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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

March 2021

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.

No new content identified for the following established categories:
BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
YOUNG PERSONS
Please note that we maintain a glossary, tools for assessment, and guidance documents on our website.

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COVID-19

Clinical Trial Ethics in the Era of COVID-19 Pandemic

Muhammet Arslan, Nuket Ornek Buken

Journal of Clinical & Experimental Investigations, March 2021; 12(1) pp 1-7

Abstract

The world has been suffering from the deadly effects of coronavirus and seemingly will continue to suffer for quite more time. Humanity has witnessed many kinds of outbreaks that have affected the population endemically or epidemically. Urgent need for treatment of COVID-19 is necessary and essential. In this article the cornerstones of clinical trial ethics, current publications and statements are analyzed to overcome the difficulties of pandemics with an additional focus on Turkey. The researching physician, volunteering patients, industry, institutions, and national/international ethico-legal bodies are playing important role in clinical research. As stated in the Hippocratic Oath, it is a physician's duty to "first do no harm". Many international documents also state the fact that preserving the dignity of people and basic rights is the most essential attitude. Clinical trials follow a certain set of principles regulated by legislative bodies. Medical ethics try to establish a common base for all research to fulfill the need for an internationally acceptable standard. Rather than serving the benefit of qualifications, ethical standards preserve qualitative values. It can be said that medical ethics is an appropriate discipline to serve the improvement of both science and morals.

Rethinking Consent for Stroke Trials in Time-Sensitive Situations Insights From the COVID-19 Pandemic

Mayank Goyal, Johanna Maria Ospel, Aravind Ganesh, Martha Marko, Marc Fisher

Stroke, 16 February 2021

Open Access

Abstract

Informed consent is a key concept to ensure patient autonomy in clinical trials and routine care. The coronavirus disease 2019 (COVID-19) pandemic has complicated informed consent processes, due to physical distancing precautions and increased physician workload. As such, obtaining timely and adequate patient consent has become a bottleneck for many clinical trials. However, this challenging situation might also present an opportunity to rethink and reappraise our approach to consent in clinical trials. This viewpoint discusses the challenges related to informed consent during the COVID-19 pandemic, whether it could be acceptable to alter current consent processes under these circumstances, and outlines a possible framework with predefined criteria and a system of checks and balances that could allow for alterations of existing consent processes to maximize patient benefit under exceptional circumstances such as the COVID-19 pandemic without undermining patient autonomy.

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BIOMEDICAL RESEARCH

An international core outcome set for evaluating interventions to improve informed consent to clinical trials: the ELICIT Study

Katie Gillies, Paula R Williamson, Vikki A Entwistle, Heidi Gardner, Shaun Treweek, Marion K Campbell

Journal of Clinical Epidemiology, 26 February 2021

Open Access
Abstract
Objective
To develop a core outcome set for the evaluation of interventions that aim to improve how people make decisions about whether to participate in RCTs (of healthcare interventions), the ELICIT Study.
Study Design
International mixed-method study involving a systematic review of existing outcomes, semi-structured interviews, an online Delphi survey, and a face-to-face consensus meeting.
Results
The literature review and stakeholder interviews (n=25) initially identified 1045 reported outcomes that were grouped into 40 individually distinct outcomes. These 40 outcomes were scored for importance in two rounds of an online Delphi survey (n=79), with 18 people attending the consensus meeting. Consensus was reached on 12 core outcomes: therapeutic misconception; comfort with decision; authenticity of decision; communication about the trial; empowerment; sense of altruism; equipoise; knowledge; salience of questions; understanding, how helpful the process was for decision making; and trial attrition.
Conclusion
The ELICIT core outcome set is the first internationally agreed minimum set of outcomes deemed essential to be measured in all future studies evaluating interventions to improve decisions about participating in an RCT. Use of the ELICIT core set will ensure that results from these trials are comparable and relevant to all stakeholders.

Adding dynamic consent to a longitudinal cohort study: A qualitative study of EXCEED participant perspectives

Research Article
Susan E. Wallace & José Miola
BMC Medical Ethics, 9 February 2021; 22(12)
Open Access
Abstract
Background
Dynamic consent has been proposed as a process through which participants and patients can gain more control over how their data and samples, donated for biomedical research, are used, resulting in greater trust in researchers. It is also a way to respond to evolving data protection frameworks and new legislation. Others argue that the broad consent currently used in biobank research is ethically robust. Little empirical research with cohort study participants has been published. This research investigated the participants' opinions of adding a dynamic consent interface to their existing study.
Methods
Adult participants in the Extended Cohort for E-health, Environment and DNA (EXCEED) longitudinal cohort study who are members of the EXCEED Public and Participant Engagement Group were recruited. Four focus groups were conducted and analysed for thematic content. Discussion topics were derived from a review of the current literature on dynamic consent.
Results
Participants were in favour of many aspects of a dynamic consent interface, such as being able to update their information, add additional data to their records and choose withdrawal options. They were supportive provided it was simple to use and not intrusive. Participants expressed a markedly high level of trust in the study and its investigators and were unanimously happy with their current participation. No strong support was found for adding a dynamic consent interface to EXCEED.
Conclusions
Trust in the study researchers was the strongest theme found. Openness and good data security were needed to retain their trust. While happy to discuss dynamic consent, participants were satisfied with the current study arrangements. There were indications that changing the study might unnecessarily disturb

their trust. This raised the question of whether there are contexts where dynamic consent is more appropriate than others. This study was limited by the small number of participants who were committed to the study and biased towards it. More research is needed to fully understand the potential impact of adding a dynamic consent interface to an existing cohort study.

