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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

July 2022

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

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

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

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS

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

POLICY GUIDANCE/PROGRAM ACTION

Informed Consent for Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing

NIH – Office of Science Policy/Office of Extramural Research, May 2022; pp 1-7

Introduction

…The following resource… outlines suggested points to consider when addressing data and biospecimen storage and sharing for future use in consent language and provides supplemental sample language that could be modified as needed when developing informed consent documents. Of note, the sample language provided below is designed to be incorporated into a primary research consent document. The use of the sample language by itself does not address federal, state, local, tribal, or international requirements that may apply to the primary research. Furthermore, this resource is designed for research consent documents; it does not address the storage and sharing of data and biospecimens initially collected for clinical purposes. Use of the information provided in this resource, including sample language, is completely voluntary.

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COVID-19

Electronic consent in a COVID-19 vaccine implementation trial in South Africa: Participant perspectives

Gonasagrie Nair, Siti M. Kabanda, Meagan M.M. Jacobs-Alfred, Adetayo E.A. Obasa, Michael G. McCaul, Keymanthri Moodley

South African Journal of Science, 31 May 2022; 5

Open Access

Abstract

The COVID-19 pandemic has warranted modifications to clinical research implementation to ensure adherence to public health and safety measures. Often, this modification has necessitated a deviation from the traditional face-to-face approach to an electronic or hybrid consent process. We assessed the acceptability and preference for electronic consent and explored understanding of the electronic consent information – an outcome which is vital in providing reassurance that consent is provided with full appreciation of the risks and benefits of study participation. In this descriptive study, healthcare professionals (HCPs) were invited, through a database of HCP contacts, snowball sampling and advertisement, to participate in an online survey between 14 July 2021 and 17 September 2021, to explore their experiences of providing electronic consent for enrolment into the largest implementation trial of a COVID vaccine in South Africa (SISONKE Trial). Descriptive analysis was used to characterise respondents and categorical data were expressed as frequencies. The prevalence of recurring responses to open-ended questions allowed for the identification of themes. A total of 1025 HCPs completed the online survey. Access to a COVID-19 vaccine was the strongest motivating factor for enrolment (82.3%) into the SISONKE Trial. Over a third of participants (38.6%) were not able to discuss the study with research staff. While the majority of participants (85.2%) indicated that online consent was acceptable, it was recognised that acceptability was

context specific. Although 64% indicated awareness that reporting both a positive COVID test and adverse events were requirements, a significant percentage (32%) did not recall that the reporting period was 2 years. The electronic consent process was easily navigated by educated HCPs with access to electronic devices and data. Vaccine access was the most important motivation for participation, thus raising questions about how voluntary the consent process was and the role of desperation in deciding to participate.

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BIOMEDICAL RESEARCH

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

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

Journal of Clinical Oncology, 1 June 2022 [2022 ASCO Annual Meeting]

Open Access

Abstract

Background

Although patient advocates have created templates for standard consent forms, assessing patient preferences for First in Human (FIH) and Window of Opportunity (WO) trials consents is important given their unique risks. FIH trials are the first time a drug is tested in humans. In WO trials, treatment naïve patients receive a therapeutic agent in the window of time between diagnosis and standard of care (SOC) surgery. Our goal was to determine patient-preferred presentation of important information in FIH and WO consent forms.

Methods

The study consisted of two phases: (1) analysis of consents for FIH and WO oncology trials open at a cancer center between 2019 and 2022; (2) interview patients who had reviewed consents for FIH or WO trials during the consent process. FIH consents were analyzed for the location(s) of information stating that the study drug has not been tested in humans (FIH info). The WO consents were analyzed for the location(s) of information stating the risk that trial may delay SOC surgery (WO info). Participants were asked about their preferred placement of the information in their own trial's consent form and whether the consent was clear. Interviews were audio-recorded and double coded. Consent form analysis was compared to patients' preferences.

Results

25 consents [20 FIH; 5 WO] were analyzed. 19/20 FIH consent forms included FIH info, and 4/5 WO consent forms included WO info. 42 patients were approached [19 FIH; 23 WO]; 34 [17 FIH; 17 WO] participated. 12/17 (71%) WO participants thought that the trial explanation in the consent form was clear. Conversely, only 9/17 (53%) FIH participants found it clear.

Conclusions

Patients preferred that the important FIH and WO information be placed early in the consent, though exactly where varied. 82% of FIH participants wanted FIH information in the purpose, while only 19% of WO participants clearly preferred that WO information be in the purpose, and 41% preferred WO information to remain in the risks section. Using consent templates that reflect patient preferences accurately is essential for ethical informed consent; however, a one-size fits all approach may not accurately capture patient preferences, so multiple templates may be necessary.

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SOCIAL SCIENCE RESEARCH

Coercion and non-consent during birth and newborn care in the United States

Original Article

Rachel G. Logan, Monica R. McLemore, Zoë Julian, Kathrin Stoll, Nisha Malhotra, Saraswathi Vedam

Birth, 23 June 2022

Open Access

Abstract

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

Methods

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

Results

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

Discussion

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

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HEALTH DATA

Formal Models for Consent-Based Privacy

Neda Peyrone, Duangdao Wichadakul

Journal of Logical and Algebraic Methods in Programming, 20 June 2022

Abstract

The General Data Protection Regulation (GDPR) has changed the way businesses handle personal data. The GDPR is a set of conditions within the European Union (EU) law on data protection and privacy. The law requires software systems that store and manage personal data to use only the necessary information (‘data minimisation’) and manage the information fairly and appropriately (‘lawfulness, fairness and transparency’). Furthermore, personal data that can lead to direct or indirect identification must be kept safe. Therefore, the risk management of personal data within software mainly depends on the developers' experience. The consent under the GDPR is an agreement between organizations (‘data controllers’) and individuals (‘data

subjects'), which provides provisions for protecting personal data. The data controller must gain explicit consent from the data subject before collecting and processing the data. Hence, consent management is an essential component of a software system. This research proposes a set of formal models for consent management that take Privacy by Design (PbD) into account. We used the Event-B method to formalize the proposed models close to a real system. The Rodin platform proved each Event-B model to be corrected and deadlock-free. We also described how developers could transform Event-B models into the actual codes and demonstrated this result by mapping Event-B models into class diagrams. The proposed models meet consent compliance and privacy awareness requirements. In particular, the models cover certain aspects of privacy, including managing the consent of data subjects and controlling authorized access based on the data subject's consent.

