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.

Each month we monitor Google Scholar for the search terms “consent” and “informed consent” in title and available text. After careful consideration, a selection of these results appear in the digest. 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, 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. We expect that these categories will evolve over time.

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No new content identified for the following established categories:
COMPASSIONATE USE/EXPANDED ACCESS
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION

Please note that we maintain a glossary and an inventory of tools for assessment as well as standards and guidance documents on our website.
COVID-19

Influence of Social and Cultural Factors on the Decision to Consent for Monoclonal Antibody Treatment among High-Risk Patients with Mild-Moderate COVID-19

Research Article
Dennis M. Bierle, Ravindra Ganesh, Caroline G. Wilker, Sara N. Hanson, Darcie E. Moehnke, Tammy A. Jackson, Priya Ramar, Jordan K. Rosedahl, Lindsey M. Philpot, Raymund R. Razonable

Journal of Primary Care & Community Health, 25 May 2021
Open Access

Abstract
Background
The clinical outcomes of patients who decline anti-spike monoclonal antibody therapies for coronavirus disease-2019 (COVID-19) is not known. Factors associated with the decision to accept or decline the offer for anti-spike monoclonal antibody therapies are not established. This study aimed to identify factors impacting the decision to consent for monoclonal antibody therapies and assess the differences in clinical outcomes of patients who accepted compared to those who declined these therapies.

Methods
This retrospective cohort study enrolled 2820 adult patients who were offered monoclonal antibody therapies, bamlanivimab and casirivimab-imdevimab, for COVID-19 at Mayo Clinic in the Midwest between 11/19/2020 and 12/31/2020. The primary endpoint is the decision to accept or decline monoclonal antibody treatment. Secondary endpoints were patient-level factors that could have impacted the decision to accept treatment (age, gender, race, ethnicity, primary language spoken, and medical comorbidities). The main clinical endpoint was hospitalization within 28 days of COVID-19 diagnosis.

Results
59.1% (n = 1669) chose to accept monoclonal antibody therapy, and 40.9% (n = 1151) chose to decline the offer for treatment. Patients were more likely to accept treatment if they were non-Hispanic White, English speaking, identified a spouse or life partner, had a religious affiliation, and possessed more medical comorbidities. Overall, 28-day hospitalization rate was 2.6% (n = 72/2820) and was higher among those who declined (3.3%) than those who accepted monoclonal antibody therapy (2.0%; Rate Ratio = 0.62, 95% Confidence Interval, 0.39-0.98).

Conclusions
Despite having more comorbidities, patients who accepted monoclonal antibody treatments had a lower rate of hospitalization compared to patients who declined treatment. Several social and cultural factors were associated with the decision to decline therapy, including race, language, ethnicity, and lack of social support. These findings can inform public health efforts to reduce social disparities in the treatment of COVID-19 and increase utilization of monoclonal antibody therapies in high risk populations.

COVID-19 vaccination: your guide to consent
Erin Dean
Nursing Standard (2014+), 3 March 2021; 36(3)pp 42-43

Excerpt
The COVID-19 vaccination campaign is the biggest in the history of the NHS, with millions of people being offered the vaccine. Consent must be obtained before starting any treatment or investigation or providing personal care. This includes the administration of all vaccines.

For many, the idea of consent is inextricably linked to signing a form, and the government has introduced a number of consent forms specifically for the COVID-19 vaccine programme, including forms for adults and care home residents.
Yet RCN and government guidance is clear: consent should be a process rather than a single event and a signature alone does not demonstrate that the consent process has been followed.

Here, we look at the key issues surrounding consent, and the implications for nursing staff who are involved in the COVID-19 vaccine programme...

BIOMEDICAL RESEARCH

Improving consent forms for first-in-human trials through participant feedback
Hannah Claire Sibold, Gavin Paul Campbell, John Bourgeois, Margie D. Dixon, R Donald Harvey, Rebecca D. Pentz
Journal of Clinical Oncology, 28 May 2021; 39(15)
Abstract
Background
Risks and benefits of investigational agents that have not been tested in humans are, at best, incompletely characterized in nonclinical investigations. Despite the growing emphasis to include patient voices in clinical trial design, no published research has explored patient preferences on how best to convey the information that the agent has not been tested in humans. This study established that First in Human (FIH) consent forms present this information in different locations and queried participants for their input on the preferable FIH consent form structure.

Methods
Consent forms for FIH oncology trials open to accrual at Winship Cancer Institute in 2019-2020 were analyzed for (1) the location of the mention that the study drug has not been used in humans before (FIH information), (2) the location of animal and other nonclinical data, and (3) placement of the risks section. Patients offered enrollment in a FIH trial were eligible for this study. Participants were interviewed during a clinic visit after consent was obtained. An ethics researcher asked questions about the participant’s opinions on the wording and placement of the FIH, nonclinical, and risk information in the specific trial consent form. All interviews were audio-recorded and double coded by two independent coders. The location of FIH and nonclinical data in the consent forms was compared to the patient’s suggested location for this information.

Results
Saturation of themes was reached after interviewing 17 (17/19, 89% accrual) participants who were enrolled in 9 different FIH trials. Twenty FIH consents were qualitatively analyzed. Preferred placement compared to actual consent placement is listed in the table. 82% (14/17) of participants thought that nonclinical data on risks and efficacy was important to mention. 95% (19/20) of consents listed nonclinical data and most participants thought the placement in the consent was appropriate but 18% (3/17) of participants wanted the information earlier in the consent. No consent forms that were analyzed had the risks section before the study schedule; however, 47% (8/17) of participants wanted to move the risks sections before the study schedule.

Conclusions
There is considerable variation in the layout of FIH consent forms that does not align with patient preferences. Standardization of FIH consent forms to better reflect patient input is essential in order to promote understandability of these important yet sometimes misunderstood clinical trials and to ensure ethical informed consent.

Preparing accessible and understandable clinical research participant information leaflets and consent forms: a set of guidelines from an expert consensus conference
Research Article
Background
In line with Good Clinical Practice and the Declaration of Helsinki, it is the investigator’s responsibility to ensure that research participants are sufficiently informed, to enable the provision of informed consent. The Participant Information Leaflet/Informed Consent Form is key to facilitating this communication process. Although studies have indicated that clinical research Participant Information Leaflets/Informed Consent Forms are not optimal in terms of accessibility, there is little or no specific guidance available. The aim of this research was to propose and agree a set of guidelines for academic researchers and sponsors for preparing accessible and understandable Participant Information Leaflets/Informed Consent Forms.

Methods
A literature review identified guidance for the preparation of patient-facing documents. Following critical appraisal, key recommendations were extracted and a set of recommendations which can be applied to clinical research Participant Information Leaflets/Informed Consent Forms were prepared. These recommendations were evaluated and amended by an Expert Consensus Conference consisting of a group of key stakeholders. The stakeholders included members of a Research Ethics Committee (both lay and expert), a patient advocate, experienced clinical researchers, a plain English editor and a Data Protection Officer. Consensus was reached regarding a final set of recommendations.

Results
44 recommendations were agreed upon and grouped into five categories: Layout, Formatting, Content, Language and Confirming Readability. These recommendations aimed to maximize accessibility for lay participants, including readers with dyslexia, literacy or numeracy challenges, thereby improving the quality of the consent process.

Conclusions
More empirical research is needed to further improve the informed consent process for research participants. However, these recommendations are informed by the current literature and have been ratified by expert stakeholders. It is hoped that these recommendations will help investigators and sponsors to consistently and efficiently produce more accessible clinical research Participant Information Leaflets/Informed Consent Forms.

Cross-sectional study on patients’ understanding and views on the informed consent procedure of a secondary stroke prevention trial

Original Article
Felizitas A Eichner, Joschua M Reis, Joaquim Dores, Vladimir Pavlovic, Luisa Kreß, Naeimeh Daneshkhah, Renate Weinhardt, Armin Grau, Johannes Mühler, Hassan Soda, Christopher J Schwarzbach, Michael Schuler, Karl Georg Haeusler, Peter U Heuschmann
European Journal of Neurology, 14 May 2021

Abstract
Improving understanding of study contents and procedures might enhance recruitment into studies and retention during follow-up. However, data in stroke patients on understanding of the informed consent (IC) procedure are sparse.

