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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

December 2022 :: Issue 48

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

In preparing this digest, we monitor *Google Scholar* 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:

COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT

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

COVID-19

Informed Consent for Risk of COVID-19 in Preoperative Trauma Patients

J. Harvey, A. Sheokand, R. Rambani

Orthopaedic Proceedings, 14 November 2022; 104

Open Access

Abstract

Introduction

The risk of Covid-19 community and hospital acquired infection (HAI) on patient outcomes in trauma is still relevant. Patient's should be routinely consented for this risk to ensure informed consent for perioperative contraction.

Method

A prospective audit was completed from December-March 2022 examining a consecutive series of patient admissions with capacity to consent. The standards for compliance was RCOS Toolkit 5#3 stating the importance of enhanced consent for risk of contraction, in operating and changes to care pathways. The target was 95% compliance. 2/2 contingency tables were generated to determine odds ratio for compliance versus Covid+ rate.

Results

This audit generated 80 consecutive patients from which 28 were excluded as non-operative or lacking capacity. It was found that 25% (13/52) had been specifically consented for risks of Covid-19. The rate of PCR-positive results was 15% (8/52) with a mortality of 25%. Approximately 2% of patients in this series were informed of the risk and had a positive Covid-PCR. An odds ratio of 0.38 indicates that being informed of the risk is not associated with rate of infection e.g by adopting enhanced personal protective measures.

Conclusions

The pandemic recovery has not removed this substantial community and nosocomial risk. Our results demonstrate poor compliance with RCS guidance despite ongoing relevance to care. Consent includes the counselling of a patient to specific Covid-related risks including thrombosis & death. Dissemination of these results will be followed by completion of the audit cycle to look for improvements in compliance.

Informed Consent in Mass Vaccination against COVID-19 in Romania: Implications of Bad Management

Sînziana-Elena Bîrsanu, Maria Cristina Plaiasu, Codrut Andrei Nanu

Vaccines, 5 November 2022; 10(11)

Abstract

Informing patients and obtaining valid informed consent were significant challenges for the COVID-19 immunization program. In Romania, the authorities issued a strategy for activities regarding vaccination against COVID-19, including the informed consent procedure. The lack of legal preparedness was evident when the medical personnel at the vaccination centers were provided with informed consent forms that did not respect the existing legal requirements. In addition, the protocol for persons seeking vaccination stated that the patient was supposed to receive the informed consent form from the receptionist in order to read and sign it. We analyzed the legal implications and the malpractice litigation risk associated with this practice. Due to essential deficiencies and in the absence of an official enactment of new regulations, we conclude

that the vaccination consent process did not comply with the legal requirements. Implications include medical personnel's legal liability, loss of malpractice insurance coverage, and public mistrust that may have contributed to a low vaccination rate. Given the potential of future pandemics or other health crises, this may be a valuable lesson for developing better legal strategies.

The approach to informed consent in acute care research

Correspondence
Rafael Dal-Ré, Arthur L Caplan
Lancet Respiratory Medicine, 3 November 2022
Open Access
Excerpt
In their discussion of the contrasting responses of the UK and the USA to the unprecedented situation posed by the COVID-19 pandemic—and the urgent need for randomised controlled trials to guide clinical practice—Jonathan D Casey and colleagues state that the Randomised Evaluation of COVID-19 Therapy (RECOVERY) trial was approved "with an alteration of informed consent" to facilitate enrolment. We are concerned that this statement could confuse clinical investigators and research ethics committee members…

> *Editor's note: The article referenced in this correspondence is Casey JD Beskow LM Brown J et al. Use of pragmatic and explanatory trial designs in acute care research: lessons from COVID-19. Lancet Respir Med. 2022; 10: 700-714.*

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BIOMEDICAL RESEARCH

Co-creation of information materials within the assent process: From theory to practice

Jaime Fons-Martinez, Cristina Ferrer-Albero, Javier Diez-Domingo
Health expectations : an international journal of public participation in health care and health policy, 23 November 2022
Open Access
Abstract
Introduction
The informed consent process is key to safeguarding the autonomy of the participant in medical research. For this process to be valid, the information presented to the potential participant should meet their needs and be understood by them. The i-CONSENT project has developed 'Guidelines for adapting the informed consent process in clinical trials' which aim to improve informed consent so that they are easier to understand and better adapted to the needs and preferences of the target population. The best way to tailor information to the characteristics and preferences of the target population is to involve the community itself.
Methods
Following guidelines developed by i-CONSENT, assent materials were co-created for a mock clinical trial of the human papillomavirus vaccine in adolescents. During the process, two design thinking sessions were conducted involving a total of 10 children and 5 parents. The objectives of the sessions were to find out the children's opinion of the informed consent (assent in their case) process in clinical trials, identify the parts that were most difficult to understand and alternatives for their presentation and wording, identify the preferred formats for receiving the information and the main characteristics of these formats, design a video explaining the clinical trial and evaluate a tool for assessing comprehension.
Results
Assent materials were co-created in three formats: a web-based material following a layered approach; a video in story format; a pdf document with an innovative way of presenting information compared to

traditional assent documents. In addition, the Comprehension of Assent Questionnaire was co-designed, based on the Quality of Informed Consent questionnaire.

Conclusion

The design thinking methodology has proven to be an easy and useful tool for involving children in designing information tailored to their needs and preferences.

Patient or public contribution

A sample of the target population participated in the design and piloting of the materials created using design thinking methodology. In addition, patient representatives participated in the design and evaluation of the guidelines developed by the i-CONSENT project that were followed for the development of the materials in this study.

Using provocative design to foster electronic informed consent innovation

Research

Evelien De Sutter, Stef Verreydt, Koen Yskout, David Geerts, Pascal Borry, An Outtier, Marc Ferrante, Corinne Vandermeulen, Nele Vanmechelen, Bart Van der Schueren, Isabelle Huys

BMC Medical Informatics and Decision Making, 17 November 2022; 22(296)

Open Access

Abstract

Background

The development of technological applications in clinical research, such as electronic informed consent (eIC), is on the rise. The involvement of end users throughout the design process of eIC is of utmost importance to improve the current informed consent process.

Methods

Using a provocative design, we conducted interviews with 30 clinical research participants. Provotypes were used as a starting base to discuss various aspects relevant to eIC. By providing a medium to encourage divergent thinking, participants' views and concerns were solicited. Thematic analysis was undertaken using NVivo.