Consent and the Right to Privacy

Kevin Mills

Journal of Applied Philosophy, 2 June 2022

Abstract

There is currently intense debate about the significance of user consent to data practices. Consent is often taken to legitimate virtually any data practice, no matter how invasive. Many scholars argue, however, that user consent is typically so defective as to be 'meaningless' and that user privacy should thus be protected by substantive legislation that does not rely (or does not rely heavily) on consent. I argue that both views rest on serious mistakes about the validity conditions for consent. User consent is sufficiently impoverished that it does not guarantee legitimacy but is not so impoverished as to be 'meaningless'; it can legitimate data practices that are independently reasonable but not those that are exploitative. Since many valuable data practices must be consented to if they are to be legitimate (or so I argue), our privacy legislation should continue emphasizing the importance of user consent, even if auxiliary protections are also desirable.

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GENOMIC MEDICINE/GENE EDITING

Informed consent in a tuberculosis genetic study in Cameroon: information overload, situational vulnerability and diagnostic misconception

Research Article

Ali Ibrahim Mohammed-Ali, Eyoab Iyasu Gebremeskel, Emmanuel Yenshu, Theobald Nji, Apungwa Cornelius Ntabe, Samuel Wanji, Godfrey B Tangwa, Nchangwi Syntia Munung

Research Ethics, 14 June 2022

Open Access

Abstract

Concerns around comprehension and recall of consent information by research participants have typically been associated with low health and research literacy levels. In genomics research, this concern is heightened as the scientific and ethical complexities of genetics research, such as biobanking, genetic susceptibility, data sharing, and incidental findings may be more difficult for potential research participants to understand. However, challenges to research participants' comprehension of consent information may be compounded by factors beyond health and research literacy levels. To identify factors that may impact research participants' understanding and recall of consent information, we designed a qualitative study to explore whether participants enrolled in a tuberculosis genetics study (TBGEN-Africa) in Cameroon understood the objectives of the study, the risks and benefits and certain key aspects of the study such as biobanking and data sharing. The results showed that research participants had limited understanding and/or recall of the TBGEN-Africa study goals and methods. Some participants were of the opinion that TBGEN-

Africa was not a genetics study because tuberculosis is not an inheritable condition. Factors that may have hindered understanding and/or recall of study information are diagnostic misconception (research participants consider research as part of medical diagnosis), and information overload and situational vulnerability (consent at a time of physical and emotional distress). There is a need for improved practices to support research participants' understanding of consent information in genetics studies including designing the consent process in ways that minimize psychological distress and diagnostic/therapeutic misconception.

Information Assessment for the Implementation of Electronic Informed Consent for Genetic Studies in a High Complexity Hospital

Juan Descalzo, Eliana Frutos, Romina Rebrij, Daniel Luna, Sonia Benítez

Studies in Health Technology and Informatics, 6 June 2022; 290 pp 227-229

Abstract

The objective of this study was to investigate and analyze the most relevant aspects that influence the development and implementation of electronic informed consent for genetic studies. Interviews were conducted with experts in the area within our institution, the different informed consents available and the number of genetic studies requested in the last 5 years were analyzed. Professionals acknowledged the ethical dilemmas related to the genetic studies and the importance of having an electronic informed consent that not only provides the patient with the information necessary to understand the implications of the study, but also be flexible enough to adapt to the various genetic studies today. The development of informed consent is a challenge for health IT professionals, due to the complexity of the information it contains and the ethical implications it represents.

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YOUNG PERSONS

Parental informed consent comprehension in childhood cancer clinical trials: Associations with social determinants of health

Paula Aristizabal, Shilpa Nataraj, Bianca Perdomo, Elena Martinez, Jesse Nodora, Courtney D Thornburg

Journal of Clinical Oncology, 1 June 2022 [2022 ASCO Annual Meeting]

Abstract

Background

Adequate informed consent (IC) comprehension is an ethical right prior to participation in clinical trials. Research investigating IC comprehension and associations with social determinants of health (SDoH) is lacking. We assessed whether SDoH and related contextual factors were associated with parental IC comprehension in therapeutic childhood cancer clinical trials.

Methods

We prospectively enrolled parents of children with newly-diagnosed cancer. Univariable and multivariable regression were used to assess whether objective IC comprehension and related domains (Purpose/Procedures/Randomization, Risks/Benefits, Alternatives, and Voluntariness) were associated with SDoH (ethnicity, marital status, language, education attainment, employment, insurance, socio-economic status, health literacy [HL]) and contextual factors (cancer type, voluntariness, satisfaction with IC).

Results

Of 223 parents included, 112 (50%) were Hispanic and 38% of Hispanics were monolingual Spanish-speaking. In adjusted multivariable analyses, limited HL was significantly associated with lower overall IC comprehension ($\beta = -7.22$; 95% CI, -10.9 to -3.59; $P < 0.001$) and lower comprehension of Purpose/Procedures/Randomization ($\beta = -7.53$; 95% CI, -11.3 to -3.73; $P < 0.001$), Risks/Benefits ($\beta = -8.14$; 95% CI, -15.5 to -0.772; $P = 0.031$), and Alternatives ($\beta = -17.0$; 95% CI, -30.5 to -3.57; $P = 0.013$). Preferred Spanish language of written/verbal medical information was significantly associated with lower

comprehension of Purpose/Procedures/Randomization (β = -8.50; 95% CI, -15.1 to -1.89; P = 0.012) and Voluntariness (β = -20.1; 95% CI, -34.9 to -5.33; P = 0.008). Lower satisfaction with informed consent (β = 0.988; 95% CI, 0.460 to 1.52; P < 0.001) and single marital status (β = -4.42; 95% CI, -7.81 to -1.02; P = 0.011) were significantly associated with lower IC comprehension.

Conclusions

Among parents of children with newly diagnosed cancer who provided consent for their child's participation in a therapeutic clinical trial, limited HL was consistently associated with lower IC comprehension in all domains analyzed, except for Voluntariness. Spanish language preference for medical information was associated with lower comprehension of two domains; and lower satisfaction was associated with lower overall IC comprehension. These findings suggests that parents with limited HL, limited English-proficiency, and lower satisfaction may not fully comprehend the IC and thereby not truly make informed decisions. Our findings highlight the potential role of language-concordant interventions tailored to the participant's HL level in order to ultimately improve IC comprehension and contribute to a reduction of disparities in clinical trial participation and promote equitable translation of discoveries and treatments to underserved groups.

Should Children Be Enrolled in Clinical Research in Conflict Zones?