Patient accrual and understanding of informed consent in a two-stage consent design

Research Article

Andrew J Vickers, Emily A Vertosick, Sigrid V Carlsson, Behfar Ehdaie, Scott Y H Kim

Clinical Trials, 2 February 2021

Abstract

Background

We previously introduced the concept of "two-stage" (or "just-in-time") informed consent for randomized trials with usual care control. We argued that conducting consent in two stages—splitting information about research procedures from information about the experimental intervention—would reduce the decisional anxiety, confusion, and information overload commonly associated with informed consent. We implemented two-stage consent in a low-stakes randomized trial of a mindfulness meditation intervention for procedural distress in patients undergoing prostate biopsy. Here, we report accrual rates and patient understanding of the consent process.

Methods

Patients approached for consent for the biopsy trial were asked to complete the standard "Quality of Informed Consent" questionnaire to assess their knowledge and understanding of the trial.

Results

Accrual was excellent with 108 of 110 (98%) patients approached for consent signing first-stage consent. All 51 patients randomized to the experimental arm and who later presented for biopsy signed second-stage consent and received the mindfulness intervention. Quality of Informed Consent data were available for 48 patients assigned to the mindfulness treatment arm and 44 controls. The mean Quality of Informed Consent score was similar in the meditation and control arms with and overall mean of 75 (95% confidence interval = 74–76) for the knowledge section and 86 (95% confidence interval = 81–90) for understanding, comparable to the normative scores of 80 and 88. On further analysis and patient interview, two of the Quality of Informed Consent questions were found to be misleading in the context of a two-stage consent study for a mindfulness intervention. Excluding these questions increased knowledge scores to 88 (95% confidence interval = 87–90).

Conclusion

We found promising data that two-stage consent facilitated accrual without compromising patient understanding of randomized trials or compliance with allocated treatment. Further research is needed incorporating randomized comparison of two-stage consent to standard consent approaches, measuring patient anxiety and distress as an outcome, using suitable modifications to the Quality of Informed Consent questionnaire and trials with higher stakes.

Details of risk–benefit communication in informed consent documents for phase I/II trials

Research Article

Hannes Kahrass, Sabine Bossert, Christopher Schürmann, Daniel Strech

Clinical Trials, 24 November 2020

Abstract

Background

Informed consent documents for clinical studies should disclose all reasonably foreseeable risks and benefits. Little guidance exists on how to navigate the complexities of risk–benefit communication, especially in early clinical research. Practice-oriented development of such guidance should be informed by evidence on what and how details of risks and benefits are currently communicated.

Method
We surveyed the responsible parties of phase I/II trials registered in ClinicalTrials.gov that started 2007 or later and completed between 2012 and 2016 to sample informed consent documents from a broad spectrum of early phase clinical trials. Based on an assessment matrix, we qualitatively and quantitatively assessed the informed consent documents for details of risk–benefit communication.
Results
The risk–benefit communication in the 172 informed consent documents differed substantially in several regards. The outcome, extent, and likelihood of health risks, for example, were described in 83%, 32%, and 63% of the informed consent documents. Only 45% of informed consent documents specified the outcome of mentioned health benefits, and the extent and likelihood of health benefits were never specified. From those informed consent documents reporting risk likelihoods, only 57% added frequency numbers to words such as "common" or "rare," and even in these cases, we found strong variations for presented frequency ranges. Substantial heterogeneity also exists for how informed consent documents communicate other risk and benefit types and related safeguards.
Conclusion
Our study points to several shortcomings and heterogeneities in how informed consent documents communicate risks and benefits to potential research participants. Health risks, for example, should be specified with frequency numbers, and health benefits should be specified at least by mentioning their outcomes. Further demand for research and policy development is needed to harmonize risk–benefit communication and to clarify ways to specify the likelihood of health benefits.

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SOCIAL SCIENCE RESEARCH

A Qualitative Analysis of Ethical Perspectives on Recruitment and Consent for Human Intracranial Electrophysiology Studies

Joncarmen V. Mergenthaler, Winston Chiong, Daniel Dohan, Josh Feler, Cailin R. Lechner, Philip A. Starr, Jalayne J. Arias
AJOB Neuroscience, 2 February 2021; pp 57-67
Abstract
Intracranial electrophysiological research methods, including those applying electrodes on the cortical surface or in deep structures, have become increasingly important in human neuroscience. They also pose novel ethical concerns, as human studies require the participation of neurological patients undergoing surgery for conditions such as epilepsy and Parkinson's disease. Research participants in this setting may be vulnerable to conflicts of interest, therapeutic misconception, and other threats to valid recruitment and consent. We conducted semi-structured interviews with investigators from NIH-funded studies involving recording or stimulation inside the human skull. We elicited perspectives on study recruitment and consent procedures, and analyzed transcripts using a modified grounded theory approach. We interviewed 26 investigators from 19 separate intracranial electrophysiology studies, who described two study types: opportunity studies (n = 15) and experimental trials (n = 4). Respondents described significant heterogeneity in recruitment and consent procedures, even among studies employing similar techniques. In some studies, clinician-investigators were specifically barred from obtaining consent, while in other studies clinician-investigators were specifically required to obtain consent; regulatory guidance was inconsistent. Respondents also described various models for subject selection, the timing of consent, and continuing consent for temporally extended studies. Respondents expressed ethical concerns about participants' vulnerability and the communication of research-related risks. We found a lack of consensus among investigators regarding recruitment and consent methods in human intracranial electrophysiology. This likely reflects the novelty and complexity of such studies and indicates a need for further discussion and development of best practices in this research domain.

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HEALTH DATA

DynamiChain: Development of Medical Blockchain Ecosystem Based on Dynamic Consent System

Review

Tong Min Kim, Seo-Joon Lee, Dong-Jin Chang, Jawook Koo, Taenam Kim, Kun-Ho Yoon, In-Young Choi

Applied Science, 10 February 2021; 11(1612)

Open Access

Abstract

Although blockchain is acknowledged as one of the most important technologies to lead the fourth industrial revolution, major technical challenges regarding security breach and privacy issues remain. This issue is particularly sensitive in applied medical fields where personal health information is handled within the network. In addition, contemporary blockchain-converged solutions do not consider restricted medical data regulations that are still obstacles in many countries worldwide. This implies a crucial need for a system or solution that is suitable for the healthcare sector. Therefore, this article proposes the development of a dynamic consent medical blockchain system called DynamiChain, based on a ruleset management algorithm for handling health examination data. Moreover, medical blockchain-related studies were systematically reviewed to prove the novelty of DynamiChain. The proposed system was implemented in a scenario where the exercise management healthcare company provided health management services based on data obtained from the data provider's hospital. The proposed research is envisioned to provide a widely compatible blockchain medical system that could be applied in future healthcare fields.