Results

The majority of participants placed trust in the principal investigator or the hospital to perform the role of eIC hosting party. Differing opinions were reported on the amount of information required related to stakeholders' access to an eIC system, and thus, to participants' personal data, to enable trust in an eIC system. Nevertheless, this study indicates a general willingness of participants to share personal data with physicians and pharmaceutical companies on an international level, and to receive requests for new research studies via an eIC system. Participants suggested to tailor an eIC system based upon their preferences, for example, regarding whom they want to share their personal data with. Moreover, they expressed a desire to choose how they can contact the research team, and to indicate which study-related information they would like to receive electronically. In addition, positive opinions were voiced on the integration of a test to assess participants' understanding before providing their eIC.

Conclusions

Following a research through design approach, insights have been generated which inform the design of eIC. Provotypes were designed to help participants think beyond what is familiar to them. Study findings revealed that not all situations were perceived as provocative, because of participants' motivation to advance scientific research and the trust they place in the research team. Nevertheless, the use of provocative design resulted in additional insights, generated by clinical research participants, which could be considered in the further design of eIC.

Overcoming barriers to informed consent in neurological research: Perspectives from a national survey

Research Article

Lauren R Sankary, Megan E Zelinsky, Paul J Ford, Eric C Blackstone, Robert J Fox

Research Ethics, 30 October 2022

Open Access

Abstract

The ethical recruitment of participants with neurological disorders in clinical research requires obtaining initial and ongoing informed consent. The purpose of this study is to characterize barriers faced by research personnel in obtaining informed consent from research participants with neurological disorders and to identify strategies applied by researchers to overcome those barriers. This study was designed as a web-based survey of US researchers with an optional follow-up interview. A subset of participants who completed the survey were selected using a stratified purposeful sampling strategy and invited to participate in an in-depth qualitative interview by phone or video conference. Data were analyzed using a mixed methods approach, including content analysis of survey responses and thematic analysis of interview responses. Over 1 year, 113 survey responses were received from US research personnel directly involved in obtaining informed consent from participants in neurological research. Frequently identified barriers to informed consent included: cognitive and communication impairments (e.g. aphasia), unrealistic expectations of research participants, mistrust of medical research, time constraints, literacy barriers, lack of available social support, and practical or resource-related constraints. Strategies to enhance informed consent included: involving close others to support participant understanding of study-related information, collaborating with more experienced research personnel to facilitate training in obtaining informed consent, encouraging participants to review consent forms in advance of consent discussions, and using printed materials and visual references. Beyond conveying study-related information, researchers included in this study endorsed ethical responsibilities to support deliberation necessary to informed consent in the context of misconceptions about research, unrealistic expectations, limited understanding, mistrust, and/or pressure from close others. Findings highlight the importance of training researchers involved in obtaining informed consent in neurological research to address disease-specific challenges and to support the decision-making processes of potential research participants and their close others.

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HEALTH DATA

An e-consent framework for tiered informed consent for human genomic research in the global south, implemented as a REDCap template

Database

Tsaone Tamuhla, Nicki Tiffin, Taryn Allie

BMC Medical Ethics, 24 November 2022; 23(119)

Open Access

Abstract

Research involving human participants requires their consent, and it is common practice to capture consent information on paper and store those hard copies, presenting issues such as long-term storage requirements, inefficient retrieval of consent forms for reference or future use, and the potential for transcription errors when transcribing captured informed consent. There have been calls to move to electronic capture of the consent provided by research participants (e-consent) as a way of addressing these issues. A tiered framework for e-consent was designed using the freely available features in the inbuilt REDCap e-consent module. We implemented 'branching logic', 'wet signature' and 'auto-archiver' features to the main informed consent and withdrawal of consent documents. The branching logic feature streamlines the

consent process by making follow-up information available depending on participant response, the 'wet signature' feature enables a timestamped electronic signature to be appended to the e-consent documents and the 'auto-archiver' allows for PDF copies of the e-consent documents to be stored in the database. When designing the content layout, we provided example participant information text which can be modified as required. Emphasis was placed on the flow of information to optimise participant understanding and this was achieved by merging the consent and participant information into one document where the consent questions were asked immediately after the corresponding participant information. In addition, we have provided example text for a generic human genomic research study, which can be easily edited and modified according to specific requirements. Building informed consent protocols and forms without prior experience can be daunting, so we have provided researchers with a REDCap template that can be directly incorporated into REDCap databases. It prompts researchers about the types of consent they can request for genomics studies and assists them with suggestions for the language they might use for participant information and consent questions. The use of this tiered e-consent module can ensure the accurate and efficient electronic capture and storage of the consents given by participants in a format that can be easily queried and can thus facilitate ethical and effective onward sharing of data and samples whilst upholding individual participant preferences.

Toward Dynamic Consent for Privacy-Aware Pervasive Health and Well-being: A Scoping Review and Research Directions

Hyunsoo Lee, Uichin Lee

IEEE Pervasive Computing, 2022; pp 1-8

Abstract

Recent advances in sensor-enabled services have facilitated the use of mobile, wearable, and IoT devices; for example, an extensive range of sensor data are used to automatically track symptoms and diagnose health and well-being status of an individual (e.g., depression). As personal data are being continuously and unobtrusively sensed and collected at large scale, this raises privacy concerns in certain contexts (e.g., GPS data collection at privacy-sensitive places). Current one-off informed consent in such pervasive sensing scenarios does not offer context-awareness support that enables selective data disclosure based on a user's needs or preferences (e.g., disabling GPS data collection when visiting hospitals). A lack of context-awareness support in informed consent would be a critical barrier to user acceptance of data-intensive pervasive computing for health and well-being. As an alternative method, we introduce the concept of "dynamic consent," a type of informed consent that enables granular data consent and management, initially introduced in biomedical research for patient data management. We explore how this consent practice within biomedical research might inform usable privacy designs in pervasive computing by conducting a scoping review of dynamic consent literature and discussing future research directions.

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BIOBANKING

A Preliminary Study to Explore the Informed Consent Approach and the Ethical Challenges in the Malaysian Biobanking for Research

Amnah Azahar, Aimi Nadia Mohd Yusof, Zahir Izuan Azhar

Asian Bioethics Review, 8 November 2022

Open Access

Abstract

Since 2005, Malaysia has established several biobanks to keep in line with the advancement of biomedical research and development of biobanks in other countries such as the UK and the USA. Despite the

establishment of several biobanks in Malaysia, little is known about the informed consent approach in biobanking research and its ethical challenges. This study aims to identify the approach in obtaining informed consent in the Malaysian biobanking for research and explore its ethical challenges. Using non-probability purposive sampling, an in-depth interview with the key informants was conducted in Klang Valley. Based on the interviews, broad consent is the main approach used in obtaining informed consent in biobanking for research in Malaysia and five major ethical challenges were identified. These challenges include the informants' opinion on the current informed consent approach, understanding participants' rights, the role of the research ethics committee, biobanking governance in Malaysia, and informants' knowledge and awareness. In summary, there is a lack of understanding among those involved in biobanking on the ethical, legal, and social aspects of biobanking for research in Malaysia.

