the day of surgery and (b) incompleteness absent or sparse risk disclosure prior to making the decision to undergo the CS, where women were unaware of specific risks and (2) Emotional overload: (a) fear of risks and (b) fear that a CS will be denied to them—women's cognitive response and notably their emotional response to their situation limited their understanding of risks disclosed.

Conclusion
The consent process for planned CS was found to lack appropriate and full risk disclosure. Risk disclosure was ill-timed or deficient in facilitating women's understanding of risks reflecting a consent process which does not meet legal and professional standards of informed consent. (Author)

Full URL: https://doi.org/10.1111/1471-0528.18049

2025-00903

Partnering with the woman who declines recommended maternity care: Development of a statewide guideline in

Queensland, Australia. Jenkinson B, Gray L, Sketcher-Baker K, et al (2025), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 65, no 2, April 2025, pp 243-247

Background
Choice, a fundamental pillar of woman-centred maternity care, depends in part on the right to decline recommended care. While professional guidance for midwives and obstetricians emphasises informed consent and respect for women's autonomy, there is little guidance available to clinicians or women about how to navigate maternity care in the context of refusal.

Aim
To describe the process and outcomes of co-designing resources to support partnership between the woman who declines recommended maternity care and the clinicians and health services who provide her care.

Materials and Methods
Following a participatory co-design process involving consumer representatives, obstetricians, midwives, maternal fetal medicine specialists, neonatologists, health service executives, and legal and ethics experts, implementation of the resources was trialled in seven Queensland Health services using Improvement Science's Plan-Do-Study-Act cycles.

Results
Resources for Partnering with the woman who declines recommended maternity care have now been implemented statewide, in Queensland, including a guideline, two consumer information brochures (available in 11 languages), clinical form, flowcharts, consumer video, clinician education, and culturally capable First Nations resources. Central to these resources is an innovative shared clinical form, that is accessible online, may be initiated and carried by the woman, and where she can document her perspective as part of the clinical notes.

Conclusion
Queensland is the first Australian jurisdiction, and perhaps internationally, to formally establish this kind of guidance in clinical practice. Such guidance is identified as an enabler of choice in the national Australian strategy Woman-centred care: Strategic directions for Australian maternity services. (Author)

Full URL: https://doi.org/10.1111/ajo.13889

2025-00889

Maternity Care Informed Consent Practices and Perspectives: A Qualitative Study at a Tertiary Maternity Unit. Ely S, Langer S, Dietz HP, et al (2024), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) 30 December 2024, online

Background
Although consent has long been accepted as necessary in maternity care, the concept of informed consent for planned vaginal birth has polarised maternity politics. The publication of the NSW Consent Manual outlines new standards of informed consent, signalling the need for examination of current maternity consent practices.

Aims
To examine informed consent and disclosure of material risks in birth in a prospective qualitative study of midwives and obstetricians.

Materials and Methods
Qualitative study using semi-structured interviews to examine practices and perspectives of obstetricians and midwives.

Results
Twenty-two telephone interviews were concluded. Five sub-themes were identified: (1) non-compliance with the NSW Consent Manual, (2) risk communication/informed consent in maternity care, (3) consent practices in instrumental birth, (4) who should deliver risk information and when (5) barriers to change in consent practice (obstetricians only).

Conclusions
One hundred per cent of participants (18 obstetricians, 4 midwives) described risk communication/informed consent practices that were non-complaint with the standards set out in the 2020 NSW Consent Manual. Eighty-three per cent

(15/18) of obstetricians reported that current hospital-wide maternity care practices in risk communication/informed consent are inadequate. Sixty-one per cent (11/18) of obstetricians specifically singled out informed consent practices regarding instrumental birth to be inadequate. Ninety-four per cent (17/18) of obstetricians believe that maternity care consent practices need to be improved. The results of this study indicate that material risks of vaginal birth, caesarean section and instrumental birth, are not routinely disclosed during antenatal courses. Urgent resources and structural change are required to uphold women's legal right to bodily autonomy. (Author)

2024-14180

Compassionate and safe home birth transfer. Madeley A (2024), The Practising Midwife vol 27, no 6, November 2024, pp 32-34

This article aims to develop a recommendation by the National Institute for Health and Care Excellence (NICE), alluding to a more compassionate approach to home birth transfer. It overviews solutions towards this through operational planning and suggestions for core skills to enhance effective and compassionate homebirth transfer planning and preparation. It underscores the crucial role of midwives in planning and executing a transfer from home to hospital, making them feel valued and integral to the process. (Author)

2024-13538

Women's experiences of vaginal examinations in labour: a literature review. Searle H, White H (2024), British Journal of Midwifery vol 32, no 10, October 2024, pp 534–543

Background/Aims

Evidence for vaginal examinations to assess labour progress is inconclusive and indicates some negative psychological impacts for women. Understanding women's perceptions of vaginal examinations is essential to guide future clinical practice. This literature review aimed to explore women's experiences of vaginal examinations in labour.

Methods

A comprehensive review of four databases was carried out, searching for publications made between 2012 and 2023. Findings were synthesised using thematic analysis.

Results

Eight relevant papers were included. Four themes emerged: frequency of vaginal examinations, true, informed consent, emotional reactions and rapport building and humanisation.

Conclusions

Negative experiences were associated with overuse and lack of properly informed consent. Positive experiences linked to continuity in carer. Further research into alternative ways of assessing labour progression to minimise non-clinically indicated vaginal examinations may improve women's labour experience.

Implications for practice

There is a need for further education for healthcare professionals on ongoing informed consent, appropriate communication, the necessary frequency of vaginal examinations and avoiding desensitisation. Additional training should be well-established in hospitals to minimise exams when not clinically indicated. (Author)

2024-12712

Advocating for yourself during pregnancy, birth and postnatally. NCT (2024), October 2024. 2 pages

These simple tools can help you advocate for your own safety, comfort, and dignity when it matters most. Knowing your rights and what you can request can help you make informed decisions that feel right for you. (Author)

Full URL: https://www.nct.org.uk/sites/default/files/2024-10/4175-NCT-AdvocatingForYourself-Flyer-A4-2pp-v2%201.pdf

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2024-12496

Beyond Montgomery – decision making, consent and the GMC. Georgiou A, Bolton H (2021), Obstetrics, Gynaecology and Reproductive Medicine vol 31, no 5, May 2021, pp 150-152

In November 2020 the General Medical Council (GMC) updated its guidance on decision making and consent. This new document reflects significant legal and ethical developments that have occurred in recent years. It is helpful to understand the context from which this guidance has arisen, and imperative to understand the implications it will have on clinical practice. As such, this article will (i) outline the evolution of consent (ii) briefly explain the landmark

case of Montgomery and (iii) highlight the key updates in the GMC's 2020 guidance. (Author)

2024-12251

Informed Consent in the Birth Space. Tucker D (2024), O & G vol 26, no 3, Spring 2024

Informed consent is crucial for ethical and patient-centred care. This article briefly presents the evolution of informed consent from the early 20th century to present and provides practice recommendations in order to promote more positive birth outcomes. (AS)

2024-12234

Obstetric Care and Consent: Navigating Legal and Ethical Challenges. Brell R (2024), O & G vol 26, no 3, Spring 2024

There has been discussion recently about informed consent in obstetrics in light of the parliamentary inquiry into birth trauma in New South Wales and associated national media coverage. The outcome and impact of this is still developing; however, the core legal principles remain settled and should continue to guide how you communicate with and obtain consent from patients. (Author)

Full URL: https://www.ogmagazine.org.au/26/3-26/obstetric-care-and-consent-navigating-legal-and-ethical-challenges/

2024-12231

CAPEA: Preparing Parents for Childbirth and Parenting. O'Brien B (2024), O & G vol 26, no 3, Spring 2024

An overview of antenatal education and how this has evolved the last decades. Modern antenatal education focuses on health literacy, informed consent, and decision-making of parents. However the author writes about criticisms of antenatal education including a lack of evidence about its efficacy in birth outcomes, lack of consideration of adult learning principles and an increasing focus on hospital policy/intervention in labour and birth rather than the participants needs. (AS)

Full URL: https://www.ogmagazine.org.au/26/3-26/capea-preparing-parents-for-childbirth-and-parenting/

2024-12063

The Importance of Informed Birth: Why it Matters For Clinicians and Parents. Dawes A (2024), O & G vol 26, no 3, Spring 2024

This article discusses the importance of informed birth, the impact of birth-related trauma and the crucial role of healthcare professionals in closing the information gap about the potential consequences of childbirth. (AS)

Full URL: https://www.ogmagazine.org.au/26/3-26/the-importance-of-informed-birth/

2024-12060

Editorial. Khot N (2024), O & G vol 26, no 3, Spring 2024

Editorial presents studies on birth experiences, highlighting two reports about birth trauma and the importance of women's education on birth choices and support for maternity care providers to undertake training in informed consent. (AS)

Full URL: https://www.ogmagazine.org.au/26/3-26/editorial-27/

2024-12056

Informed Consent: A Vital Conversation. Ballantyne A, Hicks K (2024), O & G vol 26, no 3, Spring 2024

The authors discuss about the importance of informed consent in obstetrics and maternity care. (AS)

Full URL: https://www.ogmagazine.org.au/26/3-26/informed-consent-a-vital-conversation/

2024-11637

Antepartum Preparation and Consent for Intrapartum Events: An Ethical Gap. Megregian M, Emeis CL, Tilden E (2024), Journal of Midwifery & Women's Health vol 69, no 6, November/December 2024, pp 832-835

Informed consent and shared decision-making (SDM) are essential for respectful perinatal care, supporting patient autonomy and dignity. However, translating these principles into practice is challenging, with issues like lack of informed consent, obstetric violence, and racism affecting outcomes. Pregnant individuals, especially those from marginalized groups, report insufficient SDM in birth procedures. The authors suggest the increase of antenatal education and preparation for planned and unplanned intrapartum events in order to address these ethical gaps. (AS)

2024-11568

Translating informed consent in Scottish Maternity Services. University of Edinburgh (2022), 7 October 2022

A blog from a colloquium hosted by the University of Edinburgh, held online on 7 October 2022. The colloquium welcomed UK and international researchers and practitioners from a range of fields, including midwifery, obstetrics, translation and interpreting studies, medical ethics, medical anthropology, and medical/health humanities. The purpose of the event was to address the problem of obtaining informed consent in maternity services in Scotland for women and birthing people whose first language is not English, or with limited host language ability. (JSM)

Full URL: https://blogs.ed.ac.uk/translating-informed-consent/colloquium/

2024-11480

Consent for interventions during childbirth: A national population-based study. Jacques M, Chantry AA, Evrard A, et al (2025), International Journal of Gynecology & Obstetrics vol 168, no 1, January 2025, pp 333-342

Objective
To assess the frequency and determinants of medical interventions during childbirth without women's consent at the population level.

Methods
The nationwide cross-sectional Enquête Nationale Périnatale 2021 provided a representative sample of women who delivered in metropolitan France with a 2-month postpartum follow-up (n = 7394). Rates and 95% confidence intervals (CI) of interventions during childbirth (oxytocin administration, episiotomy or emergency cesarean section) without consent were calculated. Associations with maternal, obstetric, and organizational characteristics were assessed using robust variance Poisson regressions, after multiple imputation for missing covariates, and weighted to account for 2-month attrition.

Results
Women reporting failure to seek consent were 44.7% (CI: 42.6–47.0) for oxytocin administration, 60.2% (CI: 55.4–65.0) for episiotomy, and 36.6% (CI: 33.3–40.0) for emergency cesarean birth. Lack of consent for oxytocin was associated with maternal birth abroad (adjusted prevalence ratio [aPR] 1.20; 95% CI: 1.06–1.36), low education level, and increased cervical dilation at oxytocin initiation, whereas women with a birth plan reported less frequently lack of consent (aPR 0.79; 95% CI: 0.68–0.92). Delivery assisted by an obstetrician was more often associated with lack of consent for episiotomy (aPR 1.46; 95% CI: 1.11–1.94 for spontaneous delivery and aPR 1.39; 95% CI: 1.13–1.72 for instrumental delivery, reference: spontaneous delivery with a midwife). Cesarean for fetal distress was associated with failure to ask for consent for emergency cesarean delivery (aPR 1.58; 95% CI: 1.28–1.96).

Conclusion
Women frequently reported that perinatal professionals failed to seek consent for interventions during childbirth. Reorganization of care, particularly in emergency contexts, training focusing on adequate communication and promotion of birth plans are necessary to improve women's involvement in decision making during childbirth. (Author)

Full URL: https://doi.org/10.1002/ijgo.15830

2024-10472

Informed consent to midwifery practices and interventions during the second stage of labor—An observational study within the Oneplus trial. Häggsgård C, Rubertsson C, Teleman P, et al (2024), PLoS ONE vol 19, no 6, June 2024, e0304418

Objectives: To study informed consent to midwifery practices and interventions during the second stage of labor and to investigate the association between informed consent and experiences of these practices and interventions and women's experiences of the second stage of labor.

Methods: This study uses an observational design with data from a follow-up questionnaire sent to women one month after giving birth spontaneously in the Oneplus trial, a study aimed at evaluating collegial midwifery assistance to reduce severe perineal trauma. The trial was conducted between 2018-2020 at five Swedish maternity wards and trial registered at clinicaltrials.gov, no NCT03770962. The follow-up questionnaire contained questions about experiences of the second stage of labor, practices and interventions used and whether the women had provided informed consent. Evaluated practices and interventions were the use of warm compresses held at the perineum, manual perineal protection, vaginal examinations, perineal massage, levator pressure, intermittent catheterization of the

bladder, fundal pressure, and episiotomy. Associations between informed consent and women's experiences were assessed by univariate and multivariable logistic regression.

Findings: Of the 3049 women participating in the trial, 2849 consented to receive the questionnaire. Informed consent was reported by less than one in five women and was associated with feelings of being safe, strong, and in control. Informed consent was further associated with more positive experiences of clinical practices and interventions, and with less discomfort and pain from interventions involving physical penetration of the genital area.

Conclusion: The findings indicate that informed consent during the second stage is associated with feelings of safety and of being in control. With less than one in five women reporting informed consent to all practices and interventions performed by midwives, the results emphasize the need for further action to enhance midwives' knowledge and motivation in obtaining informed consent prior to performance of interventions.

Full URL: https://doi.org/10.1371/journal.pone.0304418

2024-06676

The ethics of consent during labour and birth: episiotomies. van der Pijl M, Verhoeven C, Hollander M, et al (2023), Journal of Medical Ethics vol 49, no 9, September 2023, pp 611-617

Unconsented episiotomies and other procedures during labour are commonly reported by women in several countries, and often highlighted in birth activism. Yet, forced caesarean sections aside, the ethics of consent during labour has received little attention. Focusing on episiotomies, this paper addresses whether and how consent in labour should be obtained. We briefly review the rationale for informed consent, distinguishing its intrinsic and instrumental relevance for respecting autonomy. We also emphasise two non-explicit ways of giving consent: implied and opt-out consent. We then discuss challenges and opportunities for obtaining consent in labour and birth, given its unique position in medicine.We argue that consent for procedures in labour is always necessary, but this consent does not always have to be fully informed or explicit. We recommend an individualised approach where the antenatal period is used to exchange information and explore values and preferences with respect to the relevant procedures. Explicit consent should always be sought at the point of intervening, unless women antenatally insist otherwise. We caution against implied consent. However, if a woman does not give a conclusive response during labour and the stakes are high, care providers can move to clearly communicated opt-out consent. Our discussion is focused on episiotomies, but also provides a useful starting point for addressing the ethics of consent for other procedures during labour, as well as general time-critical medical procedures.

Keywords: Ethics; Ethics- Medical; Informed Consent; Personal Autonomy; Quality of Health Care.

Full URL: https://doi.org/10.1136/jme-2022-108601

2024-05542

Care of women and application of the principle of informed consent to interventions during birth in the COVID-19 pandemic period. Liepinaitienė A, Bujaitė I, Galkontas A, et al (2024), European Journal of Midwifery vol 8, May 2024, p 18

Introduction:
In the early phases of the COVID-19 pandemic, inadequate intrapartum care protocols were in place. Many organizations have responded promptly and recognized the importance of adherence to appropriate guidelines. The International Confederation of Midwives issued an official statement on 29 March 2020, which states that every woman has the right to information, to give consent, to refuse consent, and to have her choices and decisions respected and upheld. No research has been conducted in Lithuania to reveal the care of women who gave birth during the COVID-19 pandemic and the application of informed consent to interventions.

Methods:
This study is quantitative of cross-sectional design. An anonymous questionnaire survey method was used. One hundred fifty-two women who gave birth in Lithuania during the COVID-19 pandemic (March 2020 – May 2022) and had

COVID-19 infection during childbirth, participated in the study. Statistical data analysis was performed.

Results:
During the COVID-19 pandemic, women's care was characterized by always or almost always adequate information from health professionals on all issues to minimize the stress of new procedures necessitated by the COVID-19 pandemic and allowing them to stay with newborns as long as possible. The application of the principle of informed consent to interventions during the COVID-19 pandemic was not always applied to the performance of transvaginal examination manual compression of the uterine fundus to facilitate the expulsion period.

Conclusions:
Most women said that they were properly informed by healthcare professionals about all questions related to the new procedures that became necessary due to the COVID-19 pandemic and felt included in their own choice. However, mothers felt the need of relatives during childbirth, and consent was often not asked for vaginal examination. (Author)

Full URL: https://doi.org/10.18332/ejm/186069

2024-03408

Informed consent - are we doing it right?. Spice J, Bradfield Z, Kuliukas L (2023), Australian Midwifery News vol 34, Spring 2023, pp 34-35

Presents the results of a descriptive phenomenological study looking at the experiences of West Australian midwives regarding obtaining and witnessing informed consent in labour and the barriers which sometimes occur during the process, including emergency situations, time pressures, acuity of the birthing suite, pain, patient transfer between maternity units, and language barriers. (JSM)

2024-02012

Consent practices in midwifery: A survey of UK midwives. Elf R, Nicholls J, Ni Y, et al (2024), Midwifery vol 129, February 2024, 103893

Objective
To explore midwives' knowledge and understanding of the law and practice of consent in the post-Montgomery world.

Design
Cross-sectional online survey. Descriptive statistical analysis of midwives' survey responses.

Settings
Social media: Instagram, Facebook and Twitter. Survey distribution was via the UCL Opinio survey platform.

Participants
A total of 402 midwives, surveyed over a four month period between 2nd March and 2nd July 2021.

Measurements
Knowledge of legal consent, 'sureness' of meeting current legal requirements and competence to gain consent.

Findings
91% of participants acknowledged correctly that consent must be voluntary. 91% reported that women must be informed of all the risks associated with their care, although 26% reported that women should be informed of some of the risks associated with their care. Most participants were 'sure' that their discussions of consent meet current legal requirements (91%). 21% rated their competence to gain consent as 'excellent', 71% rated themselves as 'very good', whilst 1% rated their competence as 'poor'. Deficiencies in fundamental knowledge of consent were noted in some participants rating themselves highest in 'sureness' of meeting legal requirements and competence to consent.

Key conclusions
Fundamental gaps in midwives' knowledge of legal consent were identified. Participants demonstrated uncertainty regarding the extent of risk disclosure and discussion of alternative care options. Participants generally rated themselves highly in their consenting practices, despite lacking in basic knowledge of legal consent, revealing a discrepancy between midwives' self-perceptions and their actual knowledge.

Implications for practice
The overconfidence displayed by some participants is concerning for clinical midwifery practice. Professional education and guidance for midwives on legal consent in keeping with Montgomery is urgently required to ensure that midwives are legally compliant in their consenting practices. (Author)

Full URL: https://doi.org/10.1016/j.midw.2023.103893

2024-01959

Parental perspectives on a trial using waived informed consent at birth. Katheria AC, Schmölzer GM, Law B, et al (2024), Journal of Perinatology vol 44, no 3, March 2024, pp pages415–418

Objectives
To determine parental perspectives in a trial with waived consent.

Study design
Anonymous survey of birth parents with term infants who were randomized using a waiver of consent, administered after infant discharge.

Results
121 (11%) survey responses were collected. Of the 121 responding parents 111 (92%) reported that this form of consent was acceptable and 116 (96%) reported feeling comfortable having another child participate in a similar study. 110 (91%) respondents reported that they both understood the information provided in the consent process and had enough time to consider participation. Four percent had a negative opinion on the study's effect on their child's health.

Conclusions
Most responding parents reported both acceptability of this study design in the neonatal period and that the study had a positive effect on their child's health. Future work should investigate additional ways to involve parents and elicit feedback on varied methods of pediatric consent. (Author)

2023-07572

Exploring informed consent in midwifery care. Madeley A (2023), British Journal of Midwifery vol 31, no 6, June 2023

One of the single most important tenets of healthcare ethics is that of informed consent. Situated in ethical, legal and human rights frameworks, informed consent at its core represents the ability to retain autonomy over one's bodily integrity and to decide freely who can and cannot touch them. While consent at its simplest means being able to say yes or no, facilitating informed consent requires a more nuanced understanding of a dynamic process that, for midwives and other healthcare professionals, might seem challenging. The aim of this article is to provide a brief introduction to historical context and key legal cases that set the foundations for that which constitutes informed consent. This article focuses on what 'informed' means in relation to consent and, importantly, aims to dispel myths around receiving informed consent in contemporary midwifery practice. (Author)

2023-07150

Consent Practices for Assisted Vaginal Births (AVB) at Two Tertiary Care Hospitals: A Retrospective Review of Physician Documentation. Sheinis M, Zhu J, Hobson S, et al (2023), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 45, no 7, July 2023, pp 496-502

Objective
To determine whether assisted vaginal birth (AVB) consent documentation, a surrogate for in vivo consent, aligns with Canadian practice guidelines at 2 Canadian tertiary-level obstetric centres.

Methods
This was a retrospective review of AVBs (vacuum and forceps) from July 2019 to December 2019 at 2 tertiary-level hospitals with template-based (Site 1) or dictation-based (Site 2) documentation. We extracted, from obstetric and neonatal charts, AVB type, physician and documenter types (resident/fellow/family doctor/generalist obstetrics and gynecology [OBGYN]/maternal-fetal medicine), and consent elements (present/absent) based on a predetermined checklist. Data were summarized and comparisons were made using chi-square test, Fisher exact test, and logistic regression, where appropriate.

Results
We identified 551 AVBs (156 forceps, 395 vacuum) with most documentation completed by generalist OBGYNs or residents (333/551, 60.5%). Most vacuum-assisted deliveries documented no specific maternal (366/395, 92.7%) or neonatal (364/395, 92.2%) risks, and 107/156 (68.6%) and 106/156 (67.9%) forceps-assisted deliveries lacked specific documentation of maternal and neonatal risk, respectively. At Site 2, postpartum hemorrhage risk at vacuum-assisted deliveries was more commonly documented (6/90 [6.7%] vs. 2/395 [0.7%], P = 0.002) as was at least 1 neonatal risk and risk of obstetrical anal sphincter injury at forceps-assisted deliveries (50/133 [37.6%] vs. 0/23 [0%], P < 0.001) and (43/133 [32.3%] vs. 0/23 [0%], P = 0.001), respectively.

Conclusions
Opportunity to improve AVB consent documentation exists, warranting quality improvement initiatives. (Author)

2022-10612

Maternity Services at Shrewsbury and Telford Hospital NHS Trust Independent Review [written answer]. House of Commons (2022), Hansard Written question 71351, 25 October 2022

Maria Caulfield responds to a written question from Helen Morgan to the Secretary of State for Health and Social Care, regarding what progress relevant authorities have made on the implementation of the immediate and essential actions from the Ockenden Review into maternity services (a) at Shrewsbury and Telford Hospital Trust and (b) nationally. (JSM)

Full URL: https://questions-statements.parliament.uk/written-questions/detail/2022-10-25/71351

2022-07265

'Petrificus Totalus': Dynamic consent in obstetric practice? Technology in obstetric practice, to help supported decision-making. Ananthram H, Rane A (2022), BJOG: An International Journal of Obstetrics and Gynaecology vol 129, no 12, November 2022, pp 1957-1960

Commentary suggesting that dynamic consent is a promising approach to bring about transformative change in obstetric practice. (LDO)

Full URL: https://doi.org/10.1111/1471-0528.17259

2022-06393

Video-Assisted Informed Consent in a Clinical Trial of Resuscitation of Extremely Preterm Infants: Lessons Learned. Odackal NJ, Caruso CG, Klitzman M, et al (2022), American Journal of Perinatology 30 June 2022, online

Objective Obtaining informed consent for clinical trials is challenging in acute clinical settings. For the VentFirst randomized clinical trial (assisting ventilation during delayed cord clamping for infants <29 weeks' gestation), we created an informational video that sites could choose to use to supplement the standard in-person verbal and written consent. Using a postconsent survey, we sought to describe the impact of the video on patient recruitment, satisfaction with the consent process, and knowledge about the study.

Study Design This is a descriptive survey-based substudy.

Results Of the sites participating in the VentFirst trial that obtained institutional review board (IRB) approval to allow use of the video to supplement the standard informed consent process, three elected to participate in the survey substudy. From February 2018 to January 2021, 82 women at these three sites were offered the video and completed the postconsent survey. Overall, 73 of these 82 women (89%) consented to participate in the primary study, 78 (95%) indicated the study was explained to them very well or extremely well, and the range of correct answers on five knowledge questions about the study was 63 to 98%. Forty-six (56%) of the 82 women offered the video chose to watch it. There were no major differences in study participation, satisfaction with the consent process, or knowledge about the study between the women who chose to watch or not watch the video.

Conclusion Watching an optional video to supplement the standard informed consent process did not have a major impact on outcomes in this small substudy. The ways in which audiovisual tools might modify the traditional informed consent process deserve further study. (Author)

2022-06061

Coercion and non-consent during birth and newborn care in the United States. Logan RG, McLemore MR, Julian Z, et al (2022), Birth vol 49, no 4, December 2022, pp 749-762

In the United States, Black, Indigenous, and People of Color (BIPOC) experience more adverse health outcomes and report mistreatment during pregnancy and birth care. The rights to bodily autonomy and consent are core components of high-quality health care. To assess experiences of coercion and nonconsent for procedures during perinatal care among racialized service users in the United States, we analyzed data from the Giving Voice to Mothers (GVtM-US) study.

Methods
In a subset analysis of the full sample of 2700, we examined survey responses for participants who described the experience of pressure or nonconsented procedures or intervention during perinatal care. We conducted multivariable logistic regression analyses by racial and ethnic identity for the outcomes: pressure to have perinatal procedures (eg, induction, epidurals, episiotomy, fetal monitoring), nonconsented procedures performed during perinatal care, pressure to have a cesarean birth, and nonconsented procedures during vaginal births.

Results
Among participants (n = 2490), 34% self-identified as BIPOC, and 37% had a planned hospital birth. Overall, we found significant differences in pressure and nonconsented perinatal procedures by racial and ethnic identity. These inequities persisted even after controlling for contextual factors, such as birthplace, practitioner type, and prenatal care context. For example, more participants with Black racial identity experienced nonconsented procedures during perinatal care (AOR 1.89, 95% CI 1.35–2.64) and vaginal births (AOR 1.87, 95% CI 1.23–2.83) than those identifying as white. In addition, people who identified as other minoritized racial and ethnic identities reported experiencing more pressure to accept perinatal procedures (AOR 1.55, 95% CI 1.08–2.20) than those who were white.

Discussion
There is a need to address human rights violations in perinatal care for all birthing people with particular attention to the needs of those identifying as BIPOC. By eliminating mistreatment in perinatal care, such as pressure to accept services and nonconsented procedures, we can help mitigate long-standing inequities. (Author)

Full URL: https://doi.org/10.1111/birt.12641

2022-04920

Informed consent should be obtained before vaginal birth: AGAINST: Informed consent should not be obtained before vaginal birth. Downe S (2022), BJOG: An International Journal of Obstetrics and Gynaecology vol 129, no 5, April 2022, p 830

No abstract available.

2022-03933

Consent for newborn screening: screening professionals' and parents' views. Ulph F, Dharni N, Bennett R, et al (2020), Public Health vol 178, January 2020, pp 151-158

Objectives
Expansion of newborn bloodspot screening (NBS) within England, which practices an informed consent model, justified examining acceptability and effectiveness of alternative consent models.

Study design
Qualitative focus groups.

Methods
Forty-five parents and 37 screening professionals (SPs) participated. Data were analysed using thematic analysis.

Results
Parents and SPs initially appeared to have differing views about appropriate consent models. Most parents accepted assumed consent, if adequately informed; however, once aware of bloodspot storage, informed consent was wanted. SPs valued informed consent, but acknowledged it was difficult to obtain. Both samples wanted parents to be informed but were unclear how this could be achieved. Most parents felt NBS was not presented as optional.

Conclusion

The simultaneous exploration of parents and SPs views, in real time is original. This rigour avoided the reliance on retrospective accounts which make it difficult to establish how decisions were made at the time. It is also unique in providing pre-interview consent models to drive the depth of data. It was rigorous in member checking. Findings suggested a preference for full disclosure of all information with some parents valuing this more than choice. Both samples queried whether current consent was sufficiently informed and voluntary. Results suggest differing tolerances of consent type if screening is solely for diagnostic purposes vs bloodspot storage. Results highlight the need for caution when examining consent model preferences without also checking knowledge, as opinions may be based on incomplete knowledge. Future research is needed to examine efficacy of proposed changes.

Funding
National Institute for Health Research Health Technology Assessment HTAProgramme (11/62/02).

Trial registration
ISRCTN70227207. (Author)

Full URL: https://doi.org/10.1016/j.puhe.2019.08.009

2022-03788

Consent for Delivery Room Studies: What Can Be Learned from Perceptions of Parents. den Boer MC, Houtlosser M, Witlox RSGM, et al (2022), Neonatology: Fetal and Neonatal Research vol 119, no 2, March 2022, pp 214-221

Background: Obtaining ethically valid consent to participate in delivery room (DR) studies from parents facing an imminent premature birth can be challenging. This study aims to provide insight into parental experiences with and perceptions of consent for DR studies. Methods: Semistructured interviews were conducted with parents of very and extreme preterm infants. Interviews were audio-recorded, transcribed, and analyzed using the qualitative data analysis software Atlas. ti V.8.4. Results: Twenty-five parents were interviewed. Despite being in an emotional and stressful situation, most parents considered being approached for DR studies as valuable. According to parents, this was mostly due to appropriate timing and communication, compassion, and investigators not being obtrusive. Interviewed parents generally decided to accept or decline study participation based on perceived risk. Parents differed widely in how risk of specific study interventions was perceived, but agreed on the fact that parental consent is needed for DR studies that involve risk. There was no consensus among parents on deferred consent for DR studies running at our NICU. However, parents considered deferred consent appropriate for observational studies. Furthermore, it became clear that parental misunderstanding of various aspects of DR studies, including aims, the concept of randomization, and risk associated with specific interventions, was common. Conclusions: Insight into parental perceptions of consent for DR studies allowed us to determine areas where the validity of parental consent can be improved. Further research on parental perspectives for consent for DR studies will allow us to establish consent procedures that are considered both valid and valuable.

Full URL: https://doi.org/10.1159/000521587

2022-03533

Deferred consent in emergency obstetric research: findings from qualitative interviews with women and recruiters in the ACROBAT pilot trial for severe postpartum haemorrhage. Sweeney L, Lanz D, Daru J, et al (2022), BMJ Open vol 12, no 5, May 2022, e054787

Objective The ACROBAT pilot trial of early cryoprecipitate for severe postpartum haemorrhage used deferred consent procedures. Pretrial discussions with a patient and public involvement group found mixed views towards deferred consent. This study aimed to build an understanding of how the deferred consent procedures worked in practice, to inform plans for a full-scale trial.

Setting Qualitative interview study within a cluster-randomised pilot trial, involving four London maternity services.

Participants Individual interviews were conducted postnatally with 10 women who had received blood transfusion for severe postpartum haemorrhage and had consented to the trial. We also interviewed four 'recruiters'—two research midwives and two clinical trials practitioners who conducted trial recruitment.

Results Consent procedures in the ACROBAT pilot trial were generally acceptable and the intervention was viewed as low risk, but most women did not remember much about the consent conversation. As per trial protocol, recruiters sought to consent women before hospital discharge, but this time pressure had to be balanced against the need to

ensure women were not approached when distressed or very unwell. Extra efforts had to be made to communicate trial information to women due to the exhaustion of their recovery and competing demands for their attention. Participant information was further complicated by explanations about the cluster design and change in transfusion process, even though the consent sought was for access to medical data.

Conclusion Our findings indicate that deferred consent procedures raise similar concerns as taking consent when emergency obstetric research is occurring—that is, the risk that participants may conflate research with clinical care, and that their ability to process trial information may be impacted by the stressful nature of recovery and newborn care. A future trial may support more meaningful informed consent by extending the window of consent discussion and ensuring trial information is minimal and easy to understand.

Trial registration number ISRCTN12146519. (Author)

Full URL: http://dx.doi.org/10.1136/bmjopen-2021-054787

2022-02797

Informed Consent is Poorly Documented when Obtaining Toxicology Testing at Delivery in a Massachusetts Cohort. Koenigs KJ, Chou JH, Cohen S, et al (2022), American Journal of Obstetrics & Gynecology MFM vol 4, no 4, July 2022, 100621

BACKGROUND

Positive toxicology testing at delivery can have enormous consequences for birthing persons and their families, including charges of child abuse/neglect and potential loss of custody for the birthing parent. State and national guidelines therefore stipulate clinicians should obtain consent prior to toxicology testing at delivery.

OBJECTIVE

We examined: (1) clinician documentation of patient consent for peripartum toxicology testing and (2) the extent to which patient and hospital characteristics were associated with documented consent.

STUDY DESIGN

Retrospective cohort of individuals who underwent toxicology testing within 96 hours of delivery between April 2016 and April 2020 at five affiliated hospitals across Massachusetts. Medical records were reviewed for documentation of: clinician intent to obtain maternal toxicology, testing indication, verbal consent to testing, and child protective services involvement. Hierarchical multivariable logistic regression was used to examine the association between patient and hospital characteristics and documentation of verbal consent.

RESULTS

Among 60,718 deliveries, 1562 maternal toxicology tests were obtained. Verbal consent for testing was documented in 29.8% of cases (n=466). Documented consent was lacking across most demographic groups. Consent was no more likely to be documented when a report was filed with child protective services, and less likely in cases where the birthing parent lost custody prior to discharge (p=.003). In our multivariable model, consent was least likely to be documented when a maternal complication (abruption, hypertension, preterm labor, preterm premature rupture of membranes, intrauterine fetal demise) was the indication for testing (aOR, 0.46; CI, 0.28 to 0.76). Verbal consent was twice as likely to be documented in delivery hospitals with established consent policies (aOR, 2.10; CI, 1.01 to 4.37).

CONCLUSION

Consent for toxicology testing at delivery appears to be infrequently obtained based on clinician documentation. Provider education and hospital policies for obtaining informed consent are needed to protect the rights of birthing individuals. (Author)

2022-02602

Patient Satisfaction with Informed Consent for Cesarean and Operative Vaginal Delivery. Levy KS, Smith MK, Lacroix M, et al (2022), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 44, no 7, July 2022, pp 785-790

Objective

To evaluate patient satisfaction with the informed consent process for elective cesarean delivery (CD), emergency CD, and operative vaginal delivery (OVD).

