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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

March 2023 :: Issue 51

This digest aggregates and distills key content addressing informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations.

In preparing this digest, we monitor *Google Scholar* using the search terms "consent", "informed consent", and "assent" in title and available text. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis and guidance beyond the journal literature globally. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

Informed Consent: A Monthly Review is a service of the Center for Informed Consent Integrity (CICI), a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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We organize content in each edition using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. Active subject areas in this edition include:

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19

FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT

Please note that while we strive to identify the primary subject area for the categorization of the monthly digest we also recognize that many articles are relevant across other subject areas. We encourage readers to gloss over the entire digest or search the website where articles are cross tagged. We maintain a glossary, an inventory of tools for assessment, as well as standards and guidance documents on the website.

BIOMEDICAL RESEARCH

Patients acceptance and comprehension to written and verbal consent (PAC–VC)

Robert C. Welsh, Shane Kimber, Justin Ezekowitz, Rabia Kashur
BMC Medical Ethics, 23 February 2023; 24(14)
Open Access
Abstract
Background
Acute myocardial infarction (AMI) research is challenging as it requires enrollment of acutely ill patients. Patients are generally in a suboptimal state for providing informed consent. Patients' understanding to verbal assents have not been previously examined in AMI research. Patients' Acceptance and Comprehension to Written and Verbal Consent (PAC–VC) compared patients' understanding and attitudes to verbal and written consents in AMI RCTs.
Methods
PAC–VC recruited patients from 3 AMI trials using both verbal N = 12 and written N = 6 consents. We compared patients' understanding using two survey questionnaires. The first questionnaire used open-ended questions with multiple choice answers. The second questionnaire used a 5-point Likert scale to measure patients understanding and attitudes to the consent process. Overall answers average scores were categorized into three groups: Adequate understanding (71–100) %, Partial understanding (41–70)% and Inadequate understanding (0–40)%.
Results
Responses showed patients with verbal assent had adequate understanding to most components of informed consent, close to those of written consent. Most patients did not read written information entirely and believed that it is not important to make a final decision. Patients favoured to have written information be part of the consent but not necessarily presented during the initial consent process. Patients felt less pressured in the verbal assent arm than those of written consent.
Conclusion
Patients had adequate understanding to most components of verbal assent and comparable to those of written consent. Utilizing verbal assents in the acute care setting should be further assessed in larger trials.

Electronic informed consent: effects on enrolment, practical and economic benefits, challenges, and drawbacks—a systematic review of studies within randomized controlled trials

Review
Ana Teresita Mazzochi, Martin Dennis, Ho-Yan Yvonne Chun
Trials, 21 February 2023; 24(127)
Open Access
Abstract
Background
Enrolment is one of the most challenging aspects of conducting clinical trials, preceded by the process of informed consent (IC). Different strategies to improve recruitment in clinical trials have been used, including

electronic IC. During COVID-19 pandemic, barriers to enrolment have been evident. Although digital technologies were acknowledged as the future of clinical research and potential advantages were shown for recruitment, electronic informed consent (e-IC) has not yet been globally adopted. The purpose of this review is to investigate the effect of using e-IC on enrolment, practical and economic benefits, challenges, and drawbacks when compared to traditional informed consent, through a systematic review.
Methods
Embase, Global Health Library, Medline, and The Cochrane Library databases were searched. No limit was set for publication date, age, sex, or study design. We included all studies within a randomized controlled trial (RCT), published in English, Chinese or Spanish, evaluating the electronic consent process used in the parent RCT. Studies were included if any of the three components ((i) information provision, (ii) participant's comprehension, (iii) signature) of the IC process was designed as electronic, whether administered remotely or face-to-face. The primary outcome was the rate of enrolment to the parent trial. Secondary outcomes were summarized according to the various findings reported on the use of electronic consent.
Results
From a total of 9069 titles, 12 studies were included in the final analysis with a total of 8864 participants. Five studies of high heterogeneity and risk of bias showed mixed results on the efficacy of e-IC on enrolment. Data of included studies suggested e-IC could improve comprehension and recall of study-related information. Meta-analysis could not be conducted due to different study designs and outcome measures and the predominantly qualitative findings.
Conclusion
Few published studies have investigated the impact of e-IC on enrolment and findings were mixed. e-IC may improve participant's comprehension and recall of information. High-quality studies are needed to evaluate the potential benefit of e-IC to increase clinical trial enrolment.

Improving oncology first-in-human and window of opportunity informed consent forms through participant feedback

Research

Anna M. Avinger, Hannah Claire Sibold, Gavin Campbell, Eli Abernethy, John Bourgeois, Tekiah McClary, Shannon Blee, Margie Dixon, R. Donald Harvey, Rebecca D. Pentz

BMC Medical Ethics, 19 February 2023; 24(12)

Open Access

Abstract

Background
Although patient advocates have developed templates for standard consent forms, evaluating patient preferences for first in human (FIH) and window of opportunity (Window) trial consent forms is critical due to their unique risks. FIH trials are the initial use of a novel compound in study participants. In contrast, Window trials give an investigational agent over a fixed duration to treatment naïve patients in the time between diagnosis and standard of care (SOC) surgery. Our goal was to determine the patient-preferred presentation of important information in consent forms for these trials.
Methods
The study consisted of two phases: (1) analyses of oncology FIH and Window consents; (2) interviews of trial participants. FIH consent forms were analyzed for the location(s) of information stating that the study drug has not been tested in humans (FIH information); Window consents were analyzed for the location(s) of information stating the trial may delay SOC surgery (delay information). Participants were asked about their preferred placement of the information in their own trial's consent form. The location of information in the consent forms was compared to the participants' suggestions for placement.
Results
34 [17 FIH; 17 Window] of 42(81%) cancer patients approached participated. 25 consents [20 FIH; 5 Window] were analyzed. 19/20 FIH consent forms included FIH information, and 4/5 Window consent forms included delay information. 19/20(95%) FIH consent forms contained FIH information in the risks section 12/17(71%)

patients preferred the same. Fourteen (82%) patients wanted FIH information in the purpose, but only 5(25%) consents mentioned it there. 9/17(53%) Window patients preferred delay information to be located early in the consent, before the "Risks" section. 3/5(60%) consents did this.