Case and Commentary

Dónal O'Mathúna, Nawaraj Upadhaya

AMA Journal of Ethics, June 2022

Abstract

This commentary examines 4 ethical issues in a case of clinicians considering conducting research on children in conflict zones: (1) whether any time or resources should be taken away from treating acute injuries in order to conduct research; (2) obtaining consent for children to participate in research, which is particularly challenging given that children can be separated from parents or guardians; (3) whether the research is feasible at the moment, since starting research that stands little chance of being completed is ethically questionable; and (4) maintaining neutrality, impartiality, and humanity. Research that puts participants and researchers at risk of additional harm must be considered carefully. Here, we propose that both research and clinical care might occur simultaneously when researchers engage humbly with involved communities as the research is being designed, conducted, and reported in order to understand and resolve ethical issues involved.

Relational ethics, informed consent, and informed assent in participatory research with children with complex communication needs

Invited Review

Leni Van Goidsenhoven, Elisabeth De Schauwer

Developmental Medicine & Child Neurology, 28 April 2022

Open Access

Abstract

There is a need for qualitative participatory research involving children with intellectual disability and complex communication needs (CCNs), but procedural ethics cannot always adequately respond to the associated realities. To tackle this challenge, procedural ethics can be expanded with relational ethics to engage with consent and assent practices in participatory research projects. By drawing on several key incidents of participatory research with children with CCNs, we explore the complex moral spaces and times of ambivalent and iterative (dis)engagements within research processes. We reconceptualize the consent/assent terrain as a relationally constituted process, more aligned with the overall epistemological frameworks of participatory research and ensuring (disabled) children's ongoing and meaningful involvement in research.

Cultural considerations for informed consent in paediatric research in low/middle-income countries: a scoping review

Original Article

Marcela Colom, Peter Rohloff

BMJ Paediatrics Open, 5 December 2018; 2

Open Access

Abstract

Introduction

Conducting research with children in low/middle-income countries (LMIC) requires consideration of socioeconomic inequalities and cultural and linguistic differences. Our objective was to survey the literature on informed consent in paediatric LMIC research, assessing for practical guidance for culturally and linguistically appropriate procedures.

Methods

We conducted a scoping review on informed consent in paediatric LMIC research searching the PubMed, Web of Science and PsycINFO databases. Eligible articles were published in English, from any date range, of any study design or format.

Results

The search identified 2027 references, of which 50 were included in the analysis following full-text review. Reviewed guidelines emphasised individual, informed and voluntary consent from parents and caregivers. Reviewed articles provided detailed practical guidance on adapting these guiding principles to LMIC settings, including considerations for community engagement, verbal or other alternative consent procedures for low-literacy settings or less commonly spoken languages and guarding against therapeutic misconception by caregivers. There was uncertainty, however, on how to best protect individual autonomy, especially when influenced by gender dynamics, leadership hierarchies or the social status of researchers themselves. There was, furthermore, limited research discussing the special case of research involving adolescents or of procedures for documenting assent by participating children.

Conclusions

A scoping review of paediatric research in LMICs revealed substantial guidance on several features of culturally appropriate informed consent. However, additional research and guidance is needed, especially in the areas of gender imbalances, research with adolescents and children's own assent to participate in research.

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CAPACITY TO CONSENT

Guiding Principles and Common Pitfalls of Capacity Assessment

Book Chapter

ByDede Ukueberuwa O'Shea, Nicolette Gabel, Sarah Aghjayan, Maximilian Shmidheiser, Ross Divers

A Casebook of Mental Capacity in US Legislation, 2022 [Routledge]

Abstract

Psychologists must consider many complexities of professional practice and individual rights when conducting capacity assessments. This chapter reviews principles and standards that guide psychologists in conducting these evaluations. This chapter provides an overview of foundational abilities of an individual's decisional capacity according to contemporary models, followed by a discussion of the widely accepted assumptions of decisional capacity assessment: inclusivity, decision-relativity, all-or-nothing assessment, value neutrality, and independence from diagnosis. In conducting capacity assessments, psychologists will also benefit from an understanding of the key bioethics principles of autonomy, beneficence, nonmaleficence, justice, informed consent, and voluntarism. This chapter then reviews specific standards of ethical practice relevant to capacity determinations that are outlined by the American Psychological

Association (APA) and medical organizations. This chapter provides details on informed consent procedures in the context of evaluating decisional capacity, as well as standards that describe the need to practice within boundaries of competence, handle third party request for services, cooperate with other professionals, maintain confidentiality and make ethical disclosures, and limit conflicts of interest. Finally, this chapter discusses common pitfalls that psychologists may face when conducting capacity assessments and outline recommendations for best practices in gathering information and working with patients of diverse histories.

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TECHNOLOGY/OTHER MEDIATION

What is the best method to ensure informed consent is valid for orthodontic treatment? A trial to assess long-term recall and comprehension

Summary Review

A. Carter, H. Al-Diwani

Evidence-Based Dentistry, 24 June 2022; 23 pp 52–53

Abstract

Design

Single-blind randomised controlled trial.

Intervention

Patient and parent pairs were randomly assigned via a random number generator to Group A or B. Both groups were given ten minutes to read a modified consent document. Group A (rehearsal) were given printouts that showed images of four core and four custom risks with handwritten descriptions of each risk and consequences. Group B were given an audio-visual presentation instead (PowerPoint). Interviews of each group were completed immediately after the informed consent and at six-month follow-up to assess recall and comprehension of information provided.

Case selection

Patients aged 11-18 years old and their parents attending for comprehensive orthodontic treatment at Ohio State University graduate orthodontic clinic. All subjects needed to be able to communicate in English, have no developmental disabilities or urgent medical conditions and neither the patients or parents or subjects' siblings were to have had orthodontic treatment in the last five years.

Data analysis

1) Exploratory analysis to test for differences in demographics and anxiety between the two groups; 2) Multiple linear regression analysis was used to assess percentage of accurate responses at baseline and six months and the change between the two different groups, with differing baseline characteristics ($p < 0.05$ was considered statistically significant); and 3) Intra- and inter-rater reliability was assessed using intra-class correlation.

Results

There were no significant differences in information retention and understanding between the two methods at six-month follow-up. For both groups, recall was significantly lower six months following consent-taking. Specific domains whereby information recall and comprehension are poor include: treatment method, risks, resorption and discomfort.

Conclusions

There is no superior method of consent-taking to ensure patients' and parents' information retention in the months following commencement of treatment. However, the study highlighted that current consent practices which are considered 'best practice' may be deficient.