Methods
We conducted a cross-sectional study among ischemic stroke patients taking part in the IC procedure of an ongoing cluster-randomized secondary prevention trial. All aspects of the IC procedure were assessed in an interview using a standardized 20-item questionnaire. Responses were collected within 72 hours after the IC
procedure and analyzed quantitatively and qualitatively. Participants were also asked regarding main reasons for participation.

Results
146 stroke patients (65±12 years, 38% female) were enrolled. On average, patients recalled 66.4% (95% CI 65.2%-67.5%) of the content of the IC procedure. Most patients understood that participation was voluntary (99.3%) and that they had the right to withdraw consent (97.1%). 79.1% of the patients recalled the study duration, 56.1% the goal. Only 40.3% could clearly state a benefit of participation and 28.8% knew their group allocation. Younger age, higher graduation and allocation to the intervention group were associated with better understanding. Of all patients, 53% exclusively stated a personal, 22% an altruistic reason for participation.

Conclusions
While understanding of patient rights was high, many patients were unable to recall other important aspects of study content and procedures. Increased attention to older and less educated patients may help to enhance understanding in this patient population. Actual recruitment and retention benefit of an improved IC procedure remains to be tested in a randomized trial.

Leveraging Technology Solutions to Automate Informed Consent in a Clinical Research Hospital
Claribel L. Sawyerr
University of Maryland Baltimore, Doctor of Nursing Practice Projects, May 2021
Open Access
Abstract
Problem: Paper informed consent (PIC) forms are associated with incomplete and or inaccurate information such as missing signatures and incorrect patient identification. The Food and Drug Administration’s Bioresearch Monitoring Program audit for the 2019 fiscal year lists failure to obtain informed consent (IC) requirements as one of the most common violations (2%) by clinical investigators in clinical trials. In a selected practice site, approximately 440 (2%) out of 25,000 PICs were returned by the medical records department to clinicians in 2019 due to incomplete and or inaccurate information. This resulted in significant delays in the start of clinical trials, incurring additional time and effort for participants and clinicians to correct and or re-consent. Purpose: The purpose of this quality improvement project was to implement electronic informed consent (EIC) for research participants in the adult oncology, infectious disease, and digestive diseases outpatient clinics in a clinical research hospital. Methods: Pre and post implementation surveys were administered to clinicians (n = 43) to obtain baseline perceptions, and compare preferences and satisfaction with using PIC versus EIC. The clinicians were trained on using EIC for signatures, then EIC was implemented and tracked for eight specific protocol studies. Results: The average confirmed IC available in the electronic health record (EHR) within one day of signing by clinicians for all three clinics increased from 52.5% (pre) to 61.3% (post). EIC use increased by 20%, and returned consents decreased from an average of 2.2% to 0.6%. Clinician preference to use EIC over PIC increased from 44.8% to 57.1%, Fisher’s Exact Test = 0.5256, 2-sided, p > .05. Conclusions: Replacing PIC with EIC was preferred by clinicians, improved documentation of consent, and decreased the time for consent availability in the EHR. The implications for practice are that automating informed consent is associated with improved consenting processes and supports remote workflows.

Symptoms of Medication Withdrawal in Parkinson’s Disease: Considerations for Informed Consent in Patient-Oriented Research
Kaitlyn R. Hay, Neevi Kukreti, Paula Trujillo, Ya-Chen Lin, Hakmook Kang, Daniel O. Claassen
Pharmaceutical Medicine, 29 April 2021
Abstract
Introduction
Dopamine medication withdrawal in Parkinson’s disease (PD) is commonly employed in clinical practice and can be required for participation in research studies. When asked to withdraw from medications, participants often enquire as to what symptoms they should expect.

Objectives
This study sought to improve the informed consent process by identifying patient-reported symptoms when dopamine treatment is withheld. We also sought to provide clinical guidance regarding the extent of these symptoms and consider participant willingness to undergo these assessments.

Methods
Participants were recruited from community-based PD programs and support groups in Nashville, Tennessee, USA. A patient-based questionnaire determined the frequency and severity of motor and nonmotor symptoms. The questionnaire also assessed whether patients would be willing to abstain from medication at a future date and under what circumstances.

Results
A total of 31/90 participants reported willingness to withdraw from dopaminergic medications for clinical or research purposes. Tremor, walking, and balance were the most common motor symptoms that worsened during this time. Sleep dysfunction, constipation, and tremor were noted as the most severe symptoms. Of note, 10% of participants indicated that they would not be willing to go off medications again, suggesting that a minority of patients find this to be most discomforting. When prompted for a reason why participants would be willing to come off of their medications again, “for clinical purposes” was selected the most.

Conclusions
Study teams should list these symptoms in the applications to their institutional review board and in the informed consent to provide guidance for participants.

SOCIAL SCIENCE RESEARCH

Ethical Considerations in Social Sciences: The Dilemmas of Informed Consent
Haji Karim Khan, Hussain, Mir Alam
Research Journal of Social Sciences & Economics Review, April-June 2021; 2(2)
Open Access
Abstract
Informed consent is an integral component of research ethics in Social Sciences. It has been observed that in Pakistan, most of the research ethics have been borrowed from the Western context. Therefore, it is vital to see how research ethics are being construed and practiced in Pakistan having different socio-cultural values and norms. In the case of informed consent, the bigger question is ‘how informed the informed consent is?’ Thus, in this paper, through a qualitative exploratory approach, we have explored how active Social Science researchers in our universities, see the notion of informed consent. We interviewed eighteen university teachers for the study. Transcribed the interviews verbatim and analyzed those using robust qualitative approaches. Findings show that ‘informed consent’ becomes a dilemma for the researchers given the variations in the socio-cultural and linguistic contexts of the settings. Findings have pertinent implications for policymakers, university management, and researchers in the context of Social Sciences.

Implementing continuous consent in qualitative research
Research Article
Fride Haram Klykken
Qualitative Research, 9 May 2021
Abstract
This article examines ways of approaching informed consent as a relationally constituted process in qualitative research practices. It argues that a researcher’s operationalization of informed consent should be coherent with the overall epistemological framework of the project. Based on empirical examples from an ethnographic inquiry in an educational setting, the principle of informed consent is discussed as a reflexive and ethical tool throughout the inquiry, including its pre-fieldwork, fieldwork and post-fieldwork phases. Strategies of explicitly and implicitly (re)negotiated consent and dissent are discussed and illustrated by drawing on some of the recent discussions of continuous consent practices. The article’s conceptualization of a continuous, situated and relational approach to informed consent is also supported by the concepts of response-ability and thinking with care in research ethics.

BIOBANKING

Thinking about the idea of consent in data science genomics: How ‘informed’ is it?
Jennifer Greenwood, Andrew Crowden
Nursing Philosophy, 12 May 2021
Abstract
In this paper we argue that ‘informed’ consent in Big Data genomic biobanking is frequently less than optimally informative. This is due to the particular features of genomic biobanking research which render it ethically problematic. We discuss these features together with details of consent models aimed to address them. Using insights from consent theory, we provide a detailed analysis of the essential components of informed consent which includes recommendations to improve consent performance. In addition, and using insights from philosophy of mind and language and psycholinguistics we support our analyses by identifying the nature and function of concepts (ideas) operational in human cognition and language together with an implicit coding/decoding model of human communication. We identify this model as the source of patients/participants poor understanding. We suggest an alternative, explicit model of human communication, namely, that of relevance-theoretic inference which obviates the limitations of the code model. We suggest practical strategies to assist health service professionals to ensure that the specific information they provide concerning the proposed treatment or research is used to inform participants’ decision to consent. We do not prescribe a standard, formal approach to decision-making where boxes are ticked; rather, we aim to focus attention towards the sorts of considerations and questions that might usefully be borne in mind in any consent situation. We hope that our theorising will be of real practical benefit to nurses and midwives working on the clinical and research front-line of genomic science.