When research becomes practice: the concept of the therapeutic misconception and challenges to consent in clinical trials

Sarah Heynemann, Wendy Lipworth, Sue-Anne McLachlan, Jennifer Philip, Tom John, Ian Kerridge
Internal Medicine Journal, 13 December 2022
Open Access
Abstract
Many factors influence patients' decisions to participate in clinical trials. For many, the primary motivation is the possibility that they might derive some benefit from participation. This is particularly true for patients with limited treatment options, such as patients with advanced cancer. While this is not surprising, it is potentially problematic if patients fail to recognise the distinction between research and clinical care (a phenomenon known as the 'therapeutic misconception'). This is becoming increasingly problematic as clinical trial designs become more complex, as clinical trials become more embedded in routine clinical care, and as trials are increasingly used by patients and clinicians to access new diagnostic platforms and therapies. We outline some of these recent trends, focusing on the cancer clinical trials landscape as this provides a good case study of the phenomenon. We conclude by making preliminary suggestions that changes to the consent process, perhaps using 'dynamic consent' platforms, might help to mitigate the therapeutic misconception and note the need for further research to guide strategies for improving communication and decision-making.

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SOCIAL SCIENCE RESEARCH

Ethics and the impossibility of the consent form: Ethnography in a Danish nursing home

Emma Jelstrup Balkin, Mette Geil Kollerup, Ingjerd Gåre Kymre, Bente Martinsen, Mette Grønkjær
Journal of Aging Studies, March 2023
Open Access
Abstract
Based on ethnographic fieldwork in a nursing home in northern Denmark, this article addresses challenges experienced in putting formal ethics requirements into practice. We consider how to unite procedural ethics with actual, lived ethics, when researching with vulnerable participants who live with a cognitively impairing condition. The article centers on the story of one resident, who wanted to share her experiences with what she had perceived as inadequate care, but who baulked once the wordy consent form was produced. The resident panicked that her words could now be used against her, that talking with the researcher would (further) compromise her care. She was caught in a bind, on the one hand she had a deep desire to tell her story, on the other the piece of paper in her hand threatened to trigger her anxiety and depression. In this article we therefore approach the consent form as an agent. By mapping out these unintended consequences of the consent form, we wish to draw attention to the complexities of ethical research conduct in practice, ultimately arguing that the concept of appropriate informed consent should be broadened so that it is sensitive to the lifeworld of participants.

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HEALTH DATA

REPRESENT: REPresentativeness of RESearch data obtained through the 'General Informed ConsENT'

Research

Cristina Bosmani, Sonia Carboni, Caroline Samer, Christian Lovis, Thomas Perneger, Angela Huttner, Bernard Hirschel

BMC Medical Ethics, 13 February 2023; 24(10)

Open Access

Abstract

Background

We assessed potential consent bias in a cohort of > 40,000 adult patients asked by mail after hospitalization to consent to the use of past, present and future clinical and biological data in an ongoing 'general consent' program at a large tertiary hospital in Switzerland.

Methods

In this retrospective cohort study, all adult patients hospitalized between April 2019 and March 2020 were invited to participate to the general consent program. Demographic and clinical characteristics were extracted from patients' electronic health records (EHR). Data of those who provided written consent (signatories) and non-responders were compared and analyzed with R studio.

Results

Of 44,819 patients approached, 10,299 (23%) signed the form. Signatories were older (median age 54 [IQR 38–72] vs. 44 years [IQR 32–60], $p < .0001$), more comorbid (2614/10,299 [25.4%] vs. 4912/28,676 [17.1%] with Charlson comorbidity index ≤ 4, $p < .0001$), and more often of Swiss nationality (6592/10,299 [64%] vs. 13,813/28,676 [48.2%], $p < .0001$).

Conclusions

Our results suggest that actively seeking consent creates a bias and compromises the external validity of data obtained via 'general consent' programs. Other options, such as opt-out consent procedures, should be further assessed.

A GDPR-Compliant Dynamic Consent Mobile Application for the Australasian Type-1 Diabetes Data Network

Zhe Wang, Anthony Stell, Richard O. Sinnott

Healthcare, 8 February 2023; 11(4)

Open Access

Abstract

Australia has a high prevalence of diabetes, with approximately 1.2 million Australians diagnosed with the disease. In 2012, the Australasian Diabetes Data Network (ADDN) was established with funding from the Juvenile Diabetes Research Foundation (JDRF). ADDN is a national diabetes registry which captures longitudinal information about patients with type-1 diabetes (T1D). Currently, the ADDN data are directly contributed from 42 paediatric and 17 adult diabetes centres across Australia and New Zealand, i.e., where the data are pre-existing in hospital systems and not manually entered into ADDN. The historical data in ADDN have been de-identified, and patients are initially afforded the opportunity to opt-out of being involved in the registry; however, moving forward, there is an increased demand from the clinical research community to utilise fully identifying data. This raises additional demands on the registry in terms of security, privacy, and the nature of patient consent. General Data Protection Regulation (GDPR) is an increasingly important mechanism allowing individuals to have the right to know about their health data and what those data are being used for. This paper presents a mobile application being designed to support the ADDN data collection and usage processes and aligning them with GDPR. The app utilises Dynamic Consent—an informed specific consent model, which allows participants to view and modify their research-driven consent decisions through an interactive interface. It focuses specifically on supporting dynamic opt-in consent to

both the registry and to associated sub-projects requesting access to and use of the patient data for research purposes.

