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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

June 2024 :: Issue 66

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

In preparing this digest, we monitor a broad range of academic journals and utilize *Google Scholar* to search articles referencing informed consent or assent. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic journal literature globally, including calls for public consultation and symposia/conferences which address consent/assent in whole or in part. 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 this digest using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. We lead each edition with a spotlight section highlighting content which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, evidence, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

No new content was identified for the following established categories:

ARTIFICIAL INTELLIGENCE
BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
GENERAL/OTHER
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT

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

SPOTLIGHT ARTICLES

This month we would like to spotlight two articles focused on the applications of artificial intelligence technologies in healthcare. In an article in *Machine Learning and Knowledge Extraction* – **Evaluation of AI ChatBots for the Creation of Patient-Informed Consent Sheets –** Raimann et al. assessed the ability of large language models (LLMs) to generate information sheets for six basic anesthesiologic procedures.The authors found that that the three LLMs tested fulfilled less than 50% of the predetermined requirements for a satisfactory and compliant information sheet. They also found that the descriptions of key elements such as risks and documentation regarding consultation varied. The authors assess that LLMs have "clear limitations" in generating patient information sheets.

Park addresses the patient perspective on AI use in healthcare provision in the *Digital Health* article – **Patient perspectives on informed consent for medical AI: A web-based experiment.** Through this work Park adds a new voice to the debate about whether, when using LLMs as a decision aid, healthcare providers ought to disclose this to the patients. It was found that patients trust second opinions from other physicians more than an AI diagnosis, but as the risk level increased for procedures, as did the importance of AI generated information. This study found the disclosure of AI use in diagnosis to be necessary from a patient perspective.

The Center for Informed Consent Integrity is exploring use of ChatGPT 4.0 to analyze the informed consent landscape, specifically how the 60+ editions of this digest might function as a specific content base for inquiry. We have encountered some limitations given our purpose, albeit different than those found by the authors below. We will continue to explore generative AI to strengthen our work and keep our readers updated.

Evaluation of AI ChatBots for the Creation of Patient-Informed Consent Sheets

Florian Jürgen Raimann, Vanessa Neef, Marie Charlotte Hennighausen, Kai Zacharowski, Armin Niklas Flinspach

Machine Learning and Knowledge Extraction, 24 May 2024

Abstract

Introduction

Large language models (LLMs), such as ChatGPT, are a topic of major public interest, and their potential benefits and threats are a subject of discussion. The potential contribution of these models to health care is widely discussed. However, few studies to date have examined LLMs. For example, the potential use of LLMs in (individualized) informed consent remains unclear.

Methods

We analyzed the performance of the LLMs ChatGPT 3.5, ChatGPT 4.0, and Gemini with regard to their ability to create an information sheet for six basic anesthesiologic procedures in response to corresponding questions. We performed multiple attempts to create forms for anesthesia and analyzed the results checklists based on existing standard sheets.

Results

None of the LLMs tested were able to create a legally compliant information sheet for any basic anesthesiologic procedure. Overall, fewer than one-third of the risks, procedural descriptions, and preparations listed were covered by the LLMs.

Conclusions

There are clear limitations of current LLMs in terms of practical application. Advantages in the generation of patient-adapted risk stratification within individual informed consent forms are not available at the moment, although the potential for further development is difficult to predict.

Patient perspectives on informed consent for medical AI: A web-based experiment

Hai Jin Park

Digital Health, 30 April 2024

Abstract

Objective

Despite the increasing use of AI applications as a clinical decision support tool in healthcare, patients are often unaware of their use in the physician's decision-making process. This study aims to determine whether doctors should disclose the use of AI tools in diagnosis and what kind of information should be provided.

Methods

A survey experiment with 1000 respondents in South Korea was conducted to estimate the patients' perceived importance of information regarding the use of an AI tool in diagnosis in deciding whether to receive the treatment.

Results

The study found that the use of an AI tool increases the perceived importance of information related to its use, compared with when a physician consults with a human radiologist. Information regarding the AI tool when AI is used was perceived by participants either as more important than or similar to the regularly disclosed information regarding short-term effects when AI is not used. Further analysis revealed that gender, age, and income have a statistically significant effect on the perceived importance of every piece of AI information.

Conclusions

This study supports the disclosure of AI use in diagnosis during the informed consent process. However, the disclosure should be tailored to the individual patient's needs, as patient preferences for information regarding AI use vary across gender, age and income levels. It is recommended that ethical guidelines be developed for informed consent when using AI in diagnoses that go beyond mere legal requirements.

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BIOMEDICAL RESEARCH

The Ethics of Decentralized Clinical Trials and Informed Consent: Taking Technologies' Soft Impacts into Account

Original Article

Tessa I. van Rijssel, Ghislaine J. M. W. van Thiel, Johannes J. M. van Delden

Health Care Analysis, 19 May 2024

Open Access

Abstract

Decentralized clinical trials (DCTs) have the potential to advance the conduct of clinical trials, but raise several ethical issues, including obtaining valid informed consent. The debate on the ethical issues resulting from digitalization is predominantly focused on direct risks relating to, for example, data protection, safety, and data quality. We submit however, that a broader view on ethical aspects of DCTs is needed to touch upon the new challenges that come with the DCT practice. Digitalization has impacts that go beyond its direct purposes, by shaping behaviors, experiences, social relations, and values. We examine four elements of the informed consent procedure that are affected by DCTs, while taking these soft impacts of technologies into account: (i) informing participants and testing understanding, (ii) freedoms in relation to responsibilities and burdens, (iii) trust in participant-researcher relations, and (iv) impacts on the concept of privacy. Our analysis reveals that a broad view is key for optimal conduct of DCTs. In addition, it provides insight into the ethical impacts of DCTs on informed consent. Technologies such as DCTs potentially have profound impacts which are not immediately addressed by the existing regulatory frameworks, but nonetheless important to recognize. These findings can guide future practices of DCTs to foster the important values of clinical research in this novel approach for conducting clinical trials.

When describing harms and benefits to potential trial participants, participant information leaflets are inadequate

Research

Laura Cuddihy, Jeremy Howick, Ellen Murphy, Frances Shiely

Trials, 1 May 2024

Open Access

Abstract

Background

Providing informed consent for trials requires providing trial participants with comprehensive information about the trial, including information about potential risks and benefits. It is required by the ethical principle of respecting patient autonomy. Our study examines the variation in the way information about potential trial benefits and harms is shared in participant information leaflets (PILs).

Methods

A total of 214 PILs and informed consent forms from clinical trials units (CTUs) and Clinical Research Facilities (CRFs) in Ireland and the UK were assessed by two authors independently, to check the extent to which they adhered to seven recently developed principles. Discrepancies were resolved by a third.

Results

Usage of the seven principles varied widely between PILs regardless of the intended recipient or trial type. None of the PILs used more than four principles, and some (4%) used none. Twenty-seven per cent of PILs presented information about all known potential harms, whereas 45% presented information on all known

potential benefits. Some PILs did not provide any potential harms or potential benefits (8%). There was variation in the information contained in adult and children PILs and across disease areas.

Conclusion

Significant variation exists in how potential trial benefits and harms are described to potential trial participants in PILs in our sample. Usage of the seven principles of good practice will promote consistency, ensure informed ethical decision-making and invoke trust and transparency. In the long term, a standardised PIL template is needed.

Editor's note: The seven principles as described in the abstract appear in Table 2 in the paper.