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GENOMIC MEDICINE/GENE EDITING

Equitable and Informed Consent in Genetic Studies

Editor's Note
Ann Marie Navar, Sadiya S. Khan
JAMA Cardiology, 16 November 2022
Excerpt
…Importantly, these participants comprised an already highly selected population in whom higher levels of both genetic knowledge and researcher trust would be expected. Participants were recruited largely from tertiary care academic centers, were cared for by a heart failure program, and had consented to undergo whole-exome sequencing. Despite this, several knowledge gaps were identified. For example, 1 in 5 patients believed that once a genetic variant is found, disease can always be prevented or cured. Genetic knowledge was also lower in Hispanic participants and non-Hispanic Black participants compared with non-Hispanic White participants. Reasons for this are unknown, likely multifactorial, and may include differences in exposure to prior education about genetics, disparities in prior referrals for genetic counseling, and differences in the effectiveness of the informed consent process in addressing gaps in knowledge about genetic testing…

Core elements of participant consent documents for Canadian human genomics research and the National Human Genome Library: guidance for policy

Holly Longstaff, Jaime Flamenbaum, Etienne Richer, Jeanne Egar, Christopher R. McMaster, Ma'n H. Zawati
Canadian Medical Association Journal, 15 November 2022; 194(44)
Open Access
Excerpt
…The purpose of this guidance for policy is to present a core set of elements for participant consent documents to be used in local human genome–based research projects across Canada and to support the development of the national CHGL. These core elements can be also used as a research ethics tool when evaluating human genome–based research projects…

Sharing genomic data for health research: institutional trust and trustworthiness, and informed consent

Mackenzie Graham
Canadian Medical Association Journal, 15 November 2022; 194(44)
Open Access

Excerpt

Recent years have seen a dramatic increase in the collection, storage and curation of human genomic data for biomedical research. These data sets hold great promise for research into the genetic basis of disease, and represent more diverse populations than have traditionally been accessible in research. Large-scale federated data networks like the proposed Canadian Human Genome Library (CHGL) represent a potential way of providing secure access to these data to researchers beyond select institutions. However, the promise of human genomics research has been encumbered by ethical concerns about data sharing. One particular concern is whether it is possible to obtain informed consent to the population-level research that genomic databases like the CHGL are intended to facilitate.

Participants in genome-based research or patients who receive genome or exome sequencing as part of their clinical care may be asked to consent to allow their data — not only genomic data but associated clinical or administrative data stored by an institution — to be made available to future researchers. Because the future uses of these data are unknown at the time of data collection, concern has been raised about whether consent for this future data use is, or can be, informed…

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CAPACITY TO CONSENT

Importance of decisional capacity tools in obtaining informed consent in clinical settings

Original Article
Miroslav Radenković
Bioethics, 24 November 2022
Open Access
Abstract
Informed consent represents a specific protocol for obtaining consent from a fully informed human subject to take part in clinical research. Still, informed consent is not only required for clinical trials but it also represents a critical precondition before enrolment in standard everyday medical procedures. Relevant fundamental criteria for obtaining informed consent must be followed, and that is that patient must have the decisional capacity to reach autonomous decision. The patient must be adequately informed and not coerced. Evaluating decisional capacity is crucial to providing the required level of care. The decision of which decisional capacity tool to use can be challenging because of various dissimilarities among the instruments. In this paper, four widely documented instruments have been evaluated, namely, the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), the Hopkins Competency Assessment Test (HCAT), the Structured Interview for Competency/Incompetency Assessment Testing, Ranking Inventory (SICIATRI), and the Capacity Assessment Tool (CAT). Some of them include a fully structured interview; semi-structured forms characterise others. Most of them are adaptable for different scenarios, and yet, some are tailored for specific treatment decisions. Some evaluate all four components of decisional capacity, while others do not. Although a broad range of capacity assessment tools is available, it has been shown that they notably improve the accuracy of capacity evaluations. Given that many pathological conditions could result in impaired decisional capacity, physicians must be able to correctly and consistently assess the capacity for which education and previous experience are pivotal.

Working in a gray area—Healthcare staff experiences of receiving consent when caring for persons with dementia

Research Article
Lena Östlund, Marie Ernsth Bravell, Linda Johansson
Dementia, 15 November 2022
Abstract

Background
Every person has the right to autonomy, and to be involved in decisions about their care. When persons with dementia have difficulties in expressing what they want, their autonomy is challenged. Staff should strive to involve the person in care decisions, to obtain consent and to avoid the use of coercion and restraints. However, care without consent exists and coercion and restraints are being used. In order to improve care, further knowledge is warranted.
Aims
The purpose of this study was to explore staff's experiences of obtaining consent when caring for persons with dementia.
Methods
In total 14 focus group interviews were conducted with staff with experience of dementia care who work in either home care or residential care in Sweden. An inductive qualitative content analysis was used to analyze the collected data.
Results
Three categories were generated describing staff experiences of consent in dementia care: the person as the decision-maker, the staff as the decision-makers, and the viability of the consent. Overall, staff found it difficult to know if they really had consent from the individual. Even if the person verbally gave consent, it was challenging to know if the person really understood what they had consented to. Common to all three categories was the significance of the relationship between the person with dementia and staff: getting to know the person, recognizing the person's response in terms of their facial expressions and body language as well as being able to explain and justify specific actions to the person.
Conclusion
Staff need better conditions in dementia care, including training and time to reflect on how to obtain consent. A person-centered approach can be one way to develop care and ensure that persons with dementia are allowed autonomy and to share in making decisions.