HEALTH DATA

Trust, but Verify: Informed Consent, AI Technologies, and Public Health Emergencies
Brian Pickering
Future Internet, 18 May 2021; 13 (132)
Open Access
Abstract
To use technology or engage with research or medical treatment typically requires user consent: agreeing to terms of use with technology or services, or providing informed consent for research participation, for clinical trials and medical intervention, or as one legal basis for processing personal data. Introducing AI
technologies, where explainability and trustworthiness are focus items for both government guidelines and responsible technologists, imposes additional challenges. Understanding enough of the technology to be able to make an informed decision, or consent, is essential but involves an acceptance of uncertain outcomes. Further, the contribution of AI-enabled technologies not least during the COVID-19 pandemic raises ethical concerns about the governance associated with their development and deployment. Using three typical scenarios—contact tracing, big data analytics and research during public emergencies—this paper explores a trust-based alternative to consent. Unlike existing consent-based mechanisms, this approach sees consent as a typical behavioural response to perceived contextual characteristics. Decisions to engage derive from the assumption that all relevant stakeholders including research participants will negotiate on an ongoing basis. Accepting dynamic negotiation between the main stakeholders as proposed here introduces a specifically socio-psychological perspective into the debate about human responses to artificial intelligence. This trust-based consent process leads to a set of recommendations for the ethical use of advanced technologies as well as for the ethical review of applied research projects.

**A systematic literature review of attitudes towards secondary use and sharing of health administrative and clinical trial data: a focus on consent**

*Research*
Elizabeth Hutchings, Max Loomes, Phyllis Butow, Frances M. Boyle

*Systematic Reviews, 4 May 2021; 10(132)*

*Abstract*

*Background*
We aimed to synthesise data on issues related to stakeholder perceptions of consent for the use of secondary data. To better understand the current literature available, we conducted a systematic literature review of healthcare consumer attitudes towards the secondary use and sharing of health administrative and clinical trial data.

*Methods*
EMBASE/MEDLINE, Cochrane Library, PubMed, CINAHL, Informit Health Collection, PROSPERO Database of Systematic Reviews, PsycINFO and ProQuest databases were searched. Eligible articles included those reporting qualitative or quantitative original research and published in English. No restrictions were placed on publication dates, study design or disease setting. One author screened articles for eligibility and two authors were involved in the full-text review process. Conflicts were resolved by consensus. Quality and bias were assessed using the QualSyst criteria for qualitative studies.

*Results*
This paper focuses on a subset of 47 articles identified from the wider search and focuses on the issue of consent. Issues related to privacy, trust and transparency, and attitudes of healthcare professionals and researchers to secondary use and sharing of data have been dealt with in previous publications. Studies included a total of 216,149 respondents. Results indicate that respondents are generally supportive of using health data for research, particularly if the data is de-identified or anonymised. The requirement by participants to obtain consent prior to the use of health data for research was not universal, nor is the requirement for this always supported by legislation. Many respondents believed that either no consent or being informed of the research, but not providing additional consent, were sufficient.

*Conclusions*
These results indicate that individuals should be provided with information and choice about how their health data is used and, where feasible, a mechanism to opt-out should be provided. To increase the acceptability of using health data for research, health organisations and data custodians must provide individuals with concise information about data protection mechanisms and under what circumstances their data may be used and by whom.
TECHNOLOGY/OTHER MEDIATION

Informed Consent for Online Research—Is Anybody Reading?: Assessing Comprehension and Individual Differences in Readings of Digital Consent Forms

Research Article
Caitlin Geier, Robyn B. Adams, Katharine M. Mitchell, Bree E. Holtz

Abstract
Informed consent is an important part of the research process; however, some participants either do not read or skim the consent form. When participants do not read or comprehend informed consent, then they may not understand the potential benefits, risks, or details of the study before participating. This study used previous research to develop experimentally manipulated online consent forms utilizing various presentations of the consent form and interactive elements. Participants (n = 576) were randomly exposed to one of six form variations. Results found that the highly interactive condition was significantly better for comprehension than any of the other conditions. The highly interactive condition also performed better for readability, though not significantly. Further research should explore the effects of interactive elements to combat habituation and to engage participants with the parts of the consent form unique to the study.

Evaluation of two communication tools, slideshow and theater, to improve participants’ understanding of a clinical trial in the informed consent procedure on Pemba Island, Tanzania

Research Article
Marta S. Palmeirim, Ulfat A. Mohammed, Amanda Ross, Shaali M. Ame, Said M Ali, Jennifer Keiser
PLoS Neglected Tropical Disease, 14 May 2021

Abstract
Background
Clinical trial participants are required to sign an informed consent form (ICF). However, information is lacking on the most effective methods to convey trial relevant information prior to inviting participants to sign the ICF, being particularly pertinent in low income countries. A previous study on Pemba Island, Tanzania, found that an oral information session (IS) was significantly better than providing an ICF alone. However, knowledge gaps remained. Building on these findings, we investigated the effect of adding a slideshow or a theater to the IS in the informed consent procedure of an anthelminthic clinical trial.

Methodology/principal findings
A total of 604 caregivers were randomized into the control group that only received an ICF (n = 150) or an ICF plus one of three intervention strategies: (i) verbal IS (n = 135), (ii) verbal IS with a slideshow (n = 174) or (iii) verbal IS followed by a theater (n = 145). All modes of information covered the same key messages. Participants’ understanding was assessed using a semi-structured questionnaire. The mean score of caregivers in the control group (ICF only) was 4.41 (standard deviation = 1.47). Caregivers attending the IS alone were more knowledgeable than those in the control group (estimated difference in mean scores: 2.40, 95% confidence interval (CI) 1.95 to 2.86, p < 0.01). However, there was no evidence of an improvement compared to the IS only when participants attended a slideshow (0.09, 95% CI -0.53 to 0.35, p = 0.68) or a theater (0.28, 95% CI -0.27 to 0.82, p = 0.32). Three out of 10 key messages remained largely misunderstood, regardless of the mode of information group.

Conclusions/significance
Our study confirmed that, in this setting, an ICF alone was not sufficient to convey clinical trial-related information. An IS was beneficial, however, additional theater and slideshows did not further improve understanding. Future research should explore methods to improve communication between study teams and participants for different key messages, study types and settings.
Effect of Conventional vs. Multimedia Aid Regarding Informed Consent for Central Venous Catheter Insertion on Anxiety and Satisfaction among Patients Admitted in Selected Areas of A Tertiary Care Hospital, Ludhiana, Punjab

Ramit Sharma, Kapil Sharma

International Journal of Nursing Critical Care, 2021; 7(1)

Open Access

Abstract

Central venous catheter insertion is a very invasive procedure for prolonged administration of medication, parental fluids and blood products. Patients are involved in decision making regarding this procedure. The term Informed consent is used to discuss with patients complete, clear and easy to understand information about a medical procedure or surgical process in clinical settings or hospitals. Multimedia patient decision aid have been heavily utilized as supplemental educational tools instead of conventional method. A quasi-experimental study by using convenience sampling technique was conducted on 40 patients (control n = 20 and experimental n = 20) admitted in ICUs of DMC & Hospital, Ludhiana, Punjab. In pre-test assess the anxiety of patients for regarding central venous catheter insertion (CVC insertion) procedure done by (State-Trait Anxiety Inventory (STAI) scale.) and in intervention (Provide multimedia aid regarding informed consent for central venous catheter insertion procedure) for each patients for 5 mints (only in experimental group) and in posttest assess and compare the anxiety and satisfaction of patients by (State-Trait Anxiety Inventory (STAI) scale.) and satisfaction by using modified Agency for Healthcare Researcher and quality (AHRQ) scale. Patient satisfaction with the consent process, Most of the subjects had severe anxiety among control and experimental group in pre-test and post-test (16 vs. 15), whereas the 15 (75%) subjects among experimental group had severe anxiety in pre-test which was decreased to moderate in post-test. The finding of the present study also revealed that mean anxiety score was decreased from pre-test and post-test among experimental group (52.00 ± 04.34 Vs. 42.10 ± 05.70) and control group (54.35 ± 05.15 Vs. 50.15 ± 05.61). The difference in finding were found to be statistically significant (p<0.05). It was also revealed that all the subjects were satisfied with the multimedia (14.5 ± 1.28). Whereas only 3 (15%) subjects were satisfied (8.3 ± 1.84) with conventional method. The present study concluded that multimedia aid regarding informed consent for CVC insertion is better than the conventional aid in reference to the anxiety and satisfaction of the patients.