Table 2 Usage of the seven principles in the PILs principle

N=214		Yes, *N* (%)	No, *N* (%)	N/A[a], *N* (%)	Unclear[b], *N* (%)
Principle 1	All potential harms of an intervention should be listed	58 (27)	154 (72)	0 (0)	2 (1)
Principle 2	All potential harms should be divided into serious (life-threatening, causing permanent damage) and less serious (like a mild headache that goes away quickly)	3 (1)	185 (87)	26 (12)	0 (0)
Principle 3	It must be made explicit that not all potential harms are known	13 (6)	201 (94)	0 (0)	0 (0)
Principle 4	All potential benefits of the intervention should be listed	96 (45)	117 (54.5)	0 (0)	1 (0.5)
Principle 5	All potential benefits and harms need to be compared with what would happen if the participant did not take part in the trial	182 (85)	31 (14.5)	0 (0)	1 (0.5)
Principle 6	Suitable visual representations are recommended where appropriate to describe potential benefits and harms	1 (0.5)	0 (0)	0 (0)	213 (99.5)
Principle 7	Information regarding potential benefits and harms should not be presented apart by one or more pages	182 (85)	19 (9)	12 (5.5)	1 (0.5)

[a] Principle 2—N/A as no harms were listed; principle 7—N/A as there were either no harms or benefits listed

[b] Principle 1—unclear from the PIL what the study intervention was; principle 4—unclear because unclear what is intervention and what is standard of care; principle 5—unclear because no mention of standard care/usual care; principle 6—unclear as would need trial protocol to fully assess; principle 7—unclear as not clear what page benefits of intervention listed on

What Is "Key Information"? Consideration of the Reasons People Do or Do Not Take Part in Research

Article

Kara Berwanger, Jon F. Merz

Ethics & Human Research, 17 April 2024

Abstract

We performed a qualitative review of 50 consent forms posted on Clinicaltrials.gov, examining the content of key information sections. We found that key information disclosures are typically focused on procedures, risks, potential benefits, and alternatives. Drawing upon reviews of the large literature examining the reasons people do or do not take part in research, we propose that these disclosures should be based more directly on what we know to be the real reasons why people choose to take part or refuse participation. We propose key information language for consideration by researchers and institutional review boards.

Translating "medicalese": The case of informed consent forms

Raluca Chereji

Medical Writing, March 2024; 33(1) pp 44–47

Abstract

Informed consent forms (ICFs) are documents used in clinical research to inform prospective participants about – and obtain their consent for – partaking in a clinical trial. Evidence suggests that ICFs may not be fit for purpose because their linguistic and textual features exceed the comprehensibility needs of their non-expert target audience. These issues also impact medical translators who translate ICFs for prospective participants of international trials. This article discusses some of the main challenges of translating ICFs, such as specialised terminology and jargon, lexico-syntactic complexity, and text length, and argues for increased training and collaboration to mitigate these difficulties in medical translation.

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SOCIAL SCIENCE RESEARCH

Who to engage in HIV vaccine trial benefit-sharing negotiations? An empirical proposition of a framework

Research

Godwin Pancras, Mangi Ezekiel, Erasto Mbugi, Jon F. Merz

BMC Medical Ethics, 14 May 2024

Open access

Abstract

Background

A morally sound framework for benefit-sharing is crucial to minimize research exploitation for research conducted in developing countries. However, in practice, it remains uncertain which stakeholders should be involved in the decision-making process regarding benefit-sharing and what the implications might be. Therefore the study aimed to empirically propose a framework for benefit-sharing negotiations in research by taking HIV vaccine trials as a case.

Methods

The study was conducted in Tanzania using a case study design and qualitative approaches. Data were collected using in-depth interviews (IDI) and focus group discussions (FGD). A total of 37 study participants were selected purposively comprising institutional review board (IRB) members, researchers, community advisory board (CAB) members, a policymaker, and HIV/AIDS advocates. Deductive and inductive thematic analysis approaches were deployed to analyze collected data with the aid of MAXQDA version 20.4.0 software.

Results

The findings indicate a triangular relationship between the research community, researched community and intermediaries. However, the relationship ought to take into consideration the timing of negotiations, the level of understanding between parties and the phase of the clinical trial. The proposed framework operationalize partnership interactions in community-based participatory research.

Conclusion

In the context of this study, the suggested framework incorporates the research community, the community being researched, and intermediary parties. The framework would guarantee well-informed and inclusive decision-making regarding benefit-sharing in HIV vaccine trials and other health-related research conducted in resource-limited settings.

Upholding Informed Consent: Experiences of Note –Taking without Audio Recording of in-Depth Individual Interviews in a Qualitative Study on the Implementation of the Pregnancy ReEntry Policy in Zambia

Namakau Kakanda-Sinkala

International Journal Of Multidisciplinary Research And Analysis, 5 May 2024

Abstract

The context of the research study needs to determine the data recording method to be used in order to ensure that no harm is done to the participants. In-depth individual Interviews (IDIs) is one of the main data collecting strategy used in qualitative research on sensitive topics such as teenage pregnancy. Audio recording in capturing data during IDIs is a common practice. However, audio recording of IDIs should be

done in the context of informed consent. The objective of this paper is to elaborate on how note-taking was used to capture data within the context of informed consent. The research design was multiplecohort Case studies involving Chongwe district plus national stakeholders of the Pregnancy Re-entry policy in Zambia. Semistructured interviews were conducted with hundred (100) participants from different cohorts of stakeholders using note-taking to capture the data. Ninety percent (90%) of the interviews involved physical note-taking with 10 % being electronic notes. The results are that note-taking increased the interview time but it afforded the interviewer the opportunity to probe further as the data was being collected. The major disadvantage with note –taking is that it reduces the pace of data collection as time has to be dedicated to consolidating the notes and memory recall of information shared. The conclusion drawn is that upholding informed consent in research is key, therefore the capturing of data during IDIs should be guided by what best upholds the rights of the participants. Therefore, note-taking offers an alternative to audio recording.

The participant's voice: crowdsourced and undergraduate participants' views toward ethics consent guidelines

Research Article

Nadine S. J. Stirling, Melanie K. T. Takarangi

Ethics & Behavior, 28 April 2024

Abstract

The informed consent process presents challenges for psychological trauma research (e.g. Institutional Review Board [IRB] apprehension). While previous research documents researcher and IRB-member perspectives on these challenges, participant views remain absent. Thus, using a mixed-methods approach, we investigated participant views on consent guidelines in two convenience samples: crowdsourced (N = 268) and undergraduate (N = 265) participants. We also examined whether trauma-exposure influenced participant views. Overall, participants were satisfied with current guidelines, providing minor feedback and ethical reminders for researchers. Moreover, participant views for consent were similar irrespective of trauma-exposure. Our study has implications for IRBs and psychological researchers.

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HEALTH DATA/DATA

Comparing Attitudes Toward Different Consent Mediums: Semistructured Qualitative Study

Xengie Doan, Arianna Rossi, Marietjie Botes, Annika Selzer

JMIR Human Factors, 30 April 2024

Abstract

Background

As consent for data sharing evolves with the digital age, plain-text consent is not the only format in which information can be presented. However, designing a good consent form is highly challenging. The addition of graphics, video, and other mediums to use can vary widely in effectiveness; and improper use can be detrimental to users.

Objective

This study aims to explore the expectations and experiences of adults toward consent given in infographic, video, text, newsletter, and comic forms in a health data sharing scenario to better understand the appropriateness of different mediums and identify elements of each medium that most affect engagement with the content.

Methods

We designed mock consent forms in infographic, video, text, newsletter, and comic versions. Semistructured interviews were conducted with adults who were interviewed about their expectations for consent and were then shown each consent medium and asked about engaging elements across mediums, preferences for consent mediums, and the value of document quality criteria. We transcribed and qualitatively co-coded to identify themes and perform analyses.
Results
We interviewed 24 users and identified different thematic archetypes based on participant goals, such as the Trust Seeker, who considered their own understanding and trust in organizations when making decisions. The infographic was ranked first for enhancing understanding, prioritizing information, and maintaining the proper audience fit for serious consent in health data sharing scenarios. In addition, specific elements such as structure, step-by-step organization, and readability were preferred engaging elements.
Conclusions
We identified archetypes to better understand user needs and elements that can be targeted to enhance user engagement with consent forms; this can help inform the design of more effective consent in the future. Overall, preferences for mediums are highly contextual, and more research should be done.