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YOUNG PERSONS

A Bioethics Framework for At-risk Child/Adolescent Access to Key Reproductive Health Services Without Parental Consent

Forouzan Akrami, Alireza Zali, Mahmoud Abbasi
Iranian Journal of Pediatrics, December 2022; 32(6)
Open Access
Abstract
Context
Access of adolescents to key reproductive health services (KRHS) has been emphasized; however, how to provide it has not been addressed. This study aimed to propose a bioethics framework to justify at-risk child/adolescent access to KRHS without parental consent.
Evidence Acquisition
First, articles and documents were searched using the age of consent laws, reproductive health, and ethical/legal standards phrases with AND/OR separators in PubMed and Web of Science using the Google Scholar search engine in English. After a concise review of the age of consent in child/adolescent-related laws, at-risk child/adolescent access to KRHS without parental consent was justified using major ethical and legal principles and standards.
Results
Given the different purposes and nature of harm preventive services, in the first part, the authors argue that considering the age of consent for at-risk adolescents' access to KRHS is a limiting and inefficient factor, and KRHS could be provided for the at-risk adolescent with his/her own assent. In the second part, the authors

argue that in decision-making for at-risk adolescents' access to KRHS, the best interest standard is applicable on the ground of harm standard. Regarding the sociocultural context of the community, after assessing the seriousness of the harm and the threshold of intervention, practical steps are taken toward reducing or removing harm and choosing the option that best promotes adolescents' interests.
Conclusions
Regarding the existence of restrictive laws, the suggested framework can be applied in different communities as a bioethics policy guide for legislation and appropriate actions of adolescents' healthcare professionals.

What information and the extent of information to be provided in an informed assent/consent form of pediatric drug trials

Research article
Nut Koonrungsesomboon, Pimlak Charoenkwan, Rungrote Natesirinilkul, Kanda Fanhchaksai, Wannachai Sakuludomkan, Nimit Morakote
BMC Medical Ethics, 16 November 2022; 23(113)
Open Access
Abstract
Background
This study aimed to determine the elements and the extent of information that child participants and their parents would like to read in an informed assent form (IAF)/informed consent form (ICF) of a pediatric drug trial.
Methods
A descriptive survey was conducted to determine the perceived importance of each element of the ICF content from child participants and their parents who underwent informed assent/consent of a multi-center pediatric drug trial. The respondents were asked to indicate the level of importance of each item in a questionnaire, by giving a rating scale from 1 (not important) to 5 (very important).
Results
A total of 22 families, 17 child participants with the diagnosis of hematology or oncology diseases and 27 parents, were enrolled. Among 30 items, risk–benefit aspects (i.e., direct health benefit [mean: 4.71 for child respondents, 4.89 for parent respondents], indirect/societal benefit [mean: 4.65, 4.85], major foreseeable risk [mean: 4.47, 4.78], post-trial benefit/provision [mean: 4.59, 4.74], and all adverse effects of the drug including uncommon adverse effects [mean: 4.53, 4.74]) were perceived to be of most concerning items from both child participants' and parents' viewpoint. None of the items were considered 'slightly important' or lower by more than 20% of the respondents.
Conclusions
For pediatric drug trials, risk–benefit information (including direct health benefit, indirect/societal benefit, and post-trial benefit/provision, as well as major foreseeable risk and adverse effects of the drug) should be made a salient feature of an IAF/ICF. This empirical data could help related stakeholders arrange essential information in order of importance and tailor an IAF/ICF to better suit child participants' and parents' needs, particularly for pediatric drug trials involving children with the diagnosis of hematology or oncology diseases.

Operationalization of assent for research participation in pre-adolescent children: a scoping review

Research
Florence Cayouette, Katie O'Hearn, Shira Gertsman, Kusum Menon
BMC Medical Ethics, 3 November 2022; 23(106)
Open Access
Abstract
Background

Seeking assent from children for participation in medical research is an ethical imperative of numerous institutions globally. However, none of these organizations provide specific guidance on the criteria or process to be used when obtaining assent. The primary objective of this scoping review was to determine the descriptions of assent discussed in the literature and the reported criteria used for seeking assent for research participation in pre-adolescent children.

Methods

Medline and Embase databases were searched until November 2020 using the term "assent" in the title or abstract. Inclusion criteria were (1) studies enrolling children which specifically described operationalization of the assent process and (2) studies of the assent process which provided a description of assent. Data collected included participant information, patient criteria for seeking assent, guidelines referenced, description of assent reported, how assent was obtained and assent information presented, and reported assent rate. For qualitative articles focusing on the assent process, important themes were identified.

Results

A total of 116 articles were included of which 79 (68.9%) operationalized assent and 57 studies (%) described the assent process. The most commonly reported criterion used to determine the ability of a child to assent was age (35.4%, 28/79). The reported minimal age for obtaining pediatric assent varied considerably across and within jurisdictions (5–13 years; median 7.5 years, IQR 7.0, 9.75). Cognitive ability was reported as a criterion for obtaining assent in 5.1% (4/79) of studies. Assent rates were only reported in 17.7% (14/79) of citations and ranged from 32.0 to 100%. Analysis of the 57 studies describing the assent process identified several themes, including age thresholds, assessment of capacity, variable knowledge of pediatric assent and parental roles.

Conclusion

We found significant variation in criteria used for assessment of patient capacity, delivery of information used to obtain assent and documentation of the assent process. While we acknowledge that individual children, settings and jurisdictions may require different approaches to obtaining assent, there should be agreement on important principles to be followed with resulting common guidance on assessing capacity, delivering information and documentation of the assent process for publication.

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TECHNOLOGY/OTHER MEDIATION

A Video-Based Consent Tool: Development and Effect of Risk–Benefit Framing on Intention to Randomize

Alex Lois, Jonathan E. Kohler, Sarah E. Monsell, Kelsey M. Pullar, Jesse Victory, Stephen R. Odom, Katherine Fischkoff, Amy H. Kaji, Heather L. Evans, Vance Sohn, Lillian S. Kao, Shah-Jahan Dodwad, Anne P. Ehlers, Hasan B. Alam, Pauline K. Park, Anusha Krishnadasan, David A. Talan, Nicole Siparsky, Thea P. Price, Patricia Ayoung-Chee, William Chiang, Matthew Salzberg, Alan Jones, Matthew E. Kutcher, Mike K. Liang, Callie M. Thompson, Wesley H. Self, Bonnie Bizzell, Bryan A. Comstock, Danielle C. Lavallee, David R. Flum, Erin Fannon, Larry G. Kessler, Patrick J. Heagerty, Sarah O. Lawrence, Tam N. Pham, Giana H. Davidson

Journal of Surgical Research, March 2023; 283 pp 357-367

Abstract

Introduction

Nearly 75% of clinical trials fail to enroll enough participants, and cohorts often fail to reflect the clinical and demographic diversity of at-risk populations. Effective recruitment strategies are critically important for successful clinical trials. Framing treatment risks are known to affect medical decision-making for both physicians and patients but has not been rigorously studied in surgical trials. We sought to examine the impact of a high-quality video-based consent tool and the effect of risk–benefit framing on patient willingness to participate in a surgical clinical trial.