CAPACITY TO CONSENT

The Convention on the Rights of Persons with Disabilities and the challenge to treatment without consent of individuals with psychosocial disabilities [BOOK CHAPTER]

Bernadette McSherry, Lisa Waddington

Routledge, Human Rights Education for Psychologists, 2020

Abstract

This chapter explores the developing emphasis on human rights in mental health care and treatment and what it means in particular for the compulsory treatment of individuals with psychosocial disabilities. Informed consent to treatment is generally presumed to be central to the provision of good-quality health care. However, many countries have mental health laws that enable the detention and treatment without consent of individuals with “psychosocial disabilities”. Awareness of the need to support people with psychosocial disabilities to make their own decisions is an obvious starting point for promoting human rights in this area. Psychologists and professional associations may have a role in ensuring that mental health care and treatment are provided on a voluntary basis as much as possible. The chapter provides an overview of

::: YOUNG PERSONS :::

“Fostering Autonomy” for Adolescents to Access Health Services: A Need for Clarifications

Commentary
Julien Brisson, Vardit Ravitsky, Bryn Williams-Jones

Journal of Adolescent Health, 1 June 2021; 68(6) pp 1038-1039

Excerpt
The global health literature studying adolescent health issues has shown that adolescents are among the groups that least use health services despite having serious health-related needs [[1]]. To help promote adolescent health, the World Health Organization’s Global Accelerate Action for the Health of Adolescents advocates implementing measures to “foster the autonomy” of adolescents to access health services ([[2]], p.93). The argument is persuasive: protect the well-being of adolescents. However, there are significant challenges to understanding what is actually meant by “fostering autonomy” and the possible or necessary steps required for adolescents to be able to both choose and have access to health services. For example, fostering autonomy could entail the development of decision-making skills (e.g., knowing how, when, and where to access health services) or the implementation of enabling policies to make health services more accessible for adolescents, such as removing financial or geographic barriers that impede access...

Assessment of Factors Associated With Parental Perceptions of Voluntary Decisions About Child Participation in Leukemia Clinical Trials

Original Investigation
Paula Aristizabal, Arissa K. Ma, Nikhil V. Kumar

JAMA Network Open, 4 May 2021; 4(5)

Open Access
Abstract
Importance
Obtaining voluntary informed consent prior to enrollment in clinical trials is a fundamental ethical requirement.

Objective
To assess whether health literacy, contextual factors, or sociodemographic characteristics are associated with perception of voluntariness among parents who had consented for their child’s participation in a leukemia therapeutic clinical trial.

Design, Setting, and Participants
This cross-sectional study prospectively enrolled 97 parents of children diagnosed as having leukemia at Rady Children’s Hospital San Diego, a large tertiary academic center in California, from 2014 to 2017. Health literacy, contextual factors (acculturation, decisional regret, and satisfaction with informed consent), sociodemographic characteristics, and perception of voluntariness after consenting for a therapeutic clinical trial were measured. Univariable and multivariable regression were used to determine significant associations. The analyses for the present study were conducted from May 2019 to May 2020.

Exposures
Informed consent for a therapeutic leukemia clinical trial.

Main Outcomes and Measures
The primary outcome of interest was perception of voluntariness and its associations with health literacy and other contextual factors (acculturation, decisional regret, and satisfaction with informed consent) and sociodemographic characteristics, including age, race/ethnicity, parental language, educational level, insurance type, marital status, and socioeconomic status.

**Results**

Of 97 parents included, the majority were women (65 [67%]), married (71 [73%]), and of self-reported Hispanic ethnicity (50 [52%]). Lower perception of voluntariness was significantly associated with lower health literacy (r = 0.30; 95% CI, 0.11-0.47; P = .004), Spanish language (X = −4.50, P = .05), lower acculturation if of Hispanic ethnicity (r = 0.30; 95% CI, 0.02-0.54; P = .05), greater decisional regret (r = −0.54; 95% CI, −0.67 to −0.38; P < .001), and lower satisfaction with informed consent (r = 0.39; 95% CI, 0.21-0.54; P < .001) in univariable analysis. Lower health literacy remained significantly associated with lower perception of voluntariness in multivariable analysis after adjustment for contextual factors and sociodemographic characteristics (β = 4.06; 95% CI, 1.60-6.53; P = .001). Lower health literacy was significantly associated with Hispanic ethnicity (mean, 4.16; 95% CI, 3.75-4.57; P < .001), Spanish language spoken at home (mean, 3.17; 95% CI, 1.94-4.40; P < .001), high school or less educational level (mean, 3.41; 95% CI, 2.83-3.99; P < .001), public insurance (mean, 4.00; 95% CI, 3.55-4.45; P < .001), and unmarried status (mean, 3.71; 95% CI, 2.91-4.51; P = .03).

**Conclusions and Relevance**

Among parents of children with newly diagnosed leukemia who had consented for their child’s participation in a therapeutic clinical trial, lower perception of voluntariness was significantly associated with lower health literacy. These results suggest that parents with low health literacy may perceive external influences in their decision for their child’s participation in clinical trials. This finding highlights the potential role of recruitment interventions tailored to the participant’s health literacy level to improve voluntary informed consent in underserved populations.

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**Negotiating the practicalities of informed consent in the field with children and young people: learning from social science researchers**

Gina Sherwood, Sarah Parsons

**Research Ethics, 12 April 2021**

**Open Access**

**Abstract**

The real-world navigation of ethics-in-practice versus the bureaucracy of institutional ethics remains challenging. This is especially true for research with children and young people who may be considered vulnerable by the policies and procedures of ethics committees but agentic by researchers. Greater transparency is needed about how this tension is navigated in practice to provide confidence and effective strategies for social researchers, including those new to the field, for negotiating informed consent. Twenty-three social science researchers with a range of experience were interviewed about their practices for gaining informed consent from children and young people in social research and the development of their ‘ethics in practice’ over time. Main themes focused on navigating ethics protocols within institutions, practices to prepare for data collection, and a critical evaluation of the resources that can be applied to gaining consent and managing relationships. A range of methods and concrete steps that address ethical challenges are outlined to illustrate what can be done in practice to achieve authentic consent and appropriate participation.

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**Implementing new consent procedures for the schools-based HPV vaccination programme: a qualitative study**

Suzanne Audrey, Karen Evans, Michelle C Farr, Joanne Ferrie, Julie Yates, Marion R Roderick, Harri Fisher

**British Journal of Child Health, 22 February 2021**

**Abstract**
Background
The English schools-based human papillomavirus (HPV) programme was offered to young women aged 12-13 years. High coverage was achieved, but variations in uptake across local authorities were apparent. The requirement for written parental consent acted as a barrier to some young women with the potential to exacerbate health inequities.

Objectives
To consider the practicalities and implications of implementing new consent procedures for the schools-based HPV vaccination programme.

Design
Qualitative study.

Settings
Two local authority areas in the south-west of England with relatively lower uptake of the HPV vaccination programme.

Participants
The 53 participants included: the immunisation programme manager, three immunisation nurses, three members of staff in mainstream schools, five members of staff in alternative education provider settings, 19 young women, and 22 parents.

Methods
Digitally recorded, semi-structured interviews were undertaken. All transcripts were fully transcribed and anonymised. Thematic analysis was undertaken, assisted by the Framework approach to data management.

Results
The new consent processes for the HPV vaccination generally worked well. Telephoning parents on the day of the vaccination session was viewed as an acceptable and effective way to reach parents. Adolescent self-consent was rarely undertaken. This can be explained partially by the relative success in gaining parental verbal consent but concerns about disrupting relationships - between healthcare professionals, parents and school staff, or within families – made professionals reluctant to administer the vaccine without some form of parental consent. For young women with special educational needs and disabilities the consent process relied upon close communication between school staff and parents. Other young women whose access to the vaccine, or consent options, were unclear or problematic included: those who were registered with a school but attended an alternative setting for part of their timetable; those educated at home; those in the care of the local authority or living with a foster family, and; young people with gender dysphoria.

Conclusions
Expanding the consent procedures for the schools-based HPV vaccination programme to include parental telephone consent was broadly welcomed by the immunisation nurses, parents, and young women in our study. The requirement for young women to confirm that they had discussed vaccination with their parents, and that vaccination would not cause difficulties at home, meant adolescent self-consent was rare in this age-group. Greater understanding of the barriers to uptake outside of the mainstream school-based sessions is needed to further address inequalities in uptake.