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TECHNOLOGY/OTHER MEDIATION

Video-Assisted informed consent in endoscopic urology: a randomized trial on ureterorenoscopy

Research Article
Dr. Guglielmo Mantica, Dr. Francesco Esperto, Dr. Rafaela Malinaric, Dr. Francesca Ambrosini, Dr. Loris Cacciatore, Prof. Rocco Papalia, Dr. Daniele Panarello, Prof. Roberto Mario Scarpa, Prof. Carlo Terron
Journal of Endourology, 17 May 2024
Abstract
Purpose
The aim of this study is to evaluate the possible beneficial effect of using the video – consent in the preoperative URS consent giving process.
Material and Methods
Prospective randomized trial took place at two Italian tertiary-care centers from March 2022 to September 2022. Patients were randomly assigned to two groups: Group A (standard verbal/written informed consent) and Group B (informed consent supported by video). We investigated the impact of both types of the informed consent on the level of patients' anxiety assessed with the STAI questionnaire pre- and postoperatively. Additionally, we evaluated the effect of informed consents on the postoperative pain, measured with the VAS scale, and the number of assistances calls during hospitalization as secondary outcomes. To assess the satisfaction level related to the whole process, we asked patients to rate their experience on a scale of 1-10, with 1 indicating "not satisfied" and 10 indicating "completely satisfied."
Results
Overall, 166 patients were randomized 1:1 in each group. According to the multivariable regression model, the video-assisted informed consent significantly increased the difference between postoperative and preoperative STAI, reducing the level of anxiety. The video-assisted informed consent significantly predicted the number of assistance calls during the hospitalization.
Conclusions
Video-consent for ureteroscopies are a valid tool to improve patients' satisfaction and awareness of the procedure. Video-consent is able to reduce patients' anxiety related to the procedure and assistance calls during the postoperative period, resulting in a useful tool to administer a better-informed consent for endourological procedures.

The Impact of a Computer-Based Interactive Informed Consent for Surgery on Decision Conflict

Scientific Article

Sina Ramtin, Floor Davids, Amir Reza Farhoud, Raul Tejada, David Ring

The Journal of Hand Surgery, 12 May 2024

Abstract

Purpose

Informed consent for surgery can address the legal aspects of care while also being simple, informative, and empathic. We developed interactive informed consents and compared them with standard printed informed consents asking: (1) are there any factors associated with lower decision conflict or greater patient-rated clinician empathy including consent format? (2) Are there any factors associated with rating the consent process as informative, comfortable, and satisfying including consent format?

Methods

Ninety-four adult patients accepted an offer of surgery from one of three hand surgeons to address one of six common hand surgery diagnoses: carpal tunnel release, cubital tunnel release, trigger finger release, plate and screw fixation of a distal radius fracture, removal of a benign mass, including a ganglion cyst, and Dupuytren contracture release. Fifty-three patients were randomized to complete an interactive consent, and 41, a standard written consent. Symptoms of anxiety, depression, and unhelpful thoughts were measured. Patients completed the Decision Conflict Scale and the Jefferson Scale of Patient's Perceptions of Physician Empathy and rated the consent as informative, comfortable, and satisfactory on a scale of 0–10.

Results

Greater decisional conflict was slightly associated with greater patient unhelpful thoughts about symptoms and was not associated with consent format. A higher rating of comfort with the consent process was slightly associated with patient choice to proceed with surgical treatment, but not with consent format. Accounting for potential confounding in multivariable analysis, a higher rating of the consent process as informative was slightly associated with patient preference for surgical over nonsurgical treatment,

Conclusions

The observation that an interactive consent form was not related to decision conflict or other aspects of patient experience suggests that such tools may not have much weight relative to the interaction between patient and clinician.

Clinical relevance

Efforts to improve informed consent may need to focus on the dialog between patient and surgeon rather than how information is presented.

Power to the people? Time to improve and implement patient decision aids to strengthen shared decision-making

Invited Commentary

Sandra B Lauck, Krystina B Lewis, Michelle Carter, Catriona Jennings

European Journal of Cardiovascular Nursing, 26 April 2024

Excerpt

For many people living with heart disease, the journey from their diagnosis to their consent for treatment and beyond is rarely a straight path. Barriers along the way include the maze of diagnostic testing and consultations, the steep learning curve to grasp what options might be appropriate and feasible, the evolving emotions accompanying the diagnosis and the need for treatment, and the diverse power dynamics that might be at play with health care providers. These challenges are often compounded by the need to manage their increasing burden of symptoms. In this complex context of care, patients must make decisions about their treatment, decisions that can have implications for their current and future health and quality of life.

Recognizing the importance of engaging and supporting patients to achieve a high-quality treatment decision in partnership with their providers, multiple cardiovascular guidelines have endorsed shared

decision-making (SDM) as a core principle of patient-centred communication in multidisciplinary team best practices. This bi-directional exchange of information is a mechanism to promote patient empowerment, consideration of patients' preferences, values and priorities, and ultimately, the provision of true informed consent. Patient decision aids (PtDAs) are evidence-based, patient-facing interventions developed according to international standards and designed to facilitate SDM. Patient decision aids explicitly state the decision to be made, provide information about options (inclusive of the option of not actively intervening and choosing watchful waiting/active surveillance) and outcomes associated with each option, while helping patients clarify their values and preferences…

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YOUNG PERSONS

Obtaining Consent for Research on Risky Behaviours Among Adolescents in Canada: A Scoping Review

Lillian MacNeill, A Luke MacNeill, Shelley Doucet, Alison Luke, Alex Goudreau
Journal Of Empirical Research On Human Research Ethics, 15 May 2024
Open Access
Abstract
This scoping review explores current practices for obtaining consent in research on risky behaviours among adolescents in Canada. The JBI methodology for scoping reviews was used. The database search was conducted in August 2021 and updated in November 2022. Papers published in 2010 or later were included. Extracted data included study characteristics, sample characteristics, and consent procedures. The review included 83 reports covering 57 studies. Nearly 60% of studies relied on adolescent self-consent for participation. Adolescent self-consent was more common than parental/guardian consent for studies using in-person research methods, older adolescent groups, and particularly vulnerable populations. Parental/guardian consent was more common for studies using younger age groups and general population samples. Adolescent self-consent was more common than parental/guardian consent for most risky behaviours covered by this review. These results provide insight into current consent practices in this area and offer guidance to researchers and institutional review boards in Canada.

Racial and Ethnic Disparity in Approach for Pediatric Intensive Care Unit Research Participation

Sarah L. Mayer, Michelle R. Brajcich, Lionola Juste, Jesse Y. Hsu, Nadir Yehya
Original Investigation Pediatrics
JAMA Network Open, 15 May 2024
Key Points
Question
Are sociodemographic factors associated with rates of approach and consent for pediatric intensive care unit (PICU) research?
Findings
This cohort study of 3154 children found disparities in approach and consent according to race and ethnicity, language, religion, and degree of social deprivation. Lower consent rates were partly mediated by lower approach rates, with reduced approach mediating approximately half of the lower rates of consent for Black children.
Meaning
In this study, multiple sociodemographic variables were associated with disparate consent rates for PICU research, and strategies to increase approaches could contribute to equitable enrollment in PICU studies.

Abstract
Importance
While disparities in consent rates for research have been reported in multiple adult and pediatric settings, limited data informing enrollment in pediatric intensive care unit (PICU) research are available. Acute care settings such as the PICU present unique challenges for study enrollment, given the highly stressful and emotional environment for caregivers and the time-sensitive nature of the studies.
Objective
To determine whether race and ethnicity, language, religion, and Social Deprivation Index (SDI) were associated with disparate approach and consent rates in PICU research.
Design, Setting, and Participants
This retrospective cohort study was performed at the Children's Hospital of Philadelphia PICU between July 1, 2011, and December 31, 2021. Participants included patients eligible for studies requiring prospective consent. Data were analyzed from February 2 to July 26, 2022.
Exposure
Exposures included race and ethnicity (Black, Hispanic, White, and other), language (Arabic, English, Spanish, and other), religion (Christian, Jewish, Muslim, none, and other), and SDI (composite of multiple socioeconomic indicators).
Main Outcomes and Measures
Multivariable regressions separately tested associations between the 4 exposures (race and ethnicity, language, religion, and SDI) and 3 outcomes (rates of approach among eligible patients, consent among eligible patients, and consent among those approached). The degree to which reduced rates of approach mediated the association between lower consent in Black children was also assessed.
Results
Of 3154 children included in the study (median age, 6 [IQR, 1.9-12.5] years; 1691 [53.6%] male), rates of approach and consent were lower for Black and Hispanic families and those of other races, speakers of Arabic and other languages, Muslim families, and those with worse SDI. Among children approached for research, lower consent odds persisted for those of Black race (unadjusted odds ratio [OR], 0.73 [95% CI, 0.55-0.97]; adjusted OR, 0.68 [95% CI, 0.49-0.93]) relative to White race. Mediation analysis revealed that 51.0% (95% CI, 11.8%-90.2%) of the reduced odds of consent for Black individuals was mediated by lower probability of approach.
Conclusions and Relevance
In this cohort study of consent rates for PICU research, multiple sociodemographic factors were associated with lower rates of consent, partly attributable to disparate rates of approach. These findings suggest opportunities for reducing disparities in PICU research participation.