Methods

A cross-sectional, survey-based study was conducted among patients on the postpartum floor of our institution. Patients were approached after delivery to complete a previously pilot-tested questionnaire, based on validated literature. One hundred eighty-four surveys were included in the analysis. Levels of patient satisfaction were compared across modes of delivery using $\chi 2$ tests of independence. Secondary objectives included evaluating the relationship between satisfaction scores and the patient's recall of the consent process and emotional state during the consent process.

Results
A significant association was found between patient satisfaction with the consent process and mode of delivery (P < 0.001). Those in the elective and emergency CD groups were significantly more likely to express high rates of satisfaction compared with those in the OVD group (odds ratio [OR] 9.03; 95% CI 2.80–29.10 and OR 3.97; 95% CI 1.34–11.76, respectively). High levels of satisfaction were significantly more common among those who had greater recall of the consent process (OR 25.2; 95% CI 7.34–87.04) and those who reported low levels of distress during the process (OR 15.1; 95% CI 4.70–48.66).
Conclusion
Informed consent during OVD is associated with lower rates of patient satisfaction compared with CD. Efforts are needed to improve the consent process for OVD to increase patient satisfaction and promote patient-centred care. (Author)

2022-01938

Ockenden report - final. Findings, conclusions and essential actions from the Independent Review of Maternity Services at The Shrewsbury and Telford Hospital NHS Trust. Independent Maternity Review (2022), 30 March 2022. 234 pages

Final report of the Independent Review of maternity services at The Shrewsbury and Telford Hospital NHS Trust.

An independent multi–professional team of midwives and doctors including obstetricians, neonatologists, obstetric anaesthetists, a physician, cardiologist, neurologist and others examined the maternity care and treatment provided to 1,486 families over two decades at the Trust.

The report identifies more than 60 Local Actions for Learning for the Trust and another 15 key Immediate and Essential Actions to improve all maternity services in England, including financing a safe and sustainable maternity and neonatal workforce and ensuring training for the whole maternity team meets the needs of today's maternity services. The report states that Trust Boards must have oversight and understanding of their maternity services and ensure that they listen to and hear local families and their own staff. (Publisher, edited)

Full URL: https://www.ockendenmaternityreview.org.uk/wp-content/uploads/2022/03/FINAL_INDEPENDENT_MATERNITY_REVIEW_OF_MATERNITY_SERVICES_REPORT.pdf

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2022-01624

A comparison of MITS counseling and informed consent processes in Pakistan, India, Bangladesh, Kenya, and Ethiopia. Feroz AS, Paganelli C, Bunei M, et al (2020), Reproductive Health vol 17, no 120, 12 August 2020

Globally, more than 5 million stillbirths and neonatal deaths occur annually. For many, the cause of death (CoD) is unknown. Minimally invasive tissue sampling (MITS) has been increasingly used in postmortem examinations for ascertaining the CoD in stillbirths and neonates. Our study compared the counseling and consent methods used in MITS projects in five countries in Africa and south Asia. Key informant interviews were conducted with researchers to describe the characteristics and backgrounds of counselors, the environment and timing of consent and perceived facilitators and barriers encountered during the consent process. Counselors at all sites had backgrounds in social science, psychology and counseling or clinical expertise in obstetrics/gynecology or pediatrics. All counsellors received training about techniques for building rapport and offering emotional support to families; training duration and methods differed across sites. Counselling environments varied significantly; some sites allocated a separate room, others counselled families at the bedside or nursing stations. All counsellors had a central role in explaining the MITS procedure to families in their local languages. Most sites did not use visual aids during the process, relying solely on verbal descriptions. In most sites, parents were approached within one hour of death. The time needed for decision making by families varied from a few minutes to 24 h. In most sites, extended family took part in the decision making. Because many parents wanted burial as soon as possible, counsellors ensured that MITS would be conducted promptly after receiving consent. Barriers to consent included decreased comprehension of information due to the emotional and psychological impact of grief. Moreover, having more family members engaged in decision-making increased the complexity of counselling and achieving consensus to consent for the procedure. While each site adapted their approach to fit the context, consistencies and similarities across sites were observed. (Author)

Full URL: https://doi.org/10.1186/s12978-020-00969-w

2022-00415

Patient-centred consent in women's health: does it really work in antenatal and intra-partum care?. Nicholls J, David AL, Iskaros J, et al (2022), BMC Pregnancy and Childbirth vol 22, no 156, 25 February 2022

Background
Legal and social changes mean that information sharing and consent in antenatal and intrapartum settings is contentious, poorly understood and uncertain for healthcare professionals. This study aimed to investigate healthcare professionals' views and experiences of the consent process in antenatal and intrapartum care.

Methods
Qualitative research performed in a large urban teaching hospital in London. Fifteen healthcare professionals (obstetricians and midwives) participated in semi-structured in-depth interviews. Data were collectively analysed to identify themes in the experiences of the consent process.

Results
Three themes were identified: (1) Shared decision-making and shared responsibility –engaging women in dialogue is often difficult and, even when achieved, women are not always able or do not wish to share responsibility for decisions (2) Second-guessing women – assessing what is important to a woman is inherently difficult so healthcare professionals sometimes feel forced to anticipate a woman's views (3) Challenging professional contexts – healthcare professionals are disquieted by consent practice in the Labour ward setting which is often at odds with legal and professional guidance.

Conclusions
Results suggest that there is a mismatch between what is required of healthcare professionals to effect an antenatal or intrapartum consent process concordant with current legal and professional guidance and what can be achieved in practice. If consent, as currently articulated, is to remain the barometer for current practice, healthcare professionals need more support in ways of enabling women to make decisions which healthcare professionals feel confident are autonomous whatever the circumstances of the consultation. (Author)

Full URL: https://doi.org/10.1186/s12884-022-04493-6

2021-12630

Perinatal post-mortem consent: a national survey. Wood H, Cookson J, Shenvi A (2021), Infant vol 17, no 6, November 2021, pp 261-265

This project examined the experiences of healthcare professionals who obtain consent for perinatal post-mortem examination with the aim of using the findings to develop training resources for taking post-mortem consent. (Author)

2021-09897

Association between newborn separation, maternal consent and health outcomes: findings from a longitudinal survey in Kenya. Nakphong MK, Sacks E, Opot J, et al (2021), BMJ Open vol 11, no 9, September 2021, e045907

Objectives Disrespectful and poor treatment of newborns such as unnecessary separation from parents or failure to obtain parental consent for medical procedures occurs at health facilities across contexts, but little research has investigated the prevalence, risk factors or associated outcomes. This study examined these experiences and associations with healthcare satisfaction, use and breast feeding.

Design Prospective cohort study.

Setting 3 public hospitals, 2 private hospitals, and 1 health centre/dispensary in Nairobi and Kiambu counties in Kenya.

Participants Data were collected from women who delivered in health facilities between September 2019 and January 2020. The sample included 1014 women surveyed at baseline and at least one follow-up at 2–4 or 10 weeks post partum.

Primary and secondary outcome measures (1) Outcomes related to satisfaction with care and care utilisation; (2) continuation of post-discharge newborn care practices such as breast feeding.

Results 17.6% of women reported newborn separation at the facility, of whom 71.9% were separated over 10 min. 44.9% felt separation was unnecessary and 8.4% reported not knowing the reason for separation. 59.9% reported consent was not obtained for procedures on their newborn. Women separated from their newborn (>10 min) were 44% less likely to be exclusively breast feeding at 2–4 weeks (adjusted OR (aOR)=0.56, 95% CI: 0.40 to 0.76). Obtaining

consent for newborn procedures corresponded with 2.7 times greater likelihood of satisfaction with care (aOR=2.71, 95% CI: 1.67 to 4.41), 27% greater likelihood of postpartum visit attendance for self or newborn (aOR=1.27, 95% CI: 1.05 to 1.55), and 33% greater likelihood of exclusive breast feeding at 10 weeks (aOR=1.33, 95% CI: 1.10 to 1.62).

Conclusions Newborns, mothers and families have a right to high-quality, respectful care, including the ability to stay together, be informed and properly consent for care. The implications of these experiences on health outcomes a month or more after discharge illustrate the importance of a positive experience of postnatal care. (Author)

Full URL: http://dx.doi.org/10.1136/bmjopen-2020-045907

2021-09746

Consent on the labour ward: A qualitative study of the views and experiences of healthcare professionals. Kennedy S, Lanceley A, Whitten M, et al (2021), European Journal of Obstetrics & Gynecology and Reproductive Biology vol 264, September 2021, pp 150-154

Objective
Consent on the labour ward is a complex and controversial topic which is poorly understood. Consenting labouring women is recognised as challenging and problematic, and thus, it is uncertain that pregnant women experience true informed consent during labour. This project aims to explore healthcare professionals' views and experiences of consent practice on the labour ward.
Design
Qualitative research performed in a tertiary hospital labour ward in Central London with 5500 patients annually. Eleven obstetricians and seven midwives participated. In-depth one-on-one semi-structured interviews were conducted, and the data were analysed by thematic analysis.
Results
Three themes were identified: 1) The value of women's choice: healthcare professionals framed consent as an agreement process rather than an exercise of choice. Implicit paternalism was evident with some healthcare professionals imposing their own recommendations upon patients. 2) Communicating risk: many participants viewed full risk communication, including extremely rare risk disclosure as their duty to ensure the validity of obstetric consent despite the risk of overwhelming women. 3) Law and professional practice: many healthcare professionals lacked knowledge of the implications to practice of current law.
Conclusion
Healthcare professionals' experiences of consent on the labour ward reflect uncertainties and ambiguities in consent practice such that it sometimes falls short of legal and professional requirements. Difficulties in discussing risk with women in an appropriate way at an appropriate time threatens the lawfulness of consent. If consent is to remain as the legal standard of autonomy, we recommend the provision of specialist training to assist professionals in providing timely consultation dialogues which endorse women's right to choose. (Author)

2021-09719

A short guide to effective mental capacity assessment for midwives. Hamilton SJ (2021), The Practising Midwife vol 24, no 9, October 2021, pp 32-35

In this piece, the author presents the acronym CAPACITY as a short guide to effective mental capacity assessment for midwives, before, during and after the assessment process itself. Each dimension of the acronym is discussed with specific reference to its clinical midwifery implications and moreover, in relation to how midwives can carry out a mental capacity assessment sequentially, effectively, and in an egalitarian, woman-centred fashion. There are a number of practice-challenge questions (five in total) contained throughout the narrative specifically for the purposes of not only encouraging quantitative and qualitative reflection, but also to consolidate learning on the salient points made throughout the piece. (Author)

2021-08561

What Do Women Want? Consent for the Use of Electronic Fetal Monitoring. Dal Cin S, Low LK, Lillvis D, et al (2021), International Journal of Childbirth vol 11, no 3, 2021, pp 145-153

BACKGROUND
Guidelines published by professional associations of midwives, obstetricians, and nurses in the United States recommend against using continuous cardiotocography (CTG) in low-risk patients. In the United States, CTG or electronic fetal/uterine monitoring (EFM) rather than auscultation with a fetoscope or Pinard horn is the norm. Interpretation of the fetal heart rate (FHR) and uterine activity (UA) tracings provided by continuous EFM may be associated with the decision for a cesarean birth. Typically, consent is not sought in the decision about type of

monitoring. No studies were identified where women's attitudes about the need to consent to the type of fetal monitoring used during labor have been explored. Therefore, the purpose of this research was to examine women's attitudes about the use of EFM in a healthcare setting.

METHODS
We asked a sample of women aged 18–50 years to respond to one of three monitoringscenarios. The scenarios were used to distinguish between attitudes about monitoring in general, monitoring the health of a mother in labor, and monitoring the health of the fetus during labor. Wemeasured their level of interest in being monitored and their opinions about whether healthcare providers should be required to obtain consent for the monitoring described in the scenario.

RESULTS
Interest in receiving monitoring (across all three scenarios) was moderate, with the highest level of interest in monitoring the fetus during labor and the least interest in monitoring a general health context. Across all scenarios, 82% of respondents believed that practitioners should obtain consent for monitoring, 14% were unsure, and 4% said there should not be a requirement for consent. While low (6%), the percentage responding that consent was not needed was highest in monitoring a fetus in labor.

CONCLUSIONS
Women in our study expressed a strong preference for the opportunity to consent to the use of monitoring regardless of the healthcare scenario. There is findings suggest the need for further research exploring what women do and do not know about CTG and what their informed performance are a pressing need to rethink the role of a pressing need to rethink the role of shared decision-making and informed consent about the type of monitoring use during labor. (Author)

2021-08546

Decisions about our care are for us - the service user - to make. Yes, but .... Dagustun J (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Jo Dagustun, on behalf of the AIMS Campaign team, asks whether this term still has a place when discussing decision-making and consent. (Author)

Full URL: https://www.aims.org.uk/journal/item/shared-decision-making

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2021-08542

An open letter to my midwives. Spain H (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Heather Spain writes an open letter to her midwives after her experience of being illegally held captive in hospital with her newborn baby. (Author)

Full URL: https://www.aims.org.uk/journal/item/illegally-held-in-hospital

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2021-08541

Pregnant and non-compliant. Lyons M (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Maria Lyons calls on us to reject fear-based healthcare and to regain informed consent. (Author)

Full URL: https://www.aims.org.uk/journal/item/regain-informed-consent

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2021-08540

Informed decision-making and the antenatal educator. Smith C (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Caroline Smith explores the role of the perinatal education practitioner in equipping parents to make informed decisions. (Author)

Full URL: https://www.aims.org.uk/journal/item/perinatal-education-decisions

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2021-08539

Decision-making theory: Does Muriel have free will?. Smith A (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Alex Smith examines the forces at play when people make decisions. (Author)
Full URL: https://www.aims.org.uk/journal/item/decision-making-theory

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2021-08538

Gaining a person's consent for medical treatment has to be 'just right'. Smith A (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Alex Smith presents a 'three bears' illustration of consent. (Author)
Full URL: https://www.aims.org.uk/journal/item/consent-gaining-properly

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2021-08537

The Montgomery ruling and your birth rights. Ashworth E (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 3, September 2021

Emma Ashworth explains the Montgomery ruling and how this has strengthened people's rights when giving consent to medical treatment. (Author)
Full URL: https://www.aims.org.uk/journal/item/montgomery-consent-law

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2021-08513

AIMS Commentary on the Ockenden Interim Report, published on 10 December 2020. Madeley A (2021), Association for Improvements in Maternity Services (AIMS) vol 33, no 1, March 2021

Anna Madeley presents AIMS's commentary on the Ockenden interim report (1). (Author)
1. Ockenden D (2020). Ockenden report: emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust. London: House of Commons. https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf
Full URL: https://www.aims.org.uk/journal/item/aims-commentary-ockenden

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2021-08274

Informed consent and birth preparedness/complication readiness: A qualitative study at two tertiary maternity units. Ely S, Langer S, Dietz HP (2022), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 62, no 1, February 2022, pp 47-54

Background
Informed consent in obstetrics should involve full disclosure of risks, benefits and alternative interventions. However, we have found no evidence of a formal informed consent process before an attempt at vaginal delivery in published policy or practice. The idea of informed consent in vaginal birth has attracted controversy and has been the subject of some debate.

Aim
To explore the perspectives and experiences of informed consent and birth preparedness/complication readiness for birthing women in a high resource setting.

Materials and methods
Qualitative study using semi-structured interviews to examine experiences and perspectives of women following birth.

Results
Forty telephone interviews were concluded. Eight statement categories were identified: (i) no issues of consent, (ii) absent/inadequate informed consent, (iii) adequate birth preparedness/complication readiness, (iv) inadequate birth preparedness/complication readiness, (v) desire to forfeit decision making to a trusted and accountable health professional, (vi) belief that informed consent is not realistic in birth under some circumstances, (vii) negative feelings related to birth and (viii) poor postnatal follow-up.

Conclusions
When complications arose during birth, 20% of participants felt that informed consent was absent/inadequate, 25% of participants suggested policy change in favour of a formal informed consent process and 55% of participants suggested policy change in favour of increased birth preparedness/complication readiness. Our study suggests that informed consent for vaginal birth and formal birth preparedness/complication readiness should form part of routine antenatal

care. Women's preferences for decision-making and informed consent should be established before birth. (Author)

2021-07593

Shared decision making: translating guidance into practice. McGrath J, Vasu V, Sullivan C (2021), Infant vol 17, no 4, July 2021, pp 146-149

In 2019, the British Association of Perinatal Medicine (BAPM) updated its existing document on consent as a framework on enhancing shared decision making in neonatal care (1). This framework reflects the increasing emphasis on the role of parents in neonatal care, the decline of medical paternalism in health care and the increasing emphasis of parental involvement in neonatal clinical decision making. This article provides a summary of the main areas in the BAPM framework, how it aligns with the new GMC guidance and some practical tips for how neonatal healthcare practitioners can translate guidance into clinical practice. (Author, edited)

1. British Association of Perinatal Medicine (BAPM) (2019). Enhancing Shared Decision Making in Neonatal Care: A Framework for Practice.
https://hubble-live-assets.s3.amazonaws.com/bapm/file_asset/file/96/Shared_Decision_Making_in_Neonatal_Care.pdf

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2021-07538

Personalised care in maternity. Winfield S, Booker M (2021), British Journal of Midwifery vol 29, no 8, August 2021, pp 472-474

Although COVID-19 has placed immense pressure on healthcare professionals, Dr Sarah Winfield and Maria Booker still believe personalised care is the utmost of importance in maternity services. (Author)

2021-07506

Should we inform women about the recognised risks of childbirth?. Giddings HL, Wong J, Meagher AP (2022), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 62, no 1, February 2022, pp 37-39

Background
At present in Australia women are not routinely, systematically informed of the risks of childbirth.

Aims
It is hoped this presentation of the perspective of some women who suffer unexpected obstetric complications will encourage change.

Materials and Methods
The experience of women involved in obstetric medicolegal reports prepared by a colorectal surgeon over ten years is analysed.

Results
Twenty women were identified. Sixteen had vaginal deliveries. All 16 suffered third or fourth-degree tears, six developed rectovaginal fistulae, six required stomas and 11 developed faecal incontinence. Of the four women who delivered by caesarean section, there were two post-operative caecal perforations, one unrecognised small bowel enterotomy, and one patient developed sepsis due to an infected haematoma. Seventeen of the 20 women were noted to suffer psychological sequalae. None of the women recollected being warned of the complication they suffered, and there was no record of such warnings in their medical records.

Conclusion
Informed written 'consent' for natural vaginal delivery is, understandably, a contentious topic. Although learning from medicolegal cases may go against the grain, as medical professionals it is very difficult to ethically justify the status quo, where women are not routinely simply informed of the risks of childbirth. This is not fair. Even if informing women does not decrease the incidence of complications, the women who subsequently suffer these complications may well handle them much better, recognising they could occur. (Author)

2021-07450

What test did I have? Patient uncertainty about prenatal genetic screening. Parobek CM, Has P, Lorenzi P, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 225, no 3, September 2021, pp 341-342

Research letter exploring patient understanding of prenatal genetic screening. Results show that 30% of patients did

not remember discussing cell-free DNA screening and 16.6% did not remember discussing carrier screening. Those who were more likely to be unaware of undergoing screening were younger, had ethnic minority backgrounds and had lower educational attainment. (LDO)

Full URL: https://doi.org/10.1016/j.ajog.2021.05.030

2021-07272

The right of patients to make autonomous choices: Montgomery v Lanarkshire Health Board: a landmark decision on information disclosure to patients in the UK. Sutherland LQC (2021), International Urogynecology Journal vol 32, no 7, July 2021, pp 2005-2010

The decision in the Montgomery Supreme Court Ruling (UK 2015) has important implications for those involved in counselling pregnant women and it is suggested it is relevant not only in relation to potential risks to the baby but also potential risks to the mother. This article aims to consider the impact of the decision of the Supreme Court in Montgomery on information disclosure to patients in the UK but the decision may also have ethical implications which will be relevant in other countries. (Author)

2021-04459

Antenatal and intrapartum consent: Implications of the NSW Consent Manual 2020. Dietz HP, Caudwell Hall J, Weeg N (2021), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 61, no 5, October 2021, pp 802-805

The provision of informed consent for antenatal and intrapartum care remains a contentious issue among healthcare professionals and has been the topic of controversies in the pages of this journal. Recently, the New South Wales (NSW) Department of Health has fundamentally changed the ground rules for the provision of maternity care within the state. In this opinion piece, we try to provide guidance to clinicians to help them deal with the medicolegal environment created by this document which is likely to affect practitioners not just in NSW. (Author)

2021-04213

Understanding consent in maternity care: offers, threats, manipulation and force. McKenzie G (2021), The Practising Midwife vol 24, no 6, June 2021, pp 8-11

Informed consent is a fundamental tenet of good maternity care. Law, policy and guidance are clear about the standard midwives should meet with regards to this. Yet what are the philosophical and ethical underpinnings of this standard and how do they relate to everyday midwifery practice? Using examples from my own qualitative research on freebirth, I introduce some very basic philosophical concepts that explore offers, threats, manipulation and force. The aim of this article is to prompt discussion and help practising midwives feel confident that their interactions with pregnant women and people meet relevant legal and ethical standards. (Author)

2021-01915

Paternal consent in prenatal research: ethical aspects. Johansson M, Hermerén G, Sahlin NE (2020), Medicine, Health Care and Philosophy vol 23, no 2, June 2020, pp 325-331

The role of mothers in prenatal research has been discussed extensively. Significantly less work has been done on the father's role. In this article, focusing on ethical issues, we seek to redress this imbalance. Examining the father's position in research conducted on pregnant women, we ask whether or not paternal consent ought to be required in addition to that of the pregnant woman. Having distinguished between different concepts of father and mother, we proceed by giving an overview of the reasons for requiring consent of the woman who is carrying the child. We then examine which of these reasons apply to the biological father, and show that some of them are relevant to the father. The case, roughly speaking, revolves around privacy issues, the father's future legal responsibilities, and the likelihood that he will care about the health and wellbeing of his future child. These factors in the decision problem should all be recognized, as should the fact that they can in principle be trumped by other considerations. (Author)

2021-01446

Informed Consent and Shared Decision Making in Obstetrics and Gynecology: ACOG Committee Opinion Summary, Number 819. ACOG (2021), Obstetrics & Gynecology vol 137, no 2, February 2021, pp 392-393

Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and voluntary choice, which may include refusal of care or treatment. Shared decision making is a patient-centered, individualized approach to the

informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities. Some informed consent challenges are universal to medicine, whereas other challenges arise more commonly in the practice of obstetrics and gynecology than in other specialty areas. This Committee Opinion focuses on informed consent for adult patients in clinical practice and provides new guidance on the practical application of informed consent through shared decision making. The principles outlined in this Committee Opinion will help support the obstetrician–gynecologist in the patient-centered informed consent process.

Full URL: https://doi.org/10.1097/AOG.0000000000004248

2021-00917

Understanding Mordel: obtaining informed consent for trisomy screening. Wile EO, Einion-Waller A (2021), British Journal of Midwifery vol 29, no 2, February 2021, pp 108-114

The landmark decision of Montgomery has established that the patient's right to self-determination and autonomy underpins the doctrine of informed consent. The case of Mordel threw into question the process of obtaining informed consent and whether it was being sufficiently secured in the context of Down's syndrome screening. This case conveyed a paradigm shift to the role of the midwife and sonographers when obtaining consent for screening and the requisite legal standard of care they owe to expectant parents. However, many key issues remain unanswered from the decision in Mordel, in particular, what steps must healthcare professionals take to discharge their duty of care in the process of securing informed consent from expectant parents for screening. (Author)

2021-00324

Consent in pregnancy - an observational study of ante-natal care in the context of Montgomery: all about risk?. Nicholls JA, David AL, Iskaros J, et al (2021), BMC Pregnancy and Childbirth vol 21, no 102, 1 February 2021

Background

How to best support pregnant women in making truly autonomous decisions which accord with current consent law is poorly understood and problematic for them and their healthcare professionals. This observational study examined a range of ante-natal consultations where consent for an intervention took place to determine key themes during the encounter.

Methods

Qualitative research in a large urban teaching hospital in London. Sixteen consultations between pregnant women and their healthcare professionals (nine obstetricians and three midwives) where ante-natal interventions were discussed and consent was documented were directly observed. Data were collectively analysed to identify key themes characterising the consent process.

Results

Four themes were identified: 1) Clinical framing - by framing the consultation in terms of the clinical decision to be made HCPs miss the opportunity to assess what really matters to a pregnant woman. For many women the opportunity to feel that their previous experiences had been ‘heard’ was an important but sometimes neglected prelude to the ensuing consultation; 2) Clinical risk dominated narrative - all consultations were dominated by information related to risk; discussion of reasonable alternatives was not always observed and women’s understanding of information was seldom verified making compliance with current law questionable; 3) Parallel narrative - woman-centred experience – for pregnant women social factors such as the place of birth and partner influences were as or more important than considerations of clinical risk yet were often missed by HCPs; 4) Cross cutting narrative - genuine dialogue - we observed variably effective interaction between the clinical (2) and patient (3) narratives influenced by trust and empathy and explicit empowering language by HCPs.

Conclusion

We found that ante-natal consultations that include consent for interventions are dominated by clinical framing and risk, and explore the woman-centred narrative less well. Current UK law requires consent consultations to include explicit effort to gauge a woman’s preferences and values, yet consultations seem to fail to achieve such understanding. At the very least, consultations may be improved by the addition of opening questions along the lines of ‘what matters to you most?’

Full URL: https://doi.org/10.1186/s12884-021-03574-2

2021-00120

Abortion: Health Services [written answer]. House of Commons (2021), Hansard Written question 137338, 13 January 2021

Helen Whately responds to a written question from Scott Benton to the Secretary of State for Health and Social Care, regarding what representations his Department has received on the effect of the Government's decision to allow self-administered medical abortions at home without in-person consultation on the ability of (a) women to provide informed consent and (b) medical professionals to assess whether informed consent has been given in those circumstances. (Author, edited)

Full URL: https://questions-statements.parliament.uk/written-questions/detail/2021-01-13/137338

20201217-8*

Differences in demographics and outcomes based on method of consent for a randomised controlled trial on heat loss prevention in the delivery room. Vohra S, Reilly M, Rac VE, et al (2021), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 106, no 2, March 2021, pp 118-124

Objective Informed consent is standard in research. International guidelines allow for research without prior consent in emergent situations, such as neonatal resuscitation. Research without prior consent was incorporated in the Vermont Oxford Network Heat Loss Prevention Trial. We evaluated whether significant differences in outcomes exist based on the consent method.
Design Subgroup analysis of infants enrolled in a randomised controlled trial conducted from 2004 to 2010.
Setting A multicentre trial with 38 participating centres.
Participants Infants born 24-27 weeks of gestation. 3048 infants assessed, 2231 excluded due to fetal congenital anomalies, failure to obtain consent or gestation less than 24 weeks. 817 randomised, 4 withdrew consent, total of 813 analysed.
Main outcome measure The difference in mortality between consent groups.
Results No significant differences were found in mortality at 36 weeks (80.2%, 77.4%, p=0.492) or 6 months corrected gestational age (80.7%, 79.7%, p=0.765). Infants enrolled after informed consent were more likely to have mothers who had received antenatal steroids (95.2%, 84.0%, p<0.0001). They also had significantly higher Apgar scores at 1 (5.0, 4.4, p=0.019), 5 (7.3, 6.7, p=0.025) and 10 min (7.5, 6.3, p=0.0003).
Conclusions and relevance Research without prior consent resulted in the inclusion of infants with different baseline characteristics than those enrolled after informed consent. There were no significant differences in mortality. Significantly higher Apgar scores in the informed consent group suggest that some of the sicker infants would have been excluded from enrolment under informed consent. Research without prior consent should be considered in neonatal resuscitation research. (Author)

Full URL: http://dx.doi.org/10.1136/archdischild-2020-319045

20201210-8*

Ockenden report: emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust. Ockenden D (2020), London: House of Commons 10 December 2020. 38 pages

Report on the findings and recommendations from the independent review of maternity services at Shrewsbury and Telford Hospital NHS Trust. This is the first report and includes 250 cases from the entire period of the review. Presents four local actions for learning which cover maternity care, maternal deaths, obstetric anaesthesia and neonatal services. Highlights several immediate and essential actions which include increasing partnerships between trusts to strengthen safety, listening to women and their families, improved multidisciplinary training, robust pathways for managing women with complex pregnancies, the appointment of lead midwives and lead obstetricians, and access to accurate information for informed consent. (LDO)

Full URL: https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf

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20201126-31*

Perinatal Outcomes of Subjects Enrolled in a Multicenter Trial with a Waiver of Antenatal Consent. Katheria AC, Allman P, Szychowski JM, et al (2022), American Journal of Perinatology vol 39, no 8, June 2022, pp 904-908

Objective This study aimed to determine whether outcomes differed between infants enrolled in the PREMOD2 trial and those otherwise eligible but not enrolled, and whether the use of waiver effected these differences.
Study Design The multicenter PREMOD2 (PREmature infants receiving Milking Or Delayed cord clamping) trial was approved for waiver of antenatal consent by six of the nine sites institutional review boards, while three sites exclusively used antenatal consent. Every randomized subject delivered at a site with a waiver of consent was approached for postnatal consent to allow for data collection. Four of those six sites' IRBs required the study team to

attempt antenatal consent when possible. Three sites exclusively used antenatal consent.
Results Enrolled subjects had higher Apgar scores, less use of positive pressure ventilation, a lower rate of bronchopulmonary dysplasia, and a less frequent occurrence of the combined outcome of severe intraventricular hemorrhage or death. A significantly greater number of infants were enrolled at sites with an option of waiver of consent (66 vs. 26%, risk ratio = 2.54, $p < 0.001$). At sites with an option of either approaching families before delivery or after delivery with a waiver of antenatal consent, those approached prior to delivery refused consent 40% (range 15-74% across six sites) of the time.
Conclusion PREMOD2 trial demonstrated analytical validity limitations because of the variable mix of antenatal consent and waiver of consent. A waiver of antenatal consent for minimal risk interventional trials conducted during the intrapartum period will be more successful in enrolling a representative sample of low and high-risk infants if investigators are able to enroll all eligible subjects.
Clinical Trial Registration ClinicalTrials.gov identifier: NCT03019367. (Author)

20201126-19*

Observational study of parental opinion of deferred consent for neonatal research. Sloss S, Dawson JA, McGrory L, et al (2021), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 106, no 3, May 2021, pp 258-264

Objective To evaluate the opinions of parents of newborns following their infant's enrolment into a neonatal research study through the process of deferred consent.
Design Mixed-methods, observational study, interviewing 100 parents recently approached for deferred consent.
Setting Tertiary-level neonatal intensive care unit, Melbourne, Australia.
Results All 100 parents interviewed had consented to the study/studies using deferred consent; 62% had also experienced a prospective neonatal consent process. Eighty-nine per cent were 'satisfied' with the deferred consent process. The most common reason given for consenting was 'to help future babies'. Negative comments regarding deferred consent mostly related to the timing of the consent approach, and some related to a perceived loss of parental rights. A deferred approach was preferred by 51%, 24% preferred a prospective approach and 25% were unsure. Those who thought prospective consent would not have been preferable cited impaired decision-making, inappropriate timing of an approach before birth and their preference for removal of the decision-making burden via deferred consent. Seventy-seven per cent thought they would have given the same response if approached prospectively; those who would have declined reported that a prospective approach under stressful conditions was unwelcome and too overwhelming.
Conclusion In our sample, 89% of parents of infants enrolled in neonatal research using deferred consent considered it acceptable and half would not have preferred prospective consent. The ability to make a more considered decision under less stressful circumstances was key to the acceptability of deferred consent. (Author)

20201126-18*

Challenges of a simplified opt-out consent process in a neonatal randomised controlled trial: qualitative study of parents' and health professionals' views and experiences. Mcleish J, Alderdice F, Robberts H, et al (2021), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 106, no 3, May 2021, pp 244-250

Background More effective recruitment strategies like alternative approaches to consent are needed to facilitate adequately powered trials. Witholding Enteral feeds Around Transfusion was a multicentre, randomised, pilot trial that compared withholding and continuing feeds around transfusion. The primary clinical outcome was necrotising enterocolitis. The trial used simplified opt-out consent with concise parent information and no consent form.
Objective To explore the views and experiences of parents and health professionals on the acceptability and feasibility of opt-out consent in randomised comparative effectiveness trials.
Methods A qualitative, descriptive interview-based study nested within a randomised trial. Semistructured interview transcripts were analysed using inductive thematic analysis.
Setting Eleven neonatal units in England.
Participants Eleven parents and ten health professionals with experience of simplified consent.
Results Five themes emerged: 'opt-out consent operationalised as verbal opt-in consent', 'opt-out consent normalises participation while preserving parental choice', 'opt-out consent as an ongoing process of informed choice', 'consent without a consent form' and 'choosing to opt out of a comparative effectiveness trial', with two subthemes: 'wanting 'normal care'' and 'a belief that feeding is better'.
Conclusion Introducing a novel form of consent proved challenging in practice. The principle of a simplified, opt-out approach to consent was generally considered feasible and acceptable by health professionals for a neonatal comparative effectiveness trial. The priority for parents was having the right to decide about trial participation, and they did not see opt-out consent as undermining this. Describing a study as 'opt-out' can help to normalise

participation and emphasise that parents can withdraw consent. (Author)
Full URL: http://dx.doi.org/10.1136/archdischild-2020-319545

20201103-23*

What does respect for autonomy require in birth?. Holbeach N, Tumilty E, Brennan A (2020), O & G vol 22, no 3, Spring 2020, pp 17-18

Discusses the ethical principles of autonomy and informed consent for women in labour. Draws upon a case study of a woman who requests analgesia despite previously communicating her preference for minimal intervention. (LDO)
Full URL: https://www.ogmagazine.org.au/wp-content/uploads/2020/08/OG-Magazine-Spring-2020-Birthing-Issue-Web.pdf

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20200714-22*

Informed consent in obstetrics - a survey of pregnant women to set a new standard for consent in emergency obstetric interventions. Sturgeon TE, Ayaz H, McCrorie K, et al (2021), Journal of Obstetrics and Gynaecology vol 41, no 4, 2021, pp 541-545

Informed consent is necessary for all medical, surgical and obstetric interventions. Whilst informed consent can be obtained for elective procedures, it is much more challenging to obtain for emergency interventions. It can be difficult for women to understand the need for emergency intervention when pregnancy has been low risk. This can lead to problems with psychological trauma from the delivery being foremost in their minds in the postnatal period and in future pregnancies. The Montgomery ruling of 2015 encouraged informing women about risks and benefits of interventions and letting the women take responsibility for their own decision-making. Here, a patient-focused survey collected information on pregnant women's knowledge and wishes regarding emergency interventions. The responses were analysed in relation to local and Scottish national delivery data. We have initiated a novel programme to ensure all of our pregnant women are empowered to give informed consent for emergency interventions.
IMPACT STATEMENT
What is already known on this subject? There has been very little published on this subject to date and what has been published has involved focus groups or very small numbers of women.
What do the results of this study add? This study adds significantly to our understanding of current Scottish and Highland regional delivery statistics to help foster realistic delivery expectations in our pregnant women. This study is the first to report on pregnant women's understanding of the possibility of requiring emergency intervention in labour and the relevant risks. It also highlights the fact that women prefer to get their information from community midwives, friends and family rather than their obstetricians or GPs. This study is also the first to report women's actual preferences and comments with regard to information provision, labour and delivery experiences and their wishes for the future.
What are the implications of these findings for clinical practice and/or further research? The findings from this study have allowed us to develop and implement a novel means of obtaining informed consent in emergency obstetrics and the success of this programme will be reported following future analysis of patient experiences. (Author)