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RIGHTS/LEGAL/LEGISLATIVE

Will EU’s GDPR Act as an Effective Enforcer to Gain Consent?
Junhyoung Oh, Jinhyoung Hong, Changsoo Lee, Jemin Justin Lee, Simon S.Woo, Kyungho Lee
IEEE, 26 May 2021
Open Access
Abstract
Since the GDPR was implemented in 2018, organizations that collect data from the EU residents are required to receive the user’s consent. Organizational measures to ensure that the organizations are compliant to the
recently enacted GDPR are still abstract and ambiguous. Moreover, data subjects and controllers have demanded the practice of obtaining consent from organizations. By observing the case law and guidelines related to the GDPR provisions, we deduced four consent conditions. Then, we examined how online service provider’s websites are making efforts to implement the GDPR framework. For this, we identified key characteristics of these websites, such as the existence of consent buttons. In order to help the data subjects obtain consent, we proposed an automatic tool that can check the consent conditions by checking the websites. Our study examined 10,000 websites for 26 days using the Python libraries with the tool automatically crawling the website information and analyzes the HTML structure according to the specified conditions. In addition, this tool crawls the privacy policy of each website. Moreover, it automatically determines whether it meets the four consent conditions by calculating it according to the formula defined in the consent condition. To evaluate the tool’s accuracy, the researchers manually analyzed 500 websites and compared the manual analysis with the results of the tool’s automatic analysis. We found that this tool differentiates itself through qualitative comparisons with other GDPR meters.

**How Has ‘Montgomery’ Changed the Way We Document Risks on Consent Forms for Deceased Donor Kidney Transplantation? A Single-Centre Audit and Re-Audit**
A M Hussein, C J Callaghan
*British Journal of Surgery, 4 May 2021; 108(Supplement 2)*

**Abstract**

**Introduction**
The 2015 Montgomery case changed the remit of risk discussions required during the consent process. This audit reviewed single kidney transplant (SKT) consent forms to establish which risks are documented, and whether this legal case affected discussions. Following the audit, we introduced a pre-printed consent form and closed the audit loop by assessing its uptake.

**Method**
Trust paper consent forms for all patients aged 50+ who received a deceased donor SKT in our centre in 2014 (n = 58; pre-Montgomery) and 2017 (n = 70; post-Montgomery) were reviewed to see if 20 perceived ‘gold standard’ risks were documented. A pre-printed procedure-specific consent form including all gold standard risks was then introduced in July 2019. A re-audit reviewed the case-notes of every alternate recipient aged 50+ of a deceased donor SKT from 01/08/19 to 29/02/20 to check if the pre-printed form was used.

**Results**
Overall, 53% of the 20 ‘gold standard’ risks were documented in 2014 versus 59% in 2017 (p = 0.55). There was a 91% uptake of the pre-printed consent form.

**Discussion**
This audit established the importance of using a pre-printed consent form to standardise risk discussions. We propose that pre-printed procedure-specific forms should be encouraged throughout the NHS to support ‘Montgomery-appropriate’ consent discussions.

**Consent in privacy laws: Analysis of India’s PDPB, ECPA of USA and GDPR of EU**
Prashant Mali
*International Journal of Law, 25 March 2021; 7(2) pp 142-152*

**Open Access**

**Abstract**
Consent refers to an affirmative action on the part of the individuals indicating their agreement to the use of their personal data by the collectors or processors for the purpose of processing. Consent has been viewed as an expression of a person’s autonomy or control, which has the consequence of allowing another person to legally disclaim liability for acts, which have been consented to. Consent has many connotations in various privacy laws, somewhere it tows the line of prevailing international laws and in some laws it gets localized, but largely consent remains individuals’ will to share his / her data. This paper analysis the established
Towards a coherent model of informed consent: is there, and should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? [DISSERTATION]
Louise Austin
University of Bristol, 2021; PhD Thesis

Abstract
Utilising the empirical ethics methodology and method of 'reflexive balancing' (RBL), this thesis asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? It concludes that whilst presently there is not a coherent model across these three areas, there should be, and a proposed model is outlined. In reaching this conclusion, the thesis draws upon ethical literature, the medical regulatory and legal standards of informed consent, and my empirical analysis of fitness to practice decisions and court judgments concerning informed consent in the context of surgery. Such a detailed analysis of these decisions and judgments has not been done before and this thesis, therefore, makes an original and significant contribution to existing scholarship. This contribution is developed further by the use of RBL to bring the data together to address the question the thesis asks. RBL has not previously been used to bring together medical ethics, medical professional regulation, and medical law. Chapter One sets out the methodology and methods underpinning the thesis. Chapters Two to Four illustrate there is not a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. Chapters Five and Six set out the empirical analysis and Chapter Seven draws upon that analysis to develop a model of informed consent to surgery. RBL is then utilised to challenge that model, leading to a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. This model enables autonomous choices about surgery, utilising objective and subjective perspectives in determining what information should be given to patients, and requiring understanding and reflection. The thesis concludes with recommendations for the model's implementation, and for further research suggested by the thesis' findings.

Medical Violence, Obstetric Racism, and the Limits of Informed Consent for Black Women
Colleen Campbell
Michigan Journal of Race and Law, Winter 2021; 26 (Special Issue)
Open Access

Abstract
The United States’ alarmingly high C-section rate and its equally alarming maternal mortality rate make it clear that reproductive healthcare is failing women. But it is especially failing Black women, who are today disproportionately exposed to these and other reproductive health risks just as they have been throughout history. The Michigan Journal of Gender & Law selected this Essay because it traces a direct line from early gynecology’s reliance on the bodies of unconsenting Black women to how medicine and the law’s failure to reckon with this history continues to harm Black women now. While these institutions now purport to embrace ethical principles like bodily autonomy and individual agency, this Essay critically examines why Black women must still navigate reproductive healthcare against a backdrop of both racist medical violence that puts their health at risk and a legal doctrine of informed consent that cannot realistically protect them.

Editor’s note: The Michigan Journal of Race & Law is a legal journal associated with the University of Michigan Law School that serves as a forum for the exploration of issues relating to race and law.
FREE PRIOR INFORMED CONSENT (FPIC)

The right to free, prior, and informed consent (FPIC): Reflections on experiences of two Indigenous communities in northern regions of Canada and Chile [BOOK CHAPTER]
Terry Mitchell, Courtney Arseneau, José Aylwin, Darren Thomas
Decolonizing Law [Routledge 2021]

Abstract
In this chapter, we focus on the ongoing pressures faced by Indigenous communities in responding to growing global investments in extractive activities such as mining. In highlighting the obligations of states and businesses to adhere to consultation processes and practices of the right to free, prior, and informed consent (FPIC), we provide a comparative analysis of the barriers faced by Indigenous Peoples in mining affected communities in northern Ontario (Canada) and in northern Chile. We also call attention to the extraterritorial responsibilities of Canada's mining investments in Chile, presenting the situation of global extractive practices as a new wave of colonialism known as extractive imperialism. We share reflections from our work across the two case study sites, including a workshop that brought together leaders from both regions to share experiences, strategies of resistance, and Indigenous perspectives of consultation and FPIC from across the Americas. We discuss key Pan-American findings of (1) a lack of consultation and information; (2) inducement and division; and (3) environmental impacts as parallel experiences across both regions. We conclude with reflections on decolonial approaches to consultation and policy recommendations for the implementation of FPIC and the monitoring of Indigenous rights in Canadian mining activities across the Americas.

Who Are the Métis? The Role of Free, Prior and Informed Consent in Identifying a Métis Rights-Holder [BOOK CHAPTER]
Karen Drake
Indigenous-Industry Agreements, Natural Resources and the Law [Routledge 2020]

Abstract
Using free, prior and informed consent as a framework for analysis, this chapter explores issues related to the communities involved in Indigenous-industry agreements by relying on the particularly poignant experience of the Métis. A major issue that Indigenous-industry agreements encounter is the identification of the Indigenous party to the agreement. This chapter analyzes bases for identifying the Métis rights-holder for the purposes of consultation and consent. It argues that the Métis Nation of Ontario has developed an approach to consultation and that approach ensures that the Métis Nation of Ontario's consent to Indigenous-industry agreements is fully informed. This approach also responds to some of the questions that impact Indigenous-industry agreements including questions regarding persons who qualify as rights-holders and to whom the duty to consult and accommodate is owed, how to determine the geographic scope of the rights-holder, and persons who are entitled to represent the rights-holder during consultation about the right.