Comparing shared decision making using a paper and digital consent process. A multi-site, single centre study in a trauma and orthopaedic department

Rory Dyke, Edward St-John, Hemina Shah, Joseph Walker, Dafydd Loughran, Raymond Anakwe, Dinesh Nathwani

The Surgeon, 11 June 2022

Abstract

Introduction

The importance of shared decision making (SDM) for informed consent has been emphasised in the updated regulatory guidelines. Errors of completion, legibility and omission have been associated with paper-based consent forms. We introduced a digital consent process and compared it against a paper-based process for quality and patient reported involvement in shared decision making.

Methods

223 patients were included in this multi-site, single centre study. Patient consent documentation was by either a paper consent form or the Concentric digital consent platform. Consent forms were assessed for errors of legibility, completion and accuracy of content. Core risks for 20 orthopaedic operations were pre-defined by a Delphi round of experts and forms analysed for omission of these risks. SDM was determined via the 'collaboRATE Top Score', a validated measure for gold-standard SDM.

Results

72% (n = 78/109) of paper consent forms contained ≥1 error compared to 0% (n = 0/114) of digital forms (P < 0.0001). Core risks were unintentionally omitted in 63% (n = 68/109) of paper-forms compared to less than 2% (n = 2/114) of digital consent forms (P < 0.0001). 72% (n = 82/114) of patients giving consent digitally reported gold-standard SDM compared to 28% (n = 31/109) with paper consent (P < 0.001).

Conclusion

Implementation of a digital consent process has been shown to reduce both error rate and the omission of core risks on consent forms whilst increasing the quality of SDM. This novel finding suggests that using digital consent can improve both the quality of informed consent and the patient experience of SDM.

Characteristics of Electronic Informed Consent Platforms for Consenting Patients to Research Studies: A Scoping Review

Jennifer Guarino, Irena Parvanova, Joseph Finkelstein

Studies in Health Technology and Informatics, 6 June 2022; 290 pp 777-781

Abstract

Informed consent process assures that research study participants are properly informed about the study prior to their consent. Due to the increasing significance of electronic informed consent (eIC) platforms, particularly during the COVID-19 pandemic, we conducted a scoping review of eIC systems to address the following characteristics: 1) technological features of current eIC platforms, 2) eIC platforms usability and efficacy, and 3) areas for future eIC research. We performed a literature search using publicly available PubMed repository, where we included studies discussing an eIC platform or multimedia educational module given to patients prior to signing a consent form. In addition, we tracked first author, year of publication, sample size, study location, eIC procedure, methodology, and eIC's comparison to paper consent. Our results showed that with a few noted exceptions, electronic consent improves patient usability, satisfaction, knowledge, and trust scores when compared to traditional paper consent.

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RIGHTS/LEGAL/LEGISLATIVE

Informed consent: more than just a signature

Parker O'Neill, Sierra Schaffer, Fallon O'Neill, Andrew Poullis

Gut, 19 June 2022; 71

Abstract

Introduction

Informed consent is a core component of ethical medical practice and is vital to ensure patient autonomy is upheld. However, consent is not a static concept and physicians need to remain engaged with the literature to ensure they minimise their liability. This study aims to clarify the legal duties of gastroenterologists when gaining informed consent by analysing the current literature and past legal precedents.

Methods

A bibliometric analysis of the Web of Science (WoS) Core Collection database was performed with the MeSH terms 'gastroenterology' AND 'informed consent'. The top 50 most-cited articles were extracted and analysed. A scoping review was performed of the case law surrounding informed consent in the UK and the USA.

Results

A total of 383 articles were identified on the WoS, with 228 articles excluded due to not meeting the inclusion criteria. of the top 50 articles, 48% were from American institutions and 16% were from the UK. The American Journal of Gastroenterology had published 20% and the Journal of Digestive Diseases had published 8% of the top 50 articles. Since 1970, there has been a steady rise in citations of articles pertaining to informed consent in gastroenterology with the record of 63 citations occurring in 2015. Thematic analysis showed 72% of the top 50 articles discussed informed consent in relation to diagnostic procedures, 14% regarding treatment, and 14% regarding research participation. of the articles discussing diagnostic procedures, half specified the type of diagnostic tool evaluated. Thirty-three percent of articles focused on colonoscopy, 26% on OGD, 22% on ERCP, 11% on flexible sigmoidoscopy, and 7% on genetic testing. The UK has progressed from what was previously a paternalistic Bolam's test with the Bolitho addendum to the Montgomery test 2015 which demands physicians establish what is relevant to their specific patient when gaining informed consent. The USA experienced a similar evolution, progressing from the Natanson case holding physicians to the standard of a 'reasonable and prudent medical doctor' to the Canterbury case 1972 requiring physicians to disclose what would be important to a 'reasonable patient'. Exponentially more articles have been published since the American Canterbury case came into effect. Most articles focused on invasive procedures and discussed complex ethical questions seeking to increase patient autonomy.

Conclusion

Physicians in both the UK and USA now have a legal duty to ensure their patients are fully informed to a standard that their individual patient deems appropriate. Most articles published are American-based and focus on informed consent in the context of diagnostic colonoscopy. Physicians may benefit from international guidelines on consenting patients for invasive procedures in gastroenterology.

The need for a standard for informed consent for collection of human fetal material

Commentary

Roger A. Barker, Gerard J. Boer, Elena Cattaneo, R. Alta Charo, Susana M. Chuva de Sousa Lopes, Yali Cong, Misao Fujita, Steven Goldman, Göran Hermerén, Insoo Hyun, Steven Lisgo, Anne E. Rosser, Eric Anthony, Olle Lindvall

Stem Cell Reports, 14 June 2022; 17(6) pp 1245-1247

Summary

The ISSCR has developed the Informed Consent Standards for Human Fetal Tissue Donation and Research to promote uniformity and transparency in tissue donation and collection. This standard is designed to assist those working with and overseeing the regulation of such tissue and reassure the wider community and public.

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CULTURAL/COUNTRY CONTEXT

How Informed is Informed Consent? Experiences of Research Participants at the KAVI-Institute of Clinical Research, Kenya

Emily Nyariki, Robert R. Lorway, Omu Anzala, Joyce M. Olenja

African Journal of Health Sciences, 20 June 2022; 35(2)

Abstract

Introduction

Informed consent (IC) is a key yardstick for the ethical and legal conduct of clinical research involving human subjects. However, the extent to which it meets its obligations in low-income settings remains under-examined. This study explored the views and experiences of informed consent among research participants at the KAVI-Institute for Clinical Research, Nairobi, Kenya.