Ethical Frameworks of Informed Consent in the Age of Pediatric Precision Medicine

David Chen

Precision Medicine, 6 May 2024

Abstract
Precision medicine is an emergent medical paradigm that uses information technology to inform the use of targeted therapies and treatments. One of the first steps of precision medicine involves acquiring the patient's informed consent to protect their rights to autonomous medical decision making. In pediatrics, there exists mixed recommendations and guidelines of consent related practices designed to safeguard pediatric patient interests while protecting their autonomy. Here, we provide a high-level, clinical primer of 1) ethical informed consent frameworks widely used in clinical practice and 2) promising modern adaptations to improve informed consent practices in pediatric precision medicine. Given the rapid scientific advances and adoption of precision medicine, we highlight the dual need to both consider the clinical implementation of consent in pediatric precision medicine workflows as well as build rapport with pediatric patients and their substitute decision-makers working alongside interdisciplinary health teams.

Editor's note: The modern adaptions mentioned by the authors include having a two-step consent process, providing options for pediatric patients to exercise their right to re-consent for continued use of genomic data at the age of majority, and using broad consent strategies.

The Role of Parental Consent in Counseling for Minors: Requirement or Necessity?

Novianti Novianti, Nandang Budiman, Nadia Aulia Nadhirah

Indonesian Journal of Guidance and Counseling Research, 27 April 2024

Abstract

The purpose of this study is to determine the Role of Parental Consent in Counseling Minors. This research uses the systematic literature review (SLR) method. Based on the results of the synthesis, the urgency of parental consent before the implementation of counseling for minors is as a condition, not a necessity, which means that it must only be fulfilled administratively so that counseling can be carried out but does not have a significant impact on the implementation of counseling. The conclusion of the study reveals that counselors must continue to prioritize the rights and trust of children in conducting counseling, the limits of decisions that can be taken by minors without intervention from parents need to be studied more deeply in further research. The contribution of this research can be used as one of the ethical references for school counselors both theoretically and practically, especially when dealing with minors.

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CAPACITY TO CONSENT

Consent and Inclusion of People Living with Dementia (PLWD) in Research: Establishing a Canadian Agenda for Inclusive Rights-Based Practices

Amanda Grenier, Deborah O'Connor, Krista James, Daphne Imahori, Daniella Minchopoulos, Nicole Velev, Laura Tamblyn-Watts, Jim Mann

Canadian Journal on Aging, 20 May 2024

Abstract

Background

People living with dementia (PLWD) may want to participate in research, but the guidelines and processes enacted across various contexts may prohibit this from happening.

Objective

Understanding the experiences of people with lived experiences of dementia requires meaningful inclusion in research, as is consistent with rights-based perspectives. Currently, the inclusion of PLWD in Canadian research is complex, and guidelines and conceptual frameworks have not been fully developed.

Methods

This research note outlines a three-year proof-of-concept grant on the inclusion and consent of PLWD in research.

Findings

It presents a brief report on some of the contradictions and challenges that exist in legislation, research guidelines, and research practices and raises a series of questions as part of an agenda on rights and inclusion of PLWD in research.

Discussion

It suggests conceptual, legal, and policy issues that need to be addressed and invites Canadian researchers to re-envision research practices and to advocate for law and policy reform that enables dementia research to align and respect the rights and personhood of PLWD.

Framework to elicit consent from lightly sedated mechanically ventilated intensive care patients in nursing practice

Yoko Onishi, Yoshiko Murai, Emiko Nakajima

Japan Journal Of Nursing Science, 2 May 2024

Abstract

Aim

The study aimed to ascertain a framework of nursing practices to elicit consent from lightly sedated ventilated patients.

Methods

Study participants were nurses working in intensive care and critical care wards, whose observations and semi-structured interviews were assessed using a modified grounded theory approach.

Results

A total of 15 concepts were generated, from which three categories and three subcategories were generated. Category 1: Nurses taking the lead in providing assistance by sharing signs of change while continuing the invasive treatment, working to maintain the patient's life, alleviation of pain, promotion of awareness of the current situation, and acclimating them to the treatment environment as the basis for building a relationship between patients and nurses. Category 2: Searching for points of agreement and reaching a compromise involves the nurse drawing out the patient's thoughts, hopes, and expectations, and transforming the relationship into a patient-centered one by sharing goals with the patient in order to achieve them. Category 3: Organizing collaboration within care supported the patient's ability to move safely while maintaining the patient's pace to achieve shared goals, and guided the patient's independent actions.

Conclusions

Even when patients recover from an acute life-threatening situation, their physical sensations remain vague and their functional decline continues. Rather than simply eliciting consent from patients, the structure of nursing practice to elicit such response from patients involves drawing out the patient's thoughts, hopes, and expectations, as well as guiding the patient toward goals that they have created together with the nurse and utilizing the patient's strengths to achieve these goals.

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RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT

Editor's Note:

We recognize a growing literature which argues [in whole or in part] that norms requiring the individual, prior, free, express and informed consent of persons to be involved in research must accommodate notions which integrate terms such as ‘community-driven’, ‘decolonized’, or ‘culturally-appropriate’ and which insist that consent processes “prioritize local/indigenous values and protocols.” As an editorial policy, we have decided to group such literature together in this section of the digest.

More broadly, we recognize that this literature raises critically important issues around consent integrity. Our Center for Informed Consent Integrity is actively developing a position on this matter, mindful of core guidance in research involving human participants overall, and selected instruments such as the Universal Declaration on Bioethics and Human Rights [2005] which notes:

> *Article 12. Respect for cultural diversity and pluralism*
> The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

We will keep readers advised of our progress. If you have an interest in participating in our working group, please contact Paige Fitzsimmons [paige.fitzsimmons@ge2p2global.org].

Exploring the consent process among pregnant and breastfeeding women taking part in a maternal vaccine clinical trial in Kampala, Uganda: a qualitative study

Research

Agnes Ssali, Rita Namugumya, Phiona Nalubega, Mary Kyohere, Janet Seeley, Kirsty Le Doare

BMC Medical Ethics, 16 May 2024

Open access

Abstract

Background

The involvement of pregnant women in vaccine clinical trials presents unique challenges for the informed consent process. We explored the expectations and experiences of the pregnant women, spouses/partners, health workers and stakeholders of the consent process during a Group B Streptococcus maternal vaccine trial.

Methods

We interviewed 56 participants including pregnant women taking part in the trial, women not in the trial, health workers handling the trial procedures, spouses, and community stakeholders. We conducted 13 in-depth interviews and focus group discussions with 23 women in the trial, in-depth interviews with 5 spouses, and 5 women not in the trial, key informant interviews with 5 health workers and 5 other stakeholders were undertaken.

Results

Decision-making by a pregnant woman to join a trial was done in consultation with spouse, parents, siblings, or trusted health workers. Written study information was appreciated by all but they suggested the use of audio and visual presentation to enhance understanding. Women stressed the need to ensure that their male partners received study information before their pregnant partners joined a clinical trial. Confidentiality in research was emphasised differently by individual participants; while some emphasised it for self, others were keen to protect their family members from being exposed, for allowing them to be involved in research. However, others wanted their community participation to be acknowledged.

Conclusion

We found that pregnant women make decisions to join a clinical trial after consulting with close family. Our findings suggest the need for an information strategy which informs not only the pregnant woman, but also her family about the research she is invited to engage in.

The ethics of research informed consent from the Kyrgyz perspective: A qualitative study

Tamara Kudaibergenova

Developing World Bioethics, 14 May 2024

Abstract

To ensure informed consent is tailored to ethnic Asian communities, it is necessary to establish an ethical foundation that is relevant to the specific populations. We hypothesized that certain communitarian factors unique to traditional Kyrgyz culture may influence an individual's decision to participate in research. Guided by Seedhouse's (2005) Rational Field Theory, we conducted qualitative, in-depth interviews with cultural experts in Kyrgyzstan to identify the ethical foundations of decision-making for informed consent in Kyrgyz culture. The results indicate that Kyrgyz people have a distinctive decision-making style influenced by their nomadic culture and history, which values and prioritizes family integrity and reputation. These findings indicate that a multidimensional approach based on socio-cultural sensitivities is necessary to assess the appropriateness of consent procedures. We believe our results may have implications for revising the guidelines of local and regional research ethics committees in Kyrgyzstan and other Central Asian countries.