CULTURAL/COUNTRY CONTEXT

Community Consent [BOOK CHAPTER]
Henk ten Have, Maria do Céu Patrão Neves
Dictionary of Global Bioethics [Springer 27 May 2021]

Abstract
In medical practice and research the principle of individual prior informed consent has a crucial role to play. However, the emphasis on individuals is not the same across the world. Communities in many cultures and traditions play an important role in determining human well-being and in individuals living their lives to the full. From a global perspective the moral status of a community is recognized in the concept of community consent.

Parental and professional perceptions of informed consent and participation in a time-critical neonatal trial: a mixed-methods study in India, Sri Lanka and Bangladesh

**Abstract**

Introduction

Time-critical neonatal trials in low-and-middle-income countries (LMICs) raise several ethical issues. Using a qualitative-dominant mixed-methods design, we explored informed consent process in Hypothermia for encephalopathy in low and middle-income countries (HELIX) trial conducted in India, Sri Lanka and Bangladesh.

Methods

Term infants with neonatal encephalopathy, aged less than 6 hours, were randomly allocated to cooling therapy or usual care, following informed parental consent. The consenting process was audio-video (A-V) recorded in all cases. We analysed A-V records of the consent process using a 5-point Likert scale on three parameters—empathy, information and autonomy. In addition, we used exploratory observation method to capture relevant aspects of consent process and discussions between parents and professionals. Finally, we conducted in-depth interviews with a subgroup of 20 parents and 15 healthcare professionals. A thematic analysis was performed on the observations of A-V records and on the interview transcripts.

Results

A total of 294 A-V records of the HELIX trial were analysed. Median (IQR) score for empathy, information and autonomy was 5 (0), 5 (1) and 5 (1), respectively. However, thematic analysis suggested that the consenting was a ceremonial process; and parental decision to participate was based on unreserved trust in the treating doctors, therapeutic misconception and access to an expensive treatment free of cost. Most parents did not understand the concept of a clinical trial nor the nature of the intervention. Professionals showed a strong bias towards cooling therapy and reported time constraints and explaining to multiple family members as key challenges.

Conclusion

Despite rigorous research governance and consent process, parental decisions were heavily influenced by situational incapacity and a trust in doctors to make the right decision on their behalf. Further research is required to identify culturally and context-appropriate strategies for informed trial participation.

Quality of written informed consent forms for electroconvulsive therapy in Australia: a comparative analysis

**Abstract**

Objectives

We compared the quality of the written informed consent forms for electroconvulsive therapy (ECT) in Australian jurisdictions.
Method
For this comparative audit-type study, a checklist was developed to compare informed consent forms from different jurisdictions. The main information sources for consent forms were government health department websites and Google. The directors of clinical services were contacted if a consent form was not available through a web source.

Results
Majority of the informed consent forms covered information about ECT, general anaesthesia and alternative treatments, supports available for decision making, and a reference to the right to withdraw consent. Missing information affected information areas such as likely outcome if no ECT, lack of guaranteed response and cultural and linguistic supports.

Conclusions
A standardised consent form that can be used across all jurisdictions can help improve the ECT practice.

Normative framework of informed consent in clinical research in Germany, Poland, and Russia

Research
Marcin Orzechowski, Katarzyna Woniak, Cristian Timmermann & Florian Steger

BMC Medical Ethics, 1 May 2021; 22(53)

Abstract
Background
Biomedical research nowadays is increasingly carried out in multinational and multicenter settings. Due to disparate national regulations on various ethical aspects, such as informed consent, there is the risk of ethical compromises when involving human subjects in research. Although the Declaration of Helsinki is the point of reference for ethical conduct of research on humans, national normative requirements may diverge from its provisions. The aim of this research is to examine requirements on informed consent in biomedical research in Germany, Poland, and Russia to determine how each national regulatory framework relates to the provisions of the Declaration of Helsinki.

Methods
For this analysis, we conducted a search of the legal databases “Gesetze im Internet” for Germany, “Internetowy System Aktow Prawnych” for Poland, and “ГАРАНТ – Garant” for Russia. The search was complemented by a review of secondary literature contained in the databases Google Scholar, PubMed, Polish National Library, and eLibrary.ru. We have identified 21 normative regulations containing provisions on informed consent in clinical research in all three countries. The content of these documents was systematically categorized and analyzed.

Results
The normative framework in all three countries shows a strong commitment towards the core ethical principles of research envisaged in the Declaration of Helsinki. Nevertheless, provisions on informed consent vary between these three countries. The differences range from the method and language in which information should be provided, through the amount of information required to be disclosed, to the form of documenting consent or withdrawal. In the case of research on vulnerable groups, these differences are particularly visible.

Conclusions
The identified differences can negatively impact the ethical conduct of international clinical studies. Attention needs to be paid that flexibilities within national regulations are not misused to undermine the protection of research subjects. Achieving global or regional legislative harmonization might prove impossible. Such lack of legal consensus reinforces the significance of the international ethical agreements.

Informed consent process: ethical and practical challenges in clinical trials regarding subject enrollment, protection, and informed consent in developing countries (India, Pakistan & Iran)

Andaleeb Fatima
In this study, we are discussing the rationale behind informed consent in clinical trials in developing countries. It elaborates how informed consent has remained an ethical and practical issue. Poverty, endemic diseases, and a lack of investment in healthcare systems influence the ease of conducting and selecting trials that can benefit the people of developing countries. Differences in cultural perspectives, religious beliefs, a lack of formal training for clinical staff, children, time zone difference, literacy, vulnerable population, and language barriers for subject enrollment, protection, and informed are also challenges. This report doesn’t only highlight the right the wrongs of the past or reiterate cases where clinical trials have hurt subjects in developing countries. The current study investigates the conditions of human research in developing countries to make them more ethically sound. The extends proposals to investigators, scientists, governments, sponsors, and other groups who are interested where appropriate.

MEDICAL/SURGICAL

Adequacy of measures of informed consent in medical practice: A systematic review

Kerry A. Sherman, Christopher Jon Kilby, Melissa Pehlivan, Brittany Smith

PLoS One, 27 May 2021

As a critical component of medical practice, it is alarming that patient informed consent does not always reflect (1) adequate information provision, (2) comprehension of provided information, and (3) a voluntary decision. Consequences of poor informed consent include low patient satisfaction, compromised treatment adherence, and litigation against medical practitioners. To ensure a well-informed, well-comprehended, and voluntary consent process, the objective and replicable measurement of these domains via psychometrically sound self-report measures is critical. This systematic review aimed to evaluate the adequacy of existing measures in terms of the extent to which they assess the three domains of informed consent, are psychometrically sound and acceptable for use by patients. Extensive searching of multiple databases (PsychINFO, PubMed, Sociological Abstracts, CINAHL, AMED) yielded 10,000 potential studies, with 16 relevant scales identified. No existing scale was found to measure all three consent domains, with most only narrowly assessing aspects of any one domain. Information provision was the most frequently assessed domain, followed by comprehension, and then voluntariness. None of the identified scales were found to have adequate evidence for either high quality psychometric properties or patient user acceptability. No existing scale is fit for purpose in comprehensively assessing all domains of informed consent. In the absence of any existing measure meeting the necessary criteria relating to information, comprehension and voluntariness, there is an urgent need for a new measure of medical consent to be developed that is psychometrically sound, spans all three domains and is acceptable to patients and clinicians alike. These findings provide the impetus and justification for the redesign of the informed consent process, with the aim to provide a robust, reliable and replicable process that will in turn improve the quality of the patient experience and care provided.