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CAPACITY TO CONSENT

Informed consent in psychotic decompensation

Matea Podgornjak, Lea Hrvat Matić, Anita Stanišić, Ena Gutić, Igor Salopek
European Journal of Bioethics, 20 February 2023
Abstract
The consent of an informed patient is not merely a signature on a legally binding document, but rather a process in which the patient is empowered and becomes an active ally in a treatment. Valid informed consent includes adequate information that is given to the patient in an appropriate manner, the voluntariness of consent, and the patient's ability to make a decision regarding treatment. Meeting these conditions when treating patients with mental health disorders can be challenging. Mental disorders can compromise a person's ability to understand relevant information about the nature of their illness as well as their ability to make decisions regarding treatment. However, a psychiatric diagnosis does not imply that a person is unable to make a decision regarding their treatment, nor does it exclude them as an equal partner in the therapeutic process. By reviewing the case of a 39-year-old patient who developed an acute psychotic disorder during the treatment of COVID pneumonia, we dive into the ethical dilemmas that arise when approaching a patient who is experiencing psychotic decompensation.

Prioritizing choice and assent in the assessment and treatment of food selectivity

Holly C. Gover, Gregory P. Hanley, Kelsey W. Ruppel, Robin K. Landa, Juliana Marcus
International Journal of Developmental Disabilities, 1 February 2023; pp 53-65
Abstract
Food selectivity affects up to 72% and 45% of individuals with and without disabilities, respectively, and there is a need for interventions that rely on positive, unrestrictive strategies. We evaluated an assessment and treatment package for food selectivity for young children with developmental disabilities that prioritized caregiver collaboration, client autonomy, and did not rely on restrictive procedures (e.g. escape extinction). The process involved: (a) collaborating with caregivers on the selection of foods and design of the children's functional analyses; (b) indirectly and directly measuring food preferences prior to treatment; (c) evaluating the sensitivity of mealtime problem behavior to environmental variables through an interview-informed synthesized contingency analysis (IISCA); and (c) incorporating the assessment results into a progressive treatment process consisting of choice-making opportunities and differential reinforcement of successive approximations to consumption. Children also had the ability to opt in and out of treatment sessions. The treatment was effective in increasing consumption of nonpreferred foods and successfully extended to caregivers. Practical implications and directions for future research are discussed.

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YOUNG PERSONS

Adolescent Self-Consent for COVID-19 Vaccination: Views of Healthcare Workers and Their Adolescent Children on Vaccination Autonomy

Original Article

Jeanne R. Delgado, Lisa N. Mansfield, Katia Bruxvoort, Mayra Macias, Joseph Grotts, Bruno Lewin, David Bronstein, Corrine Munoz-Plaza, Peter Szilagyi, John Chang, Kristen Choi

Journal of Adolescent Health, 10 February 2023

Abstract

Purpose

This study explored the perceptions of healthcare worker parents (physicians, nurses, and staff) and their adolescents (aged 12–17 years) on adolescent self-consent to COVID-19 vaccination by applying the concept of positive deviance of those already vaccinated against COVID-19.

Methods

We used a qualitative descriptive design to conduct individual, semi-structured interviews with COVID-19–vaccinated healthcare workers in Southern California and their vaccinated adolescent children. Separate interviews were conducted with parents and adolescents from November to December 2021 using digital phone conferencing software. All interviews were recorded and transcribed. Thematic and constant comparative analysis techniques were used to identify relevant themes and subthemes.

Results

Twenty one healthcare workers (9 nurses, one nurse practitioner, one technologist, and 10 physicians) and their adolescents (N = 17) participated. Three overarching themes were identified to describe participants' perspectives about adolescent self-consent for COVID-19 vaccination: (1) Family values and practices around adolescent vaccination; (2) Differences in parent and adolescent support for vaccine self-consent laws; and (3) Parent and adolescent uncertainty on readiness for vaccine self-consent laws. Adolescents largely supported self-consent while parents supported the policy if they would be able to have a discussion with their adolescent prior to the decision.

Discussion

Parents and adolescents supported adolescent self-consent for COVID-19 vaccination, with the reservation that adolescents should discuss the decision alongside their parents to exercise their medical autonomy with supportive guidance. Greater adolescent involvement in making decisions and providing self-consent for healthcare, including vaccines, could prepare adolescents to have a greater sense of autonomy over their health and contribute to population health measures.

Consent Rights of Gender Diverse Children in Australia and the United Kingdom: Will the Court's Involvement End?

Jacko G

Journal of law and Medicine, 1 December 2022; 29(4) pp 1269-1287

Abstract

Gender diversity allows individuals to express their innate sense of self and has been increasingly recognised over time. Consequently, paediatric gender services have seen exponential increases in referrals internationally. This has resulted in novel issues for courts, such as a child's "best interests" when accessing puberty-suppressing and gender-affirming medical care. Most recently, in the United Kingdom, the adequacy of information provided to transgender children and their families was also debated. Progression of the common law in Australia has resulted in transgender children consenting to medical treatment once Gillick competent. Yet, Bell v Tavistock [2020] EWHC 3274 temporarily halted the care of the United Kingdom's transgender children, who were previously afforded consenting rights. On appeal it was determined to be inappropriate for the divisional court to have provided generalised guidance on children's capacity to consent to medical therapy. Through comparative analysis of case law, the adequacy of these regulations will be assessed.

Children and bioethics: clarifying consent and assent in medical and research settings

Invited Review

Merle Spriggs

British Medical Bulletin, 8 December 2022
Open Access
Abstract
Introduction
The concept of consent in the pediatric setting is complex and confusing. Clinicians and researchers want to know whose consent they should obtain, when a child can provide independent consent and how that is determined. The aim of this article is to establish what produces the justification to proceed with medical or research interventions involving children and the role of consent in that. I clarify concepts such as consent, assent, capacity and competence.
Source of data
Literature review.
Areas of agreement
Engaging with children and involving them in decisions about matters that affect them is a good thing. Areas of controversy: The role of competence or capacity and the question of when a child can provide sole consent.
Growing points
Flawed assumptions around competence/capacity.
Areas for developing research
An account of children's well-being that accommodates children's interests during the transition to adulthood.