A Systematic Review of Blockchain for Consent Management

Review

Prasanth Varma Kakarlapudi, Qusay H. Mahmoud

Healthcare, 1 February 2021

Abstract

Blockchain technology was introduced through Bitcoin in a 2008 whitepaper by the mysterious Satoshi Nakamoto. Since its inception, it has gathered great attention because of its unique properties—immutability and decentralized authority. This technology is now being implemented in various fields such as healthcare, IoT, data management, etc., apart from cryptocurrencies. As it is a newly emerging technology, researchers and organizations face many challenges in integrating this technology into other fields. Consent management is one of the essential processes in an organization because of the ever-evolving privacy laws, which are introduced to provide more control to users over their data. This paper is a systematic review of Blockchain's application in the field of consent and privacy data management. The review discusses the adaptation of Blockchain in healthcare, IoT, identity management, and data storage. This analysis is formed on the principles of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and a process of systematic mapping review. We provide analysis of the development, challenges, and limitations of blockchain technology for consent management.

H3Africa Report on Informed Consent and Commercialisation

Ruth Chadwick, Patricia Marshall, Charmaine DM Royal

H3Africa Report, February 2021

Open Access

Background

…In light of the vast amount of genetic diversity in African populations, H3Africa provides an unparalleled research resource for the benefit of people in Africa and across the globe. Thus, the sharing of data is a guiding principle for H3Africa, and the translation of research findings to commercial products, resources, and services is consistent with its mission. Driven by a commitment to transparency and accountability, the H3Africa leadership convened a panel of experts (authors) to review the research ethics processes and practices being employed in the H3Africa Consortium projects with the aim of identifying gaps and making recommendations for improvements going forward with regard to commercialisation. Specifically, the panel was asked to review H3Africa consent documents and talk with key members of the Consortium, including members of the Ethics Working Group, to determine how H3Africa Consortium projects have implemented informed consent procedures for studies involving biobanking and the sharing of data and/or biospecimens…

Ethical issues in using ambient intelligence in health-care settings

Viewpoint

Nicole Martinez-Martin, Zelun Luo, Amit Kaushal, Ehsan Adeli, Albert Haque, Sara S Kelly, Sarah Wieten, Mildred K Cho, David Magnus, Li Fei-Fei, Kevin Schulman, Arnold Milstein

The Lancet Digital Health, 21 December 2020

Open Access

Summary

Ambient intelligence is increasingly finding applications in health-care settings, such as helping to ensure clinician and patient safety by monitoring staff compliance with clinical best practices or relieving staff of burdensome documentation tasks. Ambient intelligence involves using contactless sensors and contact-based wearable devices embedded in health-care settings to collect data (eg, imaging data of physical spaces, audio data, or body temperature), coupled with machine learning algorithms to efficiently and effectively interpret these data. Despite the promise of ambient intelligence to improve quality of care, the continuous collection of large amounts of sensor data in health-care settings presents ethical challenges, particularly in terms of privacy, data management, bias and fairness, and informed consent. Navigating these ethical issues is crucial not only for the success of individual uses, but for acceptance of the field as a whole.

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TECHNOLOGY/OTHER MEDIATION

Digital tools in the informed consent process: a systematic review

Research Article

Francesco Gesualdo, Margherita Daverio, Laura Palazzani, Dimitris Dimitriou, Javier Diez-Domingo, Jaime Fons-Martinez, Sally Jackson, Pascal Vignally, Caterina Rizzo & Alberto Eugenio Tozzi

BMC Medical Ethics, 27 February 2021; 22(18)

Open Access

Abstract

Background

Providing understandable information to patients is necessary to achieve the aims of the Informed Consent process: respecting and promoting patients' autonomy and protecting patients from harm. In recent decades, new, primarily digital technologies have been used to apply and test innovative formats of Informed Consent. We conducted a systematic review to explore the impact of using digital tools for Informed Consent in both clinical research and in clinical practice. Understanding, satisfaction and participation were compared for digital tools versus the non-digital Informed Consent process.

Methods

We searched for studies on available electronic databases, including Pubmed, EMBASE, and Cochrane. Studies were identified using specific Mesh-terms/keywords. We included studies, published from January

2012 to October 2020, that focused on the use of digital Informed Consent tools for clinical research, or clinical procedures. Digital interventions were defined as interventions that used multimedia or audio–video to provide information to patients. We classified the interventions into 3 different categories: video only, non-interactive multimedia, and interactive multimedia.

Results

Our search yielded 19,579 publications. After title and abstract screening 100 studies were retained for full-text analysis, of which 73 publications were included. Studies examined interactive multimedia (29/73), non-interactive multimedia (13/73), and videos (31/73), and most (34/38) studies were conducted on adults. Innovations in consent were tested for clinical/surgical procedures (26/38) and clinical research (12/38). For research IC, 21 outcomes were explored, with a positive effect on at least one of the studied outcomes being observed in 8/12 studies. For clinical/surgical procedures 49 outcomes were explored, and 21/26 studies reported a positive effect on at least one of the studied outcomes.

Conclusions

Digital technologies for informed consent were not found to negatively affect any of the outcomes, and overall, multimedia tools seem desirable. Multimedia tools indicated a higher impact than videos only. Presence of a researcher may potentially enhance efficacy of different outcomes in research IC processes. Studies were heterogeneous in design, making evaluation of impact challenging. Robust study design including standardization is needed to conclusively assess impact.