Incorporating religious and cultural background: Patient informed consent in the era of acellular dermal matrix breast reconstruction

J.A. Foppiani, E. Kim, K. Beltran, A. Hernandez Alvarez, I. Taritsa, M.J. Escobar-Domingo, D. Lee, K.A. Schuster, S. Terkonda, S.J. Lin, O. Ho

ESMO Open, May 2024; Volume 9, Supplement 4

Open Access

Background

Acellular Dermal Matrices (ADMs) have become an integral part of breast reconstruction. An additional level of informed consent may hinge on personal and cultural beliefs, especially concerning the source matrix. This study seeks to evaluate socio-cultural factors influencing patient decisions on ADM use, with the end goal of enhancing practice through better-informed consent and comprehension of patient values.

Methods

A survey of adult women in the U.S. and India was conducted via Amazon Mechanical Turk. Chi-squared tests were used to compare preferences across dietary and religious groups.

Results

645 complete responses were analyzed, with 12.2% from India and 87.8% from the USA. Predominantly, respondents were White (68.2%) or Asian (26.2%), with major religious affiliations being Christianity (68.4%) and Hinduism (23.7%). The most common dietary preferences were Vegetarian (36.2%), Omnivorous (27.9%), and Vegan (21.3%). Upon disclosing the composition of ADMs, 49 (6.5%) individuals changed their answers and opted against Human Cadaveric ADM; 82 (10.8%) against Bovine-derived ADM; 101 (13.3%) against Porcine-derived ADM; and 73 (9.6%) against Ovine-derived ADM. Both religion and diet type significantly impacted individuals' decisions to forgo ADM usage upon understanding its composition ($P < 0.001$), and also notably influenced their choices of ADM types ($P = 0.024$).

Conclusions

Disclosing ADM's origin significantly impacted patient choices, and in some cases, shifted the patient's opinion of potential choice. Thorough counseling of surgical preferences is a crucial component of patient care. The findings advocate for the importance of culturally sensitive discussions in improving healthcare equity in our diverse society.

Editor's note: ESMO Open is published by the European Society for Medical Oncology.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Knowledge, and Practice of Nurses regarding informed consent at Friendship Hospital in Sudan

Zeinab Taha Ali Omer

Egyptian Journal of Health Care, June 2024

Abstract

Aim

To assess the knowledge and practice of nurses about informed consent at Friendship Hospital in Sudan.

Methods

A descriptive cross-sectional hospital-based methodology was used. A hundred nurses enrolled in a study as total coverage, and data were gathered using an interview questionnaire. SPSS version 22 was used to analyze the data.

Results

The study had A hundred participants, 69%Female making up most of the sample. The majority of participants age range between 35-39years. A large number of participants had 7-10 years of experience. Regarding the informed consent process, half of the participants (50%) reported that they had enough

information about the informed consent process. Also, forty percent of participants informed the patients about the risks and complications of their planned treatment.
Conclusion
In conclusion, the study found that half of the participants knew the process of consent. Majority of participants were aware that mental status was an important indicator of the ability to consent.
Recommendations
The findings manifest the need for an efficient education program that concentrates on learning nurses about consent.

Readability and Comprehension of Anesthesia Informed Consent Forms in a Spanish County Hospital: An Observational Study

José Manuel García-Álvarez, Alfonso García-Sánchez
Nursing Reports, 24 May 2024; 14(2) pp 1338-1352
Abstract
Background
The wording of informed consent forms could hinder their comprehension and hinder patients' autonomous choice. The objective of this study was to analyze the readability and comprehension of anesthesia informed consent forms in a Spanish county hospital.
Methods
Descriptive and cross-sectional study carried out on patients who were going to undergo anesthetic techniques. The readability of the forms was analyzed using the INFLESZ tool and their subjective comprehension using an ad hoc questionnaire.
Results
The analyzed forms presented a "somewhat difficult" legibility. A total of 44.2% of the patients decided not to read the form, mainly because they had previously undergone surgery with the same anesthetic technique. The language used in the forms was considered inadequate by 49.5% of the patients and 53.3% did not comprehend it in its entirety. A statistically significant negative correlation of age and INFLESZ readability score with the overall questionnaire score was found. A statistically significant association was observed as a function of age and educational level with the different criteria of the questionnaire.
Conclusions
The anesthesia informed consent forms presented low readability with limited comprehension. It would be necessary to improve their wording to favor comprehension and to guarantee patients' freedom of choice.

Prevalence of different variations of non-consented care during the childbirth process in Mexico by geographical regions: comparing ENDIREH survey data from 2016 to 2021

Research
Marian Marian, Kathryn M. Barker, Elizabeth Reed, Amanda C. McClain, Rebecka Lundgren, Samantha Hurst, Ramona L. Pérez
BMC Pregnancy and Childbirth, 13 May 2024
Open Access
Abstract
Introduction
Non-consented care, a form of obstetric violence involving the lack of informed consent for procedures, is a common but little-understood phenomenon in the global public health arena. The aim of this secondary analysis was to measure the prevalence and assess change over time of non-consented care during childbirth in Mexico in 2016 and 2021, as well as to examine the association of sociodemographic, pregnancy-, and childbirth-factors with this type of violence.

Methods
We measured the prevalence of non-consented care and three of its variations, forced sterilization or contraception, forced cesarean section, and forced consent on paperwork, during childbirth in Mexico for 2016 (N = 24,036) and 2021 (N = 19,322) using data from Mexico's cross-sectional National Survey on the Dynamics of Household Relationships (ENDIREH). Weighted data were stratified by geographical regions. We performed adjusted logistic regression analyses to explore associations.
Results
The national prevalence of non-consented care and one of its variations, pressure to get a contraceptive method, increased from 2016 to 2021. A decrease in the prevalence was observed for forced contraception or sterilization without knowledge, forcing women to sign paperwork, and non-consented cesarean sections nationally and in most regions. Women between the ages of 26 and 35 years, married, cohabiting with partner, living in urban settings, who do not identify as Indigenous, and who received prenatal services or gave birth at the Mexican Institute of Social Security (IMSS) facilities experienced a higher prevalence of non-consented care. Being 26 years of age and older, living in a rural setting, experiencing stillbirths in the last five years, having a vaginal delivery, receiving prenatal services at IMSS, or delivering at a private facility were significantly associated with higher odds of reporting non-consented care.
Conclusion
While a decrease in most of the variations of non-consented care was found, the overall prevalence of non-consented care and, in one of its variations, pressure to get contraceptives, increased at a national and regional level. Our findings suggest the need to enforce current laws and strengthen health systems, paying special attention to the geographical regions and populations that have experienced higher reported cases of this structural problem.

Informed Consent in Clinical Studies in the Republic of Srpska

Snežana Pantović, Dijana Zrnić
Review of European and Comparative Law, 6 May 2024
Abstract
As human medicine is developing at a galloping pace, continuously offering new medical products, diagnostic methods and preventive programmes, there is almost no time gap between their creation and application in medical practice. All these biomedical achievements are primarily intended to improve public health and the patient's quality of life and health. Hence, it is important to define potential risks, side effects, and unwanted outcomes when applying a medical product/treatment before integrating it into healthcare. Unlike any other product/treatment intended for human use, medical products/treatments require prior clinical testing on human subjects (sick or sound). The authors of this paper have restricted their scientific interest to the participant (human subject) of a clinical study as one of the core elements of a clinical investigation, representing at the same time its means and its aim. By analyzing relevant international as well as national legal rules and ethical principles of the Republic of Srpska related to the participation of humans in clinical studies, it will be concluded that the participants' safety and right to self-determination, integrity, and autonomy manifested through their independent right to either consent or refuse to participate in a clinical study supersedes the interests of science or society. However, clinical trial-related statistical data obtained from randomly chosen healthcare institutions in the Republic of Srpska will show certain derogations from prescribed ethical policies. Considering this fact, the authors have paid special attention to thematising the ethicality of recruiting participants for a clinical study based on partial or no information related to the purpose, methods, potential risks and side effects of the investigation in the name of the greater good for humanity. Such practice has accentuated the discretionary powers of ethical review committees on the one side and the uncertainty of the right to informed consent on the other.

Editor's note: The Republic of Sprska is one of the two entities of Bosnia and Herzegovina.