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TECHNOLOGY/OTHER MEDIATION

Application of 3D printing technology for pre-operative evaluation, education and informed consent in pediatric retroperitoneal tumors

Joong Kee Youn, Sang Joon Park, Young-Hun Choi, Ji-Won Han, Dayoung Ko, Jeik Byun, Hee-Beom Yang, Hyun-Young Kim
Scientific Reports, 30 January 2023
Open Access
Abstract
To investigate usefulness of 3D printing for preoperative evaluations, student and resident education, and communication with parents or guardians of patients with pediatric retroperitoneal tumors. Ten patients planning retroperitoneal tumor resection between March and November 2019 were included. Preoperative computed tomography (CT) images were used for 3D reconstruction and printing. Surveyed items were understanding of preoperative lesions with 3 different modules (CT, 3D reconstruction, and 3D printing) by students, residents, and specialists; satisfaction of specialists; and comprehension by guardians after preoperative explanations with each module. The median age at operation was 4.2 years (range, 1.8–18.1), and 8 patients were diagnosed with neuroblastoma. The 3D printing was the most understandable module for all groups (for students, residents, and specialists, P = 0.002, 0.027, 0.013, respectively). No significant intraoperative adverse events or immediate postoperative complications occurred. All specialists stated that 3D printing enhanced their understanding of cases. Guardians answered that 3D printing were the easiest to comprehend among the 3 modules (P = 0.007). Use of 3D printing in treatment of pediatric patients with retroperitoneal tumors was useful for preoperative planning, education, and parental explaining with obtaining informed consent.

Effects of a video-based positive side-effect information framing: An online experiment

Friederike L. Bender, Winfried Rief, Joscha Brück, Marcel Wilhelm

Health Psychology, 2023

Abstract

Objective

Despite the public health value of vaccines, vaccination uptake rates are stagnating. Expected adverse events following immunization are a major source of concern and play a role in the emergence of vaccine hesitancy. Since nocebo mechanisms are involved in the perception of adverse reactions, positive side-effect communication is warranted. The aim of the present study was to compile a comprehensive communication strategy that minimizes expectations of nocebo effects while respecting the informed consent procedure.

Method

In a randomized 2 × 2 between-subject design, 652 participants received information about COVID-19 or influenza vaccination using either standard side-effect messaging or messaging enriched with proven elements of expectation-optimizing framing. A physician presented information online via video. Moderation analyses were conducted to examine effects among particular subpopulations. Expected adverse event ratings following an imagined immunization, cost-benefit ratios of the vaccination, and future vaccination intentions were assessed.

Results

Information content ratings were equally high in each group. Positive framing significantly decreased adverse event expectations in the COVID-19 information group and raised the cost-benefit ratio in the influenza condition, indicating higher benefits than cost expectations. Moderation analysis revealed that the framed side-effect communication lowered the expected COVID-19 vaccination uptake willingness in individuals with strong anti-vaccination attitudes.

Conclusions

Facing the ongoing coronavirus mass vaccinations, positive information frames have a small but significant impact on vaccination concerns while upholding informed consent. Although intervention trials are still pending, this approach could help decrease vaccine hesitancy by reducing fearful expectations. However, it seems that it should not be used without considering vaccination attitudes.

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POLICY/GUIDANCE/CODES/PROGRAM ACTION

Individualised consent for endoscopy: update on the 2016 BSG guidelines

Guideline

Nicholas Ewin Burr, Ian D Penman, Helen Griffiths, Andrew Axon, Simon M Everett

Frontline Gastroenterology, 7 February 2023

Abstract

In 2016, the British Society of Gastroenterology (BSG) published comprehensive guidelines for obtaining consent for endoscopic procedures. In November 2020, the General Medical Council (GMC) introduced updated guidelines on shared decision making and consent. These guidelines followed the Montgomery ruling in 2015, which changed the legal doctrine determining what information should be given to a patient before a medical intervention. The GMC guidance and Montgomery ruling expand on the role of shared decision making between the clinician and patient, explicitly highlighting the importance of understanding the values of the patient. In November 2021, the BSG President's Bulletin highlighted the 2020 GMC guidance and the need to incorporate patient -related factors into decision making. Here, we make formal recommendations in support of this communication, and update the 2016 BSG endoscopy consent guidelines. The BSG guideline refers to the Montgomery legislation, but this document expands on the findings and gives proposals for how to incorporate it into the consent process. The document is to accompany, not replace the recent GMC and BSG guidelines. The recommendations are made in the

understanding that there is not a single solution to the consent process, but that medical practitioners and services must work together to ensure that the principles and recommendations laid out below are deliverable at a local level. The 2020 GMC and 2016 BSG guidance had patient representatives involved throughout the process. Further patient involvement was not sought here as this update is to give practical advice on how to incorporate these guidelines into clinical practice and the consent process. This document should be read by endoscopists and referrers from primary and secondary care.