Consent in medical practice

H K Shreekrishna, Aruna B Rao

International Journal of Preclinical and Clinical Research, 4 June 2021

Open Access
Abstract
Consent is an expression of autonomy and represents the right of a patient to make a decision in a medical matter concerning him. Consent is not just a procedural formality but also a legal requirement. The process of informed consent occurs when communication between a patient and physician results in the patient’s authorization or agreement to undergo a specific medical intervention. In India, the number of suits against doctors is increasing because of failure to take informed consent or inadequate consent from patients for various procedures. Any examination of a patient by the doctor without his consent amounts to assault (351 IPC). Ignorance of laws is not a defense in negligence cases, so every practicing doctor should be aware of their responsibilities about consent in medical practice. Consent is not an option but a necessity in medical practice.

Donor Factors Associated with Familial Consent for Organ Donation among Trauma Casualties: a 10-Year Retrospective Study
Naama Bursztyn, Tomer Arad, Tamar Fink, Jonathan Cohen, Michael Stein
The Israel Medical Association Journal, 23 May 2021; 23(5) pp 286-290
Open Access
Abstract
Background
Consent rates for organ donation remain one of the most important factors determining the number of organs available for transplantation. Trauma casualties constitute a substantial part of the deceased organ donor pool and have unique characteristics that distinguish them from the general donor population. However, this group has not been extensively studied.
Objectives
To identify donor factors associated with positive familial consent for solid organ donation among trauma casualties.
Methods
This retrospective study included all trauma casualties who were admitted to the Rabin Medical Center, Beilinson hospital, during the period from January 2008 to December 2017, who were potential organ donors. Data collected included demographic features, the nature of the injury, surgical interventions, and which organs were donated. Data was collected from the Rabin Medical Center Trauma Registry.
Results
During the study period 24,504 trauma patients were admitted and 556 died over their hospital course. Of these 76 were potential donors, of whom 32 became actual donors and donated their organs. Two factors showed a statistically significant correlation to donation, namely female gender (P = 0.018) and Jewish religion of the deceased (P = 0.032).
Conclusions
Only a small group of in hospital trauma deaths were potential solid organ donors (13.7%) and less than half of these became actual donors. Consent rates were higher when the deceased was female or Jewish.

Comparison of The Quality of Informed Consent in Angiography Patients in Selected Hospitals in Mashhad from The Perspective of Patients and Physicians and Providing Solutions
Original Article
N Atashdeghhan, M Meraji, J Jamali, Mehdi Yousefi, S Fazaeli
Journal of Paramedical Sciences & Rehabilitation, 23 May 2021
Abstract
Purpose
Obtaining informed consent from patients, which is the basis of medical ethics and the most basic rights of patients, requires compliance with the conditions. The aim of this study was to compare the quality of
informed consent of patients admitted to angiography in selected hospitals of Mashhad in 1398 from the perspective of patients and physicians.

Methods
This study has a descriptive-cross-sectional design. First, by examining the texts, the quality indicators of obtaining informed consent were extracted and a questionnaire for patients and physicians was compiled. Questionnaire was developed and validated to assess the views of patients and physicians in this field. Then, 10 doctors who had the most angiography in the selected hospitals of Imam Reza (AS) and Ghaem (AS), were randomly selected the questionnaire for doctors and 30 patients for each physician, and completed the questionnaire of the patients.

Results
Physicians' questionnaire with 11 questions and 4 dimensions and patients' questionnaire with 22 questions and 6 dimensions were developed. The answers in each question were scored as a Likert scale from very low (1) to very high (5) and the average score of each dimension was determined. In evaluating the quality of informed consent, the highest score from the perspective of patients and physicians was related to the dimension of "physician-patient interaction". The mean score was 2/94 in the evaluation of patients and 3/8 in the self-assessment of physicians. A significant relationship was found between the level of education of patients and the dimensions of understanding and volunteering (p ≤0/05). Informed consents were obtained before the day of admission to the treating physician and after providing the necessary explanations by the physician, effective communication training workshop for residents and physicians and explaining the legal, religious, therapeutic aspects, etc. Delfi was emphasized.

Conclusion
In all respects, the score of the patient's evaluation was less than the desired level also lower than the score of the physicians' self-assessment. It is suggested that the proposed solutions be used in the way of obtaining satisfaction.

The Relation Between Patient Education and Doctors' Compliance on Informed Consent Implementation
Roshnya Linggar Andatu, Arlina Dewi
Turkish Journal of Physiotherapy and Rehabilitation; 20 March 2021; 32(3)
Open Access

Abstract

Introduction
Informed consent is a patient's right and doctor's obligation to explain the patient's condition and disease to obtain medical approval. Doctors do not fully provide the information and explanation. Research conducted on informed consent patients showed 77.3% of respondents did not understand medical terms and explanations about the informed consent. The lack of knowledge from patients or families can lead to malpractice suits if there is a problem in administering medical treatment. Purpose to determine patient education's impact on doctors' compliance in implementing informed consent.

Method
Quantitative research with pre-experimental research design (one group pre and post-test design). The research subjects were doctors who gave informed consent. The research object is patients or families who received informed consent. Researcher did the pre test by asking the patient or family about the content of informed consent whether they can answer or not and explained after all the questions had given that they had the right to know what they should know for the invasive procedure. Patient or family had the opportunity to ask the doctor some hours before invasive procedure. Then, researcher came back to evaluate the understanding of patient and family about the procedure by asking the same questions. The study was conducted for 3 (three) months, March - May 2020 on 30 patients or their families. The data analysis used Mann Whitney test to determine how significant the difference between two populations was taken from the same population. This research instrument used a structured interview checklist based on

Result
Pre-test showed that 83% of respondents know the doctor’s name in charge, 63% of the diagnosis, 43% of the procedure’s aim, and 3% of the prognosis. 50% of patients cited 2 points of informed consent, and 3.33% mentioned 4 points. In the post-test, 100% of respondents mentioned the doctor’s name, the diagnosis, the purpose of the procedure, and when the patient’s condition monitors, 73.33% of respondents mentioned 8 points of informed consent, 3.33% were able to mention 9 points. Mann Whitney test showed the following results (p = 0.000).

Conclusion
Education to patients or families improve doctors’ compliance in implementing informed consent.

Consent for blood transfusion: summary of recommendations from the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO)
Michael F Murphy, Andrea Harris, James Neuberger
Clinical Medicine Journal, 17 May 2021
Abstract
The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) decided that its 2011 recommendations on consent for blood transfusion needed to be reviewed and revised due to evidence of poor compliance and recent legal guidance on consent. The recommendations are to ensure that patients are informed about and understand the purpose, benefits and potential risks of transfusion, and have an opportunity to discuss their treatment options. They should be incorporated into local practices for all patients.

The effectiveness of handout assisted versus verbal consent on post-operative recall and understanding - A randomized control study
Jun Kit Koong, Retnagowri Rajandram, Naveendran Sidambram, Vairavan Narayana
The Surgeon, 8 May 2021
Abstract
Background
Consent is an important component of surgical care. Poorly attempted consent bears significant ethical and legal implications. We assessed the effectiveness of handouts in improving postoperative consent understanding and recall compared to standard verbal consent during laparoscopic cholecystectomy as a tool that may improve information retention and leads to better treatment satisfaction.

Methods
This is a prospective block randomized, non-blinded study conducted at a single tertiary hospital. Patients undergoing elective laparoscopic cholecystectomy between August 2017 and October 2018 were recruited and randomized into Handout Assisted Consent (HC) and Verbal Consent (VC) group. The HC group was given an adjunct handout on laparoscopic cholecystectomy during consent process in addition to the standard verbal consent. A validated open-ended verbal understanding and recall questionnaire was administered to all patients in both groups at Day 1, 30 and 90 after surgery. Patient satisfaction of the consent process was evaluated with Likert scale.

Results
A total of 79 patients were enrolled, 41 patients and 38 patients in VC and HC groups respectively. Level of understanding among patients were equal and consistent across time in both groups (P > 0.05). There was significant decline (P < 0.0001) for both groups in ability to recall information between Day 1 to Day 30 and Day 30 to Day 90. A slightly higher satisfaction rate was found among patients that received HC (P > 0.05).

Conclusion
There is good consistent understanding of the surgery in both groups. However, recall of specific surgical consent items decreased significantly over time in both groups. Handouts may have increased satisfaction among patients but did not improve recall in this preliminary study.