20200511-45*

How well do women understand and remember information in labour versus in late pregnancy? A pilot randomised study. Ayling L, Henry A, Tracy S, et al (2019), Journal of Obstetrics and Gynaecology vol 39, no 7, 2019, pp 913-921

Medical informed consent is the process by which a 'competent', non-coerced individual receives sufficient information including risks of a medical procedure and gives permission for it to occur. The capacity to give an informed consent might be impaired during labour. This study aimed to examine women's abilities to understand and remember during labour. Women were prospectively recruited at 36 weeks of gestation and randomised to undertake questionnaires which assessed their ability to understand and remember information. They were randomised to: (1) information given in labour only, written format (2) information in labour, verbal (3) information at 36 weeks plus labour, written (4) information at 36 weeks plus labour, verbal. Immediate comprehension and retention was assessed at 36 weeks, in labour, and 24-72 hours after birth. Forty-nine women completed the questionnaires regarding understanding and retention of information at 36 weeks, six intrapartum, and five postpartum (90% attrition). Women receiving information at 36 weeks and in labour versus in labour had a higher comprehension of pregnancy-related information, its retention, and total score. Women receiving information in late pregnancy and labour may comprehend and retain it better than women only receiving information during labour. Given small sample size, further research is needed to support these preliminary findings.
Impact statement
What is already known on this subject? The evidence regarding the capacity of labouring women to give informed

consent is largely based on women's self-reported experiences or expert opinions and has mixed findings. Existing guidelines recommend that an informed consent should be given antenatally for both clinical practice and research. Studies show that obtaining an informed consent antenatally is neither feasible nor widely implemented.
What do the results of this study add? A novel approach to providing empirical evidence regarding women's capacity to comprehend and retain information during labour. Our study confirms the difficulty with antenatal recruitment for intrapartum research.
What are the implications of these findings for clinical practice and/further research? This raises ethical concerns regarding the current intrapartum research in which consent is largely sought at the time of the study. Emphasises the need to explore the question 'Do labouring women have the capacity to consent to research?' in order to ensure that women are protected during labour. (Author)

20200429-63*

Investigation of informed consent procedures initiated in the intrapartum period. Alvarez M, Hotton E, Harding S, et al (2020), British Journal of Midwifery vol 28, no 4, April 2020, pp 251-258

Background
When research involves procedures initiated in the intrapartum period, there is considerable variation in information provision. If midwives are to optimise the process of information provision and facilitate good understanding of the research, we need to understand how information is currently being provided.
Aim
To investigate the feasibility and acceptability of an approach to investigating information provision for informed consent to research involving interventions initiated during the intrapartum period.
Methods
Audio recordings of seven study recruitment consultations and six structured interviews were transcribed and analysed to construct a 'hints and tips' for recruitment document for midwives.
Findings
Most women and three out of five midwives agreed to audio-recording consultations. All participants confirmed the acceptability of audio-recording recruitment consultations. Midwives varied in their experiences.
Conclusion
This approach to exploring the informed consent processes is feasible and acceptable to women and midwives. Findings will inform further investigation of information provision in the ASSIST II study. (Author)

Full URL: https://doi.org/10.12968/bjom.2020.28.4.251

20200422-13*

Consent in Obstetrics. Blake J (2020), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 42, no 4, April 2020, pp 391-393

Consent is a fundamental requirement to the practice of obstetrics. However, consent becomes complicated when there is shared care or transfer of care or where past or present circumstances have created barriers to developing a relationship of trust. Particularly troubling are the stories we've been told by Aboriginal women in Canada who felt coerced to undergo sterilization. These experiences challenge us to, among other things, reflect on the dynamics of the physician-patient relationship from the point of view of racialized or vulnerable women and on the complicated nature of consent in obstetrics. (Author)

20200304-81

Antenatal education and informed consent: Some questions to ponder. Newnham E (2020), International Journal of Birth and Parent Education vol 7, no 2, January 2020, pp 30-31

This article is a summary of an ethnographic study of epidural analgesia that was undertaken in a large hospital providing maternity services in Australia. It describes the way in which information about epidural analgesia was given in antenatal classes, and how it was received by women. It also discusses informed consent. When examined critically, this seemingly straightforward ethical concept that underpins maternity care provision reveals a complicated set of ethical challenges, including how information about birth options is produced, provided and discussed. (13 references) (Author)

20200221-42

Obtaining and confirming consent. Symon A (2019), British Journal of Midwifery vol 27, no 12, December 2019, pp 798-799

The question of how practitioners provide information and verify that a woman understands the issues and consents

to a procedure was raised in the High Court. Andrew Symon reports on Mordel v Royal Berkshire NHS. (3 references) (Author)

20200212-9*

Misoprostol [written answer]. House of Commons (2020), Hansard Written question 12206, 4 February 2020

Caroline Dinenage responds to a written question asked by Sir Edward Leigh to the Secretary of State for Health and Social Care, with reference to his Department's guidance allowing misoprostol to be taken at home, what steps he has (a) taken and (b) plans to take in the next six months to ensure that (i) misoprostol is only given to the women who wish to use it, and (ii) there is appropriate screening to ensure women are not being compelled to take misoprostol against their will; and if he will make a statement. (JSM)

Full URL: https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-02-04/12206/

20200212-7*

Abortion [written answer]. House of Commons (2020), Hansard Written question 12205, 4 February 2020

Caroline Dinenage responds to a written question asked by Sir Edward Leigh to the Secretary of State for Health and Social Care, regarding what recent discussions he has had with representatives of abortion clinics licensed by his Department on ensuring that those clinics (a) report cases of suspected sexual abuse and exploitation, (b) flag cases of underage girls being brought to their clinic for abortion by the same unrelated adult, (c) ensure that consent is provided in writing by minors; and if he will make a statement. (JSM)

Full URL: https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-02-04/12205/

20200212-3*

Abortion [written answer]. House of Commons (2020), Hansard Written question 12204, 4 February 2020

Caroline Dinenage responds to a written question asked by Sir Edward Leigh to the Secretary of State for Health and Social Care, regarding what steps he has (a) taken and (b) plans to take to ensure that abortion clinics (i) report cases of suspected sexual abuse and exploitation, (ii) flag cases of underage girls being brought to their clinic for an abortion by the same unrelated adult and (iii) ensure that consent is properly obtained from minors; and if he will make a statement. (JSM)

Full URL: https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-02-04/12204/

20200129-32

Multimedia in improving informed consent for caesarean section: A randomised controlled trial. Truong A, Ellett L, Hicks L, et al (2020), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 60, no 5, October 2020, pp 683-689

Background
Multimedia modules have been used as an adjunct to improve patient knowledge and recall for various elective surgical procedures, but have been incompletely evaluated in patients undergoing caesarean section.
Aims
To compare the use of a supplementary multimedia module with written information in improving the informed consent process prior to elective caesarean section.
Materials and methods
This was a prospective randomised controlled trial (ACTRN12616000430437). Primary outcomes were knowledge and anxiety scores immediately following the intervention and on the day of surgery. Secondary outcomes were patient satisfaction, length of stay, time to cessation of analgesia, and patient assessment of the consent types.
Results
Seventy-five patients completed the study. Both multimedia module and written information groups demonstrated a significant increase in knowledge scores with no difference between the groups. In the multimedia-assisted consent group, scores improved from baseline by +2.31 ($P < 0.001$) immediately after watching the multimedia module and by +2.41 ($P < 0.001$) on the day of surgery. In the written information group, scores improved by +1.76 ($P < <0.001$), and +2.31 ($P < 0.001$) respectively. There was no adverse impact on anxiety in either group. Patient-reported understanding (92.4% vs 78.5%, $P = 0.001$), and helpfulness (90.1% vs 73.3%, $P = 0.001$) was significantly higher in the multimedia module group than in the written information group. The multimedia module was assessed as 'slightly too long' and provided 'slightly too much information'.

Conclusions
Multimedia modules are a valuable adjunct to traditional processes of obtaining informed consent for elective caesarean section and should be offered and made available to patients prior to surgery. (26 references) (Author)

20200128-43*

Would you like to participate in this trial? The practice of informed consent in intrapartum research in the last 30 years. Widmer M, Bonet M, Betrán AP (2020), PLoS ONE vol 15, no 1, 24 January 2020, e0228063

Background
Informed consent is the cornerstone of the ethical conduct and protection of the rights and wellbeing of participants in clinical research. Therefore, it is important to identify the most appropriate moments for the participants to be informed and to give consent, so that they are able to make a responsible and autonomous decision. However, the optimal timing of consent in clinical research during the intrapartum period remains controversial, and currently, there is no clear guidance.
Objective
We aimed to describe practices of informed consent in intrapartum care clinical research in the last three decades, as reported in uterotonics for postpartum haemorrhage prevention trials.
Methods
This is a secondary analysis of the studies included in the Cochrane review entitled 'Uterotonic agents for preventing postpartum haemorrhage: a network meta-analysis' published in 2018. All the reports included in the Cochrane network meta-analysis were eligible for inclusion in this analysis, except for those reported in languages other than English, French or Spanish. We extracted and synthesized data on the time each of the components of the informed consent process occurred.
Results
We assessed data from 192 studies, out of 196 studies included in the Cochrane review. The majority of studies (59.9%, 115 studies) reported that women were informed about the study, without specifying the timing. When reported, most studies informed women at admission to the facility for childbirth. Most of the studies reported that consent was sought, but only 59.9% reported the timing, which in most of the cases, was at admission for childbirth. Among these, 32 studies obtained consent in the active phase of labour, 17 in the latent phase and in 10 studies the labour status was unknown. Women were consented antenatally in 6 studies and in 8 studies the consent was obtained indistinctly during antenatal care or at admission. Most of the studies did not specified who was the person who sought the informed consent.
Conclusion
Practices of informed consent in trials on use of uterotonics for prevention of postpartum haemorrhage showed variability and substandard reporting. Informed consent sought at admission for childbirth was the most frequent approach implemented in these trials. (27 references) (Author)

Full URL: https://doi.org/10.1371/journal.pone.0228063

20200110-12*

Montgomery and informed consent: where are we now?. Chan SW, Tulloch E, Cooper ES, et al (2017), BMJ vol 357, 12 May 2017, j2224

The Montgomery case in 2015 was a landmark for informed consent in the UK.Two years on, Sarah Chan and colleagues discuss the consequences for practising doctors. (27 references) (Author)

Full URL: https://www.bmj.com/content/bmj/357/bmj.j2224.full.pdf

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20200107-12*

Pre-post implementation survey of a multicomponent intervention to improve informed consent for caesarean section in Southern Malawi. Zethof S, Bakker W, Nansongole F, et al (2020), BMJ Open vol 10, no 1, January 2020, e030665

Objective Surgical informed consent is essential prior to caesarean section, but potentially compromised by insufficient communication. We assessed the association between a multicomponent intervention and women's recollection of information pertaining to informed consent for caesarean section in a low-resource setting, thereby contributing to respectful maternity care.
Design Pre-post implementation survey, conducted from January to June 2018, surveying women prior to discharge.
Setting Rural 150-bed mission hospital in Southern Malawi.
Participants A total of 160 postoperative women were included: 80 preimplementation and 80 postimplementation.
Intervention Based on observed deficiencies and input from local stakeholders, a multicomponent intervention was

developed, consisting of a standardised checklist, wall poster with a six-step guide and on-the-job communication training for health workers.
Primary and secondary outcome measures Individual components of informed consent were: indication, explanation of procedure, common complications, implications for future pregnancies and verbal enquiry of consent, which were compared preintervention and postintervention using χ2 test. Generalised linear models were used to analyse incompleteness scores and recollection of the informed consent process.
Results The proportion of women who recollected being informed about procedure-related risks increased from 25/80 to 47/80 (OR 3.13 (95% CI 1.64 to 6.00)). Recollection of an explanation of the procedure changed from 44/80 to 55/80 (OR 1.80 (0.94 to 3.44)), implications for future pregnancy from 25/80 to 47/80 (1.69 (0.89 to 3.20)) and of consent enquiry from 67/80 to 73/80 (OR 2.02 (0.73 to 5.37)). After controlling for other variables, incompleteness scores postintervention were 26% lower (Exp(β)=0.74; 95% CI 0.57 to 0.96). Recollection of common complications increased with 0.25 complications (β=0.25; 95% CI 0.01 to 0.49). Recollection of the correct indication did not differ significantly.
Conclusion Recollection of informed consent for caesarean section changed significantly in the postintervention group. Obtaining informed consent for caesarean section is one of the essential components of respectful maternity care.
 (44 references) (Author)

Full URL: http://dx.doi.org/10.1136/bmjopen-2019-030665

20191114-65

Parents' and clinicians' views on conducting paediatric diagnostic test accuracy studies without prior informed consent: qualitative insight from the Petechiae in Children study (PiC). Waterfield T, Lyttle MD, Shields M, et al (2019), Archives of Disease in Childhood vol 104, no 10, October 2019, pp 979-983

Objective: The Petechiae in Children (PiC) study assesses the utility of presenting features and rapid diagnostic tests in the diagnosis of serious bacterial infection in feverish children with non-blanching rashes. An embedded qualitative study explored parents' and clinicians' views on the acceptability of the PiC study, including the use of research without prior consent (RWPC) in studies of diagnostic test accuracy.
Design: Semistructured qualitative interviews. Analysis was thematic and broadly interpretive, informed by the constant comparative approach.
Participants: Fifteen parents were interviewed 55 (median) days since their child's hospital attendance (range 13-95). Five clinicians involved in recruitment, and consent were interviewed.
Results: Parents and clinicians supported RWPC for the PiC study and future emergency paediatric diagnostic test accuracy studies as long as there is no harm to the child and emergency care is not delayed. Parents and clinicians made recommendations around the timing and conduct of a consent discussion, which were in line with RWPC guidance. Parents enrolled in the PiC study preferred a design that included consent discussions with the research team over the alternative of 'opt-out' consent only.
Conclusions: This embedded qualitative study demonstrates that RWPC is appropriate for use in paediatric emergency studies of diagnostic test accuracy and that the approach used in PiC was appropriate. Future diagnostic studies involving additional invasive procedures or an opt-out only approach to consent would benefit from exploring parent and clinician views on acceptability at the pretrial stage.(37 references) (Author)

20191108-21*

Consent to treatment post Montgomery - plus ça change?. Bramley S (2019), Association for Improvements in Maternity Services (AIMS) vol 31, no 3, September 2019

Stuart Bramley explores the impacts of the Montgomery V Lanarkshire ruling on women's rights in birth. (6 references) (Author)

Full URL: https://www.aims.org.uk/journal/item/montgomery

20191031-53*

In search of justice. Whitehead B (2019), Association for Improvements in Maternity Services (AIMS) vol 31, no 1, May 2019

The author shares her experiences of assault and disrespect during labour and tells how, when she reported the

incident to the police one year after it had taken place, they were unable to help her. (JSM)
Full URL: https://www.aims.org.uk/journal/item/justice-for-birth-assault

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20191029-46*

To Consent, or Not to Consent, That Is the Question: Ethical Issues of Informed Consent for the Use of Donor Human Milk in the NICU Setting. McGlothen-Bell K, Cleveland L, Pados BF (2019), Advances in Neonatal Care vol 19, no 5, October 2019, pp 371-375

Background: Evidence supports the superiority of mother's own milk (MOM) in reducing the comorbidities common to prematurity and very low birth weight. In situations where an insufficient amount of MOM is available or maternal contraindications prevent its use, pasteurized donor human milk (DHM) is a viable substitution. When DHM is deemed best, a common practice in many neonatal intensive care units (NICUs) is for parents to provide their consent. However, no universal mandate for informed consent exists. Often, healthcare providers present and obtain the consent for DHM use prior to delivery or shortly after birth and this consent may be 'bundled' along with other standardized NICU treatment consents. This approach is likely less than ideal since it provides insufficient time for decision making and often precedes the mother's ability to initiate the expression of her own milk.
Purpose: To review the history of DHM use and the ethics surrounding the consenting process including the ethical principles involved in infant feeding decision making. We argue for the standardization and consistent use of informed consent for DHM in the NICU and offer clinical practice implications.
Findings/Results/Implications for Practice and Research: Providers face several challenges in the consenting process for the use of DHM in the NICU setting. These include limited time to support parents and educate them appropriately during the decision-making process. Standardized and consistent use of informed consent is essential to address the ethical concerns surrounding the use of DHM in the NICU setting. (15 references) (Author)

Full URL: https://journals.lww.com/advancesinneonatalcare/Fulltext/2019/10000/To_Consent,_or_Not_to_Consent,_That_Is_the.6.aspx

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20190208-12

Choosing to decline: finding common ground through the perspective of shared decision making. Megregian M, Nieuwenhuijze M (2018), Journal of Midwifery & Women's Health vol 63, no 3, May/June 2018, pp 340-346

Respectful communication is a key component of any clinical relationship. Shared decision making is the process of collaboration that occurs between a health care provider and patient in order to make health care decisions based upon the best available evidence and the individual's preferences. A midwife and woman (and her support persons) engage together to make health care decisions, using respectful communication that is based upon the best available evidence and the woman's preferences, values, and goals. Supporting a woman's autonomy, however, can be particularly challenging in maternity care when recommended treatments or interventions are declined. In the past, the real or perceived increased risk to a woman's health or that of her fetus as a result of that choice has occasionally resulted in coercion. Through the process of shared decision making, the woman's autonomy may be supported, including the choice to decline interventions. The case presented here demonstrates how a shared decision-making framework can support the health care provider-patient relationship in the context of informed refusal. (37 references) (Author)

20190117-15

We need to treat pregnant women as adults. Dietz HP, Callaghan S (2018), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 58, no 6, December 2018, pp 701-703

Since the mid-90s, Australian law has required doctors to disclose material risks of proposed treatment. Medical practitioners have had two decades to adapt, and, by and large, patient autonomy is acknowledged and respected by obtaining 'informed consent'. While problems with obtaining consent do surface in medico-legal litigation, practitioners are generally aware of the need to do so and usually comply with requirements. However, not in obstetrics. Here, even if material risk of a serious adverse event in an attempt at vaginal birth in a given case is over 50% (as it would be in the case of a 35-year-old primigravida at 41 + 3) obtaining informed consent is the exception rather than the rule. This degree of paternalism is not just unethical and immoral. It is illegal - and it needs to change. (Author)

20190116-47

Vaginal delivery: An argument against requiring consent. Petersen RW (2018), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 58, no 6, December 2018, pp 704-706

Birth by vaginal delivery is an evolutionary process refined over millennia to create a sustainable and safe method of human reproduction. A key argument against requiring consent for vaginal birth acknowledges that from an evolutionary point of view, vaginal delivery has successfully accompanied human development and remains the natural and default form of human birth. Concern has been raised by the Montgomery court case in the United Kingdom; however, the ruling does not mean consent is required for normal birth. What it does reaffirm is the need to engage patients in their care decisions when complications occur in pregnancy and delivery. Effective communication, rather than a legalistic consent pathway, is required for positive healthcare outcomes. (15 references) (Author)

20181204-47*

Assessment of a shortened informed consent form for pediatric research: a pilot study. Murray PD, Bierer BE, Hirschfeld S, et al (2018), Pediatric Research vol 84, no 4, 2018, pp 516-519

Background
Inherent to clinical research is the informed consent process, with the informed consent form (ICF), a key component of human participant protections. We wished to examine whether a shortened and simplified ICF, accompanied by an appendix, improved participant understanding of a study compared with a conventional ICF.
Methods
A shortened ICF was developed from an existing conventional ICF for a neonatal study. Either the shortened or conventional ICF was randomly distributed to members of two parental advocacy groups. Participants answered survey questions about the form they received.
Results
Thirty-one out of forty-one (76%) parents in the shortened ICF and 28/41 (68%) in the conventional ICF group responded. Significantly more parents in the shortened ICF group found their form 'short and to the point'. Although they also stated that the shortened ICF did not provide enough information, there were no significant differences between groups measuring the understanding of key study components.
Conclusion
A shortened ICF did not impact the understanding of the clinical trial. It will be important to compare the shortened and conventional forms in actual clinical trials. (23 references) (Author)

Full URL: https://www.nature.com/articles/s41390-018-0043-7?WT.ec_id=PR-201812&sap-outbound-id=35745F79F668B66F2E86B1588FF97592204CBD2C

20181119-30*

Informed consent in pediatric anesthesia: a narrative review. Feinstein MM, Pannunzio AE, Lobell S, et al (2018), Anesthesia & Analgesia vol 127, no 6, December 2018, pp 1398-1405

Informed consent for pediatric anesthesia challenges practitioners to navigate complex ethical, medical, and legal ambiguities. A patient's status as a minor does not negate the importance of his or her participation in the decision-making process but, rather, necessitates a nuanced evaluation of age and development to involve the patient to an appropriate extent. Given the complexities involved with pediatric informed consent in anesthesia practice and research, it is important to understand the experience of key stakeholders involved. For this review, we searched Medline, the Cochrane database, PROSPERO, and Clinicaltrials.gov for studies involving pediatric anesthesia informed consent. Inclusion and exclusion criteria were designed to select for studies that included issues related to informed consent as primary outcomes. The following data were extracted from included studies: title, authors, date of publication, study type, intervention, data collection method, participant type (ie, parent, pediatric patient, anesthesia provider), number of participants, pediatric patient age range, and primary outcome measures. Twenty-two articles were included for final review: studies of informed consent in pediatric anesthesia span many aspects of informed consent. Parental understanding has been studied most often (7/22 studies), followed by parental preferences (5/22 studies) and provider-related outcomes (5/22 studies) such as time spent interacting with patients, subjective reporting on amount of training related to informed consent, and provider satisfaction with the informed consent process. Outcomes pertaining to pediatric patients themselves constitute the smallest number of studies, including child anxiety (1/22), child understanding (1/22), and child refusal (1/22). Among the parties involved, parents have been most frequently identified as the subjects of these studies (2719/3805 subjects across all included studies, or 71% of all subjects). Pediatric patients are the least frequently involved subjects of studies that investigate informed consent in pediatric anesthesia (493/3805, or 13% of all subjects). Anesthesia providers and investigators have been study subjects (593/3805, or 16% of all subjects) for a range of topics including time spent interacting with patient, nature of informed consent conversation in relation to trainee status, satisfaction with informed consent process, and priorities for informed consent content. The aim of the present narrative review is to summarize the work that has been done on informed consent for pediatric anesthesia. (Author)

20181116-22*

Written consent should not be obtained at the time of emergency caesarean section: AGAINST: Written consent should be obtained. Chervenak FA, McCullough LB (2018), BJOG: An International Journal of Obstetrics and Gynaecology vol 125, no 13, December 2018, p 1756

Argues that written consent of a pregnant patient to emergency caesarean section constitutes a documentation of her authorisation; the professional responsibility model of obstetrics and gynaecology directs the informed consent process. According to the authors, as caesarean section is a possible outcome in all pregnancies, the pregnant patient should be informed and written consent obtained well in advance. (KRB)

20181116-21*

Written consent should not be obtained at the time of emergency caesarean section: FOR: Written consent for emergency caesarean section is not legally required, may delay delivery, and can cause distress. Steer PJ (2018), BJOG: An International Journal of Obstetrics and Gynaecology 13 November 2018. vol 125, no 13, December 2018, p 1757

Argues that there is no legal requirement in the United Kingdom for consent to medical treatment to be written, that giving written consent can be frightening for women, and that those signing forms often cannot recall the form's contents. These and other factors make the process meaningless in medical and legal terms, and threaten to delay the life-saving operation of an emergency caesarean. Explaining the treatment verbally is sufficient to inform the patient. (Author)

20181019-9*

Clinical research with pregnant women: perspectives of pregnant women, health care providers, and researchers. Wada K, Evans MK, de Vrijer B, et al (2018), Qualitative Health Research vol 28, no 13, November 2018, pp 2033-2047

Limited clinical research with pregnant women has resulted in insufficient data to promote evidence-informed prenatal care. Charmaz's constructivist grounded theory methodology was used to explore how research with pregnant women would be determined ethically acceptable from the perspectives of pregnant women, health care providers, and researchers in reproductive sciences. Semistructured interviews were conducted with a purposive sample of 12 pregnant women, 10 health care providers, and nine reproductive science researchers. All three groups suggested the importance of informed consent and that permissible risk would be very limited and complex, being dependent on the personal benefits and risks of each particular study. Pregnant women, clinicians, and researchers shared concerns about the well-being of the woman and her fetus, and expressed a dilemma between promoting research for evidence-informed prenatal care while securing the safety in the course of research participation. (Author)

20180918-16

Informed consent for a neonatal clinical trial: parental experiences and perspectives. Shah AR, Wilfond BS, Silvia A, et al (2018), Journal of Perinatology vol 38, no 7, July 2018, pp 865-872

Objective

There is a variability regarding timing of consent and personnel used in patient recruitment for neonatal research. We explored the associations between the study personnel and timing of consent with parents' decisional conflict and ultimately their decision to enroll.

Study design

This was a multi-site, cross-sectional survey conducted between August 2015 and October 2017. Participants were parents approached to enroll their 24-28-week infant in a clinical trial. Parents completed an interviewer-administered 61-item questionnaire.

Results

Overall, 163 surveys were completed; 105 by parents of enrolled infants and 58 by parents of non-enrolled infants (54.5% participation rate). Neither the individual requesting nor timing of consent was associated with parents' knowledge score, decisional conflict, or decision to enroll. Parents preferred to be approached prenatally and by their infant's doctor.

Conclusion

Study designers and IRBs may allow flexibility in personnel and timing of consent as it is respectful of parents and may enhance trial enrollment. (27 references) (Author)

20180830-49

Improved pregnant women's understanding of research information by an enhanced informed consent form: a randomised controlled study nested in neonatal research. Koonrungsesomboon N, Traivaree C, Chamnanvanakij S, et al (2018), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 103, no 5, September 2018, pp F403-F407

Objective
This study aimed to test the applicability and effectiveness of the enhanced informed consent form (ICF) methodology, proposed by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), in neonatal research requiring maternal consent.
Design
A single-centre open-label randomised controlled study.
Setting
Antenatal care clinics at Phramongkutklao Hospital, Thailand.
Patients
234 pregnant women who were at risk of preterm labour were enrolled; 232 individuals completed the study.
Interventions
The participants were randomly assigned to read either the SIDCER ICF or the conventional ICF.
Main outcome measures
The participants' understanding of essential trial-related information was assessed using 25 closed-ended questions. The primary endpoint was the proportion of the participants who obtained the satisfactory level of understanding at 80% (score of ≥20/25).
Results
72.5% (87/120) of the participants in the SIDCER ICF group and 59.8% (67/112) of the conventional ICF group achieved the primary endpoint (relative risk (RR)=1.212, 95% CI 1.005 to 1.462, p=0.041). The superiority of the SIDCER ICF over the conventional ICF was significant, particularly among the participants whose education was at the high school level or below (63.5% vs 44.1%, RR=1.441, 95% CI 1.022 to 2.030, p=0.031).
Conclusions
The SIDCER ICF methodology is applicable to neonatal research requiring maternal consent. The SIDCER ICF significantly improved the understanding of pregnant women, particularly among those with lower levels of education. The present study confirms the value of the SIDCER ICF methodology in research involving individuals with a limited academic background. (40 references) (Author)

20180807-6*

Electronic Informed Consent to Facilitate Recruitment of Pregnant Women Into Research. Phillippi JC, Doersam JK, Neal JL, et al (2018), JOGNN: Journal of Obstetric, Gynecologic and Neonatal Nursing vol 47, no 4, July 2018, pp 529-534

Methods to obtain informed consent digitally or electronically may increase the participation of racially and geographically diverse pregnant women in prospective research, which is essential to improve the evidence base for maternity care. We evaluated the feasibility and utility of e-consent in the first year of a multiyear clinical trial involving pregnant women. Of the 86 women screened, 71 were eligible, 65 (93% of eligible) agreed to review the e-consent form, and 61 (86% of eligible) completed the e-consent process. Of the interested women who were sent the e-consent link, all were able to complete the e-consent process, even those who reported low health literacy. Women of all racial and ethnic groups were equally likely to consent, and the sample of women who consented was consistent with practice demographics. E-consent is feasible and easy to use with pregnant women and may expedite enrollment of a representative sample. (23 references) (Author)

20180717-20

Coercion or consent?. Golden P (2018), British Journal of Midwifery vol 26, no 7, July 2018, pp 482-483

Discusses the legal issue of coercion in maternity care, also referred to as obstetric violence. All patients in the United Kingdom have the right to refuse health care, even when their life depends on it, but many breaches do take place. It is crucial to have express consent from clients in midwifery as it is such an intimate area of personal care. The article suggests possible solutions to problems of coercion and how to demonstrate and effect fully informed consent and refusal. (9 references) (KRB)

20180619-19

Extremely premature birth, informed written consent, and the Greek ideal of sophrosyne. Kaempf JW, Dirksen K (2018),

Journal of Perinatology vol 38, no 4, April 2018, pp 306-310

Most extremely premature infants die in the intensive care unit or suffer significant neurologic impairment. Many therapies result in unhealthy consequences, and the emotional and financial turmoil for families warrant reappraisal of our motives. Shared decision-making and informed consent in preference-sensitive conditions imply the family: (a) understands the medical problem, (b) grasps the risks and benefits of each therapy, (c) has the opportunity to ask questions and reflect upon options, (d) knows their values and preferences are understood, and (e) accepts or declines therapies without judgment or penalty. Mandatory resuscitation of premature infants or inflexible palliative comfort care policies are inconsistent with the principles of informed consent and shared decision-making. Physicians should emulate the Greek ideal of sophrosyne-virtue inherent to balance, reasoned limits, freedom but restraint, and humility. Informed choice is fundamental to liberty; evidence-based periviability guidelines and decision aids bolstered by structured informed consent ensure process integrity. (Author) (50 references)

20180508-13

Never fear. The way we share information with midwives. Hitchick M (2018), The Practising Midwife vol 21, no 5, May 2018, pp 14-17

The young woman clutches a tissue and dabs at her eyes while she tells the story. 'I have to have an induction. They told me that the baby might grow too big to get out, or that the placenta might stop working, so he has to come out now.'

At the midwives' station, the clinician is writing notes up.

'Well, I'm sorry she's upset. But I have to speak to her about the risks, you know. It's my job. The baby measures on the 84th percentile already. But she's consented to be induced now, so we'll get her started.'

Two perspectives, arising from one conversation. But who is really in control? What is this woman's perception of the 'choice' she is making?

Although legally they must respect women's autonomy, clinicians are able to exert control over pregnant and birthing women by manipulating with fear or distorted risk profiles and justifying actions with 'informed consent'. (Author)

20180327-20*

Parental And Clinician Views Of Consent In Neonatal Research. O'Shea N, Doran K, Ryan CA, et al (2018), Irish Medical Journal vol 111, no 3, March 2018, P706

Aim

To determine parental and clinician views of the informed consent process in neonatal research.

Methods

A questionnaire-based study on the informed consent process. Two questionnaires were developed and distributed to parents and clinicians over a four-month period.

Results

Thirty-four parents (79%) surveyed had consented their baby to a research study. The majority of clinicians (72%) had a preference for antenatal provision of information. A desire to help future babies (97%, n=32) and a belief that their baby's healthcare would directly benefit (72%, n=28) were primary reasons for consenting. The majority (76% n=28) of parents were not in favour of a waiver of consent. However twenty clinicians (56%) agreed that a waiver of consent may be appropriate in neonatal research. Thirty-one (86%) clinicians rated GCP training as important.

Discussion

Parents are generally supportive of neonatal research. Good clinical practice training is essential for clinicians involved in neonatal research. (Author)

Full URL: http://imj.ie/parental-and-clinician-views-of-consent-in-neonatal-research/

20180130-64

Induction of labour: How do women get information and make decisions? Findings of a qualitative study. Jay A, Thomas H, Brooks F (2018), British Journal of Midwifery vol 26, no 1, January 2018, pp 22-29

Background

Induction of labour is one of the most frequent interventions in pregnancy. While it is not always unwelcome, it is associated with increased labour pain and further interventions. Evidence from earlier studies suggests that induction is often commenced without full discussion and information, which questions the validity of women's consent. This study aimed to add depth and context to existing knowledge by exploring how first-time mothers acquire information about induction and give consent to the procedure.

Method

A qualitative study into women's experiences of induction was undertaken, comprising 21 women, who were interviewed 3-6 weeks after giving birth following induction.
Findings
Information from midwives and antenatal classes was minimal, with family and friends cited as key informants. Midwives presented induction as the preferred option, and alternative care plans, or the relative risks of induction versus continued pregnancy, were rarely discussed. Women reported that midwives often appeared rushed, with little time for discussion.
Conclusions
Providers of maternity care need to devise more flexible ways of working to create time and opportunities for midwives to discuss induction in detail with women and to promote fully informed decision-making. (Author)

20180102-19*

Retrospective Consent in a Neonatal Randomized Controlled Trial. Songstad NT, Roberts CT, Manley BJ, et al (2018), Pediatrics vol 141, no 1, January 2018

BACKGROUND AND OBJECTIVES: The requirement for prospective consent in clinical trials in acute settings may result in samples unrepresentative of the study population, potentially altering study findings. However, using retrospective consent may raise ethical issues. We assessed whether using retrospective consent affected recruitment, participant characteristics, and outcomes within a randomized controlled trial.
METHODS: We conducted a secondary analysis of a randomized trial, which compared nasal high flow (nHF) with nasal continuous positive airway pressure (CPAP) for primary respiratory support in preterm infants. In Era 1, all infants were consented prospectively; in Era 2, retrospective consent was available. We assessed inclusion rates of eligible infants, demographic data, and primary trial outcome (treatment failure within 72 hours).
RESULTS: In Era 1, recruitment of eligible infants was lower than in Era 2: 111 of 220 (50%) versus 171 of 209 (82%), P < .001; intrapartum antibiotic administration was lower: 23 of 111 (21%) versus 84 of 165 (51%), P < .001; full courses of antenatal steroids were higher: 86 of 111 (78%) versus 103 of 170 (61%), P = .004; and more infants received pre-randomization CPAP: 77 of 111 (69%) versus 48 of 171 (28%), P < .001. In Era 1, nHF failure (15 of 56, 27%) and CPAP failure (14 of 55, 26%) rates were similar, P = .9. In Era 2, failure rates differed: 24 of 85 (28%) nHF infants versus 13 of 86 (15%) CPAP infants, P = .04. The $\chi 2$ interaction test was nonsignificant (P = .20).
CONCLUSIONS: The use of retrospective consent resulted in greater recruitment and differences in risk factors between eras. Using retrospective consent altered the study sample, which may be more representative of the whole population. This may improve scientific validity but requires further ethical evaluation.
Accepted October 3, 2017.