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RIGHTS/LEGAL/LEGISLATIVE

Informing a European guidance framework on electronic informed consent in clinical research: a qualitative study

Research
Evelien De Sutter, Pascal Borry, Isabelle Huys, Liese Barbier
BMC Health Services Research, 21 February 2023; 23(181)
Open Access
Abstract
Background
Electronic informed consent (eIC) may offer various advantages compared to paper-based informed consent. However, the regulatory and legal landscape related to eIC provides a diffuse image. By drawing from the perspectives of key stakeholders in the field, this study aims to inform the creation of a European guidance framework on eIC in clinical research.
Methods
Focus group discussions and semi-structured interviews were conducted with 20 participants from six stakeholder groups. The stakeholder groups included representatives of ethics committees, data infrastructure organizations, patient organizations, and the pharmaceutical industry as well as investigators and regulators. All were involved in or knowledgeable about clinical research and were active in one of the European Union Member States or at a pan-European or global level. The framework method was used for data analysis.
Results
Stakeholders underwrote the need for a multi-stakeholder guidance framework addressing practical elements related to eIC. According to the stakeholders, a European guidance framework should describe consistent requirements and procedures for implementing eIC on a pan-European level. Generally, stakeholders agreed with the definitions of eIC issued by the European Medicines Agency and the US Food and Drug Administration. Nevertheless, it was raised that, in a European guidance framework, it should be emphasized that eIC aims to support rather than replace the personal interaction between research participants and the research team. In addition, it was believed that a European guidance framework should include details on the legality of eIC across European Union Member States and the responsibilities of an ethics committee in the eIC assessment process. Although stakeholders supported the idea to include detailed information on the type of eIC-related materials to be submitted to an ethics committee, opinions varied on this regard.
Conclusion
The creation of a European guidance framework is a much needed factor to advance eIC implementation in clinical research. By collecting the views of multiple stakeholder groups, this study advances recommendations that may facilitate the development of such a framework. Particular consideration should go to harmonizing requirements and providing practical details related to eIC implementation on a European Union-wide level.

[Improper informed consent of the patient: legal and expert assessment]

Kratenko MV

Sudebno-meditsinskaia Ekspertiza, 1 January 2023; 66(1) pp 59-62

Abstract

The purpose of the study is to draw the attention of the legal and medical community to the problem of insufficient awareness of the patient about the upcoming medical intervention; to identify the scope of interaction between the court and the expert in relation to disputes related to improper information. Despite the fact that the conclusion about improper informing of the patient implies a legal assessment of the circumstances, special medical knowledge is needed to identify some defects of voluntary informed consent. The expert, in particular, can answer the questions of the court about what risks are characteristic of a certain type of medical intervention (perforations, bleeding, etc.) and how high their probability was in relation to a particular patient (taking into account his state of health, anatomical features); whether there were alternative treatment options. Based on the explanations received, the court will be able to assess whether the patient's attention was focused on the relevant circumstances, whether his consent was conscious, and the complications that occurred were foreseeable.

Editor's note: This is a Russian language publication.

Principles of Informed Consent for Perinatal and Neonatal Nurses

Rebecca L. Cypher

The Journal of Perinatal & Neonatal Nursing, January-March 2023; 37(1) pp 10-13

Excerpt

An informed consent process includes a patient's ability to make a decision, a conversation explaining pertinent information to make a choice, and an agreement to receive a definitive type of care. Malpractice disputes are sometimes centered on whether a patient received adequate consent from a clinician prior to a treatment or procedure. In fact, The Joint Commission reported 49 informed consent–related sentinel events over an 11-year period. Consent arguments may arise in perinatal and neonatal allegations when an action results in an adverse event. As an illustration, a family claims that an infant's death from a subgaleal hemorrhage was caused by an operative vaginal birth. These allegations stem from an accusation that informed consent incorporating maternal and newborn risks was not attained beforehand.

Obtaining informed consent goes beyond a signature on a form. Consent for care is vital for communication and shared decision-making between a clinician (eg, physician or advanced practice nurse) and a patient, a newborn's parent, or a guardian. This process is designed to provide precise measures that allow patients to have an opportunity to ask questions and make an informed decision. From a liability perspective, when individuals fully comprehend risks and benefits of a treatment, they may cope better with a less than optimal outcome resulting from any care provided. In some circumstances, patients may be less likely to file a malpractice claim. This column offers a primer addressing certain doctrines of informed consent in a perinatal or neonatal setting…

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CULTURAL/COUNTRY CONTEXT

Informed Consent in Dental Practice: A Qualitative Analysis of Awareness and Apprehensions Among Practitioners in South India

Dr Baiju R M, Dr Elbe Peter, Dr Vivek Narayan, Dr Roshna E K, Dr Abhilash Babu, Dr Nandimath Omprakash V

International Journal of Social Science And Human Research, 2 February 2023; 6(2)

Open Access

Abstract

Context
The push for autonomy and liberalization has transformed the practice of medicine and dentistry from paternalism to a patient cantered model. Patient's choice to accept or reject the proposed treatment is central to this new paradigm of health care. Informed consent is an essential tool for an ethical dental practice.
Aim
The objective of the present study was to explore the knowledge, attitudes, perceptions and prevailing practices among dentists regarding the informed consent process.
Materials and methods
A phenomenological approach was undertaken. A semi structured telephonic interview was conducted based on a flexible topic guide and continued until data saturation.
Statistical analysis
The data was transcribed verbatim. Coding and categorisation done. Anonymity was ensured in all steps. The data was subjected to a thematic analysis.
Results
Participants were apprehensive about the influence of social media on the new paradigm of doctor patient relationship and the increasing utility of specialists as a protection from litigation. Lack of clarity regarding the consent method has prevented its routine application.
Conclusions
It can be concluded that a comprehensive understanding regarding informed consent process was lacking among the participants.

Iranian women's experiences of the episiotomy consent process: a qualitative study

Malihe Ghiasvand, Fatemeh Nahidi, Sedigheh Sedigh Mobarakabadi, Hamid Alavi Majd
British Journal of Midwifery, 1 February 2023; 31(2)
Abstract
Background
Knowledge of the benefits and complications of interventions related to medical procedures, such as episiotomy, enables women to make informed decisions regarding these interventions. This study investigated women's experiences of the episiotomy consent process in Iran.
Methods
This qualitative study gathered data from 20 women through in-depth semi-structured interviews. The participants were selected from hospitals, health centers and gynecology clinics in Tehran. Content analysis was used to establish themes from the gathered data.
Results
The participants' experiences showed that they felt that their needs were not met and that they were excluded from decision making regarding their birth.
Conclusions
Women were excluded from decision making and their unmet needs presented ethical challenges in the performance of episiotomy procedures. Neglecting women's expectations, inducing absolute trust in obstetricians or midwives and failing to obtain informed consent paved the way for forced episiotomies. Proper education and obtaining informed and voluntary consent may facilitate women's rights being respected.