**Psychotropic Medication Informed Consent: A Cross-Specialty Role-Playing Skill Builder**
Emily Diana, Derrick Hamaoka, Matthew Goldenberg, Kelly L. Cozza
*MedEdPORTAL, 5 May 2021; 17(11)*

**Open Access**

**Abstract**

**Introduction**

Obtaining informed consent (IC) is an essential medical practice. Utilization of IC role-playing training with medication study cards and self-peer-supervisor review should improve student fund of knowledge and strengthen IC skills for clerkship-level medical students.

**Methods**

Between 2017 and 2020, approximately 555 clerkship medical students used our formative role-playing exercise tools. Students independently prepared psychotropic medication study cards and role-played IC during group didactics. Peer and supervisor reviews were not recorded but were discussed as a group. Students completed routine anonymous post clerkship surveys regarding the IC exercise. An enhanced IC curriculum was deployed in 2020, adding a training video and peer/supervisor feedback form. Student feedback and specialty shelf exam scores were reviewed to assess the exercise’s effectiveness.

**Results**

Surveys indicated satisfaction with the exercise and increased confidence in obtaining IC. Interestingly, the student group that received enhanced IC training had fewer shelf exam failures than those without, perhaps indicating improved fund of psychotropic medication knowledge.

**Discussion**

Peer role-playing IC training is well accepted by students, allows practice of essential elements of IC and shared decision-making, and provides an engaging way to improve medication fund of knowledge. Our clerkship has initiated development of an IC objective structured clinical examination station and is adapting the exercise across specialties for longitudinal learning in response to the positive feedback and ease of use. Structured review of psychotropics and peer IC role-playing can be tailored for other specialties, medications, and procedures and further developed for use in pre- and postclerkship education.

*Editor’s note: MedEdPORTAL is the Association of American Medical Colleges journal of teaching and learning resources.*

**Reaudit and Completing the Audit Cycle of Quality of Informed Consent for Surgery on Neck of Femur Fracture in Royal Stoke University Hospital**
T Khaleeq, U Hanif, Y Maqsood, K Ahmed, A Patel
*British Journal of Surgery, 4 May 2021; 108(Supplement 2)*

**Abstract**

Using guidelines highlighted by the British Orthopaedic Association an reaudit was performed within our department to assess the adequacy of informed consent for NOF fractures to complete the audit cycle. 50 patients were included in the Audit and reaudit. Risk was classified as common, less common, rare and ‘other’. The adequacy of informed consent was evaluated by assessing the quality and accuracy of documentation. Infection, bleeding risks, clots and anaesthetic risks were documented in all patients (100%). Areas of improvement were seen in the documentation of neurovascular injuries (98%), pain (90%) and altered wound healing (87%). There was no significant change in the documentation of failure of surgery (83%) and neurovascular injuries (98%). The Poorly documented risk factors from the initial audit were seen to improve which included mortality (70%), prosthetic dislocation (90%) and limb length discrepancy (50%). There has been a significant improvement in the quality of Informed consent in the department and this
could be attributed to the installation of ward posters and verbal dissemination of information to junior doctors. Recommendation for interventions would be to present in the next clinical governance meeting and presenting at the new junior doctors’ induction at August.

**The Value of a Support Person During the Surgical Consent Process: A Prospective Cohort Study**
Elisabeth C. Sappenfield, David M. O’Sullivan, Adam C. Steinberg
*Female Pelvic Medicine & Reconstructive Surgery, 12 April 2021*

**Abstract**

**Objective**
The objective of this study is to investigate the impact of support person participation during the preoperative appointment.

**Methods**
This is a prospective cohort study involving patients scheduled to undergo pelvic reconstructive surgery. Eligible patients were enrolled at the preoperative appointment and compared by presence or absence of a support person. Questionnaires were completed before and after the preoperative appointment, 1–3 days before surgery, and at the postoperative appointment. Previsit questionnaires included the Generalized Anxiety Disorder-7, 6-item short form of the Spielberger State-Trait Anxiety Inventory (STAI-6), and Brief Health Literacy screen. Postvisit questionnaires included the STAI-6, satisfaction with decision scale for pelvic floor disorders, preoperative preparedness questionnaire, and knowledge questionnaire. At the postoperative appointment, participants completed the patient global impression of improvement and postoperative symptom and satisfaction questionnaire. Primary outcome was patient anxiety measured by the STAI-6.

**Results**
Seventy-six patients participated in the study: 37 were categorized in the support person cohort and 39 were categorized in the no support person cohort. The mean scores of the STAI-6 did not differ between the support person and no support person cohorts at all time points (previsit: 42.97 ± 13.23 vs 41.53 ± 17.11, P = 0.68; postvisit: 38.11 ± 12.76 vs 36.33 ± 11.72, P = 0.53, and 1–3 days before surgery: 42.61 ± 13.0 vs 41.05 ± 16.39, P = 0.65). Overall preparedness, satisfaction with decision scale for pelvic floor disorders, and knowledge questionnaire did not differ between cohorts at both time points. Perioperative phone calls were similar between cohorts.

**Conclusion**
Our study suggests that the presence of a support person at preoperative counseling for pelvic floor surgery should be a personal preference and not a recommendation.

**GENERAL/OTHER**

**Informed Consent—We Can and Should Do Better**
*Invited Commentary — Ethics*
Stefan C. Grant
*JAMA Network Open, 28 April 2021; 4(4)*

**Excerpt**
...Informed consent generally is understood to represent a process, with the informed consent document having a central role. The characteristics of a well-designed consent form are well known: the document must contain information, some statutorily defined, necessary to allow a participant to make an informed decision; be written at a reading level appropriate for its audience; and be of a length that enables complete and thorough reading. Yet, the content and structure of this document has been the subject of discussion for
at least 3 decades, with a consistent consensus throughout this time that these documents are too difficult to read, too complex, and too long and, as a result, frequently fail to facilitate truly informed consent by study participants. While much of the blame for the failure to provide sufficiently detailed, readable, and brief consent forms has been laid at the feet of sponsors and investigators, the reality is that, while it is possible to incorporate 2 of these 3 elements into a consent form, it is all but impossible to incorporate all 3, ie, concise, sufficiently detailed yet easily readable, for anything but the simplest of clinical trials...

**Consent Notices and the Willingness-to-Sell Observational Data: Evidence from User Reactions in the Field [CONFERENCE PAPER]**
Stefan Mager, Johann Kranz

**European Conference on Information Systems, 2021; Marrakech**

Abstract
Privacy regulations like the EU’s General Data Protection Regulation (GDPR) require e-commerce shops to request opt-in consent for usage data collection from EU website visitors. Despite the regulation’s intentional strengthening of consumer rights, consent notices are often regarded as burdensome by consumers and shops alike. Thus, ever more consumers turn to consent-automating browser extension tools, which decreases opt-in rates for e-commerce shops. To investigate potential for a win-win solution, we examined in cooperation with a fashion retailer in Germany how consumers react when they are presented a coupon for the website’s shop in the moment of cookie consent decision. Using the Becker-DeGroot-Marschak mechanism, we elicited consumers’ willingnesses-to-sell (WTS) for cookie consent. Our unique field dataset of 1274 participants allows us to derive the WTS of consumers for any desired consent rate. For instance, 65.05 % of consumers are ready to trade their consent to cookies for a 10€-coupon value.

**Artificial Intelligence, Personal Decisions, Consent, and the Confucian Idea of Oneness [BOOK CHAPTER]**
Pak-Hang Wong

**Harmonious Technology, [Routledge 2021]**

Abstract
The pervasiveness of artificial intelligence (AI) systems has brought forth a new background condition labeled by the author as “the interconnectedness condition”, where every individual is tightly and seamlessly interconnected. In this chapter, the author shows that personal decision-making and consent have acquired new moral significance due to the changing moral character of these acts in the interconnectedness condition. In particular, he argues that personal decision-making and consent are transformed from self-regarding acts to other-regarding acts, and that the transformation introduces a new moral responsibility for individuals qua users AI systems to account for others’ values and interests in making personal decisions and giving consent. However, the author also admits that the new responsibility can be difficult for Western ethics and political philosophy to understand and accept. Accordingly, he turns to the Confucian idea of oneness to make sense of the new responsibility in the interconnectedness condition.

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