Methods

A standardized video consent was shown to all potential participants in the Comparison of Outcomes of antibiotic Drugs and Appendectomy (CODA) trial, a randomized controlled trial comparing antibiotics and surgery for acute appendicitis. We report (1) differences in recruitment between two versions of a video-based tool that differed in production quality and (2) the impact of risk–benefit framing on participant randomization rates. The reasons for declining randomization were also assessed.

Results

Of 4697 eligible patients approached to participate in the CODA trial, 1535 (33% [95% confidence interval (CI): 31%-34%]) agreed to randomization; this did not change from video version 1 to version 2. There was no difference in participation between positively framed videos (32% [95% CI: 30%-34%]) versus negatively framed videos (33.0% [95% CI: 30.8-35.2]). The most common reason for declining participation was treatment preference (72% for surgery and 18% for antibiotics).

Conclusions

Neither the change from video 1 to video 2 nor the positive versus negative framing affected participant willingness to randomize. The stakeholder-informed video-based consenting tool used in CODA was an effective strategy for the recruitment of a heterogeneous patient population within the proposed study period.

Electronic informed consent criteria for research ethics review: a scoping review

Research

Mohd Yusmiaidil Putera Mohd Yusof, Chin Hai Teo, Chirk Jenn Ng

BMC Medical Ethics, 21 November 2022; 23 (117)

Open Access

Abstract

Background

The research shows a growing trend in using an electronic platform to supplement or replace traditional paper-based informed consent processes. Instead of the traditionally written informed consent document, electronic informed consent (eConsent) may be used to assess the research subject's comprehension of the information presented. By doing so, respect for persons as one of the research ethical principles can be upheld. Furthermore, these electronic methods may reduce potential airborne infection exposures, particularly during the pandemic, thereby adhering to the beneficence and nonmaleficence principle. This scoping review aims to identify the ethics related criteria that have been included in electronic informed consent processes and to synthesize and map these criteria to research ethics principles, in order to identify the gaps, if any, in current electronic informed consent processes.

Methods

The search was performed based on internet search and three main databases: PubMed, SCOPUS and EBSCO. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation guideline was used to report this work.

Results

Of 34 studies that met the inclusion criteria, 242 essential original constructs were collated, and 7 concepts were derived. Digital content showed the highest percentage of collated original constructs (27%, n = 65) followed by accessibility (24%, n = 56), comprehension engagement (18%, n = 43), autonomy (14%, n = 34), confidentiality (11%, n = 25), language (5%, n = 13), and parental consent (1%, n = 2). Twenty-five new items were synthesized for eConsent criteria which may provide guidance for ethical review of research involving eConsent.

Conclusion

The current study adds significant value to the corpus of knowledge in research ethics by providing ethical criteria on electronic informed consent based on evidence-based data. The new synthesized items in the criteria can be readily used as an initial guide by the IRB/REC members during a review process on electronic informed consent and useful to the future preparation of a checklist.

Learning to listen: A complementary approach to informed consent for patients with visual impairments

Forum

Kayo Takashima, Takeshi Soma, Kaori Muto, Kohji Nishida, Jusaku Minari

Stem Cell Reports, 10 November 2022

Open Access

Excerpt

This forum describes an exploratory approach for assisting individuals with visual impairment during the informed consent (IC) process to participate in a cutting-edge trial. Our approach has been developed to focus on potential participants' preparedness to give IC, along with the creation of supporting audio material…

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RIGHTS/LEGAL/LEGISLATIVE

Body donation in Italy and the issue of consent: Operational suggestions

Gianluca Montanari Vergallo, Vittoria Masotti, EnricoMarinelli

Legal Medicine, February 2023; 60

Abstract

The authors aimed to analyze the Italian law of 10 February 2020, n. 10, which governs the post mortem donation of one's body and tissues for training, educational and scientific research purposes. The different models of consent set forth in this set of norms are discussed, reaching the conclusion that the most suitable option for balancing the interests at stake is the one that authorizes all uses of the body for the sole purposes expressly permitted by the donor. After briefly laying out the current legislation on the subject, particularly regarding the ways of expressing consent, the authors highlight how the legislation enacted by Italian lawmakers is meant to codify the absolute preeminence to the donor's right to self-determination.

Italian law n. 219/2017 on consent and advance directives: survey among Ethics Committees on their involvement and possible role

Research

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BMC Medical Ethics, 16 November 2022; 23(114)

Open Access

Abstract

Background

On December 2017 the Italian Parliament approved law n. 219/2017 "Provisions for informed consent and advance directives" regarding challenging legal and bioethical issues related to healthcare decisions and end-of-life choices. The law does not contain an explicit reference to Ethics Committees (ECs), but they could still play a role in implementing the law.

Methods

A questionnaire-based survey was performed among the ECs of the Italian Institute for Research and Care belonging to the Network of neuroscience and neurorehabilitation, with the aim of (1) knowing whether the ECs participated and, if so, how in the process of implementation of law n. 219/2017 in the referring institutes; (2) investigating the point of view of the ECs regarding their possible involvement in the process; (3) exploring the contribution ECs can provide to give effective implementation to the law principles and provisions.

Results
Seventeen ECs out of thirty took part in the survey; the characteristics of the responding and non-responding committees are similar, so the responding ECs can be regarded as representative of all ECs in the Network. Nine ECs did not discuss the law in anyway: the main reason for this is that the referring institutions (6) and the health care professionals (3) did not ask for an EC intervention. Nevertheless, the large majority of the ECs believe that their involvement in the implementation of the law as a whole is appropriate (8) or absolutely appropriate (6), while 3 of them are neutral. No EC believes that the involvement is inappropriate. The aspect of the law on which the 14 ECs converge in considering the EC involvement appropriate/absolutely appropriate is the one related to the health facilities obligation to guarantee the full and proper implementation of the principles of the law.
Conclusions
Our survey confirms that ECs believe they can play a role in the implementation of law n. 219/2017, although this does not entirely correspond to what the committees have actually done in reality. This role could be better exercised by ECs specifically established for clinical practice, which would have a composition, functioning and a mandate better suited to the purpose. This supports the call for a national regulation of ECs for clinical practice.