The effect of animated consent material on participants' willingness to enrol in a placebo-controlled surgical trial: a protocol for a randomised feasibility study

Study Protocol

Elizabeth Nelson, Cade Shadbolt, Samantha Bunzli, Angela Cochrane, Peter Choong & Michelle Dowsey

Pilot and Feasibility Studies, 8 February 2021; 7(46)

Open Access

Abstract

Background

Placebo-controlled surgical trials are recognised as the gold standard way to test the efficacy of a surgical procedure. Despite a rise in arthroscopic subacromial decompression (ASD) surgeries for the treatment of shoulder pain, only two placebo-controlled surgical trials have been conducted. These trials encountered significant recruitment challenges, threatening the external validity of findings. Difficulties with recruitment are common in clinical trials and likely to be amplified in placebo-controlled surgical trials. This mixed method feasibility trial aims to address the following questions: (i) Feasibility: What proportion of patients who have consented to undergo ASD report that they would be willing to enrol in a placebo-controlled trial for this procedure? (ii) Optimisation: Can patients' willingness to enrol in, or understanding of, such a trial be improved by supplementing written consent materials with a brief visual animation that outlines the details of the trial? And (iii) exploration: What factors influence patients stated willingness to enrol in such a trial, and how do they believe the recruitment process could be improved?

Methods

This study aims to recruit 80 patients on the waiting list for ASD. Participants will be randomised (1:1) to either view a brief video animation explaining the hypothetical placebo-controlled trial in addition to written information or to written information only. Participants in both groups will be required to state if they would be willing to opt-in to the hypothetical ASD trial after immediately being presented with the consent material and again 1 week after completion of the consent process. Patients in both groups will also be required to complete a measure of trial literacy. Twenty participants will be purposively sampled to take part in an embedded qualitative study exploring understanding of trial concepts and factors contributing to willingness to opt-in.

Discussion

This feasibility study will provide evidence for optimising participant recruitment into a placebo-controlled trial of ASD by consenting patients using animated trial information in addition to written information. This

pilot and feasibility data may also be relevant to placebo-controlled surgical trials more broadly, which are characterised by recruitment challenges.

Can a Checklist Improve the Informed Consent Process?

Original Article

Eric Shirley, Veronica H. Mai, Kevin M. Neal, Kathryn V. Blake

Cureus, 5 February 2021; 13(2)

Abstract

Informed consent often fails to provide patients and families with a full understanding of the proposed procedure. We developed an informed consent checklist for identifying specific aspects of the surgical consent that were not fully understood by families. The purpose of this study was to measure the effect of using this checklist on families' knowledge, satisfaction, experience, and decisional conflict during the consent process. The families of pediatric patients scheduled for an orthopaedic preoperative visit were prospectively randomized into one of two groups: checklist or traditional appointment. Families in the checklist group completed the informed consent checklist which was then used by the surgeon to further discuss aspects of the surgery that needed clarification. Those in the traditional group had similar discussions about surgery without the aid of a checklist. Sixty-one families participated in the study; 27 in the checklist group and 34 in the traditional group without a checklist. The checklist group reported no difference in mean scores for all satisfaction (P = 0.37), decisional conflict (P = 0.51), and knowledge items (P = 0.31). For patient experience, the traditional group reported the visits were significantly more relaxed (mean 4.9, 95% confidence interval (CI) 4.8-5.0) than the checklist group (mean 4.5, 95% CI 4.3-4.7). Our results suggest that having a family member complete the informed consent checklist prior to meeting with the surgeon did not improve, and may worsen, the consent experience for some families. Other methods need to be evaluated to determine the optimal consent process from the family's perspective.

Educational Informed Consent Video Equivalent to Standard Verbal Consent for Rhinologic Surgery: A Randomized Controlled Trial

Research Article

Joseph P. Penn, Rohit Nallani, Erin L. Dimon, Taylor C. Daniels, Kevin J. Sykes, Alexander G. Chiu, Mark R. Villwock, Jennifer A. Villwock

American Journal of Rhinology & Allergy, 2 February 2021

Abstract

Background

Informed consent is an integral part of pre-operative counseling. However, information discussed can be variable. Recent studies have explored the use of multimedia in providing informed consent for rhinologic surgery.

Objective

To measure impact of an educational video (Video) compared to verbal informed consent (Verbal) on knowledge gained, alleviation of concerns, and efficiency.

Methods

Patients undergoing endoscopic sinus surgery (ESS), septoplasty, or ESS+septoplasty were prospectively enrolled and randomized to receive Video or Verbal consent. The Video group watched an educational video; the Verbal group received standard verbal consent from an Otolaryngology resident per institutional protocol. Both groups had the opportunity to discuss questions or concerns with their attending surgeon. Prior to, and after, consent was signed, both groups completed surveys regarding knowledge of purpose, risks, and benefits of surgery as well as surgical concerns. Decision regret and patient satisfaction were also assessed post-operatively.

Results

77 patients were enrolled (39 Video, 38 Verbal). Demographics were not significantly different between groups. Overall knowledge significantly improved ($p < 0.005$) and concerns significantly decreased ($p < 0.001$) following consent in both groups. Improvements in these metrics were equivalent between groups ($p < 0.02$). Furthermore, resident time to complete consent, patient satisfaction, and decision regret were not significantly different between groups.
Conclusion
Use of an educational video was equivalent to standard verbal informed consent for patients undergoing rhinologic surgery. Otolaryngologists can consider developing procedure-specific videos to allow allocation of time to other tasks, standardized education of patients, and streamlining of the informed consent process.