20171108-79

Informed consent in theatre. Anon (2017), The Practising Midwife vol 11, no 10, November 2017, pp 47-50

Drawing on her own experience, the author discusses the importance of ensuring that women are fully informed about every step of the process before they are asked to give consent prior to caesarean section. (MB)

20171108-65

Key concepts in care: exploring basic legal and ethical concepts in maternity care. Feeley C (2017), The Practising Midwife vol 11, no 10, November 2017, pp 8-11

This article revisits some key concepts within maternity care: women's choice, autonomy, decision-making and consent through basic legal and ethical frameworks. It is intended as a 'beginner's guide': a starting point into the tricky terrain to provide a basic platform for readers to conceptualise these ideas, and is by no means exhaustive. (21 references) (Author)

20171108-125

Consent for newborn screening and storage of blood samples. Ulph F, Lavender T, Bennett R (2017), British Journal of Midwifery vol 25, no 11, November 2017, pp 730-732

Newborn bloodspot screening is a routine procedure that is undertaken in most developed countries in order to identify nine different conditions, including sickle cell disease and cystic fibrosis. It is a procedure that requires parental consent, although studies have shown that parents may be unaware that they are also consenting to the storage of bloodspot samples. As part of a wider study aiming to identify the best means of communicating with parents, this article will examine how midwives can ensure that parents are informed and consent is valid. (7

references) (Author)

20170926-20

The influence of counseling on the mode of breech birth: A single-center observational prospective study in the Netherlands. Abdessalami S, Rota H, Pereira GD, et al (2017), Midwifery vol 55, December 2017, pp 96-102

Objective
Women in the Netherlands, with a fetus in breech presentation, are thoroughly counseled to make an informed choice for the mode of delivery. The aim of this study was to assess the influence of counseling techniques on women's choices for the mode of delivery and subsequently to compare fetal and maternal outcomes of vaginal breech birth versus planned caesarean section.
Study design
We performed an observational prospective study. Data on breech deliveries were prospectively collected. We used ANOVA to identify variables influencing women's choice for the mode of delivery.
Setting
The obstetric department of the Red Cross Hospital in Beverwijk, the Netherlands.
Participants
Women with a singleton gestation (>37+0 weeks) and a fetus in breech presentation were included.
Measurements and findings
Between January 2007 and December 2015 364 women were included. Counseling technique (p= <0.001) and maternal education (p=0.046) were significantly associated with the choice of mode of delivery. Of all included women 33% (N=119) opted for a vaginal breech delivery and 52% (N=190) opted for a planned cesarean section. 15% (N=55) were unexpected breeches. Of the planned vaginal delivery group 66% (N=79) delivered vaginal, whereas 99.5% (N=189) of the women in the planned cesarean section group underwent a planned cesarean section. There were no significant differences in maternal and neonatal outcomes.
Key conclusions
Women's choice on the mode of delivery and the eventual modus partus of fetuses in breech presentation is strongly influenced by the counseling technique. Vaginal breech birth in low-risk women is a safe option without long term morbidity in neonates.
Implications for practice
Counselors should be aware of their influence on women's choice for mode of delivery in breech presentation. Counseling should be done using evidence based information. (32 references) (Author)

20170918-10

'It's your body, but -' Mixed messages in childbirth education: findings from a hospital ethnography. Newnham E, McKellar L, Pincombe J (2017), Midwifery vol 55, December 2017, pp 53-59

Objective
To investigate the personal, social, cultural and institutional influences on women making decisions about using epidural analgesia in labour. In this article we discuss the findings that describe practices around the gaining of consent for an epidural in labour, which we juxtapose with similar processes relating to use of water for labour and/or birth.
Design
Ethnography.
Setting
Tertiary hospital in Australian city.
Participants
Sequential interviews were conducted with 16 women; hospital staff (primarily midwives and doctors) participated during six months of participatory observation fieldwork.
Findings
Women were not given full disclosure of either practice and midwives tailored the information they gave according to the institutional policies rather than evidence.
Key conclusions
Informed consent is an oft-cited human right in health care, yet in maternity care the micro-politics of how informed consent is gained is difficult to ascertain, leading to a situation whereby the concept of informed consent is more robust than the reality of practice; an illusion of informed consent exists, yet information is often biased towards medicalised birth practices.
Implications for practice

As primary maternity care-givers, midwives have a role in providing unbiased information to women; however it appears that hospital culture and policy affect the way that this information is presented. It is arguable whether women in such instances are giving true informed consent, and for this reason, the ethics of these hidden practices are questioned. (27 references) (Author)

20170831-103*

Informed consent and refusal in obstetrics: A practical ethical guide. Kotaska A (2017), Birth vol 44, no 3, September 2017, pp 195-199

Discusses the ethical tension when pregnant women refuse treatment, which may induce caregivers to attempt to coerce consent. Touches on the primacy of maternal autonomy; dichotomy versus nuanced thinking; the subjective nature of risk and benefit; patient competence; weighing autonomy against beneficence and nonmaleficence; 'detached caring'; and the ethical and legal implications of informed refusal. (16 references) (KRB)

20170725-49

Choice, informed consent and risk-managing women's care choices in the absence of midwifery supervision: the Birth Choice Clinic. Sonmezer E (2017), MIDIRS Midwifery Digest vol 27, no 3 September 2017, pp 299-303

Women with 'low-risk' pregnancies are largely encouraged through research and national policy to deliver in midwifery-led units or at home; however, the majority continue to attend consultant- led hospital settings. Much research exists to support midwives in facilitating informed choice but it has been identified that midwives are often influenced by internal and external factors when providing this and that time constraints can hinder the process. Supervisors of midwives (SoM) provide a complex care planning service to women. However, with SoM removed from statute and the new Advocating for Education and Quality Improvement (A-EQUIP) model not yet widely operational, a 'gap' area has been identified as a potential concern. This 'gap' is complex care planning with women. In response to national changes, an alternative approach at Gloucestershire Hospitals NHS Foundations Trust to SoM providing complex care planning is the Birth Choice Clinic. (47 references) (Author)

20170405-73

No means no! Let's talk about consent. Feeley C (2017), The Practising Midwife vol 20, no 4, April 2017, pp 25-27

Current changes in midwifery raise concerns about the erosion of women's choices and midwives' autonomy. This article is an exploration of women's legal rights that relate to consent and declining care. Using examples of poor practice, women's negative experiences are highlighted. However, this article demonstrates how midwifery practice can be grounded in the current legal framework in such a way that women's decisions are upheld and midwives feel supported in theri advocacy role. (19 references) (Author)

20170306-22*

Ambiguous subjects: Obstetric violence, assemblage and South African birth narratives. Chadwick R (2017), Feminism & Psychology 1 January 2017. Online version ahead of print

Obstetric violence is gaining recognition as a worldwide problem manifesting in a range of geopolitical contexts. While global public health attention is turning to this issue, there has been a lack of theoretical engagement by feminist psychologists with the phenomenon of obstetric violence. This paper contributes to the literature on obstetric violence via a feminist social constructionist analysis of 'marginalized' and low-income South African women's narratives of giving birth in public sector obstetric contexts. Drawing on interviews conducted in 2012 with 35 black, low-income women living in Cape Town, South Africa, the analysis focuses on obstetric violence as a relational, disciplinary, and productive process that has implications for the construction of women's subjectivities and agency during childbirth. The findings focus on relational constructions of violence and agency in women's narratives, including (a) the performance of docility as an act of ambiguous agency and (2) resistant bodies and modes of discipline. Framed within a Foucauldian approach to power and using the concept of assemblage, I argue that obstetric violence needs to be conceptualized as more than isolated acts involving individual perpetrators and victims. Instead, the analysis shows that obstetric violence functions as a mode of discipline embedded in normative relations of class, gender, race, and medical power. (54 references) (Author)

20161103-4*

Medicolegal update on consent: 'The Montgomery Ruling'. Cheung E, Goodyear G, Yoong W (2016), The Obstetrician and

Gynaecologist vol 18, no3, July 2016, pp 171-172

Gives an overview of a case of obstetric negligence, Montgomery vs Lanarkshire, which has brought about a change in English law after a new precedent was set by the Supreme Court in the UK. Mrs. Montgomery, a primagravida with type 1 diabetes, had not been informed of the risk of shoulder dystocia, despite having voiced her concerns after she was found to be carrying a large baby at the 36-week scan, because her consultant believed the risk to be very small. States that she was advised by her consultant to have a vaginal birth and was induced at 38+5 weeks' gestation. Complications arose during the forceps delivery and her son developed severe dyskinetic cerebral palsy as a result of hypoxia. Mrs. Montgomery's initial claim of negligence was rejected by the Court of Session as the judge ruled the consultant had acted in line with 'a reasonable body of medical professionals' at the time, details of which appear in this article. However, Mrs. Montgomery's claim for negligence was upheld when the case was heard at the Supreme Court for appeal in 2015. Describes how this ruling has changed the law on informed consent and has brought it in line with guidance issued by the General Medical Council (GMC) with the aim of more closely involving the patient in the choice of their care. Discusses the legal challenges unique in the field of obstetrics (11 references) (JSM)

20161025-71*

Optimizing participation of pregnant women in clinical trials: factors influencing decisions about participation in medication and vaccine trials. Palmer S, Pudwell J, Smith GM, et al (2016), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 38, no 10, October 2016, pp 945-954

Objective

To obtain information on women's attitudes and opinions about participation in vaccine and medication trials during pregnancy.

Methods

A quantitative, cross-sectional survey was administered to 110 consenting women over a four-week period in the waiting room of an ambulatory obstetrics and gynaecology clinic in Ontario.

Results

The final response rate was 74.8%, with the majority of participants agreeing with statements about the importance of obtaining safety data about products in pregnancy and the importance of a woman having the ability to choose whether to participate in such research. Of all participants, 16.3% indicated they would consider participating in vaccine research during pregnancy and 20.0% would consider participating in medication research during pregnancy. Factors relating to maternal or fetal/child health were the most frequently cited factors influencing willingness to participate, with lack of trust in researchers and pharmaceutical companies as factors that would discourage participation.

Conclusion

A minority of pregnant women were willing to consider participating in medication or vaccine research during pregnancy. Optimizing participation requires providing women (and if appropriate, their partners) with detailed, multidisciplinary education about the maternal and fetal benefits and risks of such trials. Education about the principles of research ethics, including the limits of involvement of pharmaceutical companies, would be beneficial. (33 references) (Author)

20161021-26*

A review of consent documents from Canadian IVF clinics, 1991 to 2014. Krahn TM, Baylis F (2016), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 38, no 5, May 2016, pp 470-482

Objective

We reviewed the content of IVF consent documents (i.e., consent forms and accompanying information sheets) used by Canadian IVF clinics in 1991, 2004, and 2014, paying particular attention to the inclusion of information that should be provided to patients in accordance with minimum ethical standards for disclosure.

Methods

We contacted all Canadian IVF clinics in operation in 1991 (17 clinics), 2004 (24 clinics), and 2014 (35 clinics) by mail and requested blank copies of their IVF consent documents. Documents received were reviewed for the inclusion of information about the nature of IVF, the potential benefits of IVF, the potential harms and inconveniences of IVF, confidentiality, voluntariness, and options for the use or discarding of embryos not transferred in the original stimulated cycle (sometimes referred to as supernumerary, excess, or spare embryos).

Results

We received responses from 11 of 17 clinics operating in 1991 (response rate 65%), 14 of 24 clinics operating in 2004 (response rate 58%), and 11 of 35 clinics operating in 2014 (response rate 31%). In general, comparisons of the 1991, 2004, and 2014 data sets showed a long-term decrease in documented disclosure of information that should be

provided to patients in accordance with minimum ethical standards. The only cases in which this trend appeared to be reversed was with disclosure about the probability of supernumerary embryos, long-term risks of treatment, the right to revoke consent to the use or discarding of supernumerary embryos, and some of the options for the use of supernumerary embryos. In these few instances, there was a notable improvement in the disclosure of relevant information between 1991 and 2014.
Conclusion
The disclosure of information relevant to the interests of those undergoing IVF and those who are born as a result of IVF appears to be decreasing. Furthermore, the information that increasingly is being disclosed in consent documents appears to be directing the orientation and content of these documents away from the primary interests of the relevant women, couples, and children. These two trends are inconsistent with the goal of informed consent. (39 references) (Author)

20160815-21*

BJOG Debates: Are we misinforming our low-risk mothers regarding birthplace outcomes: is it time for formal consent?. Wijesuriya JD, Buitendijk SE, de Jonge A (2016), BJOG: An International Journal of Obstetrics and Gynaecology vol 123, no 9, August 2016, p1531

The authors present the case for and against formal consent in planned home birth. (CI)

20160606-7

'Montgomery consent': decision of the UK Supreme Court. Beckett H, Radford J (2016), The Practising Midwife vol 19, no 6, June 2016, pp 27-29

This landmark legal case has changed the law on consent in health care. All health care workers must be aware of the implications of this for their practice when 'sharing information' with patients and the assertion of consent by the patient. Essentially, Montgomery banishes medical paternalism, putting the focus firmly with the patient. This is the standard that will now be used by both the courts and the regulators. (7 references) (Author)

20160524-27*

'Informed' consent: an audit of informed consent of cesarean section evaluating patient education and awareness. Kirane AG, Gaikwad NB, Bhingare PE, et al (2015), Journal of Obstetrics and Gynecology of India vol 65, no 6, December 2015, pp 382-385

INTRODUCTION:
Better diagnosis and early referral due to increased health care coverage have increased the cesarean deliveries at tertiary-care hospitals of India. Improvements in the health care system raise many concerns and need of cross-checking system in place to counter the problems pertaining to patient education and participation of patient. While most of the cesarean sections are done in good faith for the patient, it does not escape the purview of consumer awareness and protection.
MATERIALS AND METHODS:
This cross-sectional study was undertaken at a tertiary level government institution to understand the level of awareness of 220 patients regarding the various aspects of cesarean delivery which are essential for women to know before giving an informed consent.
RESULTS:
71 % of the women had knowledge about the indication and need to do cesarean delivery. Of these, only one-third (25 % of total women) were properly explained about procedure and complications. Other demographic and social characteristics were also evaluated.
DISCUSSION:
While the health care schemes have had their improved results, the onus lies upon the caregivers to improve and maintain the quality of health care in these tertiary-care government hospitals in proportion to the increase in patient load. The results of this study highlight the need for proper counseling of patients regarding complications of cesarean section. The fact that only 25 % of total cases were explained proper procedure and complication as opposed to 71 % of patients having proper knowledge about the indication of cesarean section points out the lack of information in seemingly 'informed' consent.
THE WAY FORWARD:
To bring about awareness about the risks and complications of cesarean section, there is a need that patients be counseled during the antenatal visits, specifically when patients visit near term for antenatal check up. (Author)

20160516-33

Supporting an ethnic minority woman's choice for pain relief in labour: a reflection. Hughes F, Hughes C (2016), British Journal of Midwifery vol 24, no 5, May 2016, pp 339-342

Despite professional expectations for midwives to provide care to women that is founded in equality and recognises diversity (Nursing and Midwifery Council, 2015), women from ethnic minority populations consistently suggest that they are not heard (Briscoe and Lavender, 2009; Tobin et al, 2014). This article reflects on a situation where a Portuguese woman with limited English-speaking ability was denied access to epidural anaesthesia as the midwife felt that the woman could not give valid consent to the procedure without the presence of an interpreter. The midwife's role in this situation is reflected on, and implications for midwifery practice identified. (34 references) (Author)

20150708-24

Informing clients of risk: immediate implications of a landmark supreme court decision. Terry L, Deegan M (2015), British Journal of Midwifery vol 23, no 7, July 2015, pp 516-521

In March 2015, the Supreme Court published its decision in Montgomery v Lanarkshire Health Board, a case involving the failure to warn a pregnant diabetic woman of the risk of shoulder dystocia and the possibility of having a caesarean section to avoid this risk. The risk materialised and the baby suffered oxygen deprivation. The lower courts had applied the test for the standard of care that had been in place since 1985, which has been criticised for protecting doctors not patients. The Supreme Court has introduced a new, autonomy-based, patient-centred standard. This article examines the case and explains the importance of the change for future midwifery practice. When disclosing risks, midwives must identify what a reasonable person in the woman's position, with this woman's specific characteristics, would consider a significant risk. They could be held liable for non-disclosure even if the woman does not ask about specific risks. (30 references) (Author)

20150623-36

Landmark case on negligence and consent. Symon A (2015), British Journal of Midwifery vol 23, no 6, June 2015, pp 446-447

Andrew Symon comments on a recent ruling by the Supreme Court that an obstetrician - who failled to give information to a diabetic woman who was expecting a large baby information on the potential risk of shoulder dystocia - was negligent. (7 references) (MB)

20150605-5*

Pregnancy: Prepare for unexpected prenatal test results. Bianchi DW (2015), Nature vol 522, no 7554, 3 June 2015

Women are learning about their own health problems through fetal screening. Revise consent forms and raise awareness, urges Diana W. Bianchi. (Author)

20150603-32

Concerns about consent, the NICE guidelines regarding resuscitation and early cord clamping. Hutchon D (2015), Infant vol 11, no 3, May 2015, pp 71-72

The author challenges changes to the law on consent regarding resuscitation and early cord clamping in light of a UK Supreme Court judgement in an obstetric case with an adverse neonatal outcome. (9 references) (MB)

20150226-12*

Contraceptive methods and informed consent among women receiving medications with potential for adverse fetal effects: a Washington, Wyoming, Alaska, Montana, Idaho (WWAMI) region study. Force RW, Keppel GA, Guirguis-Blake J, et al (2012), Journal of the American Board of Family Medicine: JABFM vol 25, no 5, September 2012, pp 661-668

Background: Increasing diabetes, hypertension, and hypercholesterolemia rates expose some young women to medications with potential adverse fetal effects, such as angiotensin-converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs), and statins. This study examined whether quality improvement (QI) interventions promote informed consent and contraception to minimize risks with use of ACE-I/ARB/statins.
Methods: This longitudinal cohort study at 7 clinics abstracted medical records of 328 women aged 18 to 44 with ≥1 prescription for ACE-I/ARB/statins and ≥1 visit for hypertension, diabetes, or hypercholesterolemia during the previous year. We measured informed consent documentation and contraceptive methods before and after QI interventions in which providers contacted their patients to discuss medication risks and benefits.
Results: Of 179 women who were not surgically sterilized, only 11.7% had documented informed consent related to

the risks of ACE-I/ARB/statin use. One hundred fifty-eight women were eligible for the QI intervention (not surgically sterilized, no documented informed consent); only 76 (48.1%) received the intervention. Before the intervention, 23.7% of these 76 were 'at risk' of an adverse fetal effect. After the intervention, only 7.9% (P ≤ .001) were 'at risk' because some women started contraception, discontinued ACE-I/ARB/statins, or changed drug class.
Conclusions: Women prescribed ACE-I/ARB/statins were not consistently using contraception or were not consistently informed of the risks. Provider-implemented QI interventions improved care but were difficult to accomplish, suggesting that new interventions are needed. (Author)

20150130-14*

Obtaining valid consent. Morris EP (2015), London: RCOG January 2015. 13 pages

This is the third edition of this guidance, which was previously published in December 2008 and October 2004 under the same title.
The purpose of the advice is to provide a good practice framework for obtaining valid consent in obstetrics and gynaecology. This revised document provides guidance on obtaining consent in obstetrics and gynaecology in the UK. After discussing the overarching principles of consent, it considers specific issues relating to gynaecological and obstetric practice, such as the consent required for pelvic examinations and obtaining consent from women in labour. Further sections include consent for multimedia images and tissue samples. An appendix provides guidance on completing the English/Welsh/Northern Irish Consent Form 1.
Specific advice for some individual procedures has been published separately in the RCOG Consent Advice series. (Publisher)

Full URL: https://www.rcog.org.uk/globalassets/documents/guidelines/clinical-governance-advice/cga6.pdf

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20150107-28

Newborn metabolic screening at its best. Carll J (2014), Midwifery News (New Zealand College of Midwives) no 75, December 2014, p 28

Joan Carll, midwife and screening educator, Auckland District Health Board, reflects on a recent case that outlines the importance of teamwork in newborn metabolic screening. (Author)

20141014-82

Second opinion: Should informed consent be required for routine newborn screening and for storage of blood samples?. Lewis J, Kenner C (2014), MCN - American Journal of Maternal/Child Nursing vol 39, no 5, September/October 2014, pp 282-283

How much should parents be told about routine newborn screening and their options to decide if their baby is tested? These experts provide a thoughtful discussion on the pros and cons of obtaining parental consent for routine newborn screening and storage of blood samples that should be considered by every nurse caring for newborn babies. (8 references) (Author)

20140917-44

What women want: lead considerations for current and future applications of noninvasive prenatal testing in prenatal care. Farrell RM, Agatisa PK, Nutter B (2014), Birth vol 41, no 3, September 2014, pp 276-282

BACKGROUND: Noninvasive prenatal testing (NIPT) will change the delivery of prenatal care for all women, including those considered low risk for fetal chromosomal abnormalities. This study investigated pregnant women's attitudes, informational needs, and decision-making preferences with respect to current and future applications of NIPT. METHODS: A survey instrument was used to identify aspects of the decision-making process for NIPT among low-risk and high-risk populations. RESULTS: Both low-risk and high-risk women (n = 334) expressed interest in incorporating NIPT as a screening test into their prenatal care. Information specific to NIPT's detection rate (86%), indications (77%), and performance in comparison with conventional screens and diagnostic tests (63%) were identified as lead factors when considering its use. The future availability of NIPT as a diagnostic test increased women's willingness to undergo testing for fetal aneuploidy, cancer susceptibility, and childhood-onset and adult-onset diseases. Despite its noninvasive aspects, participants expressed the need for a formal informed consent process (71%) to take place before testing. CONCLUSIONS: This study demonstrates that NIPT will introduce new challenges for pregnant women and their health care practitioners who will be charged with supporting informed decision making about its use. It is critical that obstetric professionals are prepared to facilitate a patient-centered decision-making process as its clinical

application rapidly changes. (38 references) (Author)

20140827-7

Pregnant women's views on informed consent for research in labour. George RT, Butcher M, Yentis SM (2014), International Journal of Obstetric Anesthesia vol 23, no 3, August 2014, pp 233-237

BACKGROUND:
Studies of the optimal treatment of accidental dural puncture occurring during epidural insertion in labour are difficult for practical reasons and because of the ethical issues around seeking consent. In a recent study of accidental dural puncture, participants were assigned to one of two treatment groups and only informed about the study and consent sought, after treatment. We sought the views of parturients on the timing of consent for such a study.
METHODS:
After ethical approval and written consent, 100 nulliparous women in the third trimester of pregnancy completed a structured, facilitated questionnaire, rating the acceptability of the consent process occurring: (i) in antenatal clinic; (ii) after the epidural was requested in labour; (iii) after the accidental dural puncture had occurred but before treatment; (iv) after the allocated treatment; or (v) without consent (waived consent). Results were analysed with the Friedman and Wilcoxon signed-rank tests.
RESULTS:
Antenatal consent was considered the most acceptable option, whilst consent on request for epidural analgesia and after accidental dural puncture were least acceptable. Consent after treatment and waived consent were rated in-between these extremes. There was a statistically significant difference between these three groups (P<0.0001). There was a wide range of opinions on each option presented.
CONCLUSIONS:
Antenatal consent was the preferred option but if this is not possible and the need for the research is strong, consent for the use of women's data after intervention, or waived consent, is acceptable to many women. It is important to seek the views of the participants themselves before planning research with difficult ethical aspects. (13 references) (Author)

20140430-67*

Implementation of written consent for newborn screening in Victoria, Australia. Charles T, Pitt J, Halliday J, et al (2014), Journal of Paediatrics and Child Health vol 50, no 5, 2014, pp 399-404

AIMS:
There has been increasing evidence of a lack of public awareness of newborn screening and concern about inadequate consent being obtained from parents. Apprehension also exists in relation to storage and secondary use of screening samples. Our objective was to introduce a written consent process across Victoria as a means of strengthening programme transparency, quality and supporting parental choice. In addition, more comprehensive information covering all aspects of the programme was developed.
METHODS:
A 'two-stage' written consent protocol allowed parents to give separate consent for (i) their baby to be screened and (ii) secondary use of the sample in de-identified health research. At the time of sample collection, parents were asked to complete the consent form, included as part of the screening card. The protocol was piloted in four public hospitals and subsequently implemented statewide.
RESULTS:
Twelve months of laboratory data showed that although refusals for screening increased, overall participation remained above 99%. The percentage of parents opting out of research use was 6.5%. Provider compliance with the new protocol was high, with only 1.4% of cards received without a completed consent form.
CONCLUSION:
This quality improvement project has demonstrated that parents can participate more fully in newborn screening without jeopardising high uptake. As a secondary benefit, the public health resource of stored cards can be maintained with parental support. Future work needs to examine the quality of consent being given by parents and investigation of the reasons why some choose to decline. (Author)

20140409-93

Sands' learning outcomes for consent taker training: Seeking consent/authorisation for a hospital post mortem examination of a baby. Henley A, Schott J (2014), The Journal of Neonatal Nursing vol 20, no 1, February 2014, pp 11-13

Provides guidance on the knowledge and skills required by those involved in obtaining consent for postmortem in

cases of stillbirth and neonatal mortality. (SB)

20140228-31

Review: Information shared with mothers prior to caesarean section: a national audit of compliance with recommended information. McIntosh T (2014), Essentially MIDIRS vol 5, no 1, February 2014, pp 28-32

The caesarean rate in England currently stands at 25%, a figure which has remained reasonably stable for the last few years (Thomas & Paranjothy 2001, HSCIC 2012). Debate continues internationally about reasons for this and about interventions and pathways which might help to reduce this rate and bring it closer to the World Health Organization [WHO] recommendation that caesarean section rates should not be higher than 10-15% (WHO 1985). Regardless of academic and policy discussions, however, it seems obvious that the pregnant women who will birth by caesarean need effective and meaningful communication with health professionals about the procedure they will undergo. This article reviews a study that assesses compliance with recommendations about the information that women receive prior to a caesarean. (9 references) (Author)

20140224-1*

Baby boy died after nurse removed him from a ventilator without permission at scandal-hit hospital trust. Edmonds L (2014), Daily Mail 23 February 2014

Reports the case of a premature baby boy who died at St. Michael's Hospital in 2012, Bristol, after a nurse allegedly took him off the ventilator keeping him alive, without first gaining the consent of his parents. (JSM)

Full URL: http://www.dailymail.co.uk/news/article-2565898/Baby-boy-died-nurse-removed-ventilator-without-permission-scandal-hit-hospital-trust.html?ITO=1490&ns_mchannel=rss&ns_campaign=1490

20131205-29*

C-section decision 'totally unreasonable' says lawyer. (2013), BBC News 4 December 2013

Reports that the lawyer defending the Italian woman who was forced to undergo a caesarean section before her baby was taken away for adoption without her consent because she has biopolar disorder, has branded the decision 'totally unreasonable'. Includes audio-visual footage. (JSM)

Full URL: http://www.bbc.co.uk/news/health-25214448#

20131205-22

Informed consent for induction of labour?. Vincent H (2013), Midwifery Matters no 134, Autumn 2012, pp 4-6

A student midwife reflects on the care she provided for a woman who had reached her expected date of delivery and was being recommended for induction of labour, and considers how she could have improved the woman's care so that consent was truly informed. (29 references) (SB)

20131104-72

The quality of consent - what is the evidence?. Robertson CG, Verco CJ (2013), Australian and New Zealand Journal of Obstetrics and Gynaecology (ANZJOG) vol 53, no 5, October 2013, pp 502-504

The documentation of consent is an important component of the clinical encounter. This study assesses the quality of documentation of that consent for a common surgical procedure, caesarean section, in an obstetric unit at a major teaching hospital and compares this quality between elective and emergency cases. There was a significant difference in the quality of documentation between the elective and emergency groups in some, but not all, categories assessed. Overall, the standard of consent documentation in the obstetric unit was less than desired. A proforma was designed to be included in the case notes of women undergoing caesarean section to improve the efficient and thorough documentation of consent. (9 references) (Author)

20130829-6

A story from the north. Philp A (2009), Association for Improvements in Maternity Services (AIMS) vol 21, no 1, 2009, pp 12-15

Describes the author's own personal experience of labour and how the natural birth she had planned to have at a midwife led centre, turned into a medicalised birth at a hospital, with delivery by ventouse, the administration of syntometrine and episiotomy, all performed without discussion or informed consent from her. Summarises the author's conclusions following her discussions with health care professionals concerning the care she had received, and her subsequent complaint. (JSM)

20130520-15

Caught between autonomy and caring: still struggling towards an ethics of midwifery. Katz Rothman B (2013), MIDIRS Midwifery Digest vol 23, no 2, June 2013, pp 143-150

Barbara Katz Rothman's thought- provoking article on autonomy and the struggle midwives face in achieving this whilst also providing genuine care. The author questions the meaning of caring, and partnership and shared decision making within a system that is stretched to its limits, and where fragmented care is the norm. (3 references) (ABS)

20130503-67

Assessing the decision-making competence of girls under 16. Griffith R (2013), British Journal of Midwifery vol 21, no 5, May 2013, pp 373-374

Discusses issues relating to Gillick competence and how midwives must apply the rule when assessing whether a girl under the age of 16 has competence to consent to care and treatment during pregnancy. (6 references) (SB)

20121109-6*

Maternal autonomy on health in a community as assessed by signing of consent for caesarean section and its sociodemographic correlates. Enabudoso E, Igbarumah S (2012), Journal of Maternal-Fetal and Neonatal Medicine vol 25, no 10, October 2012, pp 1980-1982

Objective: To assess the level of maternal autonomy in a Nigerian community using maternal preference to sign the consent for caesarean section as the assessment tool and to evaluate the sociodemographic and obstetric correlates. Methods: A cross-sectional survey of parturients 2-5 days after caesarean delivery in a tertiary health facility in Benin City, Nigeria using a pretested interviewer administered questionnaire to obtain information on whom they would prefer to sign the consent form for caesarean section. Results: A total of 197 parturients were interviewed. The consent form was signed by 177 (90%) of the respondents. However, 96 (48.7%) preferred their spouses to sign. Maternal attainment of tertiary level education and a higher mean maternal age was significantly associated with maternal preference to sign the consent form. Conclusion: The level of maternal autonomy on reproductive health issues based on this simple survey is less than satisfactory. However, this study has provided baseline data for surveillance and follow-up studies of this important variable. (Author)

20121107-2*

Implementing an induction scheduling procedure and consent form to improve quality of care. Doyle JL, Kenny TH, von Gruenigen VE, et al (2012), JOGNN: Journal of Obstetric, Gynecologic and Neonatal Nursing vol 41, no 4, July/August 2012, pp 462-473

Inappropriate elective inductions of labor put patients at increased risk of cesarean, neonatal morbidity, and elevated cost. A scheduling procedure and consent form were implemented to eliminate elective induction at less than 39 weeks gestation and align indications for induction with American College of Obstetricians and Gynecologists guidelines. In 25 of the 28 months following implementation of the new process, we achieved the goal of eliminating elective induction of labor at less than 39 weeks gestation. (37 references) (Author)

20120912-38

Testing consent. Dixon A (2012), Association for Improvements in Maternity Services (AIMS) vol 24, no 3, 2012, p 15

Highlights that many women are unaware of what they are being tested for during routine blood screening in pregnancy and the lack of regard given to informed consent. (SB)

20120912-33

Consent - a commonly understood concept?. Chippington Derrick D (2012), Association for Improvements in Maternity Services (AIMS) vol 24, no 3, 2012, pp 3-6

Debbie Chippington Derrick explores the professional and legal position on consent. (12 references) (Author)

20120315-12

Factors associated with information satisfaction among parents of sick neonates in the neonatal unit. Lanlehin R (2012), Infant vol 8, no 2, 2012, pp 60-63

It is vital that parents of sick babies on the neonatal unit receive effective communication from the health

professionals caring for their baby and that they are included in decision making regarding proposed treatment. However in this very stressful environment parents may not always understand or retain the information given to them. This article reviews the literature concerning parents' satisfaction with information received on the neonatal unit and identifies the factors important in effective communication. (13 references) (Author)

20120124-14*

Historical trends in the timing of informed consent for research into intrapartum complications. Patel D, Nasir S, Elati A, et al (2012), BJOG: An International Journal of Obstetrics and Gynaecology vol 119, no 3, February 2012, pp 362-365

Obtaining informed consent for clinical trials involving the management of intrapartum complications is complex. This article describes the strategies used to obtain consent over the last 60 years using data from the Cochrane Library. Of 138 intrapartum randomised studies, 37% had no record of the consent procedures. Of the remainder, 74% sought consent only when the complication developed, 11% sought consent from all women in early labour, and 13% gave all women antenatal information and then sought written consent when the complication arose. Despite the existence of ethics guidelines for intrapartum consent, many studies fail to follow their advice. (9 references) (Author)

20120116-2*

Dorset baby was buried without brain. Anon (2012), BBC News 13 January 2012

Reports that a mother from Dorset has been told her baby son's brain is still in storage, 13 years after he died and was buried. States that as part of a nationwide inquiry, an audit of retained human tissue samples is being undertaken by Dorset Police, and families affected will be informed as soon as possible. Explains that in cases such as cot death or death in suspicious circumstances, examinations must be made to try to establish a possible cause, and these can take several weeks; it was permitted to take organs and other tissue samples after death without the consent of the families, until a change in the law in September 2006 made it compulsory to inform relatives first. (JSM)

20111003-12822*

Complications within consent. Alderson P (2005), Bulletin of Medical Ethics no 210, 2005, pp 15-19

The consent process is intended to protect patients, prevent complaint and litigation, and help practitioners to be accountable, to justify their decisions, and to inform and involve patients/parents in their health care. Medico-legal guidance poses uncertainties and dilemmas that can undermine these aims and deter some practitioners from informing and involving patients/parents in decision making. Greater recognition of contradictions and limitations in the guidance on consent could assist practitioners and patients/parents in their shared decision making. (Author)

20111003-10536

Midwifery - who cares what women want?. Beech B (2010), Association for Improvements in Maternity Services (AIMS) vol 22, no 1, 2010, pp 3-4

Beverley Beech looks at when 'informed consent' becomes bullying.