Materials and Methods

A mixed-methods study was conducted between March and June 2014. Participants were drawn from six selected KAVI-ICR studies. Data collection involved a survey questionnaire with 164 participants and in-depth interviews with 44 participants purposively selected from the survey questionnaire respondents. Descriptive statistics via SPSS and thematic analysis via Atlas Ti were used, for quantitative and qualitative data analysis respectively.

Results

The majority of participants had learnt about the KAVI studies from friends (41%) and community mobilisers/ peer educators (47%). The information relayed by these relations regarding participation had led some participants to reach their decisions before undergoing the informed consent process. All participants reported attending information meetings, passed the assessment of understanding tests, and autonomously gave their written consent. Incomplete understanding of research concepts such as randomization and associated terminologies, placebo, and vaccine-induced positivity were expressed.

Conclusion

Beyond understanding the information received before enrolment, participants' decisions are shaped by individual and community factors as well as trust relations with trial staff and own friends. There is, therefore, a need for innovative approaches to implementing and evaluating informed consent in low-resource settings.

Informed consent: an empty promise? A comparative analysis between Italy and England, Wales, and Scotland

Research Article

Caterina Milo

Medical Law International, 16 June 2022

Open Access

Abstract

Informed consent (IC), as the process of sharing information between patients and clinicians before undertaking a medical treatment, signals a number of 'good intentions'. IC, in its theoretical formulation, can be seen as valuing the expertise and contributions of both clinicians and patients, giving expression to the aspirations of both promoting patient autonomy and facilitating doctors to work in partnership with their patients. The Supreme Court judgement in Montgomery v Lanarkshire Health Board1 and the Italian legislation on IC2 are, in this respect, worthy of analysis as both provide valid examples of these 'good intentions'. However, the reality of how IC has been translated in courtrooms does not always match the expectations. This article, through a comparative reflection, will claim that a gap between the 'law in theory'

and the 'law in practice' is common to both legal systems. The article ultimately claims that changes in both legal and policy approach are needed in order to better safeguard IC.

Clinical adolescent decision-making: parental perspectives on confidentiality and consent in Belgium and The Netherlands

Research Article

Jana Vanwymelbeke, David De Coninck, Koen Matthijs, Karla Van Leeuwen, Steven Lierman, Ingrid Boone, Peter de Winter, Jaan Toelen

Ethics & Behavior, 15 June 2022

Abstract

This study investigated Belgian and Dutch parental opinions on confidentiality and consent regarding medical decisions about adolescents. Through an online survey, we presented six cases (three on confidentiality, and three on consent) to 1,382 Belgian and Dutch parents. We studied patterns in parental confidentiality and consent preferences across and between cases through binomial logistic regressions and latent class analysis. Participants often grant the right to consent for a treatment to the adolescent, but the majority diverges from the adolescent's preferences regarding confidentiality. More educated participants would rather not be informed about cases regarding a sexually transmitted disease or depression than lower educated participants. Further analysis shows that participants' preferences correspond to authoritative (47%), permissive (30%) and authoritarian (17%) parenting styles. Belgian and Dutch parents are willing to grant some degree of autonomy, but they want to be informed about specific health issues. Parental views on confidentiality and granting consent appear to mirror existing parenting styles.

Evaluating Knowledge, Practice, and Barriers to Informed Consent Among Professional and Staff Nurses in South Africa: An Empirical Study

Sylvester C. Chima

Canadian Journal of Bioethics, 13 June 2022; 5(2) pp 44-70

Abstract

Background

Informed consent (IC) is an ethical and legal obligation protected by constitutional rights to bodily integrity, well-being, and privacy in South Africa. The National Health Act 2003 codified IC regulations, requiring that all healthcare professionals inform patients about diagnosis, risks, benefits, options, and refusal rights while factoring in patients' language and literacy levels.

Objectives

This study's primary aim was to determine the extent of South African professional/staff nurses' compliance with current IC regulations and ascertain socio-cultural impediments impacting proper IC practice.

Methods

A cross-sectional survey using semi-structured questionnaires was used to evaluate knowledge and practice of IC among nurses in KwaZulu-Natal province. Data were analyzed using SPSS, v.21. Descriptive statistics, chi-squared tests, and content analysis were used to compare nursing domains.

Results

Three hundred fifty-five (355) nurses, 92% females, with 1 to 41 years of professional experience, completed this study. Information disclosed by nurses to patients included diagnosis (77%), treatment benefits (71%), risks (69%), recommendations (65%), risks of refusal (80%), and right of refusal (67%). Nurses (80%) felt information disclosure was adequate, while 85% reported that patients understood disclosed information.

Conclusions

Nurses practicing in local public hospitals had moderate knowledge of IC regulations. Practical implementation appeared deficient. Barriers to IC included language, workload, time constraints, lack of interpreters, and skewed gender norms in the nursing profession. Nurses require continuing professional

education in healthcare law and ethics, a “corps of trained interpreters”, and gender transformation in the nursing profession to improve IC practice and overall quality of healthcare service delivery in South Africa.

Informed Consent: The Surgical Patient's Experience in a Tertiary Hospital in Northwest Nigeria

B A Grema, S T Tanimu, G C Michael, I Aliyu, S A Aji, I U Takai, A I Sulaiman

West African Journal of Medicine, 27 May 2022; 5 pp 471-478

Abstract

Background

Obtaining informed consent (IC) before a surgical procedure is the cornerstone of medical practice. The practice of IC continues to evolve as litigations increase. Most studies on patients' perspectives of IC are either old or were done in southern Nigeria. This study assessed the surgical patients' IC experience in a tertiary hospital in northwest Nigeria.

Methods

This cross-sectional study assessed 244 consecutive patients who had elective surgeries in surgical departments of a tertiary hospital. Pretested questionnaires were used to collect data regarding their perception of the meaning of IC, the process of obtaining it, satisfaction with how it was obtained, and factors associated with satisfaction on how consent was obtained.

Results

Most were females (61.9%); their mean age was 34.8±14.3 years; 52.9% and 61.9% of respondents did not believe that IC enables patient-clinician shared decision-making or patient's self-decision making, respectively. Most were allowed to ask questions (83.2%), received information on the surgical procedure (91.4%), diagnosis (97.9%); however, 38.5% and 48.8% did not receive information about surgical procedures' immediate and long-term complications, respectively. Surgical procedure explanation was mostly provided by Resident Doctors (53.7%). Most (88.9%) were satisfied with how IC was obtained; satisfaction was associated with being allowed to ask questions, receiving explanations on diagnosis, surgical-procedure, complications of surgery, available alternative treatments, and when the resident/ consultants gave the explanation (all $P<0.05$).