Awareness of Post-Operative Patients Regarding Informed Consent Form in Public Tertiary Care Hospital of Peshawar Khyber Pakhtunkhwa: A Cross Sectional Survey

Original Article
Bakhtyar Ali Shah, Muhammad Anwar, Nusrat Begum, Naheed Akhtar, Amir Sultan, Muzamil Tariq, Sumaira Bibi

Pakistan Journal Of Health Sciences, 31 January 2023

Open Access

Abstract

The informed consent form is one of the components of bioethics. Written consent from the patient must be obtained prior to any medical or surgical procedure to give the patient freedom of choice. This factor has always been neglected when caring for patients in most third world countries.

Objective

To assess postoperative patient awareness of informed consent at Peshawar KP Tertiary Public Hospital (HMC).

Methods

This study was conducted from April 2021 to August 2021 at Hayatabad Medical Complex, a tertiary care public hospital in Peshawar. A total sample of 70 patients was drawn by consecutive selection. An adopted and pre-tested questionnaire was used for data collection. Questions were filled in by having the patient understand the question and receiving the answer from the patient.

Results

The majority (59%) of the patients included in this study were male, while the mean age was 35 years and the majority of the patients (44%) were illiterate. Awareness of variables (2–7) was 60%, 47%, 30%, 47%, 69%, and 53%, respectively, while awareness levels from questions 8–12 were 59%, 47%, 82%, 40%, and 60%, respectively.

Conclusions

The results of the current study indicate that the perception of informed consent among patients in tertiary care public hospitals is reasonably satisfactory, although some lack of participant knowledge of key issues has been identified and needs to be improved through education and awareness.

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MEDICAL/SURGICAL

Surgical Informed Consent: A Scoping Review of Physician-facing Decision Support Tools

Review

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Annals of Surgery Open, March 2023; 4(1)

Abstract

Objectives

Physician-facing decision support tools facilitate shared decision-making (SDM) during informed consent, but it is unclear whether they are comprehensive in the domains they measure. In this scoping review, we aimed to (1) identify the physician-facing tools used during SDM; (2) assess the patient-centered domains measured by these tools; (3) determine whether tools are available for older adults and for use in various settings (elective vs. emergent); and (4) characterize domains future tools should measure.

Methods

Using the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews, Embase, Medline, and Web of Science were queried for articles published between January 2000 and September 2022. Articles meeting inclusion criteria underwent title and abstract review. Eligible studies underwent data abstraction by two reviewers.

Results

Of 4365 articles identified, 160 were eligible. Tools to aid in surgical SDM focus on elective procedures (79%) and the outpatient setting (71%). Few tools are designed for older adults (5%) or for nonelective procedures (9%). Risk calculators were most common, followed by risk indices, prognostic nomograms, and communication tools. Of the domains measured, prognosis was more commonly measured (85%), followed

by alternatives (28%), patient goals (36%), and expectations (46%). Most tools represented only one domain (prognosis, 33.1%) and only 6.7% represented all four domains.
Conclusions and Implications
Tools to aid in the surgical SDM process measure short-term prognosis more often than patient-centered domains such as long-term prognosis, patient goals, and expectations. Further research should focus on communication tools, the needs of older patients, and use in diverse settings.

Factors impacting informed consent in cosmetic breast augmentation

Stephen Whyte, Laura Bray, Martin Brumpton, Ho Fai Chan, Tim S. Peltz, Manisha Tamar, Uwe Dulleck, Dietmar W. Hutmacher
The Breast, 22 February 2023
Open Access
Abstract
Background
For women who undergo cosmetic breast augmentation, their post-operative risk assessment may not match their pre-operative understanding of the involved risks and likelihood of revision surgeries. This may be due to the potential issues surrounding whether patients are being fully informed about all possible risks and related financial implications during the consent phases of patient/doctor consultation.
Methods
To explore comprehension, risk preference, and perceptions of breast augmentation procedure, we conducted a recorded online experiment with 178 women (18–40 years) who received varying amounts of risk-related information from two experienced breast surgeons in a hypothetical first consultation scenario.
Results
We find patient's age, self-rated health, income, education level, and openness to experience to be significant factors impacting initial breast augmentation risk preferences (before receiving any risk information). Further, more emotionally stable patients perceived greater breast augmentation risks, were less likely to recommend breast augmentation, and were more likely to acknowledge the likelihood for future revision surgery. After providing women with risk-related information we find increases in risk assessment in all treatment conditions, and that increased amounts of risk information do decrease women's willingness to recommend breast augmentation. But that increased risk information does not appear to increase women's assessment of the likelihood of future revision surgery. Finally, we find some participant individual differences (such as education level, having children, conscientiousness and emotional stability) appear to impact risk assessment post receiving risk information.
Conclusion
Continuous improvement of the informed consent consultation process is vital to optimising patient outcomes efficiently and cost-effectively. Greater acknowledgement and emphasis on disclosure of related risks and financial burden when complications arise is also important. As such, future behavioural research is warranted into the factors impacting women's understanding both prior to and across the BA informed consent process.

A randomized controlled trial of patient recall after detailed written consent versus standard verbal consent in adults with routine orthopaedic trauma

Amjad M. Aslam, James Kennedy, Haider Seghol, Nikhil Khisty, Thomas A. Nicols, Sam Adie
Bone & Joint Open, 20 February 2023; 4(2) pp 104–109
Open Access
Abstract
Aims

Patient decision aids have previously demonstrated an improvement in the quality of the informed consent process. This study assessed the effectiveness of detailed written patient information, compared to standard verbal consent, in improving postoperative recall in adult orthopaedic trauma patients.