20110811-62

An ethical framework for the informed consent process for trial of labor after cesarean delivery. Chervenak FA, McCullough LB (2011), Clinics in Perinatology vol 38, no 2, June 2011, pp 227-231

In 2010, a National Institutes of Health Consensus Panel and the American College of Obstetricians and Gynecologists issued updated statements on trial of labor after cesarean delivery (TOLAC). This article presents an ethical framework for the informed consent process for TOLAC. Three conclusions are reached. For women with one previous low transverse incision, TOLAC and elective repeat cesarean delivery should be offered. Obstetricians should recommend against TOLAC when a pregnant woman has had a previous classical incision. TOLAC after two previous low transverse incisions may be offered provided that the informed consent process presents the uncertainties of the evidence. (11 references) (Author)

20110713-33

An observational study to explore the power and effect of the labor ward culture on consent to intrapartum procedures. Marshall JE, Fraser DM, Baker PN (2011), International Journal of Childbirth vol 1, no 2, 2011, pp 82-99

AIM: To explore the concept of informed consent to intrapartum procedures within a hospital labor ward. DESIGN: An ethnographic study using participant observation and follow-up semistructured interviews with women and the

attending midwives. Data analysis used principles of grounded theory assisted by the computer-assisted qualitative data analysis software (CAQDAS) package, Non-numerical Unstructured Data Indexing, Searching, and Theorizing (NUD*IST). The study was approved by the Local Research Ethics Committee. PARTICIPANTS AND SETTING: 100 healthy English-speaking women in spontaneous labor who were to give birth within the labor ward of a large teaching hospital in England and the attending health professionals. FINDINGS: • The fragmented Western technocratic model of childbirth affected gaining informed consent to intrapartum procedures within the labor ward environment. • Midwives and women adopted certain stereotypical roles relating to how information was given and decisions made about intrapartum procedures. • Not all women wanted to be fully informed about intrapartum care and procedures and trusted the midwife or doctor to make decisions, especially concerning the health of their newborn. • Where a birth plan had been completed, women felt valued and enabled by having contributed to decisions made about their care. CONCLUSIONS: The study revealed that true choices to childbearing women were limited and informed consent was rarely obtained. Further exploration is required to establish the optimal timing of information disclosure to gain consent to intrapartum practices prior to the onset of labor, because during labor is not ideal. The 2 typologies may be used by midwives to examine how the culture of the birthing environment can affect women's choice and the obtaining of informed consent to intrapartum procedures, especially where care is fragmented. Until birth is viewed through a holistic birthing model, health professionals will continue to control the birth experience. However, what is provided in practice should be congruent with the needs and expectations of childbearing women. (80 references) (Author)

20110511-3

Informed consent and midwifery practice in New Zealand: lessons from the Health and Disability Commissioner. Godbold R (2011), New Zealand College of Midwives Journal no 42, May 2010, pp 12-16

Informed consent appears to be a challenging and sometimes problematic area of practice for midwives. It is not always clear, for example, what amount of information is required to be supplied to women to ensure fully informed consent. Similarly it is unclear whether midwives can provide unbiased information, and what midwives' communication responsibilities are when other health care providers become involved in care and treatment decisions. This paper examines the Code of Health and Disability Services Consumers Rights and selected Commissioner's opinions which consider potential breaches of the Code in relation to informed consent. Case analysis demonstrates how the principles relating to informed consent are applied in the midwifery context, and examines how the Commissioner's opinions can offer practical guidance to midwives. (30 references) (Author)

20110418-5*

Focused review: informed consent in obstetric anesthesia. Broaddus BM, Chandrasekhar S (2011), Anesthesia & Analgesia vol 112, no 4, 2011, pp 912-917

Patient consent for obstetric analgesia and anesthesia involves several confounding issues in addition to the basic elements of consent. These include capacity during active labor, maternal-fetal conflict, and the care of pregnant minors. In this review, we focus on these unique consent issues. Despite pain and anxiety, women maintain the capacity to understand and recall information imparted during labor. Anesthesia providers generally disclose high-frequency and high-morbidity side effects and complications. The use of written materials and early antenatal education may improve retention of information and maternal satisfaction. Successful navigation of the consent process requires knowledge of the guidelines and laws that govern each provider's individual jurisdiction. (Author)

20110316-2

Informed consent: ethical issues for midwife research. Ledward A (2011), Evidence Based Midwifery vol 9, no 1, March 2011, pp 23-29

Background: It is respect for the woman's autonomy that underpins the requirement for informed consent. Midwives with obstetricians are the only healthcare professionals who have the delicate task of balancing two parties' interest, that is the autonomy and beneficience-based obligations to the woman and beneficence-based obligations to the fetus. This is because the fetus is non-autonomous and is incapable of having its own perspective on its best interests. Therefore the obligations owed to the fetus are beneficience-based. Aim: This philosophically-based paper aims to critically evaluate the ethical dimensions of informed consent relating to research in pregnancy. The main point is that the midwifery knowledge-base should be increased, but the wider implications of such research should be appropriately weighted towards ensuring maternal autonomy and fetal wellbeing. Included in the paper will be a debate pertaining to some of the complexities of informed consent. In this respect, guidance for midwives which is central to the theoretical aspect of the paper and ethically justifiable will be identified. Method: The paper examines

the three threshold elements of informed consent in turn: namely information, competence and voluntariness (Montgomery, 1997). In so doing, some of the dilemmas which beset the woman and midwife in the research process will be debated and discussed and an ethical framework for midwives suggested. Clinical examples illustrate specific points. Conclusion: Midwives have a responsibility to be cognisant with the three key elements necessary for the woman's consent to participate in a research study, that is, disclosure of information, this must include benefits and risks and details of participation for both woman and fetus, ratification that the woman is mentally competent to understand the given information and finally that her decision is made freely, that is without resort to coercion. These three elements are informed by the principle of respect for maternal autonomy, which is the yardstick by which acceptable intervention can be measured. Seeking the woman's valid informed consent to participate in research raises distinct ethical concerns among midwives. Concepts explained: The ethical principles of respect for autonomy and beneficence, when applied in practice, generate obligations that safeguard the patient's best interests (Beauchamp and McCullough, 1984). `Respect for autonomy' promotes the woman's freedom of choice, which incorporates her wish to bring her own perspective to bear on her decision-making. `Beneficence' is to act for others' benefit by securing the best possible options (Chervenak and McCullough, 1985: 442). (40 references) (Author)

20110131-17*

Obtaining valid consent to participate in research while in labour. Ismail KMK, Selman T (2010), London: RCOG August 2010. 4 pages

This guidance is designed for use with Clinical Governance Advice No. 6: Obtaining valid consent. It is intended to provide a good practice framework for researchers who, due to the nature of their study, are limited to obtaining a valid consent for participation in research while in labour or in the immediate postpartum period. This document will not cover issues relating to undertaking medical research in women who are deemed to lack the mental capacity to consent. Guidance on these issues is thoroughly covered by the Mental Capacity Act and the Medical Research Council. (7 references) (Publisher)

Full URL: http://www.rcog.org.uk/obtaining-valid-consent-participate-research-while-labour

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20110120-19

Consent to examination and treatment. Griffith R (2011), British Journal of Midwifery vol 19, no 1, January 2011, pp 44-45

Provides an overview of the legal issues surrounding consent in midwifery care. Explains the elements of a valid consent - full, freely given and reasonably informed. Also looks at trespass to the person, clinical negligence and obtaining consent. (11 references) (MB)

20101103-74

Presence of both parents during consent process in non-therapeutic neonatal research increases positive response. Korotchikova I, Boylan GB, Dempsey EM, et al (2010), Acta Paediatrica vol 99, no 10, October 2010, pp 1484-1488

Aim: To investigate factors that influenced parental consent/non-consent in a non-therapeutic electroencephalogram (EEG) study in healthy newborns. Methods: Parents of healthy newborns were approached to participate in a neonatal EEG study within 36 h of birth. The rationale and risks/benefits of the study were explained. Any concerns were discussed, and detailed information about the EEG study was provided in the consent form. In the case of refusing/withdrawing consent, an informal interview was used to investigate the reasons, which were subsequently analysed and grouped according to the four principles of the consent process. Results: A total of 123 parents were included in the study. Parental consent was obtained in 72/123 (59%) cases, 10/123 (8%) parents subsequently withdrew their consent and 41/123 (33%) parents refused to participate in the study. Consent was more likely if both parents were present ($p < 0.0001$). When the mothers were approached alone, obtaining consent was significantly more difficult within the first 6 hours of delivery, compared to a later approach (37% vs. 67% respectively; $p = 0.009$). Refusals were classified into issues of voluntariness (7%), informed choice (10%), understanding (54%) and competence (29%). Conclusion: Parents of healthy newborns demonstrated a positive attitude towards non-therapeutic neonatal research with maximal consent occurring when both parents were present. Parental perception of harm was the main reason for declining consent. (18 references) (Author)

20101015-51*

Consent to treatment. Lynch J (2010), Oxford: Radcliffe Publishing 2010, 244 pages

An understanding of the law and the way in which it impacts upon roles, responsibilities and care is a vital component in everyday healthcare. The law of consent is particularly complex, and its inadvertent misinterpretation,

misapplication or maladministration by health professionals has led to an increasing number of legal claims for compensation. This book explains the legal issues around consent to treatment in England and Wales simply and straightforwardly. It uses real-life examples to set out the professional obligations, basic principles of consent and detailed information on each area, enabling health professional to approach consent methodically and to ensure that it is validly obtained and recorded. (Publisher)

20100824-9

The perils of the imperfect expectation of the perfect baby. Chervenak FA, McCullough LB, Brent RL (2010), American Journal of Obstetrics & Gynecology (AJOG) vol 203, no 2, August 2010, pp 101-102

Advances in modern medicine invite the assumption that medicine can control human biology. There is a perilous logic that leads from expectations of medicine's control over reproductive biology to the expectation of having a perfect baby. This article proposes that obstetricians should take a preventive ethics approach to the care of pregnant women with expectations for a perfect baby. We use Nathaniel Hawthorne's classic short story, 'The Birthmark,' to illustrate the perils of the logic of control and perfection through science and then identify possible contemporary sources of the expectation of the perfect baby. We propose that the informed consent process should be used as a preventive ethics tool throughout the course of pregnancy to educate pregnant women about the inherent errors of human reproduction, the highly variable clinical outcomes of these errors, the limited capacity of medicine to detect these errors, and the even more limited capacity to correct them. (Author)

20100429-34

Ethical considerations in first-trimester Down syndrome risk assessment. Chervenak FA, McCullough LB (2010), Current Opinion in Obstetrics and Gynecology vol 22, no 2, April 2010, pp 135-138

PURPOSE OF REVIEW: First-trimester risk assessment has now become sophisticated and of increasing relevance and applicability to decision-making by pregnant woman about invasive diagnosis. Ethics is an essential dimension of understanding this relevance and applicability. This paper addresses the ethical dimensions of first-trimester risk assessment for trisomy 21. RECENT FINDINGS: It is now well established in the ethics and law of the informed consent process that physicians are obligated to offer to patients all medically reasonable alternatives for managing the patient's condition. This disclosure should be guided by the reasonable person standard: the physician should provide clinically important information about the patient's condition or diagnosis, the medically reasonable alternatives for managing it, and the clinical benefits and risks of each such alternative. SUMMARY: On the basis of the ethics of informed consent, we argue that routinely offering first-trimester risk assessment in centers qualified to provide it is ethically obligatory. We describe how pregnant women can be expected to respond to this offer. We then argue that routinely withholding the results of first-trimester risk assessment is ethically unjustified. The ethics of informed consent is an essential dimension of first-trimester risk assessment for trisomy 21. (26 references) (Author)

20100407-86*

Caesarean section. Morris EP (2009), London: RCOG Oct 2009. 5 pages

This is the second edition of this guidance, which was previously published in 2006 under the same title. This paper provides advice for clinicians in obtaining consent of a woman undergoing caesarean section. This paper is intended to be appropriate for a number of procedures and combinations and the consent from should be carefully edited under the heading 'Name of proposed procedure or course of treatment' to accurately describe the exact procedure to be performed, after discussion with the woman. The paper follows the structure of Consent Form 1 of the Department of Health, England/Welsh Assembly Government/Scottish Government/Department of Health, Social Services and Public Safety, Northern Ireland. It should be used in conjunction with RCOG Clinical Governance Advice, Obtaining Valid Consent. The aim of this advice is to ensure that all women are given consistent and adequate information for consent; it is intended to be used together with dedicated patient information. (5 references) (Author)

20100309-46

The quality of operative consenting against RCOG advice as standard. Touqmatchi D, Boret T, Nicopoullous J (2010), Journal of Obstetrics and Gynaecology vol 30, no 2, February 2010, pp 159-165

Clinical Governance Advice published by the RCOG states that 'before seeking a women's consent ... you should ensure that she understands the nature of the condition for which treatment is being proposed, its prognosis, likely consequences and risks of receiving no treatment at all'. The importance of obtaining informed consent within obstetrics and gynaecology is highlighted by the litigious nature of our specialty, with CNST data, demonstrating that it makes up 21% of all claims and incur highest cost of any other specialty. We present an audit of the quality of

operative consenting for 120 procedures over a 3-month period for five procedures (diagnostic hysteroscopy and laparoscopy, total abdominal hysterectomy, vaginal repair/hysterectomy and lower segment caesarean section) for which we have RCOG advice (Numbers 1, 2, 4, 5, 7, respectively). The quality of consent was also assessed by grade of clinicians. The results identify significant deficiencies when various gynaecological and obstetric procedures are being consented for, and we have discussed various options recommended for improvement. (6 references) (Author)

20100224-69

Informed consent in labour. Took A, Dewhurst F, Court D (2009), O & G vol 11, no 4, Summer 2009, pp 58-61

Perspectives on legal aspects of informed consent in labour in Australia and New Zealand. (15 references) (AEP)

20100218-54

Ethical issue and consent form in the management of high-risk pregnancy. Riviello C, Ottanelli S, di Tommaso MR, et al (2010), Journal of Maternal-Fetal and Neonatal Medicine vol 23, no 2, February 2010, pp 179-183

Through the description of two high risk unplanned pregnancy cases and the subsequent interview of the patients, a few years after delivery, this article focuses on the following issues: The importance of a planned pregnancy in a woman with diabetes or other chronic disease; The ethical role of counselling and how it should not be influenced by the ethical belief of the obstetrician; The legal aspect related to the knowledge and qualifications of the obstetrician in the management of a high-risk pregnancy to improve both maternal and fetal outcomes. Here, two cases of complicated type 1 diabetes in women with unplanned pregnancies and the importance of counselling in high-risk pregnancy are presented. (15 references) (Author)

20090930-55

Best practices in perinatal nursing: partnering with patients to enhance informed decision making. Mahlmeister LR (2009), Journal of Perinatal and Neonatal Nursing vol 23, no 3, July/September 2009, pp 213-216

Discusses the concepts of consent, informed consent and informed refusal in perinatal nursing care. (17 references) (SB)

20090630-26

More information, less understanding: a randomized study on consent issues in neonatal research. Freer Y, Mcintosh N, Teunisse S, et al (2009), Pediatrics vol 123, no 5, May 2009, pp 1301-1305

BACKGROUND: Valid consent for research requires comprehensive and understandable information to be disclosed to participants. The way that information is shared varies, but regulatory bodies usually determine style. Some reports have suggested that although information may be all-inclusive, it does little to support understanding. OBJECTIVE: To explore the impact of various information-sharing approaches on parents' understanding of a research study and the validity of their consent. METHODS: This was a randomized, controlled trial. Parents of immature but well infants admitted to a large tertiary NICU in Edinburgh, Scotland, were randomly assigned within 72 hours of their infant's admission to receive 1 of 2 information leaflets, with or without a standardized verbal explanation, for a hypothetical intensive care research study. The leaflets differed in length and in the amount of detail in which the study process, risks, benefits, and patient rights were described. A questionnaire was used to elicit understanding about the purpose of the research, design of the study, procedures involved, and the consent process. RESULTS: Forty-one parents participated in the study. Those who received the longer leaflet without verbal explanation gained only limited understanding of the purpose of the research. The procedures involved in the study were understood better by those who received the shorter leaflet. Issues relating to consent and study design were readily understood in all groups. Irrespective of documentation style, verbal explanation significantly improved understanding. Differences in understanding had little effect on whether a parent would enroll his or her infant into the study. CONCLUSIONS: Verbal explanation significantly enhances understanding of the research process for participants regardless of the style of written documentation. However, shorter written information may lead to better understanding than lengthy, more complex documentation. (24 references) (Author)

20090331-113

A quiet place. The assault on freedom of conscience. O'Mara P (2009), Mothering no 153, March-April 2009, pp 8, 10, 12

Looks at the issue of 'freedom of conscience' which is protected under the doctrine of informed consent, and therefore should allow parents the right to decline. Considers this concept in relation to vaccination, neonatal circumcision, treatment for HIV, and bed sharing, drawing upon research and cases previously featured in 'Mothering'.

(JSM)

20090317-116

Chaos, vulnerability and control: parental beliefs about neonatal clinical trials. Ward FR (2009), Journal of Perinatology vol 29, no 2, February 2009, pp 156-162

OBJECTIVE: This study examined parental beliefs about participating in clinical trials involving greater than minimal risk to their neonate, and explored their views of their experiences. STUDY DESIGN:In this qualitative descriptive study, parents in the neonatal intensive care unit (NICU) who had been approached for permission for their neonates to be enrolled in research were asked to describe their decisions about their consent for or disagreement to their neonate's research participation. A total of 27 parents from three different hospital NICUs in the Mid-Atlantic region of the United States participated. Transcribed interviews were analyzed using qualitative content analysis. RESULTS:Participant decisions developed through a dynamic process of meaning-making based on their beliefs about themselves and their neonates. The processes involved making sense of the chaos that they perceived in the environment and their own vulnerability, through taking control of their situation. (31 references) (Author)

20090120-81

Teaching the facts: the dilemma of evidence-based care. Abe D (2008), International Journal of Childbirth Education vol 23, no 4, December 2008, pp 9-14

With the release of a new report, Evidence-Based Maternity Care, childbirth professionals have an additional resource to teach and promote evidence-based care. Recent data shows a widening gap between current maternity care practices and evidence-based care. Hospital based childbirth educators are often conflicted about how to teach evidence-based care, when it is not the standard of care used at the facilities they teach. (4 references) (Author)

20081007-57

A healthy baby isn't all that matters. Fiscer C (2008), Midwifery Today no 87, Autumn 2008, pp 16-19

A mother recalls her experience of having a caesarean birth without her consent, and the subsequent illness of her baby who ended up in NICU experiencing seizures. (TM)

20080925-54*

Information and consent for newborn screening: practices and attitudes of service providers. Kerruish NJ, Webster D, Dickson N (2008), Journal of Medical Ethics vol 34, no 9, September 2008, pp 648-652

OBJECTIVES: To gather information about the practices and attitudes of providers of maternity care with respect to informed consent for newborn screening (NBS). METHODS: A questionnaire concerning information provision and parental consent for NBS was sent to all 1036 registered lead maternity carers (LMC) in New Zealand. RESULTS: 93% of LMC in New Zealand report giving parents information concerning NBS, most frequently after delivery (73%) and in the third trimester (60%). The majority (85%) of LMC currently obtain some form of consent (verbal or written) for NBS from parents and consider this to be the ideal approach (94%). Despite this a significant minority of LMC (23%) reported considering that NBS should be mandatory. Of those in our survey who believed that NBS should be mandatory, paradoxically most (89%) still believed that some form of parental consent should be obtained; of those who believed testing should not be mandatory, only a small proportion (10%) would accept parental refusal without question. CONCLUSIONS: When the results of this survey are considered in conjunction with existing evidence there appears to be a consensus that good quality information in the prenatal period should be an integral part of any NBS programme. The issue of consent is more complex and there is less agreement on the preferred degree of parental involvement in decisions to allow babies to undergo NBS. A policy that both strongly recommends NBS but also allows parental choice appears to be most consistent with the views of LMC in this survey. (Author)

20080709-90

Good on ya, Trish!. Marsh W (2008), Practising Midwife vol 11, no 7, July/August 2008, pp 29-30

Wendy Marsh pays tribute to her former tutor, Tricia Anderson, for making her realise that informed consent should be at the heart of good midwifery care. (1 references) (Author)

20080709-86

Informed consent and the birth plan. Wier J (2008), Practising Midwife vol 11, no 7, July/August 2008, pp 17-18

The birth plan, while much maligned, allows women an effective voice in the decision-making process and should be used more widely. (6 references) (Author)

20080618-65

The requirement for informed consent prior to nursing care procedures. Aveyard H (2002), Journal of Advanced Nursing vol 37, no 3, February 2002, pp 243-249

AIM OF THE PAPER: The aim of this paper is to examine the extent to which there is a requirement to obtain informed consent prior to nursing care procedures. RATIONALE: The requirement for nurses to obtain consent prior to nursing care procedures is addressed in various nursing policy documents. It is important that nurses understand the legal and ethical rationale behind the principles of informed consent so that the principles are applied appropriately to the particular context of nursing care. ARGUMENT: The ethical and legal rationale behind the concept of informed consent and its relevance to nursing practice are examined. In this paper, it is argued that the function of informed consent is to protect patient autonomy and to promote meaningful decision-making. Given the potential for nursing care procedures to infringe patient autonomy, consent is clearly a relevant concept in nursing. Furthermore, in law, any touching without consent is a potential battery. Informed consent is often associated as a rigid procedure, only relevant to surgical or research procedures. Consent should be obtained prior to nursing care procedures whenever patient autonomy is at stake. However, information-giving should be determined by the needs of the patient and approached in such a way as to facilitate meaningful decision-making. Given the individual nature of infringements to patient autonomy, it is difficult to predetermine all those care procedures that require consent; any list of procedures would fail to be comprehensive. CONCLUSIONS: The principles of informed consent should underpin our approach to nursing care procedures, which should not be mechanistic but determined by the needs of individual patients. (21 references) (Author)

20080327-24

Informed consent. (2008), Association for Improvements in Maternity Services (AIMS) vol 19, no 4, 2007/2008, pp 10-11

An example of an informed consent form for giving birth in hospital which should be signed by women before giving birth.(CB)

20080114-30

Research in pregnant women. Helmreich RJ, Hundley V, Norman A, et al (2007), Nursing for Women's Health vol 11, no 6, December 2007, pp 576-585

Explores the issues surrounding informed consent when conducting research involving pregnant women and gives an overview of the US and Canadian guidelines. Suggests that nurses have an important role to play in advocacy, education and supporting potential participants in research studies. (41 references) (TC)

20071108-80*

Risk perception and decision processes underlying informed consent to research participation. Reynolds WW, Nelson RM (2007), Social Science and Medicine vol 65, no 10, November 2007, pp 2105-2115

According to the rational choice model, informed consent should consist of a systematic, step-by-step evaluation of all information pertinent to the treatment or research participation decision. Research shows that people frequently deviate from this normative model, however, employing decision-making shortcuts, or heuristics. In this paper we report findings from a qualitative study of 32 adolescents and (their) 31 parents who were recruited from two Northeastern US hospitals and asked to consider the risks of and make hypothetical decisions about research participation. The purpose of this study was to increase our understanding of how diabetic and at-risk adolescents (i.e., those who are obese and/or have a family history of diabetes) and their parents perceive risks and make decisions about research participation. Using data collected from adolescents and parents, we identify heuristic decision processes in which participant perceptions of risk magnitude, which are formed quickly and intuitively and appear to be based on affective responses to information, are far more prominent and central to the participation decision than are perceptions of probability. We discuss participants' use of decision-making heuristics in the context of recent research on affect and decision processes, and we consider the implications of these findings for researchers. (Author)

20070925-7*

When 'no' might not quite mean 'no'; the importance of informed and meaningful non-consent: results from a

survey of individuals refusing participation in a health-related research project. Williams B, Irvine L, McGinnis AR, et al (2007), BMC Health Services Research vol 7, no 59, 29 April 2007. 10 pages

Background: Low participation rates can lead to sampling bias, delays in completion and increased costs. Strategies to improve participation rates should address reasons for non-participation. However, most empirical research has focused on participants' motives rather than the reasons why non-participants refuse to take part. In this study we investigated the reasons why older people choose not to participate in a research project. Methods: Follow-up study of people living in Tayside, Scotland who had opted-out of a cross-sectional survey on activities in retirement. Eight hundred and eighty seven people aged 65-84 years were invited to take part in a home-based cross-sectional survey. Of these, 471 refused to take part. Permission was obtained to follow-up 417 of the refusers. Demographic characteristics of people who refused to take part and the reasons they gave for not taking part were collected. Results: 54% of those invited to take part in the original cross-sectional survey refused to do so. However, 61% of these individuals went on to participate in the follow-up study and provided reasons for their original refusal. For the vast majority of people initial non-participation did not reflect an objection to participating in research in principle but frequently stemmed from barriers or misunderstandings about the nature or process of the project itself. Only 28% indicated that they were 'not interested in research'. The meaningfulness of expressions of non-consent may therefore be called into question. Hierarchical log-linear modelling showed that refusal was independently influenced by age, gender and social class. However, this response pattern was different for the follow-up study in which reasons for non-participation in the first survey were sought. This difference in pattern and response rates supports the likely importance of recruitment issues that are research and context specific. Conclusion: An expression of non-consent does not necessarily mean that a fully informed evaluation of the pros and cons of participation and non-participation has taken place. The meaningfulness of expressions of non-consent may therefore be a cause for concern and should be subject to further research. Many reasons for non-participation may be specific to a particular research topic or population. Information sheets should reflect this by going beyond standardised guidelines for their design and instead proactively seek out and address areas of concern or potential misunderstanding. The use of established behavioural theory in their design could also be considered. [The full text of this article can be accessed at: http://www.biomedcentral.com/content/pdf/1472-6963-7-59.pdf] (42 references) (Author)

20070918-121

Information and informed consent for neonatal screening: opinions and preferences of parents. Detmar S, Hosli E, Dijkstra N, et al (2007), Birth vol 34, no 3, September 2007, pp 238-244

Background: The current neonatal screening program ('the heel prick') involves taking a few drops of blood from almost every newborn in the Netherlands to determine whether the child is suffering from one of three congenital disorders: phenylketonuria, congenital hypothyroid, or adrenogenital syndrome. This study investigated the preferences and views of parents and future parents with respect to information about, and consent to, neonatal screening and the possible expansion of the program. Methods: Seven focus group discussions took place with future parents, parents with a healthy child, and parents with children affected by disorders for which screening is possible, now or in the future (total of 36 participants). The discussions were audiotaped, transcribed, and analyzed for content. Results: Parents were not well informed about what the heel prick involves at present. Nevertheless, they see it as a routine procedure and do not think about the possibility of refusing it. If the heel-prick program were to be expanded, parents would like to be informed earlier, preferably during pregnancy. In addition, most parents preferred an opt-out consent approach. Conclusions: If the neonatal screening program is to be expanded, parents would prefer for information about the program be given during pregnancy. In addition, they preferred an opt-out consent approach, on condition that screening was for the purpose of preventing irreversible harm. Parental opinion was divided on this issue if the aim of screening were to be widened. (14 references) (Author)

20070730-102

Clinical trials in neonates: Ethical issues. Allmark P, Spedding M (2007), Seminars in Fetal and Neonatal Medicine vol 12, no 4, August 2007, pp 318-323

If neonates are to receive the best possible treatment, they must be involved in clinical trials. However, doing such trials raises complicated ethical issues. These issues are not unique to neonatology but some are more common or acute than in other areas of medicine. In practice, two particular issues-equipoise and informed consent-arise as many different types of problem. The question 'What is an ethical issue?' is important because issues that are not ethical are sometimes mistakenly thought to be so, and vice versa. When we can recognize what types of problem are ethical, we can also recognize the correct means to tackle them. (28 references) (Author)

20070726-83

Informed consent. McCullough LB, Chervenak FA (2007), Clinics in Perinatology vol 34, no 2, June 2007, pp 275-285

Informed consent is an essential component of the practice of perinatal medicine because, as a process of communication and decision making, it should shape the relationship between the physician and pregnant woman and between the physician and the parents of a newborn child. This article provides an account of the physician's obligations in the informed consent process in terms of ethics and law. (17 references) (Author)

20070608-40

Incapacity to consent. Symon A (2007), British Journal of Midwifery vol 15, no 6, June 2007, p 367

Discusses the issue of mental incapacity in relation to informed consent in maternity care. (5 references) (SB)

20070607-67*

The quality of parental consent for research with children: a prospective repeated measure self-report survey. Franck LS, Winter I, Oulton K (2007), International Journal of Nursing Studies vol 44, no 4, May 2007, pp 525-533

BACKGROUND: Researchers have ethical and legal responsibilities to ensure that individuals give informed consent to participate in research. The few studies of parental consent for paediatric research suggest there may be inadequate competence, information, understanding, or voluntariness for valid consent to occur. OBJECTIVES: To determine parents' level of understanding of the research study requirements and satisfaction with the informed consent process. PARTICIPANTS: English literate parents of children actively involved in research studies. METHODS: A repeated measures self-report survey was conducted to measure parent understanding (actual and perceived) of the study consented for and satisfaction with the informed consent process. Relationships between parents understanding of the research and their satisfaction with the consent process were explored and changes in parent understanding or satisfaction over time were described. RESULTS: Questionnaires from 109 parents were returned, representing 25 different studies. Parents demonstrated a high level of knowledge of information essential for informed consent, such as the purpose, benefits, and participant rights. Nervousness or inability to concentrate, and reading ease of the information sheet were found to relate to parents' knowledge and their perceptions of the adequacy of the consent. Parents overall reported high satisfaction with the consent process. CONCLUSIONS: These findings support and extend previous research on parental consent for research with children. They suggest areas where further research is indicated, including: the value and use of information and consent documents given to parents, the views and concerns of parents for whom English is not their first language, and further exploration of the concerns of the few dissatisfied parents. Current practices of obtaining informed consent for research lack supporting research evidence and may not be ethically justifiable. (Author)

20070522-96

Listening to mothers II reveals maternity care quality chasm. Sakala C, Corry MP (2006), Journal of Midwifery & Women's Health vol 52, no 3, May/June 2007, pp 183-185

Commentary on the 'Listening to Mothers II' survey, highlighting the large proportion of childbearing women in the United States who are experiencing care that does not reflect best evidence, the wishes of mothers, legal disclosure standards or the interests of mothers and infants. (11 references) (CR)

20070411-30*

What motivates British parents to consent for research? A questionnaire study. Sammons HM, Atkinson M, Choonara I, et al (2007), BMC Pediatrics vol 7, no 12, 9 March 2007. 7 pages

Background: Informed consent is the backbone of a clinical trial. In children this is given by their parents. There have been many studies in the neonatal population but little is known about the views of the parents of infants and young children from within the United Kingdom. The objectives of this study were to assess what motivates parents to consent to a randomised clinical trial (RCT), their feelings on consent and participation and the factors that would influence their decision to take part in a future study. Methods: The setting was a multi-centre randomised but non-blinded equivalence trial of oral versus intravenous (IV) treatment for community acquired pneumonia in previously well children aged 6 months to 16 years in the UK (PIVOT Study). Parents were sent a postal questionnaire at the end of the study which included open and closed-ended questions. Fishers Exact Test was used to analyse associations in non parametric categorical data. Results: 243 children were recruited into the PIVOT study. Of a possible 235, 136 questionnaires were returned (response rate 59%). Of those questionnaires returned; 98% of parents remembered consenting, 95% felt they were given enough time to make their decision and 96% felt they

received enough information. Major reasons for participation were benefit to other children in the future 31%, contribution to science 27%, benefit to their own child 18%. Most parents (85%) did not feel obliged to participate. 62% felt there was an advantage to taking part and 18% felt there was a disadvantage. 91% of parents said they would take part in a similar study in the future, stating influences on their decision being benefit to their own child (91%) and benefit to all children (89%). Conclusion: The major motivation in parents consenting for their previously well child to participate in an RCT of therapy for an acute medical illness was to increase medical knowledge in the future. Most saw an advantage in taking part in the trial and did not feel obliged to participate. [The full text of this article can be accessed at: http://www.biomedcentral.com/content/pdf/1471-2431-7-12.pdf] (12 references) (Author)

20070205-8

Informed consent: an international researchers' perspective. Rivera R, Borasky D, Rice R, et al (2007), American Journal of Public Health vol 97, no 1, January 2007, pp 25-30

We reported 164 researchers' recommendations for information that should be included in the informed consent process. These recommendations were obtained during training workshops conducted in Africa, Europe, and the United States. The 8 elements of informed consent of the US Code of Federal Regulations were used to identify 95 items of information ('points'), most related to benefits and research description. Limited consensus was found among the 3 workshops: of the 95 points, only 27 (28%) were identified as useful by all groups. These points serve as a springboard for identifying information applicable in different geographic areas and indicate the need for involving a variety of individuals and stakeholders, with different research and cultural perspectives, in the development of informed consent, particularly for research undertaken in international settings. (6 references) (Author)

20070205-58*

Chart documentation of informed consent for operative vaginal delivery: is it adequate?. Nichols CM, Pendlebury LC, Jennell J (2006), Southern Medical Journal vol 99, no 12, December 2006, pp 1337-1339

OBJECTIVES: To determine the documentation frequency of informed consent for women undergoing a trial of nonemergent instrumental delivery. STUDY DESIGN: A retrospective chart review of instrumented vaginal deliveries from 1992 to 2005 was performed. Cases were identified from a Labor and Delivery database and hospital records were reviewed for documentation of associated risks, general consent for the procedure, indication, and option of cesarean delivery (CD). RESULTS: Three hundred forty six charts were reviewed: 246 were excluded for an emergency delivery (19%), misclassification (25%), or lost notes (27%). In the remaining 100 cases, 61% had a general consent for instrumented vaginal delivery. Documentation of any maternal or neonatal risks was found in 3% and 0%, respectively. The option of a cesarean delivery was documented in 22% of the cases. When comparing 5-year time intervals before and after 2000, there was no increased frequency in documentation of maternal or neonatal risks. CONCLUSIONS: Documentation of informed consent for instrumented vaginal delivery is inconsistent and should be improved. (Author)

20070129-24

Why informed consent is important in the exercise of maternal choice. O'Boyle D (2006), In: Symon A ed. Risk and choice in maternity care: an international perspective. Edinburgh: Churchill Livingstone 2006, pp 23-33

Describes the responsibilities involved in health care delivery within the United Kingdom and the role of informed consent, particularly within the context of the maternity services. Examines the role of autonomy and competency and discusses what to do in situation where the individual does not have the capacity to give informed consent. (17 references) (MB)

20070104-8

Understanding operative intervention in childbirth: a patient perspective. Treacy A, Mahony R, Teehan M, et al (2006), Journal of Obstetrics and Gynaecology vol 26, no 8, November 2006, pp 752-754

A study was undertaken to ascertain patients' understanding of the operative interventions in labour and to assess follow-up by the operator. A total of 200 consecutive women who had undergone caesarean section or instrumental delivery were selected. These women were questioned postoperatively. Questions were asked to ascertain the patients' understanding of the procedure and to assess follow-up by the operator. Seven patients had a forceps delivery, 64 had a ventouse delivery and 129 had a caesarean section. The majority of patients felt that the reason for the operative delivery had been explained to them at delivery and that they fully understood the need for this intervention. A total of 26 women were not seen postoperatively by the doctor who delivered them. Women who underwent forceps or ventouse delivery were less likely to be seen post-delivery, although this difference did not

reach statistical significance. (16 references) (Author)

20070104-51

Informed consent: providing information about prenatal examinations. Dahl K, Kesmodel U, Hvidman L, et al (2006), Acta Obstetricia et Gynecologica Scandinavica vol 85, no 12, 2006, pp 1420-1425