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CAPACITY TO CONSENT

Consent, Informed: Rethinking Informed Consent & Competency for Patients with Schizophrenia & Anosognosia

Nina Labovich
Boston College Law Review, 24 February 2021; 62(2)
Open Access
Abstract
Anosognosia is a common symptom of schizophrenia and schizoaffective disorder that renders individuals unable to understand that they are living with a disease. This symptom often leads people to refuse anti-psychotic medication, and may increase an individual's likelihood of becoming homeless or incarcerated. When courts find individuals to be a danger to others or themselves, states can impose involuntary commitment. When a state grants involuntary commitment, however, a court may find the individual remains competent to refuse medication. This Note argues that documented anosognosia requires a finding of incompetency, whether people are a danger to themselves or not. Science suggests that a person with severe anosognosia lacks the insight to refuse treatment. This Note proposes a novel statutory definition of competency, encompassing the specific needs of people with anosognosia, and grapples with the significant interests at stake in taking away an individual's right to choose or refuse treatment, including antipsychotic medication.

Informed Consent or Assent Strategies for Research with Individuals with Deafblindness or Dual Sensory Impairment: A Scoping Review

Review
Archives of Rehabilitation Research and Clinical Translation, 22 February 2021
Abinethaa Paramasivam, Atul Jaiswal, Renu Minhas, Walter Wittich, Roxanna Spruyt-Rocks
Abstract
Objective
To synthesize evidence on existing informed consent/assent strategies and processes that enable the participation of individuals with deafblindness or dual sensory impairment in research.
Data Sources
Five scientific databases (PubMed, MEDLINE, CINAHL, Web of Science, and PsycINFO) and other sources such as Google Scholar, the Journal of Visual Impairment and Blindness, and the British Journal of Visual Impairment were hand-searched from January 2015 until July 2020.
Study Selection

Studies were selected using a priori inclusion criteria of sensory and cognitive disabilities and focused on consent/assent strategies and processes in research within this population. Articles related to the medical or sexual consent processes were excluded.

Data Extraction

An Excel spreadsheet was used to extract data from the eligible sources. Discrepancies were resolved in discussion with team members.

Data Synthesis

A total of 2163 sources were screened, of which 16 articles were included in the review. Seven sources only examined consent strategies, whereas the remaining eight included a combination of consent/assent and dissent strategies. Using thematic analysis, three key themes emerged – consent/assent strategies, researcher capacity, and capacity to consent tools. Key identified strategies included the accessibility of the consent/assent process, building relationships with participants and caregivers, identifying behavioural cues, and communication training for researchers.

Conclusion

Despite the absence of literature on consent/assent strategies within the deafblind population, the review found promising strategies applied to individuals with other cognitive or sensory disabilities that researchers can adopt. Researchers are encouraged to use best practices in creating an inclusive research environment to include individuals with deafblindness.

Decisional capacity to consent to treatment and research in patients affected by Mild Cognitive Impairment. A systematic review and meta-analysis

Review

Giovanna Parmigiani, Antonio Del Casale, Gabriele Mandarelli, Benedetta Barchielli, Georgios D. Kotzalidis, Fabrizia D'Antonio, Antonella Di Vita, Carlo de Lena, Stefano Ferracuti

International Psychogeriatrics, 15 February 2021; pp 1-14

Open Access

Abstract

Objectives

To perform a meta-analysis of clinical studies on the differences in treatment or research decision making capacity among patients with Mild Cognitive Impairment (MCI), Alzheimer's disease (AD), and healthy comparisons (HCs).

Design

A systematic search was conducted on Medline/Pubmed, CINAHL, PsycINFO, Web of Science, and Scopus. Standardized mean differences and random-effects model were used in all cases.

Setting

The United States, France, Japan, and China.

Participants

Four hundred and ten patients with MCI, 149 with AD, and 368 HCs were included.

Measurements

The studies we included in the analysis assessed decisional capacity to consent by the MacArthur Competence Assessment Tool for Treatment (MAcCAT-T), MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), Capacity to Consent to Treatment Instrument (CCTI), and University of California Brief Assessment of Capacity to Consent (UBACC).

Results

We identified 109 potentially eligible studies from 1672 records, and 7 papers were included in the metaanalysis. The meta-analysis showed that there was significant impairment in a decision-making capacity in MCI patients compared to the HCs group in terms of Understanding (SMD = − 1.04, 95% CI: − 1.31 to − 0.77, P < 0.001; I 2 =52%, P= 0.07), Appreciation (SMD = − 0.51, 95% CI: − 0.66 to − 0.36, P <0.001; I 2 = 0%, P = 0.97), and Reasoning (SMD = − 0.62, 95% CI: − 0.77, −0.47, P< 0.001; I 2 =0%, P=0.46). MCI patients scored

significantly higher in Understanding (SMD = 1.50, 95% CI: 0.91, 2.09, P =0.01, I 2 = 78%, P= 0.00001) compared to patients affected by AD.

Conclusions

Patients affected by MCI are at higher risk of impaired capacity to consent to treatment and research compared to HCs, despite being at lower risk compared to patients affected by AD. Clinicians and researchers need to carefully evaluate decisional capacity in MCI patients providing informed consent.

Surrogate Informed Consent: A Qualitative Analysis of Surrogate Decision Makers' Perspectives

Trevor Lane , Elinor Brereton , Carolyn Nowels , Jeffrey McKeehan , Marc Moss , Daniel D Matlock

Annals of the American Thoracic Society, 2 February 2021

Abstract

Rationale

Clinical critical care research often hinges on surrogate informed consent as patients commonly lack decision making capacity due to their acute illness. The surrogate informed consent process has been identified as having flaws and needing improvement. A better understanding of surrogates' perspectives is required in order to understand and address these shortcomings and thereby improve this process.

Objectives

To explore the perspectives of surrogate decision makers of critically ill mechanically ventilated patients about being approached about having their loved one participate in hypothetical research studies.

Methods

We performed semi-structured qualitative interviews of surrogate decision makers of critically ill mechanically ventilated patients exploring their decisional needs surrounding participation in research. These interviews were recorded and transcribed verbatim. A thematic analysis of transcripts was performed with an iterative group framework using a mixed inductive and deductive approach.