Conclusion

Deficiencies exist in the process of getting IC. Satisfaction with this process was high though associated with following the recommended strategies. Improving the IC process will require appropriate interventions in this and similar settings.

The Doctrine of Patient’s Informed Consent in the Legislation and Jurisprudence of Czech Republic and the Latvian Republic

Urkevich Tatjana Ivanivna, Anatoliy Anatoliyovych Lytvynenko

Medicne parvo, 2022; 1(29) pp 49-94

Abstract

The article represents the history, emergence and the contemporary state of development of the legal doctrine of the patient’s informed consent to medical interventions in Czech Republic, Austria and the Latvian Republic. The authors focus on the vaults of the doctrine of the doctor’s obligation to abstain from conducting any medical interventions without the consent, or against the will of the patient, since the expression of the patient’s will is the central element of his right to self-determination. In order to discover the main features of informed consent in the civil law perspective, the authors discuss the historical and current legal developments of the legal institute of patient’s informed consent. The authors conclude that the formation of the institute owes to the right to body integrity and limitation of the exercise of medical profession by practitioners, and that the civil law doctrine of informed consent differs from Anglo-American tort law, relying on statutory-based civil liability for negligence, as well as minor penal liability for battery, an occasional interpretation of unauthorized medical intervention. The authors emphasize, that the existing bodies of Austrian, Czech and Latvian case law relating to informed consent, which span for over a century,

are sufficient to become a branch of Continental medical malpractice case law alongside with aged and well-developed French or Belgian medical jurisprudence, whereas the Latvian medical jurisprudence, despite having a rich history of emergence since the 1920s, has developed a solid body of case law in regard with patient's rights relatively recently.

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MEDICAL/SURGICAL

Transplant donor consent and dual roles: A case study in ethical dilemmas

Original Article
R. Gassas
Ethics, Medicine and Public Health, August 2022; 23
Abstract
Summary
Background
This case study describes the ethical dilemma encountered by a Bone Marrow Transplant (BMT) coordinator upon withdrawal of a donor's consent. The case points to the pressure on the coordinator to advocate simultaneously for donor and patient, which results in conflict between the coordinator's dual roles.
Objectives
The aim of this case study is to uncover neglected facts about ethical dilemmas concerning patient donors and transplant coordinators in Saudi Arabian settings.
Methods
This paper was developed from a case study involving the ethical issues reported here. The paper also explores potential solutions to such dilemmas, especially in centres without FACT-JACIE accreditation.
Conclusion/perspective
The risk of transplant coordinators' pressuring potential donors to donate against their will is highly deserving of consideration because it is as dangerous as having the same physician treat patients and assess donors. Societal norms and pressures should be considered, particularly within Saudi Arabian culture, as they may lead to donations made without free and full consent. Health care providers may lose their ethical orientation in this context, especially in unaccredited hospitals or understaffed units. Creating a healthy donor programme is the key to safe practices that preserve donors' rights, reduce pressure on primary teams and ensure application of international JACIE standards.

How Do Prescribing Clinicians Obtain Consent to Initiate Gender-Affirming Hormones?

Gaines Blasdel, Avery Everhart, Colt St. Amand, Monica Gaddis, Frances Grimstad
Transgender Health, 21 June 2022
Abstract
Purpose
Multiple consent models exist for initiating gender-affirming hormone therapy (GAHT). Our study aim was to examine the variety of approaches utilized by clinicians.
Methods
Online and in-person recruitment of clinicians involved in gender-affirming care was undertaken from June 2019 through March 2020. Participants completed an online survey.
Results
Of the 175 respondents, 148 prescribed GAHT. Sixty-one (41.2%) prescribed to adults only, 11 (7.4%) to minors only, and 76 (51.4%) prescribed to adults and minors. Of those who prescribed to adults, more than

half (n=74, 54.4%) utilized a written consent model, one-fourth only verbal consent (n=33, 24.3%), and one-fifth required an additional mental health assessment (MHA) (n=29, 21.3%). Of those prescribing to minors, most required either written consent (n=39, 44.8%) or an additional MHA (n=35, 40.2%). Only 11 (12.6%) utilized only verbal consent for minors. Rationales provided for requiring an additional MHA in adults included protection from litigation, lack of competence in assessing psychosocial readiness for GAHT, and believing that this is the best way to ensure the patient has processed the information. Practicing in multidisciplinary clinics was associated with not requiring an MHA for adult GAHT.

Conclusion

Clinicians across fields are utilizing different models to provide the same treatment, with varying rationales for the same model. As a result, patients receive nonstandard access to care despite similar clinical presentations. Our study highlights an important area for further improvement in GAHT care.

Informed consent prior to nursing care: Nurses' use of information

Research Article

Helen Aveyard, Abimola Kolawole, Pratima Gurung, Emma Cridland, Olga Kozlowska

Nursing Ethics, 20 June 2022

Abstract

Background

Informed consent prior to nursing care procedures is an established principle which acknowledges the right of the patient to authorise what is done to him or her; consent prior to nursing care should not be assumed. Nursing care procedures have the potential to be unwanted by the patient and hence require an appropriate form of authorisation that takes into consideration the relationship between the nurse and patient and the ongoing nature of care delivery.

Research question

How do nurses obtain consent from patients prior to nursing care?

Design

Critical incident technique and the collection of critical happenings.

Participants

17 participants who were all qualified nurses took part in in-depth interviews

Ethical considerations

Ethical approval was obtained from the university ethics committee.

Findings

Information giving is a key component prior to nursing care procedures. Nurses provide information to patients as a routine aspect of care delivery, and do so even when the patient is unable to communicate themselves. Whilst some participants described how information giving might be rushed or overlooked at times, it is clearly an established part of nursing care and is provided to ensure the patient knows what to expect when care is delivered. What is less clear is the extent to which information is given in order to seek the consent – rather than merely inform the patient – about nursing care.

Conclusion

Implied consent is often an appropriate way in which consent is obtained prior to nursing care procedures. It takes into account the ongoing care provision and the relationship that exists between the nurse and patient. However implied consent should not be assumed. Nurses need to ensure that information is given not only to inform the patient about a procedure but to enable the patient to give his or her consent and to find an alternative way forward if the patient withholds their consent.