Background. Choice in prenatal care has moved on from a paternalistic approach, to increased patient autonomy and informed decision-making. This review summarises the existing literature on the information of pregnant women about prenatal examinations. The extent to which information about Down syndrome and screening tests empowers informed decision-making are investigated, as are different ways of expressing a risk estimate. Results. Knowledge scores can be improved and decisional conflict reduced by group counselling, individual sessions, and by use of leaflets. None of the interventions leads to a raise in anxiety scores or influence uptake rates. Satisfaction with information provided was found unrelated to level of knowledge, but associated with having expectations for information met. Information on Down syndrome is missing (13-21%), or restricted (13%), limitations of screenings tests rarely mentioned, and written materials often insufficient. Women experience risk expressed as proportions or relative risk ratio significantly higher than percentage, number needed to treat, or absolute risk reduction. More women correctly understand relative risk reduction compared to absolute risk reduction and number needed to treat (60 versus 42 and 30%). Using medical words rather than lay terms significantly alter risk perception. Conclusions. Information can increase the level of knowledge and reduce decisional conflict, without raising anxiety scores. A clarification of the women's expectations seems paramount to obtain a perception of good information and informed consent. The information provided about Down syndrome and screening tests does not empower an informed consent based on relevant knowledge. (40 references) (Author)

20070104-50

Informed consent: attitudes, knowledge and information concerning prenatal examinations. Dahl K, Kesmodel U, Hvidman L, et al (2006), Acta Obstetricia et Gynecologica Scandinavica vol 85, no 12, 2006, pp 1414-1419

Background. Providing women with information enabling an informed consent to prenatal examinations has been widely recommended. Objective. The primary purpose of this review is to summarise the current knowledge of the pregnant woman's expectations and attitudes concerning prenatal examinations, as well as the knowledge possessed by pregnant women undergoing prenatal examinations. Second, we explore their reasons for accepting or declining available screening tests. Results. More than 90% of the pregnant women expressed a positive attitude toward screening procedures in pregnancy. Most often (70-96%), the pregnant women were found knowledgeable about the procedural and practical aspects, but were more seldom (31-81%) able to correctly identify the purpose of tracing fetal malformations. Some 29-65% were not familiar with the existence of a false negative result, and 30-43% were found unaware of the possibility of a false positive result. The risk of miscarriage in relation to amniocentetesis [AC] is unknown to 11-53%. Uptake rates are associated with attitudes toward prenatal examinations, but no knowledge of the test offered. A total of 88% considered their health care provider an important source of information, and 57% stated that this information has influenced their decision. Conclusions. Pregnant women favor prenatal examinations, but the choice of participation does not seem to be based on insight to enable full informed consent. Health care providers are perceived as an essential source of information. (38 references) (Author)

20061214-26

Asking for permission to observe can be intrusive. Penwarden AS (2006), Nursing Times vol 102, no 48, 28 November 2006, p 13

The author, a nursing student, reflects on the unease she felt while attending a caesarean section without the permission of the woman giving birth. (MB)

20061030-29

Young people and the Fraser guidelines: confidentiality and consent. Fleming CF (2006), Obstetrician and Gynaecologist vol 8, no 4, 2006, pp 235-239

Provides an overview of legal issues concerning consent and confidentiality in relation to persons under the age of 16 years, and provides guidance on applying the Fraser guidelines when issuing sexual health advice or treatment to this group. (25 references) (SB)

20061027-55*

BOYS2MEN: running a fatherhood programme. Cummings A (2004), London: UK Youth 2004

Resource pack for youth workers and others that work with boys and young men. Contains ideas, information, activities and examples of programmes for exploring themes of personal experiences; feelings, values and attitudes; responsibility; communication; sexuality and sexual health; and maleness and masculinity. (SB)

20060925-42

Teenagers and consent issues. Grover S, Lam P (2006), O & G vol 8, no 3, Spring 2006, pp 80-81, 83

Discusses issues relating to consent and adolescents, focusing on effective communication. Includes privacy and confidentiality, taking a history, examining and investigating teenagers, and consent. (6 references) (SB)

20060920-62

Guidelines for consent and the provision of information regarding proposed treatment. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (2006), O & G vol 8, no 2, Winter 2006, pp 49-50

Position statement from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists regarding informed consent. (MB)

20060904-93

Patient's consent for publication of case report: need for developing a universal consent form. Saxena AK, Ghai B, Makkir JK (2006), Archives of Disease in Childhood vol 91, no 8, August 2006, pp 717-718

Comments on the need to produce a consent form for publication of case reports that can be used by all medical journals. (2 references) (MB)

20060904-23

Consent for neonatal research. McKechnie L, Gill AB (2006), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 91, no 5, September 2006, pp F374-376

Inherent to all medical research is respect for the rights of the individual. Neonatal research is made more complex by the issue of proxy consent. Obtaining valid informed consent for entry of an infant into a research project needs to deal with this complexity. New evidence on the role and responsibilities of parents in giving consent has implications for all clinical staff that are considering embarking on and/or recruiting infants in research projects. This review explores the issues around informed consent for neonatal research and provides a framework by which consent could be improved. It is to be hoped that such improvements to the process will increase recruitment of infants to research studies while enhancing the validity of the consent process. (23 references) (Author)

20060822-13*

Improving the quality of consent to randomised controlled trials by using continuous consent and clinician training in the consent process. Allmark P, Mason S (2006), Journal of Medical Ethics vol 32, no 8, August 2006, pp 439-443

OBJECTIVE: To assess whether continuous consent, a process in which information is given to research participants at different stages in a trial, and clinician training in that process were effective when used by clinicians while gaining consent to the Total Body Hypothermia (TOBY) trial. The TOBY trial is a randomised controlled trial (RCT) investigating the use of whole-body cooling for neonates with evidence of perinatal asphyxia. Obtaining valid informed consent for the TOBY trial is difficult, but is a good test of the effectiveness of continuous consent. METHODS: Semistructured interviews were conducted with 30 sets of parents who consented to the TOBY trial and with 10 clinicians who sought it by the continuous consent process. Analysis was focused on the validity of parental consent based on the consent components of competence, information, understanding and voluntariness. RESULTS: No marked problems with consent validity at the point of signature were observed in 19 of 27 (70%) couples. Problems were found mainly to lie with the competence and understanding of the parents: mothers, particularly, had problems with competence in the early stages of consent. Problems in understanding were primarily to do with side effects. Problems in both competence and understanding were observed to reduce markedly, particularly for mothers, in the post-signature phase, when further discussion took place. Randomisation was generally understood but unpopular. Information was not always given by clinicians in stages during the short period available before parents gave consent. Most clinicians, however, were able to give follow-up information. DISCUSSION: Consent validity was found to compare favourably with similar trials examined in the Euricon study. CONCLUSION: Adopting the elements of the continuous consent process and clinician training in RCTs should be considered by researchers, particularly when they have concerns about the quality of consent they are likely to obtain by using a conventional process. (Author)

20060808-6*

Communicating with parents of high-risk infants in neonatal intensive care

Historical and current perspectives. Yee W, Ross S (2006), Paediatrics and Child Health vol 11, no 5, May/June 2006, pp 291-294

Good communication between parents and staff about the likely outcome of high-risk infants is essential to ensure parents' full involvement in decision-making. The present paper discusses the literature on this topic to explore the best practices for professionals communicating with parents of high-risk infants. (Author)

20060510-22

Gaining consent for postmortems. Lomas C (2006), Nursing Times vol 102, no 17, 25 April 2006, pp 58-59

Laws on postmortem consent became tighter this month. A unique nursing role is helping to address this sensitive issue. (Author)

20060303-38

One-time general consent for research on biological samples. Wenderl D (2006), BMJ vol 332, no 7540, 4 March 2006, pp 544-547

It is now recognised that people should give informed consent for use of their biological samples in research. The literature on inidividuals' views supports one-time general consent as the best approach for this purpose. (32 references) (Author)

20060223-1

Parents' consent to neonatal decisions about feeding and discharge. Alderson P (2006), Journal of Neonatal Nursing vol 12, no 1, February 2006, pp 6-13

English law requires health care practitioners to obtain parents' consent before all touching of their child. However, nurses tend to leave doctors to request parents' consent to intensive are interventions, and it is generally assumed that before parents can start to care for their baby, they need to have practitioners', mainly nurses', permission. This paper reviews examples of neonatal feeding and discharge decisions that illustrate how consent can be an undeveloped concept in nursing care. Through the sharing of information and medical decision making, the consent process involves implicit or explicit negotiation of anxiety, trust and risk. Decisions about neonatal feeding and discharge can also involve anxiety and risk, and it is suggested that, while avoiding legalistic formalities, more overt sharing of information and decisions about the options could be to the advantage of nurses, babies and parents. (34 references) (Author)

20060125-21

The changing face of consent: past and present. Nicholas N, El Sayed M (2006), Obstetrician and Gynaecologist vol 8, no 1, 2006, pp 39-44

The law of consent is moving towards a more patient-centred standard of disclosure in order to safeguard the patient's autonomy and right to self-determination. The well-known Bolam principle upon which clinicians rely is now being challenged. This review looks at the law of consent as it currently stands and how it is evolving. All healthcare professionals should take these changes seriously and reconsider the way in which they practise. Sufficient resources - more time, in particular - are needed to train clinicians to communicate more effectively with their patients. (23 references) (Author)

20060115-76*

Cross-cultural perspectives on research participation and informed consent. Barata PC, Gucciardi E, Ahmad F, et al (2006), Social Science and Medicine vol 62, no 2, January 2006, pp 479-490

This study examined Portuguese Canadian and Caribbean Canadian immigrants' perceptions of health research and informed consent procedures. Six focus groups (three in each cultural group) involving 42 participants and two individual interviews were conducted. The focus groups began with a general question about health research. This was followed by three short role-plays between the moderator and the assistant. The role-plays involved a fictional health research study in which a patient is approached for recruitment, is read a consent form, and is asked to sign. The role-plays stopped at key moments at which time focus group participants were asked questions about their understanding and their perceptions. Focus group transcripts were coded in QSR NUDIST software using open coding

and then compared across cultural groups. Six overriding themes emerged: two were common in both the Portuguese and Caribbean transcripts, one emphasized the importance of trust and mistrust, and the other highlighted the need and desire for more information about health research. However, these themes were expressed somewhat differently in the two groups. In addition, there were four overriding themes that were specific to only one cultural group. In the Portuguese groups, there was an overwhelming positive regard for the research process and an emphasis on verbal as opposed to written information. The Caribbean participants qualified their participation in research studies and repeatedly raised images of invasive research. (Author)

20060112-57

Informed consent: can a patient ever be fully informed?. Lupton M (2005), Current Opinion in Obstetrics and Gynecology vol 17, no 6, December 2005, pp 601-604

PURPOSE OF REVIEW: The National Health Service Litigation Authority has issued a warning about the process of asking a patient for their consent prior to a medical procedure. This warning was issued in the light of the case of Chester v. Afshar. For the first time in English law the courts have appeared to state that failure to give a patient adequate information about a procedure is negligent per se. This article briefly examines the history of consent since the famous case of Bolam and reviews the recent legal commentary on the case of Chester. It will also consider a proposed solution to the question 'What is adequate information?' RECENT FINDINGS: The medicolegal literature traces the change in the legal test used to determine whether a patient has been adequately informed. It charts the evolution of a 'prudent patient' test and suggests ways in which medical practitioners might adequately fulfil their duty to inform patients properly. SUMMARY: Since the case of Chester v. Afshar it has become harder for a doctor to escape a charge of negligence if they have given inadequate information at the time of asking a patient for their consent to undergo a medical procedure. It is in everyone's interests - doctor and patient - to make the process of consent transparent and to an agreed national standard. (18 references) (Author)

20060109-81*

Parental consent for newborn screening in southern Taiwan. Huang MC, Lee CK, Lin SJ, et al (2005), Journal of Medical Ethics vol 31, no 11, November 2005, pp 621-624

OBJECTS: With the advent of genetic technologies, many genetic/metabolic disorders can be detected asymptomatically but might be untreatable, and the benefits and risks of screening for them are not fully known. The purpose of this study is to explore current practice with regard to the parental consent process in newborn screening (NBS). DESIGN: Staff in 23 obstetric clinics/hospitals that conduct NBS in one city of southern Taiwan were interviewed. Using content analysis, 15 interview transcripts, eight completed questionnaires, and other relevant documents from the 23 clinics/hospitals were analysed to reveal the framework of the parental consent process in NBS in southern Taiwan. MAIN MEASURES: Three categories-informed consent, informed dissent, and no informed/consent-were developed to analyse the parental consent process in NBS. RESULTS: The parental consent procedures in NBS and the quality of the information provided before obtaining consent vary widely. Because the traditional NBS was incorporated into routine paediatric practices in most clinics/hospitals, the most frequently encountered consent model is 'informed dissent' (60.9%) and 'no informed/consent' (30.4%); while an 'informed consent' model (45.5%) is the frequent model for screening rare metabolic/genetic disorders. CONCLUSIONS: Specific guidelines to regulate the parental consent process for NBS are essential. Further studies should investigate parental responses to NBS, taking these as the basis on which to establish an informed consent model in Taiwan. (Author)

20051214-25

The ethics of neonatal resuscitation at the margins of viability: informed consent and outcomes. Janvier A, Barrington KJ (2005), Journal of Pediatrics vol 147, no 5, November 2005, pp 579-585

OBJECTIVES: To determine the adequacy of records of parental counseling in mothers with threatened preterm delivery before 27 weeks gestation, whether interventions performed at birth were consistent with recorded antenatal decisions and whether extent of resuscitation affected the occurrence of serious short-term morbidity. STUDY DESIGN: Antenatal consultation records and records of resuscitation and short-term outcomes were analyzed of 65 mothers with threatened delivery at 21 weeks to 26 weeks and 6 days gestation, and their 61 infants who delivered before 27 weeks. RESULTS: Discussions about survival rates and the frequency of handicap were more likely to be recorded before 25 weeks gestation than after; the adequacy of the records varied among individuals. A decision not to resuscitate was present in 6 of the 13 consultations performed before 23 weeks gestation, and in none of the 52 at 23 weeks or above. A decision to resuscitate only if the infant's condition at birth was good was found in 7 consultations, 6 of which were at less than 24 weeks gestation. All infants born at 23 weeks and above were

resuscitated, including the infants with conditional resuscitation decisions. Three of the 6 infants receiving heart massage were discharged alive without major short-term morbidity (severe intracranial hemorrhage, periventricular leukomalacia, or threshold retinopathy). All 8 infants of less than 25 weeks gestation with a heart rate at 3 minutes that was still less than 100 beats/min, in spite of active resuscitation, either died or had major short-term morbidity. CONCLUSIONS: Records of antenatal consultations were often lacking important information. Variations in physician documentation practices are substantial and affect the care offered to infants at the threshold of viability. Even extensive resuscitation can be followed by intact survival if the resuscitation required is brief. (13 references) (Author)

20051207-41

Ethics: an essential dimension of first-trimester risk assessment for trisomy 21. Chervenak FA, McCullough LB, Chasen ST (2005), The Female Patient: Ob/Gyn edition vol 30, no 11, November 2005, pp 21-24

Today, the ethics of informed consent is an essential dimension of first-trimester risk assessment for trisomy 21, and should be integrated into the clinical standard of care. (22 references) (Author)

20051115-91

Implementation of informed consent for a cystic fibrosis newborn screening program in France: low refusal rates for optional testing. Dhondt JL (2005), Journal of Pediatrics vol 147, no 3, suppl, September 2005, pp S106-S108

OBJECTIVES: The French Association for Neonatal Screening implemented cystic fibrosis neonatal screening (CF NBS) region by region in France, from the beginning of the year 2002 to early 2003. The program uses an immunoreactive trypsinogen/DNA testing algorithm on dried blood samples obtained at 3 days of age. Incorporation of DNA testing necessitated compliance with official regulations and French 'bioethics' laws: the need for a written consent from the patient/guardian and specific circulation of the prescription, sample, and results. To fulfill these obligations, the Ethics and Genetics committee of the French Association for Neonatal Screening recommended that informed consent should be obtained for all neonates at birth by having the parents sign directly on the sampling paper. This study was designed to evaluate the effect of the educational efforts used to obtain informed consent on acceptance of CF NBS. STUDY DESIGN: Data from the screening center in Lille, France, were analyzed to determine the rate of refusal of CF NBS in the 18 months after initiation of the informed consent process. RESULTS: The number of refusals for CF NBS declined from 0.8% at the start of the program to 0.2% at the end of the first year of the new process for obtaining written consent. CONCLUSIONS: Efforts to inform parents and professionals resulted in a significant decrease in the number of refusals for CF NBS. (8 references) (Author)

20051031-31

Informed consent and hypoplstic left heart syndrome. Byrne PJ, Murphy A (2005), Acta Paediatrica vol 94, no 9, September 2005, pp 1171-1175

We present an ethical analysis from the perspective of shared decision-making and informed consent of a change in clinical management of infants born with hypoplastic left heart syndrome (HLHS). We reported a change in treatment of HLHS at the University of Alberta away from comfort care to life-saving surgery (LST) between 1987 and 1998. In a second review (1996-2001), 49/62 infants received LST, with 81% survival from the NICU and 58% at 35 mo. Eleven infants died preoperatively of non-cardiac conditions and two received elective comfort care. Sixteen infants had 18-mo Bayley Mental Development Index, mean score 84+/-19, but five scored <70. Although we continue to present the comfort care option to parents, since 2001 LST use for HLHS at our center is almost universal despite serious complications. Conclusion: We conclude that these findings are inconsistent with an open, shared decision-making model of informed consent and we suggest that comfort care should remain an ethically valid choice until the rate of serious long-term complications of LST decreases. (29 references) (Author)

20051024-32

A comprehensive ethical framework for responsibly designing and conducting pharmacologic research that involves pregnant women. McCullough LB, Coverdale JH, Chervenak FA (2005), American Journal of Obstetrics & Gynecology (AJOG) vol 193, no 3, part 2, September 2005, pp 901-907

OBJECTIVE: We present and defend ethically justified guidelines for pharmacologic research that involves pregnant women. STUDY DESIGN: We explain the ethical concept of the fetus as a patient and identify its ethical implications for the design and conduct of pharmacologic research that is intended to benefit pregnant women. RESULTS: This concept justifies criteria for the initiation of early-phase clinical investigation, the initiation of controlled trials, the use of placebo control subjects, the stopping of randomized controlled trials, the determination of when an experimental

intervention should be regarded as standard of care, and research that involves adolescents. The informed consent process should be shaped by the pregnant patient's obligation to take in to account her beneficence-based obligations to a fetal patient. Selection criteria should not be based on abortion preference. And, physicians are justified ethically in referring pregnant women to trials. CONCLUSION: The concept of the fetus as a patient plays an essential role in the ethically justified design and conduct of pharmacologic research in pregnant women. (16 references) (Author)

20051007-54

Improving the readability and processability of a pediatric informed consent document: effects on parents' understanding. Tait AR, Boepel-Lewis T, Malviya S, et al (2005), Archives of Pediatrics and Adolescent Medicine vol 159, no 4, April 2005, pp 347-352

OBJECTIVE: To examine whether a consent document modified to conform with the federal guidelines for readability and processability would result in greater parental understanding compared with a standard form. DESIGN: Randomized clinical study. SETTING: The preoperative waiting area of a larger tertiary care children's hospital. PARTICIPANTS: A total of 305 parents of children scheduled for minor elective surgical procedures. INTERVENTIONS: Parents were randomized to receive information about a clinical study in 1 of 4 ways: (1) standard consent form alone, (2) standard consent form with verbal disclosure, (3) modified form alone (standard form modified to meet the federal guidelines for readability and processability), and (4) modified form with verbal disclosure. MAIN OUTCOME MEASURES: Parents were interviewed to determine their understanding of 11 elements of consent, including study purpose, protocol, risks, benefits to child (direct), benefit to others (indirect), freedom to withdraw, alternatives, duration of study, voluntariness, confidentiality, and whom to contact. Their responses were scored by 2 independent assessors. RESULTS: Understanding of the protocol, study duration, risks, and direct benefits, together with overall understanding, was greater among parents who received the modified form (P<.001). Additionally, parents reported that the modified form had greater clarity (P = .009) and improved layout compared with the standard form (P<.001). When parents were shown both forms, 81.2% preferred the modified version. CONCLUSIONS: Results suggest that a consent form written according to federal guidelines for readability and processability can improve parent understanding and thus will be important in enhancing the informed consent process. (39 references) (Author)

20051007-13

When a simple `yes' or `no' is not enough. Fraser J (2005), Practising Midwife vol 8, no 9, October 2005, pp 42-43

Obtaining consent for medical treatment is usually straightforward, but sometimes the issues can be difficult and require legal advice. (1 references) (Author)

20050824-28

Ethics watch. Robinson J (2005), Association for Improvements in Maternity Services (AIMS) vol 17, no 2, 2005, pp 3-4

Editorial discusses the issues of 'consent' and 'informed choice' in maternity care and calls for an update on the Charter for Ethical Research in Maternity Care. Outlines some of the issues that need to be discussed with the National Childbirth Trust, the Maternity Alliance and Consumers for Ethics in Research and invites comments from readers to aid this discussion. (5 references) (CR)

20050718-4

Survey of informed consent for registration of congenital anomalies in Europe. Busby A, Ritvanen A, Dolk H, et al (2005), BMJ vol 331, no 7509, 16 July 2005, pp 140-141

Presents the findings of surveys conducted to report congenital abnormalities registries' experiences of opt-in informed consent. (5 references) (MB)

20050623-25

Adolescents and informed consent. Ethical and legal issues. Tillett J (2005), Journal of Perinatal and Neonatal Nursing vol 19, no 2, April-June 2005, pp 112-121

The right of adolescents to consent to various types of healthcare vary widely from state to state. Nurses have a responsibility to be aware of the issues surrounding adolescent consent and to know what state statutes guide the healthcare provider. This article describes the issues surrounding adolescent consents, including contraception, abortion, prenatal care, sexually transmitted disease testing and treatment, confidentiality, and paternity among other topics. (44 references) (Author)

20050405-41

Epidurals: why the epidemic?. Richardson H (2005), Birthing vol 8, no 1, Spring 2005, pp 9-11

Article questioning why more than ninety percent of women in Canada have epidurals. Suggests that this comes from society's view that a woman cannot successfully give birth to a healthy baby without intervention. Emphasises that women choosing epidurals must be provided with the information that will enable them to make an informed decision. (CR)

20050310-8

Consent for screening and immunisation procedures in children and young people. Moreton J, Bedford H, Elliman D (2005), Community Practitioner vol 78, no 3, March 2005, pp 83-84

Just who can give consent for procedures on behalf of a child? Here, we look at who should be informed and why, how young people can refuse treatment, and in what instances their decisions can be overridden. (7 references) (Author)

20050307-9

Will exercising informed consent stop 'unfortunate experiments'?. Young D (2005), Birth vol 32, no 1, March 2005, pp 1-3

Discusses ethical issues relating to a research project carried out in New Zealand between 1955 and 1976, which examined the natural history of carcinoma in the cervix in a group of women with abnormal cells. One group received treatment, the other did not, and the women were not told that they were 'subjects' in a research study. Outlines the impact that this study had on informed consent policies and briefly examines the issue of informed consent in relation to obstetrics. (9 references) (SB)

20050218-20

Good practice in consent. Cooke RWI (2005), Seminars in Fetal and Neonatal Medicine vol 10, no 1, February 2005, pp 63-71

Informed parental consent reminds the health professional to respect parent autonomy with respect to their infant's health care. It involves at least four elements: information, assessment of understanding, assessment of capacity, and freedom to choose. Critical issues are training of staff, timing of approach, and quality and presentation of information. In the newborn period, additional problems include parental distress and competence, consent for research into emergency treatments (exceptions to this are proposed below); screening for future disease, circumcision and withdrawing intensive care are considered as special cases. Variation in practice and policies in European neonatal units is described. (26 references) (Author)

20050217-5

Informed consent in the (mis)information age. Nelson EL (2004), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 26, no 1, January 2004, pp 43-48

Recent studies suggest that large numbers of health-care consumers are turning to the Internet as a source of health information. This article considers the potential impact of on-line health information on women's health-care decisions, and the role of physicians relating to their patients' use of the Internet as an information source. In particular, the article examines the effect of on-line health information on the informed consent process. Physicians' disclosure obligations (their legal duty to provide information to patients) and the law of informed consent are briefly described. The article then considers the Internet as a source of health information, and instances and types of misinformation. Finally, the article suggests steps physicians may take to help their patients benefit from Internet health information and to become critical consumers who do not fall victim to inaccurate or misleading information. The article concludes by suggesting that physicians make a practice of asking their patients about alternate sources of information they may have accessed, in order to help ensure that patients' health-care decisions are based on current, accurate, and complete information. (36 references) (Author)

20050215-36

Consent and caesarean section. Dass M (2005), Current Obstetrics and Gynaecology vol 15, no 1, February 2005, pp 60-64

Clinical Governance has ensured that risk management is an integral part of medical practice. All doctors are closely involved in applying legal principles in their daily practice, with the commonest and most important being consent. Consent, patient choice and co-operation are important aspects of health care in relation to decision-making. A patient can either assent to treatment or refuse it, provided he/she is competent. Consent requires the relevant mental

capacity, which means that the patient is able to receive information and retain it, believe in it, weigh it up and communicate the decision. This decision must be given freely, without undue duress or coercion from either third parties or health professionals. With the help of two case scenarios, this article illustrates issues that could arise in connection with consent, involving competent pregnant women. (25 references) (Author)

20050106-5

Consent. Obtaining permission to care. Oxtoby K (2005), Nursing Times vol 101, no 1, 4 January 2005, pp 22-24

Consent is needed for much more than just surgical procedures and invasive investigations - touching a patient without consent could be a matter for the courts. Kathy Oxtoby looks at the key factors involved in consent and how nurses can improve their skills. (Author)

20041213-26

Partner consent for participation in women's reproductive health research. American College of Obstetricians and Gynecologists (2004), Obstetrics & Gynecology vol 104, no 6, December 2004, pp 1467-1469

Recent advances in reproductive medicine include treatment of subfertility as well as investigation of agents that may serve as both contraceptives and potential prophylaxis against sexually transmitted diseases including potential protection from human immunodeficiency virus (HIV). Although there is no doubt regarding the need for informed consent by women participating in trials evaluating the safety and effectiveness of these novel agents and treatments, there has been some debate regarding the necessity and propriety of requiring consent from the partners of women involved in certain types of clinical trials involving reproductive health. Issues of partner consent are unique to research surrounding women's reproductive health as opposed to research pertaining to women's health, in general. This is due, in part, to a valid concern about a potential effect of the research on the partner. There are, therefore, legitimate reasons to obtain partner consent for a woman's participation in a clinical trial. In the absence of such reason, partner consent should not be mandated. (6 references) (Author)

20041213-25

Informed refusal. American College of Obstetricians and Gynecologists (2004), Obstetrics & Gynecology vol 104, no 6, December 2004, pp 1465-1466

Informed refusal is a fundamental component of the informed consent process. Informed consent laws have evolved to the 'materiality or patient viewpoint' standard. A physician must disclose to the patient the risks, benefits, and alternatives that a reasonable person in the patient's position would want to know to make an informed decision. Throughout this process, the patient's autonomy, level of health literacy, and cultural background should be respected. The subsequent election by the patient to forgo an intervention that has been recommended by the physician constitutes informed refusal. Documentation of the informed refusal process is essential. It should include anotation that the need for the intervention, as well as risks, benefits, and alternatives to the intervention, and possible consequences of refusal, have been explained. The patient's reason for refusal also should be documented. (2 references) (Author) [Replaces ACOG Committee Opinion no 237, June 2000]

20041213-15

Melissa Rowland and the rights of pregnant women. Minkoff H, Paltrow LM (2004), Obstetrics & Gynecology vol 104, no 6, December 2004, pp 1234-1236

On March 11, 2004, the State of Utah charged Melissa Rowland with the murder of her stillborn fetus, claiming that the death resulted from her rejection of the advice of her physicians to have a cesarean delivery. Although Ms. Rowland avoided the homicide charge by pleading guilty to lesser child endangerment charges, the approach taken by the State raises important and troubling issues regarding the autonomy rights of pregnant women, as well as their right to speak on behalf their unborn children. We use this case to review relevant ethical principals and legal precedents. We conclude that if Ms. Rowland is to be judged legally culpable for the death of her fetus, then the courts must first create a new and significant exception to the doctrine of informed consent and the common law and constitutional principles upon which it is based. Such a precedent could introduce a substantial disparity between the rights of pregnant women and those of all other persons. We would argue that a better means of assuring the health interests of the pregnant woman and the fetus in similar circumstances is through advocacy by obstetricians for pregnant women's fully realized rights, including the right to informed consent. (5 references) (Author)

20041213-12

Should refusal to undergo a cesarean delivery be a criminal offense?. Berkowitz RL (2004), Obstetrics & Gynecology vol 104, no 6, December 2004, pp 1220-1221

Discusses the case of a woman charged with the murder of her stillbirth twin baby in Utah, United States of America, after refusing to have a caesarean section, and argues that informed consent means that individuals have the right to refuse a medical option offered. (5 references) (SB)

20041112-80

Extremely preterm birth and parental authority to refuse treatment - the case of Sidney Miller. Annas GJ (2004), The New England Journal of Medicine vol 351, no 20, 11 November 2004, pp 2118-2123

Discusses the court case brought by the parents of Sidney Miller, who had a gestational age of 23 weeks at birth, against the hospital where she was born, and its parent company, HCA. Describes the circumstances under which parental decisions concerning the treatment of the baby were not adhered to, resulting in claims of battery and negligence. Gives details of the state of health of the child (aged seven at the time of the trial) who was legally blind, severely mentally retarded, and suffered cerebral palsy, seizures, and spastic quadriparesis in her limbs. (13 references) (JSM)

20041011-6

Informed choice in maternity care. Hewson B (2004), In: Kirkham M ed. Informed choice in maternity care. Basingstoke: Palgrave Macmillan 2004, pp 31-56

Discusses issues related to informed choice in maternity services, such as informed consent, legal issues, birth plans, refusal of treatment and screening. Also examines the relationship between the pregnant woman and the fetus and the experience of pregnant drug users in the United States. (74 references) (MB)

20040930-44

Implications of informed consent for obstetric research. Spencer SA, Dawson A (2004), Obstetrician and Gynaecologist vol 6, no 3, 2004, pp 163-167

The new Research Governance Framework places emphasis upon gaining fully informed consent from all potential research participants. In obstetric practice, research projects often involve emergency procedures or treatments at a time when women are distressed. There is a growing tendency not to involve such women in research because of the difficulty in obtaining consent. This could result in failure to develop improved treatments for mothers and babies. This review discusses some of these problems and suggests a number of ways to improve knowledge of research at an early stage of pregnancy as a way of addressing them. (30 references) (Author)

20040920-17

Consent and the law. Lupton M (2004), Current Obstetrics and Gynaecology vol 14, no 5, October 2004, pp 363-367

English medical law has come about in a fairly ad hoc manner and the law governing consent has evolved both from statute and common law. A doctor needs a patient's consent before he/she may lawfully touch them, and for that consent to be valid it needs to be given by an appropriately informed person who has the capacity to consent to the intervention in question. A competent adult may refuse any treatment for any reason. A competent minor, however may consent to treatment but may not always refuse it. In an emergency a doctor may act out of necessity in the best interests of their patient. (Author)

20040824-32

Not what the doctor ordered. Adamson A (2004), Midwifery Matters no 102, Autumn 2004, p 12

Presents a case study of a situation where a woman's informed consent to her newborn infant being given an antibiotic injection was assumed by the medical staff attending her rather than purposefully obtained. Considers whether labouring or newly delivered women can be expected to be able to give consent to treatment after the situation has been communicated to them only once. (RM)

20040813-5*

Intrapartum prevention of meconium aspiration syndrome. Cuttini M (2004), The Lancet vol 364, no 9434, 14 August 2004, pp 560-561

Comments on the research strategy adopted by Vain et al in its study of the perinatal management of infants born

through meconium-stained amniotic fluid (MSAF) (1), which included waiving informed consent on the grounds of the minimal risk assumption. (1) Vain et al. Oropharyngeal and nasopharyngeal suctioning of meconium-stained neonates before delivery of their shoulders: multicentre, randomised controlled trial. Lancet, 2004, vol 364, pp 597-602. (11 references) (RM)

20040723-31

Demographic differences between consenters and non-consenters in an obstetric anesthesiology clinical study. Wang LF, Tait AR, Polley LS (2004), International Journal of Obstetric Anesthesia vol 13, no 3, July 2004, pp 159-163

Willingness to participate in obstetric anesthesiology clinical studies may be influenced by age, parity or ethnicity. This study was designed to determine whether there were demographic differences between consenters and non-consenters in a minimum local analgesic concentration clinical study. Four hundred and fifty-two women were approached for the study and the age, ethnicity and parity of patients who consented or declined to participate were collected. Ethnicity was categorized as Asian or Pacific Islander, black, Hispanic, white, or other. Parametric data were analyzed using t-tests and non-parametric data using X2 tests. There were no significant differences in the consent rate based on age or parity. Black Americans were more likely to consent than Asian Americans ($P < 0.001$) and as likely to consent as white Americans. There were no statistically significant differences in the consent rate between Caucasian and Asian Americans. More studies are needed to determine the socioeconomic and demographic factors that affect consent rates of labor patients. (31 references) (Author)

20040707-18

Protecting vulnerable patients. O'Dowd A (2004), Nursing Times vol 100, no 27, 6 July 2004, pp 12-13

Reports on the proposals contained in the Mental Capacity Bill granting patients lacking mental capacity the right to draw up an advance directive ('living will') concerning their medical treatment. (RM)

20040706-21

Neonatal research: the parental perspective. Stenson BJ, Becher JC, Mcintosh N (2004), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 89, no 4, July 2004, pp F321-F324

OBJECTIVES: To investigate the recollections of parents consenting for their infants to be research subjects and determine their views about the need for consent. SUBJECTS: Parents of 154 sick newborn infants enrolled in a randomised trial in the early neonatal period. All parents had given written consent and received printed information. METHODS: A questionnaire and accompanying letter was sent to the parental home 18 months later. Non-responders were sent a further questionnaire and letter. RESULTS: Response rate was 64% (99/154). Some respondents (12%) did not remember being asked to consent to their baby joining a study, and a further 6% were unsure. Most of the respondents (79%) were happy, 13% neutral, and 8% unhappy with their decision to give consent. None felt heavy pressure to agree. Entering the trial caused 24% of respondents to feel more anxious, 56% neutral, and 20% less anxious about their baby. Most of the respondents (83%) would be unhappy to forgo the consent process for trials passed by the institutional ethics committee. CONCLUSIONS: A significant proportion of parents who give written consent for a trial in the early neonatal period do not later remember having done so. Parents who have had experience of neonatal research would be unhappy for their baby to be enrolled in a study that had ethics committee approval without their consent being obtained. (28 references) (Author)

20040622-16

Teaching informed consent in your childbirth classes. Johns L (2004), International Journal of Childbirth Education vol 19, no 2, June 2004, pp 42-43

Provides a personal account from a childbirth educator of teaching informed consent. Describes the preparations the author makes and structure of the classes. (MB)

20040621-29

Patterns of consent in epidemiologic research: evidence from over 25,000 responders. Dunn KM, Jordan K, Lacey RJ, et al (2004), American Journal of Epidemiology vol 159, no 11, 1 June 2004, pp 1087-1094

Ethical guidelines in the United Kingdom require written consent from participants in epidemiologic studies for follow-up or review of medical records. This may cause bias in samples used for follow-up or medical record review. The authors analyzed data from seven general population surveys conducted in the United Kingdom (1996-2002), to which over 25,000 people responded. Associations of age, gender, and symptom under investigation with consent to

follow-up and consent to review of medical records were examined. Consent to follow-up was approximately 75-95% among survey responders under age 50 years but fell among older people, particularly females. Consent to follow-up was also higher among responders who had the symptom under investigation (pooled odds ratio = 1.61, 95% confidence interval: 1.36, 1.92). Consent to review of medical records followed a similar pattern. Patterns of consent were relatively consistent and represented a high proportion of responders. Males, younger people, and subjects reporting the symptom under investigation were more likely to give consent, and these groups may be overrepresented in follow-up samples or reviews of medical records. Although consent is high among responders, the additive effect of nonresponse and nonconsent can substantially reduce sample size and should be taken into account in epidemiologic study planning. (28 references) (Author). Reviewer's comments: This study has reviewed data from seven general population based surveys in the UK. The method of selecting these surveys is unclear. However, the authors describe similarities in the methods of recruitment to each of the surveys and the sampling frame was consistent throughout. It appears that the studies included in this review were all undertaken in one academic institution and the authors acknowledge the limitations of this approach in terms of generalisability of the findings. Most of the studies included in this review surveyed both men and women and pain was the symptom of investigation. The focus of one of the studies, however, was increased vaginal bleeding; a symptom that only affects women and can be, but is not always, accompanied by pain. It would be interesting to know why this particular survey was included in this review. It is possible that the nature of the symptom under investigation may influence a patient's decision to agree or decline to take part in a research survey. In the survey of increased vaginal bleeding included in this review a high proportion of women consented to follow up and review of medical records. Including other surveys that focus on this symptom, or similar symptoms that affect women may have provided a more accurate idea of consent rates by women experiencing these symptoms. In examining patterns of consent in this review the authors primarily considered the effects of age and gender. Though these variables are important to consider in an epidemiological study, other variables may also influence the decision to consent or decline, as the authors found, those patients who reported that they were symptomatic were more likely to respond to the survey. As the authors suggest, increasing the sample size may capture more respondents with under-represented variables but may not alter the proportions responding between groups and where specific variables are thought to be influential it may be appropriate to target those specific patients as part of the recruitment process. This is an interesting review that gives a different perspective to random/cohort samples and suggests that even when these scientific methods of sample selection are applied, specific variables may limit the findings of the study. From a midwifery perspective this paper is difficult to read and interpret, though the findings may be important to consider in the planning of large (quantitative) epidemiological studies. In the past few years midwifery research has become more focused around a qualitative approach that does not necessarily require a large representative sample. Epidemiological studies such as those included in this review describe numbers based on pre-defined general and demographic variables and suggest that the findings can be generalised to the population. The information these studies produce tends to be superficial and, as such, may be more useful in addressing the provision of care rather than the quality of care. As midwives we need to be aware of epidemiological studies because they will be often be considered by policy makers and inform the basis recommendations for practice. We should be mindful that these data do not consider the depth and quality of the individual experience of care. As such, we should think about the way in which we implement policy into our daily practice and how we can apply recommendations of policy and national guidelines in the context of the individual woman for whom we are providing care. Midwifery practice, like other areas of health care, will be limited by external factors such as the effect of the economic climate on the availability of resources. The challenge is to be able to offer women and their families a quality experience that can be feasibly delivered to achieve a balance between the epidemiological evidence for the general provision of care and the qualitative evidence for the individual experience of care. To do this, we need to be aware and have an understanding of the external influences and the wider political picture. Comments written by Helena Knowles, senior lecturer.