Attitudes of European students towards family decision-making and the harmonisation of consent systems in deceased organ donation: a cross-national survey

Research
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BMC Public Health, 15 November 2022; 22(2080)
Open Access
Abstract
Background
European countries are increasingly harmonising their organ donation and transplantation policies. Although a growing number of nations are moving to presumed consent to deceased organ donation, no attempts have been made to harmonise policies on individual consent and the role of the family in the decision-making process. Little is known about public awareness of and attitudes towards the role of the family in their own country and European harmonisation on these health policy dimensions. To improve understanding of these issues, we examined what university students think about the role of the family in decision-making in deceased organ donation and about harmonising consent policies within Europe.
Methods
Using LimeSurvey© software, we conducted a comparative cross-sectional international survey of 2193 university students of health sciences and humanities/social sciences from Austria (339), Belgium (439), Denmark (230), Germany (424), Greece (159), Romania (190), Slovenia (190), and Spain (222).
Results
Participants from opt-in countries may have a better awareness of the family's legal role than those from opt-out countries. Most respondents opposed the family veto, but they were more ambivalent towards the role of the family as a surrogate decision-maker. The majority of participants were satisfied with the family's legal role. However, those who were unsatisfied preferred to limit family involvement. Overall, participants were opposed to the idea of national sovereignty over consent policies. They favoured an opt-out policy harmonisation and were divided over opt-in. Their views on harmonisation of family involvement were consistent with their personal preferences.
Conclusions
There is overall division on whether families should have a surrogate role, and substantial opposition to granting them sole authority over decision-making. If European countries were to harmonise their policies on consent for organ donation, an opt-out system that grants families a surrogate decision-making role may enjoy the widest public support.

The Completeness of Informed Consent Form Filling and Protection of Consumer Rights in Hospital Healthcare Services

Anggra Yudha, Ramadianto Barkah, Rosadi Hindun, Nafiah Sindy, Risa Nandiesty, Rulli Saqinah, Nur Windah Fadillah, Frisca Mahrunissa

HIV Nursing, 30 October 2022

Open Access

Abstract

Fulfillment the completeness of filling out the informed consent form is one of the minimum service standards in hospitals, but until now there are some hospitals that have not complied this obligation. This study aims to understand the legal protection of patients' rights as consumers related to the completeness of filling out an informed consent form in medical record services in hospitals. This research uses a normative legal approach through descriptive analysis. The secondary data used in this study were obtained through a study of the literature. The results of the analysis in this study show that the fulfillment of the completeness of filling out the informed consent form is a form of obligation of business actors to fulfill consumer rights which include the right to be treated or served correctly and honestly and not discriminatory and the right to obtain advocacy, protection, and consumer protection dispute resolution efforts properly. The violation of the patient's right to obtain a minimum standard of health services in the form of incomplete filling of the informed consent form is a violation of consumer rights in health services. According to the provisions of the Consumer Protection Law, the settlement of disputes regarding violations of these rights can be carried out through providing compensation to patients by business actors, filing lawsuits by patients, and even criminal charges against business actors. The conclusion obtained in this study is that the completeness of filling out the informed consent form in the medical record service at the hospital contains protection of consumer rights in the form of the right to obtain health services in accordance with the standards in legislation and legal rights. As a protection for the rights of these patients, consumer protection legal instruments in Indonesia require business actors to provide compensation to patients. Consumers are also given the authority to file claims and lawsuits. Based on these conclusions, it can be said that this study provides a new formulation regarding the protection of patient rights as consumers regarding the completeness of filling out an informed consent form in medical record services in hospitals.

Information Privacy in Healthcare — The Vital Role of Informed Consent

Roy McClelland, Colin M. Harper

European Journal of Health Law, 27 October 2022

Abstract

The use and disclosure of patient information is subject to multiple legal and ethical obligations. Within European human rights law the differences relating to consent are reflected in the separate requirements of data protection law, the common law, and professional ethics. The GDPR requires explicit consent. This contrasts with the ethical and common law availability of reliance on implied consent for the use of patient information for that patient’s care and treatment. For any proposed use of patient information for healthcare purposes other than direct care, even where GDPR may be satisfied if the patient refuses to consent to disclosure, the information should not normally be disclosed. For any proposed use or disclosure outside healthcare the justification should normally be consent. However, consent is often not possible or appropriate and an overriding public interest can be relied upon to justify the use or disclosure, both legally and ethically.

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CULTURAL/COUNTRY CONTEXT

Capacity to consent to research among adolescent-parent dyads in Rakai, Uganda

Philip Kreniske, Susie Hoffman, William Ddaaki, Neema Nakyanjo, Esther Spindler, Charles Ssekyewa, Dauda Isabirye, Rosette Nakubulwa, Nabakka Proscovia, Lee Daniel, Nao Haba, Mahlet Maru, Julia Thompson, Ivy S. Chen, Fred Nalugoda, Robert Ssekubugu, Tom Lutalo, Mary A. Ott, John S. Santelli

The Journal of Pediatrics, 17 November 2022

Abstract

Objectives

To assess the cognitive capacity of early, middle, and late adolescents, and their parents or guardians to provide informed consent to a population-based cohort study.

Study design

Adolescent-parent/guardian dyads including 40 early (N = 80; 10-14 years), 20 middle (15-17 years), and 20 late (18-19 years) adolescents were recruited from the Rakai Community Cohort Study (RCCS), an open demographic cohort in Uganda. Participants were administered the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), a structured open-ended assessment; interviews were recorded and transcribed. Twenty transcripts were scored independently by two coders; the intraclass correlation coefficient (ICC) was 0.89. The remaining interviews were scored individually. We compared mean scores for early and middle/late adolescents using a one-sided t-test and score differences between parent/guardian and adolescent dyads using two-sided paired t-tests.

Results

Early adolescents (mean score, 95% confidence interval (CI)) (28.8, 27.1-30.5) scored significantly lower ($p<.01$) than middle/late adolescents (32.4, 31.6-33.1). In paired dyad comparisons, we observed no statistically significant difference in scores between parents/guardians and middle/late adolescents (difference=-0.2, 95% CI=-1.0-0.6). We found a statistically significant difference in scores between parents/guardians and early adolescents (difference=3.0, 95% CI=1.2-4.8).

Conclusions

The capacity of adolescents of different ages and in diverse settings to comprehend risks, benefits, and other elements of informed consent is a critical but understudied area in research ethics. Our findings support the practice of having middle and late adolescents provide independent informed consent for sexual and reproductive health studies. Early adolescents may benefit from supported decision-making approaches.

Status of medical information and patient consent in orthopedic surgery and traumatology at the University Hospital of Burgos (period 2017-2018)

Original Article

Jacobo Salvat Dávila, Juan Salvat Puig, Jesús María Gonçalves Estella, Secundino Vicente González

Spanish Journal of Legal Medicine, 17 November 2022

Abstract

Introduction

The principle of autonomy is the basis of the informed consent concept. Informed consent is a patient´s right consisting in prior to the medical intervention being carried out on his body, he must express his agreement that it must be preceded by the proper information that allows him to decide according to his interests. In this work, our objective was to know the status of medical information and informed consent of the patient in the Traumatology and Orthopedic Surgery Service of the University Hospital of Burgos.