Nocebo effects on informed consent within medical and psychological settings: A scoping review

Research Article

Nadine S. J. Stirling, Victoria M. E. Bridgland, Melanie K. T. Takarangi

Ethics & Behavior, 8 June 2022

Abstract

Warning research participants and patients about potential risks associated with participation/treatment is a fundamental part of consent. However, such risk warnings might cause negative expectations and subsequent nocebo effects (i.e., negative expectations cause negative outcomes) in participants. Because no existing review documents how past research has quantitatively examined nocebo effects – and negative expectations – arising from consent risk warnings, we conducted a pre-registered scoping review (N = 9). We identified several methodological issues across these studies, which in addition to mixed findings, limit conclusions about whether risk warnings cause nocebo effects.

Abandon Informed Consent in Favor of Probability-Based, Shared Decision-Making Following the Wishes of a Reasonable Person

Research Article

John T James

Journal of Patient Experience, 7 June 2022

Open Access

Abstract

Legally and ethically physicians must provide information to patients so they may make an informed decision about invasive procedures. The problem is who decides what information to provide. Is it the reasonable patient or the reasonable physician? Individual patients and individual physicians may differ from the norm on what is reasonable. This problem may be solved by shared decision-making in which the preferences of the patient and the probability-based knowledge of the physician are used to co-produce an optimal choice. Currently, patients are seldom prepared to engage in shared decision-making, and vestiges of meaningless "informed consent" are common. The present case study illustrates how "reasonable person" survey data may be used by a patient to engage in probability-based, shared decision-making with a surgeon planning to perform a laminectomy. Recommendations include probability-based, shared decision-making training for patients and physicians and improved documentation to facilitate learning.

Patient experience of informed consent for diagnostic coronary angiogram and follow-on treatments

Research and Development

Howard T Blanchard, Diane L Carroll, Felicity Astin

British Journal of Cardiac Nursing, 1 June 2022; 17(5)

Abstract

Background/Aims

Coronary angiography requires a complex informed consent process as a legal and ethical requirement before treatment. This process may allow percutaneous coronary intervention to be completed as a continuation of a coronary angiography. Patients routinely consent to both interventions, but over one-quarter will only receive the diagnostic angiogram. This study explored views and understandings of the informed consent process, and associations with demographic characteristics, among patients who consented to coronary angiography and same-setting percutaneous coronary intervention, but were found to be ineligible for the latter.

Methods

A descriptive cross-sectional survey design was used to explore patients' views. A total of 62 participants (73% male, mean age 68.4 years) completed a 36-item survey the day after undergoing diagnostic coronary angiography.

Results

Female participants reported greater difficulty in recalling treatment information (P<0.03), found discussions about alternative treatments more confusing (P<0.02), and the disclosure of comprehensive risk information

more of a deterrent to consent for treatment (P<0.02) compared to men. Higher levels of education were associated with greater preference for information and involvement in treatment decisions (P<0.002).
Conclusions
Patients who give informed consent for diagnostic coronary angiography with or without a same-setting percutaneous coronary intervention need clear comprehensive information regarding alternative options. By recognising the patient's need for information, nurses can provide an individualised explanation and reinforcement of the information provided during informed consent.

Standardization of informed consent for oral chemotherapeutic agents

Meeting Abstract
Angela Pennisi, Kathleen Kiernan Harnden, Lauren Ann Mauro, Patricia Conrad Rizzo, Ghana Kang, Maya Leiva, Seung Yom
Journal of Clinical Oncology, 1 June 2022 [2022 ASCO Annual Meeting]
Abstract
Background
Informed consent is an essential prerequisite to the administration of any oral or parenteral chemotherapeutic agent. Obtaining informed consent for treatment is the oncologist's responsibility and all the information the oncologist and patient share and agree to in this process should be documented in the patient's medical record. Informed consents at Inova Schar Cancer Institute are created through an electronic consent, a web-based solution that creates procedure-specific consent forms that can be used for treatments and procedures for patients and is integrated in our electronic medical record system. While the oncology nurse administering parenteral chemotherapy ensures that the consent is signed before infusion starts, no clear plan existed at our institution for patients starting oral chemotherapeutic agents. In addition, with the transition to telemedicine visits during covid-19 pandemic, patients are often not in clinic at time of discussion of the new treatment plan with the oncologist or for chemotherapy teaching session therefore creating a barrier to obtain consent on the computer pad. The aim of this study is to standardize methods to obtain written informed consent for oral chemotherapy agents with 100% compliance.
Methods
Our first Plan-Do-Study-Act (PDSA) cycle conducted in the breast medical oncology clinic included the following steps: 1) the oncologist or the registered pharmacist (RPH) creates the electronic consent 2) after completion of chemotherapy teaching session, the RPH ensures that the patient and the physician have signed the consent and also signs as witness. In this first cycle we also tested the "mobile sign" modality that allows to text the informed consent to the patients so they can sign directly on their mobile phone if the teaching is conducted remotely.
Results
Baseline chart audit of seven patients who were started on oral chemotherapy regimen during the month of December 2021 revealed that all the patients received chemotherapy teaching, but none provided written informed consent. After implementation of above steps for two weeks, chart audit of five patients showed that all signed informed consent that was also completed by physician's and witness's signature. Two patients were successfully consented through the "mobile sign" modality.
Conclusions
Our study identified failure to obtain written informed consent for oral chemotherapeutic agents with some barriers created by increasing use of telemedicine. As all our patients receive chemotherapy teaching sessions, we identified this as best timing to obtain informed consent as patients have received comprehensive education on the chemotherapy agent. We also explore the option of "mobile sign" if the teaching session is conducted virtually. Our preliminary results showed 100% compliance in obtaining informed consent and feasible use of "mobile sign" option. We plan for long term chart audits to confirm above results.

Surgical Documentation, Informed Consent, and Operative Note

Book Chapter

Andreas M. Kaiser

Chassin's Operative Strategy in General Surgery, 29 May 2022; pp 89–91 [Springer]

Abstract

This chapter defines the value and describes the elements of good surgical documentation, and gives the fundamentals of writing a good operative note. Solid documentation is our friend as well as our "protective insurance," while poor, incomplete, or altered documentation can easily turn into our worst enemy. But the value of documentation is not just defined by its role in litigation cases but by its importance for continuity of care, cost-saving measures, reimbursement, as well as quality control and research efforts.

Adherence to a national consensus statement on informed consent: medical students' experience of obtaining informed consent from patients for sensitive examinations

Harsh Bhoopatkar, Carlos F C Campos, Phillipa J Malpas, Andy M. Wearn

The New Zealand Medical Journal, May 20, 2022; 135 pp 10-18

Open Access

Abstract

Aim

To determine whether the guidance from the New Zealand medical programmes' national consensus statement on obtaining informed consent from patients for sensitive examinations are being met, and to explore medical students' experience of obtaining consent.