Results

A sample of 21 surrogate decision makers were interviewed. Thematic saturation was achieved by consensus of the investigators. We identified trust as a unifying domain for the themes that emerged through the analytic process. Embedded within the domain of trust, two central themes became apparent: knowledge-based trust and context-based trust. Knowledge-based trust includes sub-themes of logistics, accountability, and mutual respect, whereas context-based trust includes trust in the individual clinicians and trust in the hospital system.

Conclusions

Our findings highlight the nuanced layers of trust central to the surrogate informed consent process. To enhance the surrogate informed consent process for participation in critical care research studies it is crucial that researchers recognize the inherent importance of trust to ensure an effective informed consent process.

Incapacity in childbirth - rare or common?

Neelam Singh, Peter Lepping, Rhiannon Whitaker, Barkat Masood, Shweta Joshi, Philip Banfield

European Journal of Obstetrics & Gynecology and Reproductive Biology, 29 January 2021

Abstract

Objective

Impaired decision making ability is common on general medical wards. Audit evidence suggests that the prevalence of incapacity may be higher than previously assumed in Obstetric Emergency Procedures (OEP) during childbirth. We investigated the prevalence of incapacity in OEP and factors associated with this.

Design

Capacity to consent to treatment was assessed retrospectively in 93 women undergoing OEP. All women were interviewed using a semi-structured questionnaire aided interview within 24 hours of the emergency. Five assessors (3 obstetricians and 2 psychiatrists) were asked to determine capacity to consent from audio recordings of the interviews.

Results
All 5 assessors determined 59% of women to have capacity to consent to treatment and 2% of women to lack capacity. In 39% of women there was some disagreement between assessors. Using a majority decision (3 assessors in agreement), 14% of women lacked capacity. High pain scores, young age and no previous history of theatre deliveries were associated with more incapacity judgments, whilst parity and history of mental illness were not. Using a 7point Likert scale only marginally improved agreement between assessors, compared to their binary decision.
Conclusion
It is often assumed that it is rare to lack capacity in an obstetric emergency procedure during childbirth, but these data suggest that incapacity may be relatively common. In particular, severe pain is a demonstrable risk factor for impaired capacity. Wide variation between assessors questions the validity of current commonly employed (informal) methods used in clinical practice to assess capacity to consent during OEP.

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RIGHTS/LEGAL/LEGISLATIVE

The Concept of "Person" in the Italian Legislation on Informed Consent and Advance Healthcare Directives

Matteo Cresti
International Journal for the Semiotics of Law, 10 February 2021
Open Access
Abstract
The aim of the paper is that of investigating the concept of "person" in the context of Italian law on informed consent and advance healthcare directives (law n. 219/2017). The following paper will first consider the importance of the concept of "person" within bioethics; secondly it will exhibit how there are different levels of bioethics, and that on the discussion level of laws and regulations, concepts worthy of metaphysical and value references cannot be used, because they must be shared by everyone in a pluralistic society. I'll then move on to discuss the law on informed consent and advance healthcare directives; first I'll discuss the references to the Italian Constitution, showing that the implied concept of "person" is closely linked to the concepts of "equality" and "autonomy", and finally I'll discuss the particular case of minors and the protection that the law provides them.

[Expert consensus on informed consent for vaccination(Part One)]

Zhonghua Yu Fang Yi Xue Za Zhi
Chinese Preventive Medicine Association, 1 February 2021; 55(2) pp 135-166
Abstract
The Vaccine Administration Law of the People's Republic of China and other relevant laws require that vaccine recipients or their guardians be educated about vaccines and how they work, and described in general the methods and contents of such vaccination education. With the new law and "Standard Operational Procedures for Immunization" as foundation documents, and in consultation with experts at home and abroad, the Chinese Preventive Medicine Association developed a consensus statement about informed consent for vaccination. This consensus statement is written for disease control and prevention health care personnel in vaccination services and describes the educational content of informed consent, a theoretical framework for immunization and immunization knowledge, the informed consent processes, principles of planning for vaccination, and an informed consent form. Part One of the consensus includes the general principles of vaccination and provides specific information on hepatitis B vaccine, Bacillus Calmette-

Guérin vaccine, poliomyelitis vaccine, diphtheria, tetanus and pertussisvaccine, measles-containing vaccine, Japanese encephalitis vaccine, meningococcal vaccine, and hepatitis A vaccine.

Editor's note: This is a Chinese language publication

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FREE PRIOR INFORMED CONSENT (FPIC)

Our land is banked: forest rights, consent and the invention of a legal exception as land banks

Arpitha Kodiveri

International Journal of Human Rights, 3 February 2021

Abstract

Land banks are a newly created administrative mechanism managed by the Odisha Industrial and Infrastructure Corporation (IDCO) and the Revenue and Disaster Management Department. Their purpose is to provide large parcels of land to industries with minimal procedural hassles in the acquisition. Thus, the administrative authorities put in place an intricate web of legal interpretations that enable it to bypass due process requirements. The legal landscape in India's forests transformed with the passing of the Forest Rights Act,2006 in the direction of democratisation and participation of forest-dwelling communities. An essential part of this legal framework was the right to free, prior, and informed consent of the village assembly. In this paper, through case studies and examples I argue that a space of exception is created within the law through the mechanism of land banks to prevent the applicability of the consent provision. This sophisticated legal interpretive exercise by the administrative authority results in the violation of the human right to free, prior, and informed consent of forest-dwelling communities in Odisha.