Analysis of Informed Consent Forms Submitted to Institutional Ethics Committee of a Medical Institute in Southern India: A Cross-sectional Observational Study

Vedavathi Hanumaiah, Shreenivas Prabhakar Revankar, Nagaraja Prasad Sai, Mohammad Arif

Journal of Clinical & Diagnostic Research, 1 April 2024

Abstract

Introduction

Informed consent is an essential component in research involving human participants. However, the informed consent obtained may be incomplete and not fulfill the essential criteria of Informed Consent Forms (ICFs). Although the guidelines for developing ICFs have been clearly spelled out by various research bodies, these guidelines are not followed completely.

Aim

To analyse the ICFs submitted to the Institutional Ethics Committee (IEC) of a Medical Institute in Southern India.

Materials and Methods

The present study was a crosssectional observational study analysing ICFs submitted to the IEC of McGann District Teaching Hospital, Shimoga Institute of Medical Sciences (SIMS), Shivamogga, Karnataka, India, for the period 2014 to January 2023. All research projects containing ICFs during the study period were included in the study. Of the research projects submitted, only 70 had ICFs, and these were subjected to analysis as per Indian Council of Medical Research (ICMR) guidelines criteria. The criteria for ICFs were: statement of research, purpose/methods of the study, duration/frequency of the study, benefits to participants/community, foreseeable risks, discomfort/inconvenience, confidentiality, payment/reimbursement for participation. In addition to these, ICFs were also analysed for additional elements as per ICMR criteria for tissue and blood samples. The results were then subjected to descriptive statistical analysis and presented as mean and percentages.

Results

Many of the required essential elements were present in nearly 50% of ICFs submitted to the IEC, which include information on the basic purpose/methods of the study 70 (100%), identity of the principal investigator/research team 57 (81.42%), freedom to participate/withdraw from the study 55 (78.57%), confidentiality of records 54 (77.14%), and foreseeable risks, discomfort, and inconvenience to participants 35 (50%). Other essential elements like benefits were present to participants/community 28 (40%), payment/reimbursement for participation 28 (40%), duration and frequency 12 (17.14%), statement of research 9 (12.85%), treatment/compensation for injury 4 (5.71%). Regarding additional elements of ICFs for biological samples, ICFs adhered to the ICMR requirements except none of the submitted forms had any information on the period of storage of biological samples.

Conclusion

The ICF is an essential requirement for conducting research. Ensuring adherence of ICF to guidelines is important from a research perspective. The present study concludes that the majority of the essential elements were present in ICFs with a few exceptions like study as research and information on the storage of biological samples, which was nil.

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RIGHTS/LEGAL/LEGISLATIVE

Clinical Teaching and Consent: An Analysis of New Zealand's Legal Requirements for Obtaining Consent to Clinical Teaching Involving Consumers of Health and Disability Services

Lydia Wadsworth

Journal Of Law and Medicine, May 2024

Abstract
Student involvement in patient care without consent has attracted recent attention in New Zealand. New Zealand's Code of Health and Disability Services Consumers' Rights (Code) gives patients the right to give or refuse consent to participate in clinical teaching, but its practical application to clinical teaching, particularly postgraduate, is unclear. This article explores the history and precedent of the Code and ethical considerations, to inform where amendment to the Code is desirable in the interests of clarity, pragmatism, and to reflect better the legislature's intent.

The Law On Informed Consent In Medical Procedures In Nigeria: Organ And Tissue Transplant In Focus

Ikenga K. E. Oraegbunam, Eyiuche Stella Ifediora
International Review of Law and Jurisprudence, January 2024
Abstract
During medical procedures, the law, generally, mandate medical personnel to seek and get the consent of patients before proceeding with any medical treatment. The rule on informed consent, simply put, entails health professionals properly informing patients, to their understanding, about any medical treatment to be administered to such patient and getting approval before proceeding with such treatment. This basically aligns with the medical and legal positions that recognize the autonomy of a patient and recognizes such patient's right to either accept or reject any medical treatment and also the right to participate in every decision regarding the patient's medical treatment. The informed consent rule allows some exceptions which include emergency cases where it would be fatal to insist on seeking and getting a patient's consent to a lifesaving medical intervention. The present research is focused reviewing the current state of the law with respect to informed consent in transplant procedures in Nigeria to determine its adequacy. **It is recommended inter alia that the National Health Act be amended to specifically mandate health personnel to seek and get the informed consent of parties to transplant procedures – where possible – to prevent the legal implications of doing otherwise.** Also, medical personnel should be trained continually to practice informed consent when handling patients that come to them for any form of medical treatment.

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COVID-19

Care of women and application of the principle of informed consent to interventions during birth in the COVID-19 pandemic period

Research Paper
Alina Liepinaitienė, Izabelė Bujaitė, Aurimas Galkontas, Vaidas Jotautis,Audrius Dėdelė
European Journal of Midwifery, 8 May 2024
Abstract
Introduction
In the early phases of the COVID-19 pandemic, inadequate intrapartum care protocols were in place. Many organizations have responded promptly and recognized the importance of adherence to appropriate guidelines. The International Confederation of Midwives issued an official statement on 29 March 2020, which states that every woman has the right to information, to give consent, to refuse consent, and to have her choices and decisions respected and upheld. No research has been conducted in Lithuania to reveal the care of women who gave birth during the COVID-19 pandemic and the application of informed consent to interventions.
Methods

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

Results

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

Conclusions

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

Informed consent and trial prioritization for clinical studies during the COVID-19 pandemic. Stakeholder experiences and viewpoints

Research Article

Stefanie Weigold, Susanne Gabriele Schorr, Alice Faust, Lena Woydack, Daniel Strech

Plos One, 30 April 2024

Open Access

Abstract

Background

Very little is known about the practice-oriented challenges and potential response strategies for effective and efficient translation of informed consent and study prioritization in times of a pandemic. This stakeholder interview study aimed to identify the full spectrum of challenges and potential response strategies for informed consent and study prioritization in a pandemic setting.

Methods

We performed semi-structured interviews with German stakeholders involved in clinical research during the COVID-19 pandemic. We continued sampling and thematic text analysis of interview transcripts until thematic saturation of challenges and potential response strategies was reached.

Results

We conducted 21 interviews with investigators, oversight bodies, funders and research support units. For the first topic informed consent we identified three main themes: consent challenges, impact of consent challenges on clinical research, and potential strategies for consent challenges. For the second topic prioritization of clinical studies, we identified two main themes: perceived benefit of prioritization and potential strategies for prioritization. All main themes are further specified with subthemes. A supplementary table provides original quotes from the interviews for all subthemes.

Discussion

Potential response strategies for challenges with informed consent and study prioritization partly share common ground. High quality procedures for study prioritization, for example, seem to be a core response strategy in dealing with informed consent challenges. Especially in a research environment with particularly high uncertainty regarding potential treatment effects and further limitations for valid informed consent should the selection of clinical trials be very well justified from a scientific, medical, and ethics viewpoint.

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MEDICAL/SURGICAL

Exploring the role of the oncologist in promoting shared decision making during treatment planning for older adults with acute myeloid leukemia

Research Letter to the Editor

Marissa LoCastro, Marielle Jensen-Battaglia, Chandrika Sanapala, Rachel Rodenbach, Jason H. Mendler, Jane Liesveld, Eric Huselton, Kah Poh Loh

Journal of Geriatric Oncology, June 2024

Introduction

Shared decision making (SDM), a process that promotes both patient autonomy and engagement, is associated with increased patient knowledge and decreased decisional regret [1]. Due to acute myeloid leukemia's (AML) sudden onset and frequent need for rapid management decisions, achieving SDM in older patients is challenging [2]. Older adults with AML also have various vulnerabilities (e.g., functional and cognitive impairments) which further complicate decision making. This study evaluated oncologists' current practices to promote SDM among older adults with AML using a communication tool designed to systematically elicit patient preferences regarding treatment planning.

Clear aligner therapy informed consent forms: A quality and readability evaluation

Original Article

Maurice J. Meade, Sven Jensen, Xiangqun Ju, David Hunter, Lisa Jamieson

International Orthodontics, June 2024

Open Access

Summary

Objective

The aim of the present study was to evaluate the quality and readability of content contained within clear aligner therapy (CAT) informed consent forms.

Methods

CAT informed consent forms were identified via an online search. The presence of details related to CAT-related processes, risks, benefits and alternatives in each form was recorded. A 4-point Likert type scale was used to determine the quality of content (QOC). The readability of content was evaluated with the Simple Measure of Gobbledegook (SMOG) and Flesch Reading Ease Score (FRES).