20040609-16

[Court order obtained by a Pennsylvania hospital to force a woman to have a caesarean section]. (2004), Birth vol 31, no 2, June 2004, pp 155-6

Reports that a hospital in Pennsylvania sought and obtained a court order to force a woman to have a caesarean section without her consent. The family fled the hospital and found another where she delivered a healthy baby vaginally. (RM)

20040604-35

Dimensions of informed consent to treatment. Dickens BM, Cook RJ (2004), International Journal of Gynecology & Obstetrics vol 85, no 3, June 2004, pp 309-314

Modern law approaches patients' consent to treatment not only through liability for unauthorized touching, namely criminal assault and/or civil (non-criminal) battery, but also through liability for negligence. Physicians must exercise appropriate skill in conducting procedures, and in providing patients with information material to the choices that patients have to make. The doctrine of informed consent serves the ethical goal of respecting patients' rights of self-determination. Information is initially pitched at the reasonable, prudent person in the patient's circumstances, and then fine-tuned to what is actually known about the particular patient's needs for information. Elements to be disclosed include the patient's prognosis if untreated, alternative treatment goals and options, the success rate of each option, and its known effects and material risks. Risks include medical risks, but also risks to general well-being such as economic and similar reasonable interests. Consent is a continuing process, not an event or signed form. (25 references) (Author)

20040527-1

Is it murder to refuse a caesarean?. Hewson B (2004), Association for Improvements in Maternity Services (AIMS) vol 16, no 1, 2004, pp 1, 3-4

Discusses the implications of the case of a cocaine-using woman in Salt Lake City, Utah who has been charged with murder following her refusal to have a caesarean section after fetal distress of her twin fetuses was allegedly diagnosed, with the outcome that one of the twins was stillborn. Considers the circumstances of the case in the context of US laws on the legal status and rights of the fetus generally, and where the mother is found to have used illegal drugs or other harmful substances during the pregnancy. Outlines efforts in the UK to grant legal status to the fetus. (2 references) (RM)

20040420-33

The morning after the morning-after pill. McMillan J, Hope T (2004), The Lancet vol 363, no 9417, 17 April 2004, p 1330

Discusses the case of Mary, a 20-year old woman with bipolar disorder, who is admitted to a psychiatric ward. Her friends tell staff that she has had several sexual partners in the last few days, which is uncharacteristic behaviour, so the consultant decides that it is in her best interests to take the morning-after pill. The following day, when Mary's mental state has improved, she is very distressed at having been given the pill. The appropriate care, which would have respected Mary's autonomy, is outlined. (SB)

20040414-2

The real and present danger. Biancuzzo M (2004), Breastfeeding Outlook no 1, 2004, pp 2, 7

Advocates health professionals obtaining informed consent from parents before providing infant formula. (SB)

20040330-40

Consent for regional anaesthesia in the United Kingdom: what is material risk?. Kelly GD, Blunt C, Moore PAS, et al (2004), International Journal of Obstetric Anesthesia vol 13, no 2, April 2004, pp 71-74

Legal principles that apply to the process of informed consent have changed in recent years. Patients should now be given the information that they wish to receive, not the information that health professionals may consider reasonable for them. In obstetric practice informed consent is especially important as young, fit patients may request and receive non-essential but potentially life-threatening interventions. The quantity and detail of information parturients desire do not remain static. They vary over time and from country to country. Our paper examines current opinion amongst parturients in the United Kingdom. We asked 100 obstetric patients to choose the complications of regional anaesthesia that they would like to learn about during informed consent. Nearly all women (82-94%) wished to know about common, less severe side effects. A substantial majority (70-77%) also wished to know about rarer but more severe complications, such as permanent neurological deficit, meningitis and high spinal block. Despite the availability of information for patients from sources such as the Obstetric Anaesthetists' Association and the National Electronic Library for Health, there remains little consensus amongst anaesthetists about what information to provide. Frequently some complications that patients would consider important are not discussed. Changing legal and public expectations demand that we adapt our current practice and improve the accuracy and timing of information provided. (15 references) (Author)

20040330-39

Women in the 21st century deserve more information: disclosure of material risk in obstetric anaesthesia. Plaat F, McGlennan A (2004), International Journal of Obstetric Anesthesia vol 13, no 2, April 2004, pp 69-70

Discusses the importance of informed consent for obstetric anaesthesia in the context of research published in this issue (1) that explores the disparity between the information women are receiving and what they actually want to know. 1. Kelly GD, Blunt C, Moore PAS et al. Consent for regional anaesthesia in the United Kingdom: what is material risk? International Journal of Obstetric Anaesthesia, vol 13, 2004, pp 71-74. (16 references) (SB)

20040329-86*

Nurses and 'difficult' patients: negotiating non-compliance. Russell S, Daly J, Hughes E, et al (2003), Journal of Advanced Nursing vol 43, no 3, August 2003, pp 281-287

BACKGROUND: There is a large body of nursing literature on patient non-compliance. While some articles address non-compliance as a patient problem to be resolved by nursing interventions, there is also a growing number that critique this approach. This reflects the discomfort many nurses feel about the practice of labelling patients as non-compliant. AIM: The aim of this discussion paper is to build on the critical nursing literature to offer an alternative to the interventions commonly directed at patients who do not follow health care advice. This alternative approach locates patients within their social context and focuses on those who adapt health care advice to fit with their beliefs, life situation and circumstances. The aim is to encourage nurses to learn about how health care treatments affect patients' lives, and not merely their health. METHOD: Specific nursing articles were reviewed to demonstrate the ways in which the concept of compliance is used within the nursing literature. These articles were then used to support an argument that promotes a patient-centred approach to health care. CONCLUSION: A patient-centred approach involves transferring power and authority away from health care professionals and towards patients. We encourage nurses to take a leadership role by changing the way in which health care is delivered towards a focus on patients'lives. Learning about patients' lives may assist nurses to offer health information to patients that is more relevant and, therefore, useful. (49 references) (Author)

20040324-2*

Ethical aspects of informed consent in obstetric anesthesia - new challenges and solutions. Hoehner PJ (2003), Journal of Clinical Anesthesia vol 15, no 8, December 2003, pp 587-600

Informed consent is a cornerstone and routine component of the ethical practice of modern medicine. Its full theoretical application to specific clinical situations, however, presents a number of ethical dilemmas for health care providers. Obstetric anesthesia, in particular, presents many unique challenges to the process of informed consent. In this review, the ethical background to the doctrine of informed consent within the context of 'principlism' is explored and critiqued. The application of principlism to actual clinical situations, the limitations of principlism in the peculiarities of the patient-physician encounter, as well as possible alternative models of ethical discourse is discussed. The process of informed consent can be broken down into seven elements: Threshold elements or preconditions, which include 1) decision-making capacity or competency of the patient, 2) freedom or voluntariness in decision-making, including absence of over-riding legal or state interests; informational elements, including 3) adequate disclosure of material information, 4) recommendation, and 5) an understanding of the above; consent elements, which include 6) decision by the patient in favor of a plan and 7) authorization of that plan. Each of these elements is discussed in turn, and their implications, especially for the anesthesiologist and the obstetric patient, are addressed. (Author)

20040323-53

Whoops!. Robinson J (2003), Association for Improvements in Maternity Services (AIMS) vol 15, no 4, 2003/04, p 10

Relates the experience of a 16-year old who presented at A&E complaining of abdominal pain and bleeding and was diagnosed by an obstetrician as having suffered a miscarriage at 12 weeks. After she had been given anaesthetic for evacuation of retained products of conception, it emerged that she was actually 30-32 weeks pregnant. Discusses the issue of obtaining consent and the consequences of the obstetrician's failure to perform an ultrasound examination before anaesthetic was administered. (3 references) (MB)

20040303-9

The duty to inform. Dimond B (2002), In: Dimond B. Legal aspects of midwifery. Oxford: Books for Midwives 2002. 2nd ed. pp 114-122

Of increasing importance in the field of consent is the extent and nature of the information which should be given to the mother before she decides to go ahead with certain procedures. In the case of Chatterton v Gerson the distinction was made between an action for trespass, which will not succeed if a valid consent has been given, and an action in

negligence on the basis that insufficient information has been given. What standard is applied to the giving of information to the patient? Is there a difference between where the patient asks questions compared to situations where the patient does not ask for further information? Is it ever lawful to withhold information from the patient? These questions will be considered in the light of the cases of Sidaway v Bethlem Royal Hospital Governors and others, and Blythe v Bloomsbury Health Authority. (7 references) (Author, edited)

20040303-8

Consent. Dimond B (2002), In: Dimond B. Legal aspects of midwifery. Oxford: Books for Midwives 2002. 2nd ed. pp 90-113

This chapter covers the following areas: when is consent needed?; can children consent for themselves?; who is the right person to seek consent? what information should be provided?; is the patient's consent voluntary?; does it matter how the patient gives consent?; refusals of treatment; and adults who are not competent to give consent. (28 references) (Author)

20040302-29

Ethics and consent in midwifery. Draper H (2004), In: Frith L Draper H. Ethics and midwifery. 2nd ed. 2004. Edinburgh: Books for Midwives 2004. 2nd ed, pp 19-39

Discusses the process of gaining consent and its justification in ethical theory. Explains what constitutes consent and examines circumstances in which consent can cause ethical problems for midwives. (7 references) (MB)

20040225-25*

Ethics and midwifery. Draper H, Frith L (2004), Edinburgh: Books for Midwives Press 2004. 311 pages

Contains chapters on: ethics and consent in midwifery; ethical issues relating to epidural analgesia in uncomplicated labour; routine antenatal HIV testing and its implications for informed consent; risk and normality in maternity services; midwives and sexuality; ethical issues in the neonatal intensive care unit (NICU); ethics of fetal tissue transplantation and research on embryos; reproductive technologies; midwifery and homeopathy; midwife autonomy and the code of professional conduct; ethical issues for midwifery research; and researching sensitive issues. (RM)

20040223-84

Consent and refusal. Jones SR, Jenkins R (2004), In: Jones SR Jenkins R. The law and the midwife. Oxford: Blackwell 2004. 2nd ed. pp 113-130

Discusses the development of Department of Health guidelines defining informed consent and establishing it in practice. Outlines policies for the obtaining of consent to treatment offered to mentally competent adults, to minors, to adults whose mental faculties are temporarily impaired through unconsciousness, and to adults who lack mental capacity to consent on their own behalf. Considers, with reference to case law, whether fetuses have separate rights from those of their mother. Examines the topic of home birth as a consent issue, that is, the refusal of consent to a hospital birth. (RM)

20040115-3

Whose child is it anyway? Resolving parent-physician conflict in the NICU setting. Jasper J, Clark WD, Cabrera-Meza G, et al (2003), American Journal of Perinatology vol 20, no 7, October 2003, pp 373-380

Much has been written on parental involvement in decision making when dealing with critically ill children, but few articles have touched upon parental refusal of treatment in noncritically ill children. What steps should be taken when a parent refuses what is generally considered 'standard of care' medicine for their hospitalized child? Does medical advice outweigh parental views or wishes, and what does one do when our role as physician turns from medical expert into one of medical negotiator? The following case and discussion deal with parental refusal of conventional medical care, and how one may find peaceful resolutions to challenging situations for the ultimate good of the child. (23 references) (Author)

20031216-7

Does informed consent to research require comprehension?. Sreenivasan G (2003), The Lancet vol 362, no 9400, 13 December 2003, pp 2016-2018

The doctrine of informed consent is a cornerstone of ethical medicine, both in clinical and in research settings. It consists of two parts: a duty to obtain the voluntary agreement of patients or trial participants before treatment or

enrolment; and a duty to disclose adequate information to the patient or participant before seeking this agreement. The two parts evolved separately. Indeed, the first is centuries old, whereas the second is a relatively recent development. Yet, according to the standard view of informed consent, they are best understood, morally, as closely integrated parts of a single requirement. This interpretation has an ethically weighty implication; that the validity of an individual's consent depends on him or her actually comprehending the information disclosed. To remove doubt, comprehension or understanding is often listed in addition to disclosure, voluntary participation, and competence as an explicit requirement of informed consent. (25 reference) (Author)

20031201-32

Ethics: 'life before birth' and moral complexity in maternal-fetal surgery for spina bifida. Bliton MJ (2003), Clinics in Perinatology vol 30, no 3, September 2003, pp 449-464

This article considers the ethical significance of a moral belief common among pregnant women (and their partners) who seek open uterine repair for fetal spina, namely that their fetuses are already 'babies.' The need to recognize and interact sensitively with a pregnant woman's vulnerability to her own beliefs and concerns regarding potential disabilities, the fetal intervention, and its potential outcome is emphasized. Such recognition and explicit discussions are ethically important for informed consent and to safeguard against the judgements, enthusiasms, and biases of surgeons and other team members. (57 references) (Author)

20031028-6

Consent issues during pregnancy and childbirth. Rodgers L (2002), In: Wilson JH Symon SA. [eds] Clinical risk management in midwifery: the right to a perfect baby? Oxford: Books for Midwives 2002. pp 84-95

Discusses the legal meaning of the concept of patient consent, and the application of the principle in less routine childbirth cases including where a woman is unconscious or mentally incapable. Considers the midwives role in ensuring that patients give informed consent to any treatment. (4 references) (RM)

20031014-13

Informed consent, informed refusal, and informed choices. Meyer JH (2003), American Journal of Obstetrics & Gynecology (AJOG) vol 189, no 2, August 2003, pp 319-326

Presentation by the President of the South Atlantic Association of Obstetricians and Gynecologists advising health practitioners on best practice in offering pregnant women informed choice and eliciting informed consent to their care. Illustrates the concept of informed consent by relating a story of Jehovah's Witness patient who died after refusing a life-saving blood transfusion. (15 references) (RM)

20031006-99

Is there a concept of autonomy that can usefully inform nursing practice?. Aveyard H (2000), Journal of Advanced Nursing vol 32, no 2, August 2000, pp 352-358

This paper examines evidence that the contemporary use of the term autonomy is interpreted differently by different nurses. This is important because an understanding of autonomy is crucial to our approach to informed consent prior to nursing care procedures. There are many theories of autonomy. This may account for various interpretations of the term amongst nurses. In this paper it is argued that clarity may be achieved by commitment to one particular theory of autonomy. It is suggested that this commitment should be the subject of further debate within the nursing profession. It is argued that the ambiguous use of the term autonomy should be replaced by a concept that has specific meaning for nurses and which gives a working definition to a concept that is central to respect for patient choice and independence. (20 references) (Author)

20031006-19

Should women be given a choice about fetal assessment in labor?. Wood SH (2003), MCN - American Journal of Maternal/Child Nursing vol 28, no 5, September/October 2003, pp 292-298

Continuous electronic fetal monitoring (EFM) in labor is one of the most commonly used interventions during intrapartum care. However, randomized controlled trials, observational studies, and meta-analyses about the use of continuous EFM on low-risk intrapartum patients have found no significant differences in infant outcomes between infants whose mothers had EFM or intermittent auscultation (IA) of the fetal heart rate. In addition, research shows a higher incidence of cesarean birth when EFM is used. Although evidence-based practice is supposed to be our goal, the evidence about the lack of efficacy of EFM has not been used in practice. In fact, EFM has become the standard of

practice in this country. Considering these facts, should EFM continue to be the standard of practice for low-risk laboring women? Is informed consent indicated, giving women the choice between EFM and IA? Should IA be offered to all low-risk laboring women? Ethical decision-making models are used to examine those questions and to help nurses better delineate their advocacy role. (24 references) (Author)

20031006-18

Ethical nursing practice, reconsidered. Freda MC (2003), MCN - American Journal of Maternal/Child Nursing vol 28, no 5, September/October 2003, p 286

Editorial that advocates greater reflection regarding women's informed choice and consent for procedures such as electronic fetal monitoring and antenatal screening in order to ensure that care provided is ethical. (1 reference) (SB)

20030929-27

Strategies to help patients understand risks. Paling J (2003), BMJ vol 327, no 7417, 27 September 2003, pp 745-748

Explaining risks to patients in an effective way is an essential part of ensuring that consent is 'informed'. A consultant in risk communication discusses the strategies that can help doctors to communicate risks clearly, and thereby also build closer relationships with their patients. (22 references) (Author)

20030929-26

Simple tools for understanding risks: from innumeracy to insight. Gigerenzer G, Edwards A (2003), BMJ vol 327, no 7417, 27 September 2003, pp 741-744

Bad presentation of medical statistics such as the risks associated with a particular intervention can lead to patients making poor decisions on treatment. Particularly confusing are single event probabilities, conditional probabilities (such as sensitivity and specificity), and relative risks. How can doctors improve the presentation of statistical information so that patients can make well informed decisions? (24 references) (Author)

20030929-25

Risk communication in practice: the contribution of decision aids. O'Connor AM, Legare F, Stacey D (2003), BMJ vol 327, no 7417, 27 September 2003, pp 736-740

As patients want to participate more in decision making, and as the range of medical options expands, clinicians are challenged to improve their communication of risk and supportive skills. Are practitioners' counselling skills up to the job? (18 references) (Author)

20030929-24

Influence of the law on risk and informed consent. Mazur DJ (2003), BMJ vol 327, no 7417, 27 September 2003, pp 731-732, 733-734

Patients are now routinely given information on risks of treatment as part of informed consent. This has occurred partly in response to legal judgments, but further issues continue to be raised by modern medicine and research that need to be approached proactively. (15 references) (Author)

20030901-2*

Consent in clinical practice. Mayberry M, Mayberry J (2003), Abingdon: Radcliffe Medical Press 2003. 123 pages

This book explores the principles underpinning informed consent and explores issues such as autonomy, beneficence, and justice within the context of modern society. The capacity to provide consent is defined and determined, along with the amount and quality of information required to underpin a valid consent. Although the authors are not lawyers, they provide some insight into the law that underpins the practice surrounding what we tell clients about procedures and interventions. It was useful to have the cases that have influenced practice explained, such as the Bolam and Sidaway cases. The information is in an easy-to-read format, and there is no need for extensive previous knowledge of legal or ethical theory. Against that, there is scope for greater depth of debate, with more consideration of how from a moral perspective more, or less, information and/or capacity to understand could still be argued to be appropriate. Reviewed by Elizabeth Cluett, midwifery lecturer, Southampton University. [Full review on MIDIRS website]

20030814-73

Advanced directives and midwifery care. Sanders LB (2003), Journal of Midwifery & Women's Health vol 48, no 4, July/August 2003, pp 278-281

The Patient Self-Determination Act was passed by the U.S. federal government in 1990 and became effective in December 1991. This federal law requires institutions that accept Medicaid funding to provide written information about rights to make decisions about medical care to all persons admitted for care. To meet federal guidelines, many health care institutions provide this information in the admission packet. Studies have shown that compliance with addressing this subject has been uneven at best and that providers may be uncomfortable discussing this issue with clients. Midwife-attended births accounted for 7.3% of all births in 2000. The majority of these births occur in the hospital setting; therefore, laboring women are subject to the Patient Self-Determination Act. This article addresses the responsibilities of the certified nurse midwife/certified midwives in counseling women and their families regarding advanced directives. (13 references) (Author)

20030813-70

Critical incidence analysis: informed consent and the use of vaginal examinations during labour. O'Loughlin E (2003), RCM Midwives Journal vol 6, no 8, August 2003, pp 352-355

Account by a student midwife of a critical incident that occurred during a placement in which a labouring woman was caused considerable distress and discomfort by the performance of vaginal examinations without her informed consent. (38 references) (RM)

20030813-53

Involving patients in medical education. Howe A, Anderson J (2003), BMJ vol 327, no 7410, 9 August 2003, pp 326-328

Examination of what is known about involving patients in medical education in order to suggest ways to improve learning and patient satisfaction. Considers the barriers to patient understanding which may influence their ability to give informed consent to treatment. (24 references) (RM)

20030718-33

Step 53: Consent to treatment. Dimond B (2003), British Journal of Midwifery vol 11, no 5, May 2003, pp 276

Discussion of the law relating to informed consent to medical treatment following the publication of the Kennedy report on the Bristol Royal Infirmary Inquiry and the Department of Health guidelines Reference Guide for Consent to Treatment and Examination (2001) and Good Practice in Consent Implementation Guide (2001). Describes the four forms which can be used by all health professionals. (5 references) (RM)

20030710-55

Supervision in action: developing a guidance paper on consent and treatment of minors. Kulkielka M (2002), RCM Midwives Journal vol 5, no 5, May 2002, pp 204-205

This paper describes the development and implementation of a `guidance paper' on consent and refusal of treatment in pregnant teenagers under 18. (Author)

20030703-7

Women's satisfaction with their involvement in health care decisions during a high-risk pregnancy. Harrison MJ, Kushner KE, Benzies K, et al (2003), Birth vol 30, no 2, June 2003, pp 109-115

BACKGROUND: Increasingly, women seek involvement in decisions about their health care. The purpose of this study was to examine women's experience of, and satisfaction with, their involvement in health care decisions during a high-risk pregnancy. METHODS: Forty-seven women with hypertension or threatened preterm delivery (including multiple births) were interviewed after the birth of their child. They received prenatal care at home from nurses in a community program or were hospitalized. The in-depth interviews were audiotaped and transcribed; data were analyzed using constant comparative methods. RESULTS: Women identified an increased feeling of responsibility for the health of their baby and themselves, but differed in choosing active or passive involvement in health care decisions. Women who wanted active involvement achieved it through one of three processes: struggling for, negotiating, or being encouraged. Women who wanted passive involvement and women facing health crises used the process of trusting
in the expertise of nurses and physicians. Women were satisfied if the care from health care professionals was congruent with how they wanted to be involved in decision-making. CONCLUSIONS: Although most women want to be actively involved in health decision-making during a high-risk pregnancy, some prefer a passive role. The setting of

prenatal care, community-based or in-hospital, was less important than the ability of nurses and physicians to support the woman in her preferred role in decision-making. (24 references) (Author)

20030701-18

Informed consent and childbirth: coming to terms with the 21st century?. Longmore P (2003), O & G vol 5, no 1, March 2003, pp 40-44

Discusses the importance of informed consent for childbirth and the need for non-biased antenatal education that adequately informs women of the risks of all procedures and modes of delivery. (22 references) (SB)

20030625-103

Knowledge is power. Hill K (2003), Health Service Journal vol 113, no 5858, 5 June 2003, p 33

Discussion of different methods of obtaining and recording patients' informed consent to their treatment, including use of an information sheet for each patient recording their beliefs and attitudes; proper use of patient information leaflets; and use of an electronic patient information system. (RM)

20030415-46

Ethical principles and parental choice: treatment options for neonates with hypoplastic left heart syndrome. Zeigler VL (2003), Pediatric Nursing vol 29, no 1, January-February 2003, pp 65-69

Nurses caring for children with congenital heart disease face unique challenges, especially when caring for neonates diagnosed with hypoplastic left heart syndrome (HLHS). The treatment options for these neonates present difficult choices for the child's decision makers and are not without significant life-altering consequences. In order to assist in the decision-making process, nurses as patient and family advocates should acknowledge the unique role they play in the informed consent process, while simultaneously identifying specific ethical principles that are components of this process. By incorporating the principles of autonomy, beneficience, and veracity into specific nursing interventions, nurses can assist families in making informed decisions regarding a treatment option that is best for the child as well as the family. (Author)

20030410-14

Informed consent during labour and client's expectations and satisfaction comparing the practice of midwives and doctors. Ozeki N, Shindo S, Tamakuma K, et al (2002), In: International Confederation of Midwives. Midwives and women working together for the family of the world: ICM proceedings CD-ROM Vienna 2002. The Hague: ICM 2002. 4 pages

The doctor-patient relationship in Japan has been one of paternalism, yet the concepts of informed consent and client's rights have gradually been gaining ground in Japanese society since the early 1980s. This research compared the extent to which midwives and doctors sought informed consent and protected clients' rights during labour. An original anonymous questionnaire was given to mothers and collected by post. Clients' expectations of doctors and midwives were more less the same. However, clients felt that midwives practiced informed consent and protected clients rights more readily than doctors (P < 0.05). Client satisfaction was much higher with midwives than with doctors (P <M 0.01). 62.7% of clients felt that the care they received affected their mental state after delivery. (Author)

20030401-15

Readability standards for informed-consent forms as compared with actual readability. Paasche-Orlow MK, Taylor HA, Brancati FL (2003), The New England Journal of Medicine vol 348, no 8, 20 February 2003, pp 721-726

BACKGROUND: Institutional review boards (IRBs) are charged with safeguarding potential research subjects with limited literacy but may have an inadvertent role in promulgating unreadable consent forms. We hypothesized that text provided by IRBs in informed-consent forms falls short of the IRBs' own readability standards and that readability is influenced by the level of research activity, local literacy rates, and federal oversight. METHODS: To test these hypotheses, we conducted a cross-sectional study linking data from several public-use sources. A total of 114 Web sites of U.S. medical schools were surveyed for IRB readability standards and informed-consent-form templates. Actual readability was measured with the Flesch-Kincaid scale, which assigns a score on the basis of the minimal grade level required to read and understand English text (range, 0 to 12). Data on the level of research activity, local literacy rates, and federal oversight were obtained from organizational Web sites. RESULTS: The average readability score for text provided by IRBs was 10.6 (95 percent confidence interval, 10.3 to 10.8) on the Flesch-Kincaid scale. Specific readability standards, found on 61 Web sites (54 percent), ranged from a 5th-grade reading level to a l0th-grade reading level. The mean Flesch-Kincaid scores for the readability of sample text provided by IRBs exceeded the stated

standard by 2.8 grade levels (95 percent confidence interval, 2.4 to 3.2; P<0.001). Readability was not associated with either the level of research funding (P=0.89) or local rates of literacy (P=0.92). However, the 52 schools that had been made subject to oversight by the Office for Human Research Protections (46 percent) had lower Flesch-Kincaid scores than the other schools (10.2 vs. 10.9, P= 0.005). CONCLUSIONS: IRBs commonly provide text for informed-consent forms that falls short of their own readability standards. Federal oversight is associated with better readability. (40 references) (Author)

20030303-67*

Autonomy, privacy and informed consent 2: postnatal perspective. Scott PA, Taylor A, Valimaki M, et al (2003), British Journal of Nursing vol 12, part 2, January 2003, pp 117-127

The nursing and healthcare ethics literature over the past 10 years has focused on issues of patient autonomy and patient rights. Despite the growing volume of literature exploring such topics, there is little empirical work investigating what is actually happening in clinical nursing or midwifery practice in relation to patient autonomy, privacy or informed consent, from the perspective of either patients or staff. This four-part series reports the results of a Scottish study that formed part of a multisite comparative research project funded by the European Commission, investigating issues of patient autonomy, privacy and informed consent. This article, the second of four, explores the issues of autonomy, privacy and informed consent in maternity care. The research questions asked were: (1) What is the perception of mothers' autonomy, privacy and informed consent in Scottish NHS hospitals, from the point of view of both mothers and midwives? (2) Are there differences in the perceptions of mothers and midwives on these issues? Data were collected by a self-completion questionnaire for mothers (n = 243) and staff (n = 170) on postnatal units in both district general and university teaching hospital. Results indicated that there are differences between the perceptions of mothers and midwives in relation to mothers' autonomy, privacy and informed consent. Most differences were found in the information-giving and decision-making elements of autonomy. (31 references) (Author)

20030227-51*

Guidelines for consent and the provision of information regarding proposed treatment. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (2000), East Melbourne, Australia: Royal Australian and New Zealand College of Obstetricians and Gynaecologists 2000. 3 pages

Position statement from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists regarding informed consent. (SB) [Superseded by March 2006 update].