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CULTURAL/COUNTRY CONTEXT

Informed Consent Rates For Neonatal Randomized Controlled Trials In Low And Lower-Middle Income Countries Versus High-Income Countries: A Systematic Review

Denise Jones, Syed Taha, Michael S. Jones, Melissa Bauserman, Stuti Pant, Carl Bose, Sudhin Thayyil, Jackie K. Patterson and Paolo Montaldo

Pediatrics, March 2021; 147(3) pp 246-247

Abstract

Background – Consent rates for research studies in low- and lower middle-income countries (LMICs) are often greater than 90%. Uniformly high consent rates raise ethical concerns regarding the extent to which consent is both autonomous and informed. This study aimed to characterize consent rates for neonatal randomized controlled trials (RCTs) in LMICs compared to high-income countries (HICs). Methods – We searched MEDLINE, EMBASE and Cochrane for neonatal RCTS in LMICs or HICs published between 2013 and 2018. Given the disproportionately high number of HIC articles in the initial search, we used a random number generator to select a subset of HIC…

Written Informed Consent—Translating into Plain Language. A Pilot Study

Agnieszka Zimmermann, Anna Pilarska, Aleksandra Gaworska-Krzemińska, Jerzy Jankau, Marsha N. Cohen

Healthcare, 20 February 2021; 9(2)

Abstract

Background

Informed consent is important in clinical practice, as a person's written consent is required prior to many medical interventions. Many informed consent forms fail to communicate simply and clearly. The aim of our study was to create an easy-to-understand form.

Methods

Our assessment of a Polish-language plastic surgery informed consent form used the Polish-language comprehension analysis program (jasnopis.pl, SWPS University) to assess the readability of texts written for people of various education levels; and this enabled us to modify the form by shortening sentences and simplifying words. The form was re-assessed with the same software and subsequently given to 160 adult volunteers to assess the revised form's degree of difficulty or readability.

Results

The first software analysis found the language was suitable for people with a university degree or higher education, and after revision and re-assessment became suitable for persons with 4–6 years of primary school education and above. Most study participants also assessed the form as completely comprehensible.

Conclusions

There are significant benefits possible for patients and practitioners by improving the comprehensibility of written informed consent forms.

Enhancing the ethical conduct of a longitudinal cluster-randomized trial of psychosocial stimulation intervention for children with complicated severe acute malnutrition through Rapid Ethical Assessment: a qualitative study

Research Article

Tesfalem T. Tessema, Andamlak G. Alamdo, Eyoel B. Mekonnen, Fanna A. Debele, Juhar A. Bamud, Teklu G. Abessa & Tefera Belachew Lema

BMC Medical Ethics, 4 February 2021; 22(10)

Open Access

Abstract

Background

Informed consent is a universally accepted precondition for scientific researches involving human participants. However, various factors influence the process of obtaining authentic informed consent, and researchers particularly working in resource-poor countries often face considerable difficulties in implementing the universally recommended procedures for obtaining informed consent. We have conducted this Rapid Ethical Assessment (REA) to accommodate the local cultural norms and to understand the relevant ethical issues in the Silti community before the conduct of a cluster-randomized controlled trial.

Methods

This REA was conducted in two purposively selected Woredas/Districts and Worabe Town administration of Silti Zone. Data were collected using in-depth interviews and focus group discussions. Purposive and convenient sampling techniques were used to select respondents. Five in-depth interviews and 15 Focus Group Discussions were conducted in the Amharic language. The collected data was transcribed, translated, and analyzed using a thematic approach.

Result

Most of the community members never heard about research and therapeutic misconception was common. In the area, the permission of people working in the formal and informal community administration is essential before approaching individuals. The male head of the household should also be involved in the decision before individual household members participate in research. Furthermore, sensitizing the community using public and religious gatherings was suggested before individual recruitment. In the consent process, delivering selected information particularly the purpose and benefits of the research was emphasized and the tendency of preferring verbal consent was documented despite the willingness of the individuals to sign on the consent form. Local health workers were identified as appropriate personnel to communicate information and the procedures of the research were found to be acceptable. However, the

value of small incentives was suggested to motivate potential participants. Finally, involving all concerned stakeholders and respecting the cultural norm of the community was emphasized.

Conclusion

Through REA, we understand the research awareness of the community, their expectation, and the cultural norms relevant to the ethical conduct of research. It enabled us to devise culturally sensitive and scientifically sound strategies to secure authentic informed consent. The process of conducting REA was found to be feasible, quick, and efficient.

Knowledge, Attitude, and Practice about informed consent amongst Resident doctors at Rural Medical Institute of Central India

Shashank Gotarkar, Prakash Mohite, Kumar Bijyendra Sourabh, Alka Rawekar

Indian Journal of Forensic Medicine & Toxicology, January-March 2021; 15(1)

Open Access

Abstract

Informed consent is the process by which the treating health-care provider discloses appropriate information to the patient so that the patient may make a voluntary choice to accept or refuse treatment. There are few studies done amongst the medical residents in India about informed consent. The residents are the stepping stone of the Medical profession, it is proposed that the perception about the informed consent amongst the residents shall be sought.Hence, the study was undertaken with the aim, to appraise the knowledge, attitude, and practices of residents of all three years toward 'informed consent taking' with the objectives of assessing and comparing the knowledge, attitude and practices of obtaining informed consent. The survey questionnaire was circulated and data was collated. It was developed in Knowledge, Attitude and practice domain and analysis was done. Based on the result, it was concluded that, in all three domains, there was ascendency of Knowledge, Attitude and Practice in three years of resident doctors.

The readability of informed consent forms for research studies conducted in South Africa

A E Fischer, W D F Venter, S Collins, M Carman, S T Lalla-Edward

South African Medical Journal, February 2021; 111(2)

Open Access

Abstract

Background

Informed consent forms (ICFs) are used to obtain consent from participants. However the complexity and comprehensiveness of these forms may not be appropriate. Readability can be quantified by formulas in Microsoft (MS) Word, such as the Flesch Reading Ease test. The South African (SA) ethics guidelines suggest that the MS Word Flesch-Kincaid Reading Grade score should be used to assess the complexity of ICFs and should be the equivalent of grade 8 level, or lower.

Objectives

To use readability formulas to determine whether current SA ICFs are appropriate for the general population.