Method

A self-reported, online, anonymous questionnaire was developed. Data were collected in the period just after graduation from final year medical students at The University of Auckland in 2019.

Results

The response rate was 35% (93/265). Most students reported that they were "not always compliant" with the national consensus statement for obtaining informed consent for almost all sensitive examinations. The main exception was for the female pelvic examination (not in labour) under anaesthesia, where most students reported being "always compliant". We identified factors related to students, supervisors, institution, and the learning context as reasons for lack of compliance.

Conclusion

Adherence to the national consensus statement on obtaining informed consent for sensitive examinations is unsatisfactory. The medical programme needs to review the reasons for lapses in implementing the policy in practice, to ensure a safe learning environment for patients and our students.

Importance of Informed Consent in Clinical Practice

Original Investigation

Işıl Pakiş, Gülfer Bektaş, Berat Akif Kaya, Cenk Hilmi Kılıç

Istanbul Medical Journal, 2022; 23(2) pp 139-43

Open Access

Abstract

Introduction

This study aims to determine the experiences and opinions of physicians on informed consent practices, to research their awareness of their legal responsibilities, and to provide solutions to the problems encountered in practice.

Methods

This research is a descriptive field study. One hundred and eighty-four physicians working in a state hospital in İstanbul participated in this study between January 15 and February 15, 2018. The questionnaire form was

used as a data collection tool. After the participants were informed about the purpose and method of the research, their consent was obtained, and they were asked to fill in the questionnaire forms. The analysis of the data was performed using the SPSS 18.00 program. The significance level was accepted as $p<0.05$.
Results
One hundred and eighty-four physicians working in a state hospital in İstanbul participated in this study. 69% (n=127) of the physicians participating in the study were male and 31% (n=57) were female. 35.3% (n=65) of the participants were from the 30-39 years old age group. 96.7% (n=178) of the physicians in the study stated that they personally informed their patients before the surgical interventions. 83.7% (n=154) of the physicians think that the lawsuits filed against the physicians due to medical malpractice affect the health services provided by the physicians to their patients.61.4% of the participants (n=113) think that they have not received enough education in their medical education processes regarding the rights and obligations of the physicians.
Conclusion
Considering the current situation in Turkey, the informed consent process is not yet at the level it should be. Since human rights are in the process of development in the world, informed consent and many more patient rights will gain importance with studies on this subject. Therefore, training, and studies should be increased to inform physicians and patients about informed consent and to make them a behavioral model physicians.

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GENERAL/OTHER

Animal-informed consent: sled dog tours as asymmetric agential events

David A. Fennell
Tourism Management, December 2022; 93
Abstract
Standing in the way of a stronger voice for animals used in tourism is Cartesian and contractarian thinking on the part of operators and ontologically and epistemically constructed barriers by theorists. This paper pushes the animal ethics agenda forward by developing a novel, first-of-its-kind animal-informed consent framework in tourism under the assumption that sled dogs do, in fact, consent or deny consent through their emotions, preferences, behaviours, and physical state. The Five Domains model of animal welfare focused on the subjective experiences of animals is used to build the framework. The discussion culminates with a discussion on asymmetric agency, which speaks to the lack of balance between human and animal agents working in the same events.

Mapping consent practices for outpatient psychiatric use of ketamine

David S. Mathai, Scott M. Lee, Victoria Mora, Kelley C. O'Donnell, Albert Garcia-Romeu, Eric A. Storch
Journal of Affective Disorders, 1 September 2022; 312, pp 113-121
Abstract
Background
Given increasing community-based and off-label use of ketamine for psychiatric indications, we examined current informed consent processes from a convenience sample of outpatient ketamine clinics to identify areas of congruence with current evidence and opportunities for growth.
Methods
Using a rubric developed from existing practice guidelines, we conducted an exploratory analysis of informed consent documents (IC-Docs) from 23 American clinics offering ketamine as a psychiatric treatment. Domains assessed included clinical content, procedures, and syntax.
Results

Participating clinics (23/288) varied widely in their constitution, training, and services provided. We found that IC-Docs addressed a majority of consent elements, though did so variably on an item-level. Areas for improvement included communication around long-term adverse effects, treatment alternatives, medical/psychiatric evaluation prior to treatment, medical/psychological support during treatment, adjunctive psychological interventions, and subjective/dissociative-type effects. All forms were limited by poor readability.

Limitations

Our study was limited by convenience sampling along with possible underestimation of verbal consent processes.

Conclusions

As ketamine continues to emerge as a psychiatric intervention, both patients and providers will benefit from a deliberate consent process informed by scientific, ethical, and pragmatic factors toward the goal of shared decision-making regarding treatment.

Comparing shared decision making using a paper and digital consent process. A multi-site, single centre study in a trauma and orthopaedic department

Rory Dyke, Edward St-John, Hemina Shah, Joseph Walker, Dafydd Loughran, Raymond Anakwe, Dinesh Nathwani

The Surgeon, 11 June 2022

Abstract

Introduction

The importance of shared decision making (SDM) for informed consent has been emphasised in the updated regulatory guidelines. Errors of completion, legibility and omission have been associated with paper-based consent forms. We introduced a digital consent process and compared it against a paper-based process for quality and patient reported involvement in shared decision making.

Methods

223 patients were included in this multi-site, single centre study. Patient consent documentation was by either a paper consent form or the Concentric digital consent platform. Consent forms were assessed for errors of legibility, completion and accuracy of content. Core risks for 20 orthopaedic operations were pre-defined by a Delphi round of experts and forms analysed for omission of these risks. SDM was determined via the 'collaboRATE Top Score', a validated measure for gold-standard SDM.

Results

72% (n = 78/109) of paper consent forms contained ≥1 error compared to 0% (n = 0/114) of digital forms (P < 0.0001). Core risks were unintentionally omitted in 63% (n = 68/109) of paper-forms compared to less than 2% (n = 2/114) of digital consent forms (P < 0.0001). 72% (n = 82/114) of patients giving consent digitally reported gold-standard SDM compared to 28% (n = 31/109) with paper consent (P < 0.001).

Conclusion

Implementation of a digital consent process has been shown to reduce both error rate and the omission of core risks on consent forms whilst increasing the quality of SDM. This novel finding suggests that using digital consent can improve both the quality of informed consent and the patient experience of SDM.

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