Results

A total of 42 forms satisfied selection criteria. Nineteen (45.2%) were authored by companies who provided aligners to patients via clinicians. The QOC regarding CAT-related treatment processes [median 2.0; IQR 0, 2] and benefits [median 2.0; IQR 1, 2] was adequate. The QOC scores regarding treatment alternatives, consequences of no treatment and relapse were poor. There was no difference (P = 0.59) in the median (IQR) QOC of the informed consent forms provided by direct-to-consumer (DTC) aligner providers [10 (8.25, 16.25)] and non-DTC aligner providers [12 (10, 14)]. The median (IQR) SMOG score was 12.1 (10.9, 12.7) and FRES was 39.0 (36.0, 44.25).

Conclusions

The QOC of the evaluated forms was incomplete and poor. The content was difficult to read and failed to reach recommended readability standards. Consent is unlikely to be valid if it is based solely on the content of the forms. Clinicians need to be aware of the limitations of informed consent forms for CAT particularly in relation to alternatives, prognosis, risks, and the need for long-term maintenance of results.

Patient informed consent, ethical and legal considerations in the context of digital vulnerability with smart, cardiac implantable electronic devices

Leanne N. S. Torgersen, Stefan M. Schulz, Ricardo G. Lugo, Stefan Sütterlin
Plos Digital Health, 23 May 2024
Open Access
Abstract
Advancements in digitalisation with cardiac implantable electronic devices (CIEDs) allow patients opportunities for improved autonomy, quality of life, and a potential increase in life expectancy. However, with the digital and functional practicalities of CIEDs, there exists also cyber safety issues with transferring wireless information. If a digital network were to be hacked, a CIED patient could experience both the loss of sensitive data and the loss of functional control of the CIED due to an unwelcome party. Moreover, if a CIED patient were to become victim of a cyber attack, which resulted in a serious or lethal event, and if this information were to become public, the trust in healthcare would be impacted and legal consequences could result. A cyber attack therefore poses not only a direct threat to the patient's health but also the confidentiality, integrity, and availability of the CIED, and these cyber threats could be considered "patient-targeted threats." Informed consent is a key component of ethical care, legally concordant practice, and promoting patient-as-partner therapeutic relationships [1]. To date, there are no standardised guidelines for listing cybersecurity risks within the informed consent or for discussing them during the consent process. Providers are responsible for adhering to the ethical principles of autonomy, beneficence, non-maleficence, and justice, both in medical practice generally and the informed consent process specifically. At present, the decision to include cybersecurity risks is mainly left to the provider's discretion, who may also have limited cyber risk information. Without effective and in-depth communication about all possible cybersecurity risks during the consent process, CIED patients can be left unaware of the privacy and physical risks they possess by carrying such a device. Therefore, cyber risk factors should be covered within the patients' informed consent and reviewed on an ongoing basis as new risk information becomes available. By including cyber risk information in the informed consent process, patients are given the autonomy to make the best-informed decision.

Patient Consent for Medical Student Pelvic Exams under Anesthesia: An Exploratory Retrospective Chart Review

Jessica A. Jushchyshyn, Lakeisha Mulugeta-Gordon, Cara Curley, Florencia Greer Polite, and Jon F. Merz
The Journal of Clinical Ethics, 10 May 2024
Abstract
Objective
We performed this study to examine patients' choices to permit or refuse medical student pelvic examinations under anesthesia (EUAs) during planned gynecologic procedures.
Design
We conducted an exploratory retrospective chart review of electronic consent forms at a single academic medical center using contingency tables, logistic regression, and nonparametric tests to explore relationships between patient and physician characteristics and consent.
Results
We identified and downloaded electronic consent forms for a census of 4,000 patients undergoing gynecologic surgery from September 2020 through calendar year 2022. Forms were linked to anonymized medical record information. Of the 4,000 patients, 142 (3.6%) were removed from analysis because consent forms were incomplete. Of 3,858 patients, 308 (8.0%) were asked for EUA consent more than once, 46 of whom were not consistent. Overall, 3,308 (85.7%) patients consented every time asked, and 550 (14.2%) refused or limited EUA consent at least once. Nine patients limited their consent to female students, and two patients refused medical student participation at all. We performed exploratory multiple logistic regression analyses exploring differences in rates of consent across patient and physician demographic groups.
Conclusions

We find that some patients are more likely than others to refuse a pelvic EUA, magnifying the dignitary harm from a nonconsensual invasion of intimate bodily integrity and perpetuating historic wrongs visited upon vulnerable people of color and religious minorities. Patients' rights to respect and control over their bodies require that physicians take seriously the ethical obligation to inform their patients and ask them for permission.

Overlapping Surgery Verbiage in Informed Consent Documents

Original Study

Margaret B. Mitchell, George Lin, Kavita Prasad, Daniel R. S. Habib, Alexander Langerman

Annals of Surgery, 6 May 2024

Abstract

Objective

To assess informed consent documents from United States (US) institutions for verbiage regarding overlapping surgery.

Summary background data

Overlapping surgery remains a controversial practice. Recent guidance from the Senate Finance Committee and American College of Surgeons emphasizes transparency with patients regarding this practice through the informed consent process, but it remains unclear how many institutions adopted their recommendations.

Methods

Informed consent documents were collected from a national sample of 104 institutions and assessed for verbiage regarding overlapping surgery and/or attending absence during a surgical case. The verbiage of these forms was further analyzed for inclusion of key terms (e.g., "overlapping surgery," "critical portions") as well as transparency regarding surgeon absence.

Results

Thirty (29%) forms included verbiage regarding overlapping surgery and/or surgeon absence during a case. Most of these 30 utilized the terms "overlapping surgery" or "critical portions" (18 [60%] and 25 [83%], respectively), although only 3 (10%) explicitly stated that portions of the procedure that may be performed in the absence of the attending surgeon. Six forms (20%) specifically stated who may perform the procedure without the attending present, and 3 forms (10%) had patients acknowledge this section of the consent form with an additional signature or initial. Only 2 of the forms (7%) fulfilled all of the criteria set forth by the SFC.

Conclusion

Detailed information regarding overlapping surgery is infrequently included in hospitals' procedure informed consent documents. Forms that include this information rarely provide explicit statements of attending presence and trainee participation, raising concerns regarding surgeon-patient transparency.

Informed Consent Should Be Required before Brain Death Testing

Joseph M. Eble

Ethics & Medics, May 2024

Abstract

Informed consent is an important principle in medicine. It protects patients and their families from being unduly pressured into procedures they do not understand with risks they may not fully appreciate. While organ donor status is near ubiquitous for anyone with a driver's license or ID card, rarely is this status accepted with fully informed consent. As a result, patients are left vulnerable to tests that may cause them irrevocable harm or even procedures that may cause their death. The test for brain death is an example of the former possibility. This article explores the dangers of this and the apnea test, as well as the lack of informed consent present when organ donor agreements are generally made.

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PRE-PRINT SERVERS

Designing e-consent protocols for pragmatic clinical trials: case studies from a UKCRC clinical trials unit

Matt Hammond, Polly Ashford, Juliet High, Lucy Clark, Gregory Howard, Megan Jones, Susan Stirling, Claire West

BMC Trials, 22 May 2024

Abstract

Background

Interest in and use of electronic consent (e-consent) in the conduct of academic clinical trials has increased since the COVID-19 pandemic. E-consent offers advantages including increased efficiency and accessibility, and reduced burden on site staff, which can be appealing to academic trialists anticipating challenges in recruitment to complex trial designs or with limited funding. However, there are many options to consider when using e-consent in a study protocol. This paper presents five case studies from Norwich Clinical Trials Unit, demonstrating how e-consent models can be effectively tailored to the needs of different trials. These examples illustrate the options around and benefits of e-consent, the acceptability of e-consent by participants, and the design considerations that were made during the development of the trial protocols.

Case Studies

Five randomised trials are presented, selected from a range of different trial designs, disease areas, interventions, and patient populations. E-consent was either offered as an alternative to paper consent, according to participant preference, or as the sole method of consent. E-consent was generally used to facilitate remote consent in decentralised trials but was also chosen to increase efficiency and reduce burden in an emergency department setting. The technical implementation of e-consent and detailed participant procedures were tailored to the needs of the trial settings and patient populations. For example, accompanying participant information sheets were provided in paper or electronic form, and electronic signatures could be typed or drawn. Administrative data on uptake of e-consent is presented where available.