20030227-44*

Consent: what you have a right to expect: a guide for parents. (2001), London: Department of Health 2001. 5 pages

Guide for parents regarding responsibilities for giving consent for research and treatment. (SB)

20030224-40*

Consent and vaginal breech deliveries. Menjou M (2001), Health Care Risk Report November 2001, pp 6-7

Maternity units should be aware of the increasing importance of consent before breech vaginal delivery. Here two recent cases and their risk management implications are reviewed in light of Royal College of Obstetricians and Gynaecologists (RCOG) guidelines. (6 references) (Author)

20030214-21

Informed consent and the history of inclusion of women in clinical research. Stevens PE, Pletsch PK (2002), Health Care for Women International vol 23, no 8, December 2002, pp 809-819

The purposes of this paper are to (a) discuss the troubled history of informed consent for research on women and its ramifications for women and its ramifications for women's participation in clinical trials; (b) interrogate current informed consent practices as to their accountability and justice in the treatment of women; and (c) recommend to nurse researchers and clinical nurses ways of improving the practice of informed consent in research with women. (36 references) (Author)

20030107-2

Consent: whose decision is it anyway?. Panting G (2002), General Practitioner 14 October 2002, p 38

Legal expert Dr Gerard Panting explains the legal and ethical issues in seeking informed patient consent. (Author)

20030106-78*

Informed consent: from good intentions to sound practices. A report of a seminar. Wood SY, Friedland BA, McGory CE (2002), New York: Population Council 2002. 43 pages

This document is the outcome of a seminar convened in May 2001 by the Population Council's Robert H Ebert Program on Critical Issues in Reproductive Health. The seminar brought together researchers, ethicists, and advocates from a range of international organizations, who were challenged to think about the meaning of informed consent for researchers and study participants, and to take concrete steps to improve the informed consent process in our own research. A goal of the meeting was to put informed consent into historical and contemporary perspective and to explore ways that the barriers to effective implementation can be overcome. This report synthesizes the presentations and discussions at the seminar, which examined informed consent within the context of ethical research, including the elements of informed consent, how perception of risk plays a role in the informed consent process, how informed consent can vary in different contexts and within different populations, studies of informed consent, and the cost/benefit of informed consent in the research process. (Publisher)

20030103-71*

A criterion audit of women's awareness of blood transfusion in pregnancy. Khadra M, Rigby C, Warren P, et al (2002), BMC Pregnancy and Childbirth vol 2, no 7, 2002. 13 pages

Background: In the Confidential Enquiry into Maternal Deaths (CEMD) Report, the very high risk of mortality in women who refuse blood transfusions is highlighted. The objectives were to establish current knowledge about, and views of transfusion in our pregnant population and to establish the level of compliance with the set audit standard. Method: Questionnaire survey of 228 women, including both high and low risk pregnancies, attending antenatal clinic between 2-9 May 2000 at the North Staffordshire Maternity Hospital, Stoke on Trent. Results: The response rate was 100%. Only 43% were aware of the possible need for blood transfusion in pregnancy. If a blood transfusion was required, 92% stated that they would accept a blood transfusion in pregnancy. Four percent stated that they would not accept a transfusion because of religious reasons and risk of infection and the remaining four percent did not declare a reason. Conclusions: This short survey identified that 57% of women were not aware of the possible need for blood transfusion during pregnancy. There is a need for more information to be shared on this subject with all antenatal women. Women who would refuse a transfusion need to be identified at booking and be referred for counselling and a management plan made for pregnancy, labour and delivery. (16 references) (Author)

Full URL: www.biomedcentral.com

20021219-15

Informed consent: moral necessity or illusion?. Doyal L (2001), Quality in Health Care vol 10, suppl 1, September 2001, pp i29-i33

There is a professional and legal consensus about the clinical duty to obtain informed consent from patients before treating them. This duty is a reflection of wider cultural values about the moral importance of respect for individual autonomy. Recent research has raised practical problems about obtaining informed consent. Some patients have cognitive and emotional problems with understanding clinical information and do not apparently wish to participate in making decisions about their treatment. This paper argues that such research does not undermine their potential to provide informed consent. Rather, sufficient resources are required to create better communication skills among clinicians and more effective educational materials for patients. Finally, cognitive and emotional inequality among patients is maintained to be a reflection of wider social and economic inequalities. Researchers who take the right to informed consent seriously should also address these. (40 references) (Author)

20020919-54

Perinatal pathology in Australia after Alder Hey. Khong TY, Arbuckle SM (2002), Journal of Paediatrics and Child Health vol 38, no 4, August 2002, pp 409-411

Brief description of events leading to the questioning of autopsy practices in perinatal pathology in the United Kingdom and elsewhere and discussion of the importance of informed consent. (16 references) (KL)

20020827-50

Informed consent for labour epidurals: what labouring women want to know. Jackson A, Henry R, Avery N, et al (2000),

Canadian Journal of Anesthesia vol 47, no 11, 2000, pp 1068-1073

Purpose: To determine A) what a labouring woman expects to hear about epidural analgesia before consenting, B) if she feels able to understand the risks and thereby assess if we are obtaining informed consent. Methods: Sixty actively labouring women were surveyed immediately after requesting an epidural. Demographic, labour, epidural and consent information were included in the questionnaire. Answers were categorical (yes/no, multiple choice) or scored on a scale from 0 to 10 (visual analogue scale). Results: The majority of parturients wanted all potential epidural complications but not their incidences disclosed in the consent process. However, a discussion of risks would not dissuade women from consenting to an epidural in the majority of cases. Labouring women have a moderate understanding of epidural risks. The ability to understand risks was not affected by labour pain, anxiety, opioid premedication, duration of labour pain, desire for an epidural, previous epidural experience, level of education or age. Conclusion: This prospective survey characterizes what 60 reasonable labouring women wanted to know about labour epidural analgesia. Parturients wanted all risks of epidural analgesia disclosed in the informed consent process. The majority of women did not want the incidences quoted. This study suggests that labouring patients are as able to give informed consent as are other members of our patient population. (7 references) (Author)

20020814-46

Disclosing the 'inclusion benefit'. Silverman WA (2002), Journal of Perinatology vol 22, no 4, June 2002, pp 261-262

Editorial which briefly considers the issue of informed consent and, in particular, the ways in which patients are recruited into randomised controlled trials. (12 references) (MS)

20020702-36

Consent in obstetrics - a legal view. Eddy A (2002), Obstetrician and Gynaecologist vol 4, no 2, April 2002, pp 97-100

Article setting out key issues to be considered in gaining consent. The standard of proof when bringing a consent case to court is described. (15 references) (MS)

20020628-31

Implementing consent. Cowan J (2002), British Journal of Clinical Governance vol 7, no 2, 2002, pp 136-138

Responding to a commitment made in the NHS plan, the Department of Health produced a series of documents (not yet widely distributed and discussed) during 2001 aimed at improving the process of obtaining consent in the NHS and aiming for consistent practice across the NHS, So that patients and health care professionals will be familiar with the process as they are looked after by or work for different organisations. Trusts have a very tight timescale for the introduction and use of the new style consent forms and the implementation of the model policy. While the basics are there, feels debate is necessary within each organisation as to how best these forms should be used. Discusses these issues, and claims the new standards currently are not achievable within an under-resourced service. Concludes that those agencies established to assess the quality of health care need to be mindful of the severe constraints that exist in attempting to push forward this initiative by the end of 2002, before criticising trusts for their failure to do so. (8 references)
(Author)

20020618-60

Very high compliance in an expanded MS-MS-based newborn screening program despite written parental consent. Liebl B, Nennstiel-Ratzel U, von Kries R, and others (2002), Preventive Medicine vol 34, no 2, 2002, pp 127-131

Objectives. In Bavaria, Germany, an expanded MS-MS-based newborn screening program was implemented in 1999. The coverage of new additional conditions and novelty of technology required introduction of written parental consent. Here we evaluated the influence of the consent procedure on compliance by systematic demographic tracking. I Methods. Comprehensive information was provided for parents, professionals, and the public. Screening notifications were matched with all birth notifications on name and date of birth. Parents of children without screening notification were contacted and counseled. Results. Between August 1, 1999, and July 31, 2000, 123,284 children eligible for screening were born. Of these, 116,652 were matched successfully. Among 6,632 parents contacted, 2,516 (2%) did not respond. Three thousand thirty-four children were screened but the parents initially refused to participate in tracking. Five hundred ninety-four were screened outside the program. Four hundred eighty-eight untested newborns were identified. Three hundred twenty-five screening failures due to logistic problems were tested subsequently. Screening was definitely refused by the parents of 163 children (0.1% of target population). Conclusions. With appropriate information provided and surveillance by tracking, high compliance with

newborn screening can be achieved despite a written consent requirement. (20 references) (Author)

20020612-70

Changing the perception of informed consent. An interview with Dr Timothy O'Dowd FRANZCOG. (2002), O & G vol 4, no 1, March 2002, pp 14-17

The Gold Coast Obstetrics and Gynaecology Gynaecologist Specialist Services was set up in May 2000 by a group of doctors to provide pre-operative education to obtain informed consent prior to surgery. Options and general information are provided by the consultant prior to referral to a nurse or midwife for further discussion and a chance to ask questions. The woman then returns to her doctor where a mutual decision is reached whether or not to proceed with the surgery. Results of an evaluation of this service are given. (KL)

20020502-31

Obstetrical delivery of the HIV-positive woman: legal and ethical considerations. Scarrow SE (2001), Obstetrical and Gynecological Survey vol 56, no 3, March 2001, pp 178-183

Every year, thousands of perinatally HIV-infected children are born, resulting in debate about appropriate HIV treatment and interventions for pregnant women. Recent medical studies endorse the use of the cesarean delivery to reduce vertical (mother to infant) transmission of HIV. In addition to medical questions, this practice raises legal and ethical considerations for the attending physician. In the context of AIDS prevention, the potential exists for reasoned and well-informed decision making to give way to encouragement, and even duress, in cases where a woman refuses recommended surgical delivery. However, in such cases, the role of the physician should remain as that of an informed educator and counselor, enabling the patient to exercise her autonomy and personal choice within her social and cultural context. (24 references) (Author)

20020430-5*

Clinical cases by speciality: cases 7 & 8 - obstetrics. (2001), NHSLA Journal no 1, Winter 2001, pp 11-13

Briefly reports on two cases relating to informed consent in breech deliveries. (6 references) (SB)

20020422-57

Informed consent to breaking bad news. Rudnick A (2002), Nursing Ethics vol 9, no 1, 2002, pp 61-66

Informed consent to breaking (or waiving) bad news is an important yet neglected topic. It is distinct from informed consent to diagnosis and to treatment, and may be logically and ethically sound, provided patients are competent and that no considerable harm may be caused to others by breaking or waiving bad news to patients. This requires a differential assessment procedure in order to balance patient autonomy, benefit and justice towards others, preferably exploring patients' values, expectations and needs with them, so that an acceptable decision can be made on whether to act on their consent to breaking or waiving bad news, or to ignore it and act on informed consent by proxy. Future study should attempt to provide a detailed characterization of procedures for attaining informed consent to breaking or waiving bad news, and to test their success in establishing ethically sound health care. (10 references) (Author)

20020412-1

Pregnant women deserve informed consent too. Gonen JS (2002), Women's Health Issues vol 12, no 1, January/February 2002, pp 1-3

A recent case of a woman forced to undergo a caesarean section delivery in the United States against her expressed wishes on religious grounds is the starting point for a discussion of issues around rights to informed consent for pregnant women, with particular regard to screening for HIV infections. (3 references) (KL)

20020130-27

Choices must be informed, voluntary. Finger WR (2001), Network vol 21, no 2, 2001, pp 16-19

To make informed decisions, clients and research participants need reliable and complete information. Ways in which this information can be delivered in the context of the provision of reproductive health services and the participation in research in developing countries are examined. (17 references) (Author, edited)

20020121-46

Informed consent: lessons from Australia. Skene L, Smallwood R (2002), BMJ vol 324, no 7328, 5 January 2002, pp 39-41

Courts in Australia and England have begun applying a tougher standard to the information that doctors should give their patients - that of what a reasonable patient might expect rather than of what a reasonable body of doctors might think. Loane Skene and Richard Smallwood outline some recent cases in Australia and argue that doctors have not yet caught up with this change in judges' thinking and are thus laying themselves open to negligence claims. (11 references) (Author)

20011220-19*

Seeking consent: working with children. Department of Health (2001), London: Department of Health November 2001. 30 pages

Guidance on seeking informed consent for treatment from children, or from those with parental responsibility for them. (KL)

20011220-18*

Reference guide to consent for examination or treatment. Department of Health (2001), London: Department of Health November 2001. 30 pages

This booklet provides guidance on English law concerning consent to physical interventions on patients and is relevant to all health care professionals who carry out such examinations. Guidance is provided on the legal requirements for obtaining valid consent and on the situations where the law recognises exceptions to the common law requirement to obtain consent. (Author, edited)

20011220-16*

Good practice in consent implementation guide: consent to examination or treatment. Department of Health (2001), London: Department of Health November 2001. 50 pages

Model consent policy and four consent forms together with an accompanying information leaflet 'About the consent form'. This model document has been developed as part of the Department of Health's good practice in consent initiative, as promised in the NHS Plan, with the aim of assisting National Health Service organisations to promote good practice in the way patients are asked to give their consent to treatment, care or research. (KL)

20011219-43

The Bristol Inquiry Report: respect and honesty. Dimond B (2001), British Journal of Midwifery vol 9, no 11, November 2001, pp 710-713

This article analyses the recommendations of the Bristol Inquiry Report which aims to place the patient at the centre of everything which the NHS does. The implications for the midwife in respect of partnership with the woman, communications and responding when things go wrong are considered. (9 references) (Author)

20011219-42

Intimate examinations: the complexities of consent. Robinson J (2001), British Journal of Midwifery vol 9, no 11, November 2001, pp 708-709

Overview of the use of intimate examinations during pregnancy. The psychological damage that can be caused to women by such examinations is highlighted and the issues of consent and ensuring that appropriate clinical guidelines are implemented are discussed. (RGW)

20011217-12

Informed consent for treatment: a review of the legal requirements. von Tigerstrom B (2001), JOGC [Journal of Obstetrics and Gynaecology Canada] vol 23, no 10, October 2001, pp 951-956

A valid consent for treatment must fulfill three basic requirements. First, consent must be given voluntarily without undue influence, coercion or misrepresentation. Second, the person giving consent must be competent and if the patient herself is not competent, the person giving consent in her place must have the legal authority to do so. Third, the consent must be specific to the treatment and those providing it. In addition to these requirements, consent must be informed, which means that the patient must have received sufficient information to make an informed decision. The paper discusses these requirements and how to determine what information must be provided to the patient to

ensure that a fully informed decision can be made. All information that a reasonable person in the patient's circumstances would need to make a decision must be provided. This information includes the risks of the procedure, the consequences of declining treatment, alternatives, success and failure rates, recommendations, and any actual or potential conflicts of interest. A physician is responsible for ensuring that this information is provided, and that the patient understands the information. If a patient claims that she has not been properly informed, in a lawsuit she will have to show that a reasonable person in her position would have made a different decision if adequately informed, which is often difficult. However, the consent process is not just concerned with avoiding liability. The education process to inform the patient's choice regarding treatment is a key aspect of the relationship between physician and patient. It highlights the primary importance of good communication and respect for the patient's right to autonomy. (23 references) (Author)

20011025-19

Obtaining consent for epidural analgesia for women in labour. Coates J, Hill J (2001), New Zealand Medical Journal vol 114, 23 February 2001, pp 72-73

Discusses issues relating to informed consent for providing epidural analgesia to women in labour. (12 references) (SB)

20010910-22

New tool for presenting risk in obstetrics and gynecology. Stallings SP, Paling JE (2001), Obstetrics & Gynecology vol 98, no 2, August 2001, pp 345-349

BACKGROUND: The Paling Perspective Scale, a means of communicating risk in various settings, has been applied to diverse fields such as nuclear power, blood banking, and ophthalmology. TECHNIQUE: Statistics of risk for various events in obstetrics and gynecology were collected from the literature and directly applied to the risk scale. EXPERIENCE: The graphic simplicity and versatility of this scale make it adaptable for communicating risks to people of different technical and educational backgrounds. CONCLUSION: The Paling Perspective Scale might help obstetrician-gynecologists obtain informed consent for surgery, genetic counseling, and other topics. (13 references) (Author)

20010904-9

Consent to autopsy for neonates. McHaffie HE, Fowlie PW, Hume R, and others (2001), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 85, no 1, July 2001, pp F4-F7

Objectives-To determine parents' views on autopsy after treatment withdrawal. Design- Face to face interviews with 59 sets of bereaved parents (108 individual parents) for whose 62 babies there had been discussion of treatment withdrawal. Results- All except one couple were asked for permission for postmortem examination; 38% refused. The main reasons for declining were concerns about disfigurement, a wish to have the child left in peace, and a feeling that an autopsy was unnecessary because the parents had no unanswered questions. The diagnosis, the age of the child, and the approach of the consultant appeared to influence consent rates. Of those who agreed to autopsies, 92% were given the results by the neonatologist concerned. Whether or not they had agreed to the procedure, at 13 months no parent expressed regrets about their decision. Conclusions-Autopsy rates in the East of Scotland stand at 62%. Parents' perceptions are an important element in consent to postmortem examination. (21 references) (Author)

20010831-48

Informed consent in the special care baby unit: is it a reality?. Seddon HP (2001), Journal of Neonatal Nursing vol 7, issue 4, July 2001, pp 133-137

Consent to treatment is an intrinsic part of caring for sick neonates. Ethical and legal theorists suggest consent should be informed. This article highlights the difficulties faced by nurses and parents when hoping to achieve informed consent and examines the issues using the Four Principles plus Scope approach of Beauchamp and Childress. Furthermore it emphasises implications for practice so that informed consent can become the norm instead of the ideal. (34 references) (Author)

20010821-11

Ethical issues with genetic testing in pediatrics. American Academy of Pediatrics, Committee on Bioethics (2001), Pediatrics vol 107, no 6, June 2001, pp 1451-1455

Advances in genetic research promise great strides in the diagnosis and treatment of many childhood diseases.

However, emerging genetic technology often enables testing and screening before the development of definitive treatment or preventive measures. In these circumstances, careful consideration must be given to testing and screening of children to ensure that use of this technology promotes the best interest of the child. This statement reviews considerations for the use of genetic technology for newborn screening, carrier testing, and testing for susceptibility to late-onset conditions. Recommendations are made promoting informed participation by parents for newborn screening and limited use of carrier testing and testing for late-onset conditions in the pediatric population. Additional research and education in this developing area of medicine are encouraged. (40 references) (Author)

20010725-18

Consent for emergency caesareans. Robinson J (2001), British Journal of Midwifery vol 9, no 7, July 2001, p 452

Brief commentary on caesarean sections and decision-to-delivery times, and informed consent. (6 references) (RGW)

20010717-55

Obtaining consent: the use of a consent form. Pennels C (2001), Professional Nurse vol 16, no 10, July 2001, pp 1433-1434

While recent press coverage has brought the issue of consent into the public eye, it is always an issue of concern for health-care professionals. A few straightforward procedures will help improve protection for both staff and patients. (Author)

20010607-16

Overview of European legislation on informed consent for neonatal research. Dalla-Vorgia P, Mason S, Megone C, and others (2001), Archives of Disease in Childhood: Fetal and Neonatal Edition vol 84, no 1, January 2001, pp F70-F73

Discussion of areas of consistency and inconsistency in the law or practice governing informed consent for neonatal research in ten European countries (Denmark, Finland, France, Germany, Greece, Ireland, Norway, Spain, Sweden and the United Kingdom). In particular, the following areas are examined: whether there is specific law governing informed consent for research and, if so, what it is; the ethical review system, whether there are specific requirements for consent, whether benefit for the individual child is a specific requirement, and whether research of no direct benefit (so called non-therapeutic research) is legally permitted in minors for example, the taking of extra blood samples purely for research purposes. (8 references) (MS)

20010412-11

Who should gain informed consent for post mortems?. Jones SR (2001), British Journal of Midwifery vol 9, no 4, April 2001, p 203

Discussion of some of the concerns that have arisen from the Alder Hey Inquiry, about who should gain informed consent from parents for postmortems following a stillbirth or neonatal death. Although it has been suggested that pathologists should undertake this responsibility, the author believes that doctors and midwives should continue to do this. (1 reference) (MS)

20010409-11

Obtaining consent for examination and treatment: new government guide covers most of the bases. McCall Smith A (2001), BMJ vol 322, no 7290, 7 April 2001, pp 810-811

Details of a new document, produced by the Department of Health, giving guidance to doctors when gaining consent for examination or treatment. The author suggests that the new document will help doctors who fear that their instinct about what is the right way to obtain consent may not be enough to protect them from legal challenge. (6 references) (MS)

20010408-43

Consent in obstetrics and gynaecology. Mellows H (2001), Current Obstetrics and Gynaecology vol 11, no 1, February 2001, pp 54-55

The discipline of obstetrics and gynaecology provides particular challenges in consent issues, partly because it involves dealing with the most intimate and personal aspects of patients; lives and partly because the patients may be ill but also may be quite healthy and requesting elective procedures such as sterilization from which they expect a perfect outcome. Obstetrics patients always hope that their pregnancy will be normal and may be distressed if intervention is required. The range of patients seen includes children as well as patients with mental impairment.

Obstetricians and gynaecologists must be aware of all the issues involved in consent. (Author)

20010405-48

Participation in research: informed consent, motivation and influence. Hayman RM, Taylor BJ, Peart NS, and others (2001), Journal of Paediatrics and Child Health vol 37, no 1, February 2001, pp 51-54

Objective: To investigate the process and quality of informed consent, motivation and influence in parents who were invited to enrol their baby in a research project. Methodology: A mixed quantitative/qualitative questionnaire was sent to a cohort invited to participate in a physiological research project on sudden infant death syndrome (SIDS) at the Dunedin Public Hospital, Dunedin, New Zealand. Separate questionnaires were used for parents who participated (94) and those who declined to participate (103). Response rates were 69% and 47%, respectively. Results: All consenting parents felt they understood the purpose and procedure of the study. The majority (90%) thought the information about the study was very good; 6.5% felt more detail was required. Eighty-five per cent found the verbal explanation the most useful source of information. All participated for altruistic reasons such as to aid SIDS research. Although 27% had concerns about safety of the tests, after the tests all responders felt happy with the safety of the tests. Inconvenience was the main reason (53%) for declining to participate. Twenty-eight per cent of declining parents were concerned about the safety of the tests. Conclusion: Of those who responded to the questionnaire, the process for obtaining informed consent in the SIDS studies was satisfactory. Parents' motives for participating were mostly altruistic. The role of recall bias and selection bias may make the implications of this study unclear. (13 references) (Author)

20010403-33

Counselling women about choice. Harris LH (2001), Best Practice & Research: Clinical Obstetrics and Gynaecology vol 15, no 1, February 2001, pp 93-107

Patient choice - informed consent and informed refusal - is an important ethical and legal principle in medicine. In pregnancy this issue is not straightforward: should a pregnant woman's autonomous choice be respected when she may cause fetal harm by declining recommended caesarean section? Should a pregnant woman be free to choose elective caesarean section as an alternative to labour and vaginal delivery? This chapter reviews cases of court-ordered caesarean, and the ethical and legal paradigms for informed refusal in pregnancy. In general, clinicians should not seek court authority to support medical recommendations. This chapter also reviews arguments for and against offering women elective caesarean without strict medical indication. Although compelling arguments in favour of caesarean on demand can be made, clear evidence showing adequate safety and advantages of elective caesarean over vaginal delivery does not yet exist. Ethics, law, politics and history all inform the issue of choice with respect to caesarean in important ways. (75 references) (Author)

20010116-11

Presumed consent in emergency neonatal research. Manning DJ (2000), Journal of Medical Ethics vol 26, no 4, 2000, pp 249-253

Current methods of obtaining consent for emergency neonatal research are flawed. They risk aggravating the distress of parents of preterm and other sick neonates. This distress, and the inevitable time constraints, compromise understanding and voluntariness, essential components of adequately informed consent. Current practice may be unjust in over-representing babies of more vulnerable and deprived parents. The research findings may thus not be generalisable. Informing parents antenatally about the possible need for emergency neonatal research, with presumed consent and scope for opting out, would address these problems. It would spare parents of sick neonates, already terrified by their baby's illness, further distress. Experience with opting out suggests that recruitment might increase, thus generating earlier results, without compromising parental understanding of the nature and purpose of the research. (25 references) (Author)

20010115-09

Informed consent is a primary requisite of quality care. Cooper TJ (2001), British Journal of Midwifery vol 9, no 1, January 2001, pp 42-45

Pregnant women are expected to make various choices about their care. In order to make these decisions, women need information on which to base their choices and thus give their consent. For this consent to be informed, the client must be competent and able to make a decision and have the necessary information to do this. Ensuring that this information is given in a non-judgmental and unbiased way is part of the midwife's role. There are many barriers to informed consent and these need to be identified by the midwife and the issues addressed if the sharing of

information is to be successful. (25 references) (Author)

20010113-44

Magnesium sulfate therapy affects attention and working memory in patients undergoing preterm labor. Ghia N, Spong CY, Starbuck VN, and others (2000), American Journal of Obstetrics & Gynecology (AJOG) vol 183, no 4, October 2000, pp 940-944

OBJECTIVE: Patients commonly consent to undergoing invasive procedures while receiving magnesium sulfate therapy. This study evaluated the effects of magnesium sulfate on attention, comprehension, and memory in patients undergoing preterm labor. STUDY DESIGN: Consenting patients were studied while receiving (study and not receiving (control) intravenous magnesium sulfate tocolysis for preterm labor. Excluded were patients with possible preeclampsia, imminent delivery, sedative administration, or prior mental illness. Patient comprehension was assessed with the Boston Diagnostic Aphasia Examination. Level of attention and working memory were evaluated with the Paced Auditory Serial Addition Test. Verbal learning, short-term memory, and recognition were determined with the Hopkins Verbal Learning Test. Gross mental-neurologic deficits were evaluated with the Mini-Mental Status Examination. The tests were administered by the same examiner. Control testing was performed >24 hours after intravenous magnesium sulfate was discontinued. Magnesium levels were obtained at the time of testing. The primary outcome measure was the Paced Auditory Serial Addition Test score because of its ability to elicit subtle differences in attention capacity. Statistical analysis included the paired t test and the McNemar test. RESULTS: Fifteen patients completed the study Paced Auditory Serial Addition Test scores were significantly higher (ie, more errors were made) during magnesium sulfate therapy than periods without therapy (14 ± 8 vs 7 ± 7; P< .05). Comprehension (Boston Diagnostic Aphasia Examination score) was not different between the groups (P = .7). There was no difference in short-term memory (Hopkins Verbal Learning Test) or gross mental-neurologic deficits between the 2 groups (all P> .1). CONCLUSIONS: Magnesium sulfate therapy appears to have an effect on attention and working memory but not on long-term memory or comprehension. The significant differences in Paced Auditory Serial Addition Test scores reveal deficits in information-processing ability in patients on a regimen of magnesium sulfate therapy. (23 references) (Author)

20010112-12

Informed consent for obstetric anesthesia research: factors that influence parturients' decisions to participate. Dorantes DM, Tait AR, Naughton NN (2000), Anesthesia & Analgesia vol 91, no 2, 2000, pp 369-373

Patients who are approached to participate in clinical studies just before delivery may have insufficient time to make an informed decision and/or may feel pressured into participation. This study was designed to examine factors that influence parturients to consent or decline participation in an anesthesia study related to their delivery. Parturients who had been approached to participate in a continuing clinical obstetric anesthesia study were subsequently given a questionnaire that documented their reasons for consenting or declining participation. There were no demographic differences among the consenters (n = 166) and nonconsenters (n = 109). The most important factors in the patient's decision to consent were related to their understanding and perceived importance of the study and the potential benefit to other women. Forty-one (40.6%) nonconsenters strongly considered their pain/discomfort a factor in declining participation. Only one patient felt some pressure to consent, suggesting that the overall environment was noncoercive. Logistic regression analysis demonstrated that patients who read the consent form completely, those who had participated in a previous research study, and those who were less anxious about participating were more likely to consent. (9 references) (Author)

20010110-21*

Patient's autonomy, privacy and informed consent. Leino-Kilpi, Valimaki M, Arndt M, and others (2000), Amsterdam: IOS Press 2000. 166 pages

One of the most important areas of study in health care ethics is represented by the patient's status and rights. In the case of patients' rights, key issues include patient autonomy, privacy and informed consent. These are the issues that are the centre of attention in this report. The present overview of the literature is intended to benefit various groups of health care professionals. The first of these groups is that of nursing and medical professionals. the aim is to increase their knowledge about legislation, ethical codes and research and in this way to support them in ethical decision-making. This report, a comprehensive literature review, has been written as the first stage of the 'Patients' autonomy, privacy and informed consent in nursing interventions' project supported through the BIOMED2 programme by the European Commission. The project is scheduled to run for three years until 2001. This literature review provides the groundwork for empirical data collection. Gathered from the five countries involved in the project (Finland, Germany, Greece, Spain and the United Kingdom), the purpose of the empirical material is to

evaluate the realisation of autonomy, privacy and informed consent in surgical, maternity and long term elderly patients. (Author, edited)

20010103-06

Obtaining informed consent to neonatal randomised controlled trials: interviews with parents and clinicians in the Euricon study. Mason SA, Allmark PJ (2000), The Lancet vol 356, no 9247, 16 December 2000, pp 2045-2051

Background: Questions have been asked about whether the process of obtaining informed consent from parents to clinical trials on neonates leads to valid consent. We undertook a study in nine European countries to assess this issue and to seek any practical improvements. Methods: Semi-structured interviews were conducted with parents of 200 babies who had been asked for consent to neonatal trials and 107 neonatologists seeking consent. Analysis assessed the validity of the consent process against four components: parental competence; information given; parental understanding; and voluntariness of consent. Findings: 59 of the 200 parents had given valid consent or refusal but the remainder had problems in one or more of the component areas (42 for competence, 43 for information, 44 for understanding, and 21 for voluntariness). The proportions with impaired consent were greatest for research in an emergency situation and for that associated with risk or discomfort greater than standard treatment. Information sheets were little used by parents in deciding whether to consent. Parents highly valued their involvement in the informed consent process, and clinicians generally agreed on the value of the process. Interpretation: Current standards of informed consent to neonatal research projects could be improved. Research personnel should receive guidance on legal and ethical constraints governing the process. Oral and written information should be given at the same time. Parents could be made aware that research projects have been examined by research ethics committees. Little support was found for the argument that informed consent should be relinquished for the parents' own good. Further study is needed to identify which elements of the process are valued by parents and clinicians in a process that has some unavoidable limitations. (25 references) (Author)

20010103-05

Views of neonatologists and parents on consent for clinical trials. Tyson JE, Knudson PL (2000), The Lancet vol 356, no 9247, 16 December 2000, pp 2026-2027

Commentary on research published in the same issue (1), which investigates the views of parents and neonatologists regarding informed consent for clinical trials. 1. Mason SA et al. Obtaining informed consent to neonatal randomised controlled trials: interviews with parents and clinicians in the Euricon study. Lancet, vol 356, no 9247, 16 December 2000, pp 2045-2051. (10 references) (SB)

20001216-25

Whose schedule? Induced labor and informed consent in Canada. Dahl G (2000), Birthkit no 28, Winter 2000, pp 1, 10-11

Personal account of an induced labour, expressing the author's disquiet with a hospital policy of routine induction at 41 weeks gestation. (20 references) (MS)

20001107-03

Norway: valid (as opposed to informed) consent. Syse A (2000), The Lancet vol 356, no 9238, 14 October 2000, pp 1347-1348

The traditional concept of 'informed' consent may be too restrictive; 'valid' consent may be a more manageable criterion. Norway's 1999 Patients' Right Act comes into force on Jan 1, 2001. This essay asks if this new legislation is compatible with this concept of valid consent - and concludes that it is. (3 references) (Author)

20001106-07

Informed choice- are we getting there?. Newburn M (2000), RCM Midwives Journal vol 3, no 9, September 2000, pp 278-281

Informed choice is not one simple single concept, it encompasses many complex issues such as informed consent, and how much midwives should accept what parents want vs their role to provide guidance based on evidence and personal knowledge. Perhaps the most significant limiting factor to the success of informed choice is the crucial factor or time, as the amount of time midwives have available to listen and advise is limited. (20 references) (JAL)

20000911-22

Consent and clinical governance: improving standards and skills. Cowan J (2000), British Journal of Clinical Governance vol 5, no 2, 2000, pp 124-128

Obtaining appropriate and informed consent from patients is an integral part of provision of quality health care. Doctors are bound to obtain consent in a manner that is legally and ethically acceptable. The methods employed to train junior doctors in these principles vary from organisation to organisation and the knowledge base of both senior and junior clinicians is far from consistent. This paper raises some of the issues in relation to current practice and teaching and suggests ways in which the process can be improved - largely by introducing some basic standards that should be built on as expertise and skill develop. The author discusses the need for dissemination of information with regard to current national claims experience and the possibility of introducing the subject of consent into postgraduate examinations in a more widespread way. (6 references) (Author)

20000902-14

Consent in obstetrics. Eddy A (2000), Clinical Risk vol 6, no 2, 2000, pp 74-76

Discussion of the meaning of consent in obstetrics. The nature of consent is described and the standard of proof required to win a claim for damages in a consent case is briefly outlined. Issues of request for and refusal of caesarean section are discussed in some detail. (12 references) (MS)

20000810-47

An evaluation of informed consent prior to epidural analgesia for labor and delivery. Gerancher JC, Grice SC, Dewan DM, et al (2000), International Journal of Obstetric Anesthesia vol 9, no 3, July 2000, pp 168-173

This investigation was performed to determine the ability of a parturient to recall the pre-anesthesia discussion with her anesthesiologist and to determine if written consent added to this discussion improves recall. Eighty-two women presenting in labor were randomized to 'verbal' and 'verbal plus written' consent for epidural labor analgesia and were contacted 5 to 7 months after a pre-anesthetic interview. Ten objective questions were posed at this time that addressed issues that were 'true risks', 'false risks', and 'situational' issues related to the consent process. These responses were scored on a point scale so that a maximal objective recall score of 100 points was possible. Median recall score was 80 (70-90) in the 'verbal' group and 90 (80-100) in the 'verbal plus written' group. This difference was statistically significant ($P < 0.01$), In addition, three subjective questions were asked of all women at this time. All but six women (one 'verbal plus written' and five 'verbal' group patients) expressed that written consent would help them 'remember and appreciate the different anesthetic options, risks, and procedures'. Four of these same women (one 'verbal plus written' and three 'verbal' group patients) thought a written consent process was 'alarming'. Two of these same women (both 'verbal' group patients) reported that they felt unable to give informed consent. (13 references) (Author)

20000612-27

Informed consent: keeping parents in the picture. Emery M (2000), Journal of Neonatal Nursing vol 6, no 3, May 2000, pp 90-92

For a premature infant it is the parents who give consent to treatment on behalf of their offspring. If this consent is to be meaningful, they must understand what treatment is proposed for their child and the inherent risks and complications. The neonatal nurses caring for the infant have a legal responsibility to ensure that the parents have been given adequate information in a sensitive way that they can readily comprehend. (19 references) (Author)

20000607-37$

Testing a drug during labour: the experiences of women who participated in a clinical trial. Ferguson PR (2000), Journal of Reproductive and Infant Psychology vol 18, no 2, May 2000, pp 117-131

Interviews were conducted with 104 patients who had participated in medical research involving pharmaceutical drugs. All patients were asked about the amount of information they had been given prior to being invited to participate, and about their understanding of, and satisfaction with, that information. Patients were also invited to comment on their reasons for having agreed to take part in medical research. Each had participated in one of 14 different drug studies. One of these studies involved a drug that was being used for the first time during labour. When analyzing these data, it became apparent to the author that responses from some of those involved in the labour drug study were different from those of patients who had participated in the other studies. This paper compares the views of the 26 patients in the labour study with those of 78 other patients. The women in the labour trial were generally less satisfied than patients in the comparative sample with women in the labour trial were generally less satisfied than patients in the comparative sample with the information which they had been given, and report lower levels of understanding of that information. They had asked fewer questions about heir study and reported lower levels of

satisfaction with the answers they had received to those questions. This raise concerns as to whether the consent to participation given by women in the labour trial was in all cases fully informed. This in turn suggests the possibility of a gender bias in fulfilling ethical obligations in medical research. (17 references) (Author)

20000604-35$

Informed consent. Gorton M (2000), O & G vol 2, no 2, April 2000, pp 98-100

Overview of the implications of informed consent from a legal perspective that concludes with a suggestion that training for doctors in this field must be improved. (RGW)

20000508-20$

Babies and consent: yet another NHS scandal. Smith R (2000), BMJ vol 320, no 7245, 13 May 2000, pp 1285-1286

The scandal at the North Staffordshire Hospital is the latest to shake public faith in the National Health Service and cause us to question how parts of it operate. The case is complex, but the worst single accusation is that consent forms were forged. Identifying the deficiencies will hopefully help improve how research is conducted within the NHS. (7 references) (JAL)

20000413-16

Informed consent to intrapartum procedures. Marshall JE (2000), British Journal of Midwifery vol 8, no 4, April 2000, pp 225-227

This paper discusses the complex issue of obtaining informed consent for intrapartum procedures, highlighting both the moral and legal obligations of every practising midwife and obstetrician as accountable practitioners. It challenges the health professional to examine their own practice of obtaining informed consent for procedures they undertake in labour, bearing in mind they have a duty to inform the client of risks as well as benefits. Furthermore, for consent to be legally valid, the client has to demonstrate understanding (a concept that is both subjective and difficult to assess), and it must be voluntary. The author suggests that informed consent to intrapartum procedures should be obtained during the antenatal period rather than during labour itself, when the woman may be deeply distressed by pain and unable to fully make an informed decision. (19 references) (Author)

20000313-31$

A model for auditing informed consent. Gladstone J, Campbell B (2000), Journal of Clinical Excellence vol 1, no 4, 2000, pp 247-250

Ensuring that patients give `informed' consent is fundamental to good clinical practice. Consent should be based on relevant and understandable information provided by a clinician who is competent to carry out the proposed intervention. Modern emphasis on good risk management, combined with the increasing litigious trends towards the NHS, place considerable pressure on the ability to provide documented evidence of effective implementation of the consent process. Audits of the consent process carried out in March 1998 and March 1999 at the Royal Devon & Exeter Hospital examined completion of the consent form and the documented evidence of the provision of information. Completeness of the consent form scored highly in both audits, apart from description procedures which were abbreviated in 22% of forms. In the first audit, documented evidence of procedure explanations was found in 51% of clinical notes, and this improved to 91% in the second audit. Evidence of specific discussion of risks, alternative treatments and recovery showed some improvement between the first and second audit but remained generally poor. The second audit, in addition, sought evidence that information to enable informed consent was provided by a `competent' clinician: this was found in 95% of cases. These audits of consent have generated considerable local discussion and highlighted important issues for those undertaking similar studies. (9 references) (Author)