Material and methods

An anonymous questionnaire was prepared and distributed among 647 orthopedic surgery and trauma patients at the University Hospital of Burgos. Subsequently, a descriptive, cross-sectional, observational quantitative study was carried out. The association of sociodemographic variables with the responses to the questionnaire items was studied.

Results

Only 28.9% of the patients know that information is a right, but the majority (97.3%) expressed the need to receive information on risks and complications of the treatment and consider that the information does not increase fear or anxiety (63.4%). The majority stated that they were informed about the care performance (98.1%), understanding the explanations received (98.0%). The time used was sufficient (73.7%). In general, the information received was rated as sufficient (89.8).

Conclusions

Most of the patients felt informed and considered that the time that the doctor had had for this was sufficient.

A qualitative exploration of obtaining informed consent in medical consultations with Burma-born women

Anna Power, Amita Tuteja, Lester Mascarenhas, Meredith Temple-Smith

Australian Journal of Primary Health, 7 November 2022

Abstract

Background

Conciliatory attitudes, respect for medical professionals and avoidance of being direct can make health consultations with Burma-born patients difficult to navigate. Coupled with linguistic barriers, this may make the sensitive nature of many women's health consultations challenging. Little is known about current practices for obtaining informed consent in this context. The objectives of this study were to explore current practices, barriers and strategies to obtaining informed consent in medical consultations with women born in Burma.

Methods

Purposive and snowball sampling was used to recruit health practitioners (n=15, 2 male, 13 female) of different ages, years of professional experience, and country of origin, from clinics in Victoria that see a high volume of Burma-born patients. Thirty to sixty minute semi-structured interviews were conducted with 4 general practitioners, 8 nurses and 3 interpreters, and deidentified audio recordings were transcribed for inductive thematic analysis.

Results

Five key themes were generated (i) cultural cognisance; (ii) influence of community (iii) skilful navigation of communication; (iv) favourable consultation attributes; and (v) individual tailoring of consent conversations. Differing cultural expectations, and linguistic and educational barriers, were highlighted as challenges to obtaining informed consent, while thoughtful utilisation of non-verbal communication, and intentional customisation of consent conversations were identified as facilitators.

Conclusion

The findings of this study provide practical ways to optimise the informed consent process within the Australian primary healthcare context, and reinforce that accepted Western-based practices for obtaining informed consent are not a 'one-size-fits-all'.

Patient satisfaction with surgical informed consent at Jimma Medical Center, Ethiopia

Research article

Tsegaw Biyazin, Ayanos Taye & Yeshitila Belay

BMC Medical Ethics, 25 October 2022; 23(103)

Open Access

Abstract

Background

Informed consent is a process in which a healthcare provider obtains permission from an individual prior to surgery. Patient satisfaction with the informed consent process is one of the main indicators of healthcare service quality. This study aimed to assess patient satisfaction with surgical informed consent at Jimma Medical Center, Ethiopia, in 2020.

Methods
A facility-based cross-sectional study was conducted from April 1 to June 30, 2020, at Jimma Medical Center. Face-to-face interviews were conducted using structured questionnaires. A systematic sampling technique was used to select the study participants. The collected data were coded, entered into Epi data version 3.1, and analyzed using SPSS version 25. Bivariate and multivariate regression analyses were performed to determine the association between patient satisfaction and socio-demographic and facility-related factors. In multivariate regression, predictors with a P-value of < 0.05 were considered statistically significant.
Results
Totally 372 study participants were interviewed with a response rate of 97.8%. Nearly two-fifths (43%) of patients were satisfied with surgical informed consent. Living in an urban area (AOR: 2.279, 95% CI 1.257–4.131), having current referred history (AOR: 1.856, 95% CI 1.033–3.337), consent form version (AOR: 2.076, 95% CI 1.143–3.773), time spent on the provision of informed consent (AOR: 5.227, 95% CI 2.499–10.936) and having better patient-health providers relationship (AOR: 5.419, 95% CI 3.103–9.464) predictors were positively associated with patient satisfaction.
Conclusion
Patient satisfaction with the surgical informed consent process was relatively low. Therefore, Health care professionals need to emphasize a way of delivering informed consent, patients' needs and obey a standard informed consent to improve patient satisfaction.

Making Removals Part of Informed Choice: A Mixed-Method Study of Client Experiences With Removal of Long-Acting Reversible Contraceptives in Senegal

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Global Health: Science and Practice, October 2022; 10(5)
Open Access
Abstract
Background
Ensuring access to removal services for implants and intrauterine devices (IUDs) is essential to realize informed choice and voluntary family planning. We document removal desires and experiences among women who received an implant or IUD from the public sector in 3 districts of Senegal.
Methods
We conducted a phone survey of 1,868 implant and IUD users, 598 follow-up surveys with those who had ever asked a provider for a removal, and 24 in-depth interviews (IDIs) with women who had ever wanted an implant removal. We analyzed survey data descriptively and IDI data thematically.
Results
Fifty-eight percent of implant users and 54% of IUD users reported having wanted a removal. Desired pregnancy and contraceptive-induced menstrual changes (CIMCs) were the main reasons for removal desires. Fifty-four percent of implant users and 55% of IUD users who asked a provider for a removal reported challenges accessing services, with over two-thirds noting long lines or wait times. Sixty-three percent of implant users and 73% of IUD users who saw a provider were satisfied with the outcome of their first interaction. Over 90% of participants had not been told about the removal cost at insertion. Almost all participants who had their method removed obtained a complete removal during their first clinical procedure. Around two-thirds of participants who obtained a removal did not take up another method at that time. IDIs confirmed the influence of CIMCs on removal desires and show some partner influence is common in removal decision making. Barriers include lack of available qualified providers and supplies. Provider interactions play an important role in satisfaction with removal services.
Conclusion
Participants' experiences accessing removal services were generally positive. Areas of potential improvement include client flow, counseling messages at insertion, and when advising clients to keep their method, pricing, and post-removal reinsertion or method switching.

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MEDICAL/SURGICAL

The effects of modifying elements of written informed consent forms for elective surgical or invasive procedures: A systematic review

Stefanie Bühn, Elen Huppertz, Alina Weise, Julia Lühnen, Anke Steckelberg, Roland Brian Büchter, Simone Hess, Kyung-Eun (Anna) Choi, Tim Mathes

Patient Education and Counseling, February 2023; 107

Abstract

Objective

To study the effect of modifying content and design elements within written informed-consent-forms (ICF) for patients undergoing elective surgical or invasive procedures.