Methods

This randomized controlled feasibility trial was conducted at two teaching hospitals within the South Eastern Sydney Local Health District. Adult patients (age ≥ 18 years) pending orthopaedic trauma surgery between March 2021 and September 2021 were recruited and randomized to detailed or standard methods of informed consent using a random sequence concealed in sealed, opaque envelopes. The detailed group received procedure-specific written information in addition to the standard verbal consent. The primary outcome was total recall, using a seven-point interview-administered recall questionnaire at 72 hours postoperatively. Points were awarded if the participant correctly recalled details of potential complications (maximum three points), implants used (maximum three points), and postoperative instructions (maximum one point). Secondary outcomes included the anxiety subscale of the Hospital and Anxiety Depression Scale (HADS-A) and visual analogue scale (VAS) for pain collected at 24 hours preoperatively and 72 hours postoperatively. Additionally, the Patient Satisfaction Questionnaire Short Form (PSQ-18) measured satisfaction at 72 hours postoperatively.

Results

A total of 60 patients were randomized, 32 to the standard group and 28 to the detailed group. Patients in the detailed group had significantly higher total recall score compared to the standard group (mean difference 1.29 points (95% confidence interval (CI) 0.51 to 2.08); p = 0.002). There were no differences in HADS-A (mean difference 0.39 (95% CI -2.11 to 2.88); p = 0.757), VAS pain (mean difference 5.71 (95% CI -22.25 to 11.11); p = 0.499), or PSQ-18 (mean difference 0.499; 95% CI -1.6 to 3.42; p = 0.392).

Conclusion

Detailed written tools are useful in improving postoperative recall in adult orthopaedic trauma patients.

Consent during labour and birth as observed by midwifery students: A mixed methods study

Nigel Lee, Lauren Kearney, Emma Shipton, Glenda Hawley, Peta Winters-Chang, Catherine Kilgour, Susannah Brady, Ann Peacock, Loretta Anderson, Tracy Humphrey

Women and Birth, 18 February 2023

Open Access

Abstract

Background

While consent is an integral part of respectful maternity care, how this is obtained during labour and birth presents conflicting understandings between midwives' and women's experiences. Midwifery students are well placed to observe interactions between women and midwives during the consent process.

Aim

The purpose of this study was to explore the observations and experiences of final year midwifery students of how midwives obtain consent during labour and birth.

Methods

An online survey was distributed via universities and social media to final year midwifery students across Australia. Likert scale questions based on the principles of informed consent (indications, outcomes, risks, alternatives, and voluntariness) were posed for intrapartum care in general and for specific clinical procedures. Students could also record verbal descriptions of their observations via the survey app. Recorded responses were analysed thematically.

Findings

225 students responded with 195 completed surveys; 20 students provided audio recorded data. Student's observations suggested that the consent process varied considerably depending on the clinical procedure. Discussions of risks and alternatives during labour were frequently omitted.

Discussion

The student's accounts suggest that in many instances during labour and birth the principles of informed consent are not being applied consistently. Presenting interventions as routine care subverted choice for women in favour of the midwives' preferences.

Conclusions

Consent during labour and birth is invalidated by a lack of disclosure of risks and alternatives. Health and education institutions should include information in guidelines, theoretical and practice training on minimum consent standards for specific procedures inclusive of risks and alternatives.

Consent for Trainee Participation in Abortion Care: A Qualitative Study of Patient Experiences & Preferences in the United States

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Contraception, 8 February 2023

Abstract

Objectives

Abortion training for clinicians is crucial to ensure patients' future access to full spectrum reproductive health care. Given the complex sociopolitical context of abortion, consent to allow a trainee's involvement in abortion care requires careful attention to avoid harm to patients while also ensuring adequate clinician training for the future provision of care. In order to inform the development of patient-centered recommendations, we assessed patient experiences and preferences around consent for trainee participation during abortion care.

Study design

We interviewed participants who received abortion care at sites with medical trainees in the United States (US). We conducted interviews via zoom (video-off) between August 2021 and January 2022. We audio-recorded and transcribed the interviews. We coded transcripts using NVivo software and analyzed inductively using thematic analysis.

Results

Twenty-four (n=24) participants reflected a diverse range of socio-demographics as well as location of abortion service. Some reported experiences of coercion related to trainee involvement, ranging from subtle to overt. Participants preferred consent for trainee involvement in abortion care be a process outside the procedure room, while clothed, without the trainer or trainee present to allow for time to consider options without pressure to say yes.

Conclusions

Patient-centered approaches to seeking consent for trainee involvement in abortion care must reduce potential for coercion. A standardized consent before the procedure room by a trained staff member without the trainer or trainee present can help prioritize patient autonomy. Understanding care team member roles and upholding confidentiality and privacy are paramount to patients feeling safe with trainees present.

Assessment of the Factors Influencing the Patient's Comprehension of the Informed Consent to Interventional Pain Procedures

Research Article

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Pain Research and Management, 8 February 2023

Open Access

Abstract

Background

Informed consent is the first step of every medical procedure and is considered a standard of care for patients undergoing medical interventions. Our study seeks to evaluate patients' understanding of the procedure they consented to and the factors affecting the degree of understanding.

Methods

In this cross-sectional study, we used an anonymous postprocedural questionnaire to assess our patients' understanding of the procedure being performed and their level of satisfaction. It was conducted between June 2021 and January 2022 on every consenting patient who declined English interpreter services and was undergoing a first elective lumbar epidural steroid injection.