Conclusion

This paper demonstrates that the operational and technical aspects of implementing e-consent in clinical trials can be influenced by the trial design, the needs and characteristics of the trial population, financial/efficiency considerations, and level of risk. E-consent is not a one-size-fits-all tool for trials, and its use should be carefully considered during the development of the trial protocol, in conjunction with patient and public involvement contributors, site staff and other trial stakeholders.

Development and validation of a stakeholder-driven, self-contained electronic informed consent platform for trio-based genomic research studies

Bethany Y Norton, James Liu, Sara A Lewis, Helen Magee, Tyler N Kruer, Rachael Dinh, Somayeh Bakhtiari, Sandra H. Nordlie, Sheetal Shetty, Jennifer Heim, Yumi Nishiyama, Jorge Arango, Darcy Johnson, Lee Seabrooke, Mitchell Shub, Robert Rosenberg, Michele Shusterman, Stephen Wisniewski, Blair Cooper, Erin Rothwell, Michael C Fahey, M. Wade Shrader, Nancy Lennon, Joyce Oleszek, Wendy Pierce, Hannah Fleming, Mohan Belthur, Jennifer Tinto, Garey Noritz, Laurie Glader, Kelsey Steffan, William Walker, Deborah Grenard, Bhooma Aravamuthan, Kristie Bjornson, Malin Joseph, Paul Gross, Michael C Kruer, the Cerebral Palsy Research Network

medRxiv, 3 May 2024

Abstract

Increasingly long and complex informed consents have yielded studies demonstrating comparatively low participant comprehension and satisfaction with traditional face-to-face approaches. In parallel, interest in electronic consents for clinical and research genomics has steadily increased, yet limited data are available for trio-based genomic discovery studies. We describe the design, development, implementation, and validation of an electronic iConsent application for trio-based genomic research deployed to support genomic studies of cerebral palsy. iConsent development incorporated stakeholder perspectives including researchers, patient advocates, institutional review board members, and genomic data-sharing considerations. The iConsent platform integrated principles derived from prior electronic consenting research and elements of multimedia learning theory. Participant comprehension was assessed in an interactive teachback format. The iConsent application achieved nine of ten proposed desiderata for effective patient-focused electronic consenting for genomic research.

Overall, participants demonstrated high comprehension and retention of key human subjects' considerations. Enrollees reported high levels of satisfaction with the iConsent, and we found that participant comprehension, iConsent clarity, privacy protections, and study goal explanations were associated with overall satisfaction. Although opportunities exist to optimize iConsent, we show that such an approach is feasible, can satisfy multiple stakeholder requirements, and can realize high participant satisfaction and comprehension while increasing study reach.

Piloting electronic informed consenting in a pneumococcal human infection study in Blantyre, Malawi

Research Article

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Open Access

Abstract

Background

Electronic consent can potentially improve accuracy, workflow, and overall patient experience in clinical research but has not been used in Malawi, owing to uncertainty about data security and technical support.

Objectives

We explored the feasibility of using electronic consent (e-consent) in an ongoing human infection study in Blantyre Malawi. We dual-consented participants by both electronic and paper methods to assess the feasibility of electronic consent, and then compared benefits and challenges of the two methods.

Methods

The approved paper consent forms were digitized using Open Data Kit (ODK). Following participant information giving by the research staff, healthy literate adult participants with no audio-visual impairments completed a self-administered e-consent and provided an electronic signature. Signed e-consent forms were uploaded to a secure study server. While the participants were in clinic, the signed electronic consent form was printed as a copy for the participant. The feasibility, advantages and disadvantages including data safety consideration for e-consenting were evaluated by exploring issues surrounding use of e-consenting versus paper-based consenting. Consent forms were analysed by research staff for errors such as overwriting and legibility.

Results

We piloted 109 participants to e-consenting. It was found to be user friendly, had 0% (n 0/109) errors compared to 43.1% (n 47/109) in paper based methods along with enhanced data safety. The challenges

included difficult digitization of ethics stamped documents, volunteer unfamiliarity with tablet user interface and its requirement for a working internet and printer.
Conclusion
E-consenting was feasible but required additional resource investment. Benefits included error minimization and data security.

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UPCOMING CALLS FOR PUBLIC CONSULTATION

We will selectively include calls for public consultation from multilateral agencies, governments, INGOs and other sources where there is a clear intersection with consent/assent. This might be obvious from the title of the draft guidance, regulations, etc., but more often, it will be a thematic area or topic – if properly addressed at all. If you would like to explore participation with our working group developing submissions for these calls, please contact us [david.r.curry@ge2p2global.org].

Request for Information: Soliciting Input on Opportunities, Gaps, and Challenges in Global Health Research in Neurological Diseases and Stroke

Notice Number: NOT-NS-24-018 Response date: July 1, 2024
The National Institute Neurological Diseases and Stroke (NINDS) has released a Request for Information from all stakeholders to identify global health research priorities, capacity building and training needs, and best practices or strategies that could facilitate equitable global health research in neurological disorders.
Information requested
This RFI is intended to help NINDS identify global health research priorities, capacity building and training needs, and best practices or strategies that could facilitate equitable global health research in neurological disorders. The NINDS invites input from all stakeholders, including researchers, health care providers, people with lived experience (e.g., patients with neurological conditions, family members, caregivers), patient advocates, health advocacy organizations, scientific or professional organizations, federal agencies, non-profit and private sector organizations, as well as other interested members of the public. Organizations may consider submitting a response on behalf of the organization or share this RFI link with its members.

Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity in Access Planning

Posted on May 21, 2024 Comments must be received by July 22, 2024
NIH is proposing to develop and implement a new policy within the NIH's Intramural Research Program, the internal research arm of the agency. The policy would require organizations partnering with NIH through a patent licensing agreement that succeed in bringing certain products to market to submit a plan outlining steps they intend to take to promote patient access to any resulting drug, biologic, vaccine, or device. NIH seeks input on this draft policy and accompanying draft license agreement language that incorporates patient access in the commercialization process for NIH-owned inventions.
NIH will use the responses to this request for information to develop a final policy. Comments on the proposed policy must be submitted at: https://osp.od.nih.gov/comment-form-draft-nih-intramuralresearch-program-policy-promoting-equity-through-access-planning.
In addition, NIH will be hosting an informational webinar on the proposed policy on June 11, 2024. More information on the agenda and how to register will be provided shortly.

For additional context on the benefits of access planning, please see NIH's 2023 Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. Questions may be sent to SciencePolicy@od.nih.gov.

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NEW NORMATIVE/ REGULATORY GUIDANCE REFERENCING CONSENT

Informed Consent for Research Using Digital Health Technologies: Points to Consider & Sample Language

National Institute of Health, May 2024

Key Points

- This resource provides points to consider and sample language for informed consent of research studies which plan to use digital health technologies. The use of this resource is completely voluntary.
- The considerations and sample language provided in this resource may not apply to all studies or cover all potential contexts of use. Users of this resource should apply relevant considerations/sample language as applicable to their study. Points to consider and sample language below are included in the most relevant sections, although they may be relevant to multiple sections.
- This resource does not take the place of an informed consent document. The considerations and sample language included in this resource are specific to the inclusion of digital health technologies in a study; other general and population-specific informed consent considerations and language still apply. The sample language provided in this resource should be tailored for individual studies and may need further revision or clarification when used in an informed consent.
- The sample language provided in this resource does not alone satisfy the regulatory requirements for informed consent as described in the 2018 revised Common Rule at 45 CFR46.116 or the FDA's regulations governing the protection of human participants (i.e., 21 CFR parts 50 and 56).
- Within this resource, the term digital health technology refers to wearable devices, sensor technologies, and mobile software applications ("apps") most often used with tablets, watches, or phones. The resource does not address considerations for implantable devices, artificial intelligence, or other types of digital health technologies.
- This consent resource does not address future use of data collected from digital health technologies, which may have additional considerations when developing or reviewing informed consent.

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SYMPOSIA/CONFERENCES

We will selectively include information on major symposia and conferences which address issues, evidence, analysis or debates involving consent/assent. This listing will include [1] meetings already concluded but which are posting presentations/recordings, etc.; [2] future meetings which have posted registration/logistics information, and [3] meetings which have announced calls for abstracts/panels, etc.

No new symposia/conferences identified.

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