Methods

This was a descriptive study of a sample of English ICFs (solicited from our studies, as well as from local researchers) which received approval from local ethical review boards during the past 5 years, for prospective (≥6 months) drug studies that explored treatment and prevention of HIV, tuberculosis, diabetes or cardiovascular disease. ICFs were evaluated in MS Word for Flesch Reading Ease and Flesch-Kincaid Reading Grade, with the Simple Measure of Gobbledygook (SMOG) index calculated using www.readabilityformulas.com. Recommended targets for easy readability are above 60 for the Flesch Reading Ease score, and less than or equal to a grade 8 reading level for the Flesch-Kincaid Reading Grade and SMOG.

Results

A total of 75 consent forms from 35 individual research studies conducted in SA over the last 5 years were included. The consent forms had been approved by six ethics committees across seven of the SA provinces. The median (interquartile range (IQR)) Flesch Reading Ease score was 55.8 (48.7 - 59.7) and 18 (25.0%) of the ICFs had easy or standard readability, while the median (IQR) Flesch-Kincaid Grade was 10.2 (8.8 - 11.4), with 23 (30.6%) at least a grade 8 level or lower. The median (IQR) SMOG index scored below grade 8 level.
Conclusions
Two-thirds of the ICFs from this study fail to meet the SA readability standard, a result matched by using alternative readability formulas. Readability can be improved with simple techniques and by actively monitoring readability metrics.

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MEDICAL/SURGICAL

The practice of obtaining informed consent for elective surgery and anesthesia from patients' perspective: An institutional based cross-sectional study

Research Article
Tadese Tamire, Aragaw Tesfaw
Clinical Ethics, 8 February 2021
Abstract
Introduction
Informed consent is a body of shared decision-making process and voluntary authorization of patients to receive medical or surgical intervention. There are limited studies conducted so far to examine the practice of informed consent in Ethiopia. This study aimed to assess the practice of informed consent process for surgery and Anesthesia.
Method
A cross-sectional study was conducted from March to May 2019. The data were collected using interviewer-administered structured questionnaire and analyzed in SPSS version 23.
Results
A total of 139 patients were interviewed in this study. Most 42(30.2%) of patients were in the age group of 29–38 years. Nearly half 68 (48.9%) of the patients were informed the benefits of the surgical procedure and 78(56.1%) of the patients were informed on the type of anesthesia to be administered while 65 (46.8%) were not informed on any complication related to the anesthesia. About 66 (47.5%) of patients were informed on alternatives to the surgery. Of these patients, 39(59%) were not informed of any benefits and possible risks associated with the alternative modes of treatment. About half (54%) of the patients were reported as they were understood the information provided during the pre-operative informed consent process.
Conclusion
This research revealed that patients were inadequately informed on the complications of proposed procedure, alternative forms of treatment, risks and benefits of the proposed procedure. Therefore, healthcare providers should provide adequate information regarding the proposed procedure and make sure whether patients understood the risks and benefits before the consent.

Decision making and informed consent in uterus transplant recipients: A mixed-methods study of the Dallas uterus transplant study (DUETS) participants

Anji E. Wall, Liza Johannesson, Monica Sok, Ann Marie Warren, Elisa J. Gordon, Giuliano Testaa
The American Journal of Surgery, 4 February 2021
Abstract
Background

Uterus transplantation (Utx) has achieved clinical success but little is known about motivations and experiences of UTx recipients.
Methods
We conducted semi-structured interviews with 20 UTx recipients in addition to collecting quantitative demographic and clinical data. Closed-ended interview questions were treated as categorical variables. Thematic analysis was performed on qualitative data. Bivariate analysis tested associations between categorical variables.
Results
Themes that emerged included: the decision to pursue UTx is a process, primary motivations for UTx are specific to the experience of gestation, and alternative options did not offer the same value as UTx. There was no association between disease etiology, clinical status, or perception of UTx risk with information needs or donor preference.
Conclusions
Our findings suggest that UTx is a unique treatment option that some women with AUFI find preferable to adoption and surrogacy and, as such, should be discussed as a parenthood option with women diagnosed with AUFI.

Understanding Mordel: obtaining informed consent for trisomy screening

Emyr Owain Wile, Alys Einion-Waller
British Journal of Midwifery, 2 February 2021; 29(2)
Abstract
The landmark decision of Montgomery has established that the patient's right to self-determination and autonomy underpins the doctrine of informed consent. The case of Mordel threw into question the process of obtaining informed consent and whether it was being sufficiently secured in the context of Down's syndrome screening. This case conveyed a paradigm shift to the role of the midwife and sonographers when obtaining consent for screening and the requisite legal standard of care they owe to expectant parents. However, many key issues remain unanswered from the decision in Mordel, in particular, what steps must healthcare professionals take to discharge their duty of care in the process of securing informed consent from expectant parents for screening.

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GENERAL/OTHER

Legal implications of euthanasia without owner consent

Louise Olley
The Veterinary Nurse, 23 February 2021; 12(1)
Abstract
A veterinary surgeon and registered veterinary nurse must act in accordance with an animal owner's wishes and should respect their confidentiality. This can cause conflict as animal welfare should also be considered as a priority. Contradictory messages from legislation and the Royal College of Veterinary Surgeons Code of Professional Conduct for Veterinary Nurses are confusing, however, guidance from these suggests that animal welfare overrides all. To practice clinical governance, veterinary teams should discuss ethical scenarios to prepare all staff for prioritising animal welfare while considering the views of the owner.

Informed consent and compulsory medical device registries: ethics and opportunities

Daniel B. Kramer, Efthimios Parasidis

Journal of Medical Ethics, 19 February 2021

Abstract

Many high-risk medical devices earn US marketing approval based on limited premarket clinical evaluation that leaves important questions unanswered. Rigorous postmarket surveillance includes registries that actively collect and maintain information defined by individual patient exposures to particular devices. Several prominent registries for cardiovascular devices require enrolment as a condition of reimbursement for the implant procedure, without informed consent. In this article, we focus on whether these registries, separate from their legal requirements, have an ethical obligation to obtain informed consent from enrolees, what is lost in not doing so, and the ways in which seeking and obtaining consent might strengthen postmarket surveillance in the USA.

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