Results

The mean age of 201 subjects was 57.3 (23–90) years, with a race distribution of Black (44.3%), White (31.8%), and other races (23.9%). 15.9% of our subjects worked in the medical field. Older age and patients identified as Black and other races had a positive correlation with the propensity to predict a poor understanding of consent. This study failed to demonstrate any difference in understanding of informed consent content between the different subgroups when stratified by assigned sex at birth, level of education, and profession. Patients' expectation from the treatment was classified as desperate (will take any help they can) in 78 patients (38.8%), feeling hopeful (expecting partial improvement in their symptoms) in 52 patients (25.9%), and being optimistic (will obtain full recovery from this injection) in 71 patients (35.3%). 192 patients (95.5%) were very satisfied with the consent process. Seven patients (3.5%) stated that they wanted more information, and 2 patients (1.0%) did not understand the explanation. 180 patients (89.6%) were satisfied with the overall experience, while 21 patients (10.4%) were not. The Wilks test (likelihood-ratio test) resulted in a value of 0.023 and was deemed statistically significant for a relationship between understanding of consent and the satisfaction of the patient from the procedure.

Conclusions

Although patients carry a variable expectation of procedures, most patients in our pain clinic have a high level of satisfaction despite having a poor understanding of the procedure provided via informed consent. Although our patients' level of objective comprehension is low, those with a better understanding of the procedure tend to have a more satisfactory experience.

Informed or misinformed consent and use of modified texture diets in dysphagia

Debate

Shaun T. O'Keeffe, Paula Leslie, Tracy Lazenby-Paterson, Arlene McCurtin, Lindsey Collins, Aoife Murray, Alison Smith, Siofra Mulkerrin

BMC Medical Ethics, 7 February 2023; 24(7)

Open Access

Abstract

Background

Use of modified texture diets—thickening of liquids and modifying the texture of foods—in the hope of preventing aspiration, pneumonia and choking, has become central to the current management of dysphagia. The effectiveness of this intervention has been questioned. We examine requirements for a valid informed consent process for this approach and whether the need for informed consent for this treatment is always understood or applied by practitioners.

Main text

Valid informed consent requires provision of accurate and balanced information, and that agreement is given freely by someone who knows they have a choice. Current evidence, including surveys of practitioners and patients in different settings, suggests that practice in this area is often inadequate. This may be due to patients' communication difficulties but also poor communication—and no real attempt to obtain consent—by practitioners before people are 'put on' modified texture diets. Even where discussion occurs, recommendations may be influenced by professional misconceptions about the efficacy of this treatment, which in turn may poison the well for the informed consent process. Patients cannot make appropriate decisions for themselves if the information provided is flawed and unbalanced. The voluntariness of patients' decisions is also questionable if they are told 'you must', when 'you might consider' is more appropriate. Where the decision-making capacity of patients is in question, inappropriate judgements and recommendations may be made by substitute decision makers and courts unless based on accurate information.

Conclusion
Research is required to examine the informed consent processes in different settings, but there is ample reason to suggest that current practice in this area is suboptimal. Staff need to reflect on their current practice regarding use of modified texture diets with an awareness of the current evidence and through the 'lens' of informed consent. Education is required for staff to clarify the importance of, and requirements for, valid informed consent and for decision making that reflects people's preferences and values.

Informed consent research at a tertiary hospital: How impactful is competency in simpler versus standard consent forms for intravitreal injection therapy?

Hamidu Hamisi Gobeka, Yiğit Şenol, Saadet Alijanli, Mustafa Doğan, İbrahim Ethem Ay
Journal of Clinical Medicine of Kazakhstan, February 2023
Open Access
Abstract
Aim
To compare the impact of competency in intravitreal injection therapy (IVIT)-related simpler versus standard consent forms (CFs).
Material and methods
Four hundred patients scheduled for IVIT in a tertiary hospital were enrolled between April 1, 2022 and June 30, 2022. These patients were eligible for the study if they had their first IVIT in one eye; those scheduled for IVIT in the other eye were not. Data, including age, gender, educational level, whether the patient was admitted alone or with a companion, and prior IVIT status were collected. A trained clinic secretary first gave the patients the commonly used standard CFs, followed by simpler CFs.
Results
The mean age was 66.10±9.90 years. 93.80% had previously received IVIT. 53.80% of the patients consented on their own. While 98.00% consented without reading standard CFs, 56.00% consented after reading simpler CFs ($p<0.001$). The need for IVIT-related extra information and the desire against having IVIT were significantly higher in simpler than standard CFs ($p<0.001$). 5.00% of those who approved IVIT without reading both forms were illiterate, and 29.20% had vision issues. The probability of simpler CF reading increased by 4.653 and 7.510 times in high school and university graduates, respectively, relative to primary school graduates.
Conclusion
Simpler CFs had a much higher reading rate, which was linked to a higher rate of patients opting against IVIT. In medical fields like ophthalmology, where many procedures and research are performed, ethically approved informed consent requires consideration of patients' education and prior treatment experience.

The ethics of consent during labour and birth: episiotomies

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Journal of Medical Ethics, 30 January 2023
Abstract
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.

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GENERAL/OTHER

Assent in applied behaviour analysis and positive behaviour support: ethical considerations and practical recommendations

Discussion papers
Cassi A. Breaux, Kristin Smith
International Journal of Developmental Disabilities, 1 February 2023; pp 111-121
Abstract
The term positive behaviour support (PBS) is used to describe the integration of the contemporary ideology of disability service provision with the clinical framework of applied behaviour analysis (ABA). Assent, the participation consent of those not legally able to consent, has gained recent popularity in the fields of ABA and PBS. The goal of assent-based ABA and PBS is a person-centered approach to assessment, intervention, and all other decision-making. In this model, the learner's assent withdrawal for participation is honored, whether it be a vocal 'no' or a non-vocal expression of verbal behaviour. There is currently a limited subset of studies that mention or utilize assent with learners in ABA or PBS. The lack of published research can make assent-based practices seem to be a choice of the practitioner. The authors of this manuscript seek to further define assent, illuminate the necessity of assent-based practices, and offer assent-based procedures in ABA- and PBS-based intervention.

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