Methods

We included (quasi-)randomized trials in which a modified written ICF (e.g. visual aids) was compared to a standard written ICF. We searched PubMed, Web-of-Science and PsycINFO until 08/2021. Risk of Bias was assessed. The complexity of intervention was assessed using the Intervention Complexity Assessment Tool for Systematic Reviews.

Results

Eleven trials with 1091 participants were eligible. Effect sizes and levels of evidence varied from trivial to moderate and there were contradictory findings for some outcomes. Providing patients with more information in general or specific information on risks and complications mostly increased anxiety. The use of verbal risk presentation decreased anxiety and increased satisfaction. A lower readability level decreased anxiety and improved comprehension and knowledge.

Conclusion

Our results suggest that providing more information and addressing certain types of risks have differential effects. While more information improved knowledge, it also increased anxiety. We did not find any or only insufficient evidence for many other possible ICF modifications.

Practice implications

When developing ICFs the differential impact of different elements on patient important outcomes should be carefully considered.

An evaluation of the efficacy of a supplemental computer-based tutorial to enhance the informed consent process for cataract surgery: an exploratory randomized clinical study

Research

Marlies Ullrich, Oliver Findl, Katharina Kefer, Birgit Döller, Ralph Varsits, Julius Hienert, Nino Hirnschall

BMC Ophthalmology, 11 November 2022; 22(430)

Open Access

Abstract

Background

To assess whether informing patients with a computer-based tutorial in addition to standard informed consent influences the patient's attitude towards surgery and increases patient's knowledge.

Methods

In this prospective, exploratory, randomized clinical study, patients scheduled for their first eye cataract surgery were randomly allocated to two groups, receiving standard face-to-face informed consent (control group) or additionally using an interactive computer-based tool (CatInfo) containing an audiovisual presentation about cataract and its treatment (study group). Cataract-related knowledge and decisional confidence (decisional conflict scale (DCS)) were assessed as well as one-month postoperatively decisional

regret (decision regret scale (DRS)) and willingness to exchange face-to-face discussion time for the use of such a tool.

Results

The study comprised 134 patients, 64 patients in the study group and 70 in the control group. Patients in the study group answered more questions correctly, 16.3 ± 2.0 (median 16.5, 11.0–19.0) versus 15.5 ± 1.9 (median 16.0, 8.0–19.0; p = 0.01). Patients showed a high decisional confidence with a study group mean DCS score of 92.4 ± 9.8 (median 96.9, 65.6–100) and control group score of 91.6 ± 10.9 (median 95.3, 43.3–100; p = 0.52). Mean DRS score in the study group was 2.5 ± 8.0 (median 0, 0–40) and 4.3 ± 12.5 (median 0, 0–75) in the control group (p = 0.14). Of study group patients 23 (67.6%) were willing to trade time, on average 158 ± 180 s (median 120 s, 45–900). Satisfaction with the tool was high with a mean of 9.1 ± 1.3 out of 10 (median 9.7, 5.0–10).

Conclusions

Cataract-related knowledge was generally good, with slightly higher scores in the study group. In both groups, decisional confidence was high and regret after surgery was low. A tendency towards slightly higher decisional confidence and lower regret was found in the study group, although these differences were not statistically significant. Additional use of an interactive computer-based tool may prove useful in the informed consent process in a high-volume cataract outpatient setting.

The role of knowledge and medical involvement in the context of informed consent: a course or a blessing?

Caterina Milo

Medicine, Health Care and Philosophy, 1 November 2022

Open Access

Abstract

Informed consent (IC) is a key patients' right. It gives patients the opportunity to access relevant information/knowledge and to support their decision-making role in partnership with clinicians. Despite this promising account of IC, the relationship between 'knowledge', as derived from IC, and the role of clinicians is often misunderstood. I offer two examples of this: (1) the prenatal testing and screening for disabilities; (2) the consent process in the abortion context. In the first example, IC is often over-medicalized, that is to say the disclosure of information appears to be strongly in the clinicians' hands. In this context, knowledge has often been a curse on prospective parents. Framing information in a doctor-centred and often negative way has hindered upon prospective parents' decision-making role and also portrayed wrong assumptions upon disabled people more widely. In the second context, information is more often than not dismissed and, in a de-medicalized scenario, medical contribution often underplayed. The latter leads to an understanding of the dialogue with clinicians as a mere hinderance to the timely access to an abortion. Ultimately, I claim that it is important that knowledge, as derived from IC, is neither altogether dismissed via a process of de-medicalization, nor used as a curse on patients via a process of over-medicalization. None of the two gives justice to IC. Only when a better balance between medical and patients' contribution is sought, knowledge can aspire to be a blessing (i.e. an opportunity for them), not a curse on patients in the IC context.

The "teach-back" method improves surgical informed consent and shared decision-making: a proof of concept study

Research

Kevin D. Seely, Jordan A. Higgs, Lindsey Butts, Jason M. Roe, Colton B. Merrill, Isain Zapata, Andrew Nigh

Patient Safety in Surgery, 28 October 2022; 16(33)

Open Access

Abstract

Introduction

The teach-back method is a communication tool that can improve patient safety and shared decision-making. Its utility in patient care has been studied extensively in many areas of clinical medicine. However, the literature on teach-back in surgical patient education and informed consent is limited, and few studies have been conducted to test its impact on perioperative patient interactions. The objective of this study was to evaluate if the teach-back method can improve informed consent and surgeon trust. An assessment of the time required to be implemented was also evaluated.

Methods

A standardized interaction role-playing a pre-operative informed consent discussion was designed. Laparoscopic cholecystectomy was selected as the proposed procedure. Standardized patients were split into two groups: teach-back and a control group. The control group was delivered a script that discloses the risks and benefits of laparoscopic cholecystectomy followed by a concluding prompt for any questions. The teach-back group was presented the same script followed by the teach-back method. Interactions were timed and patients completed a quiz assessing their knowledge of the risks and benefits and a survey assessing subjective perceptions about the interaction. Statistical analysis through Generalized Linear Models (GLMs) was used to compare visit length, performance on the comprehension quiz, and subjective surgeon trust perceptions.

Results

34 participants completed the scenario, the comprehension quiz, and the survey (n = 34). Analysis of the subjective evaluation of the physician and encounter was significant for increased physician trust ($p = 0.0457$). The intervention group performed higher on the knowledge check by an average of one point when compared to the control group ($p = 0.0479$). The visits with intervention took an average of 2.45 min longer than the control group visits ($p = 0.0014$). People who had the actual procedure in the past (evaluated as a confounder) were not significantly more likely to display the same effect as the teach-back method, suggesting that the knowledge and trust gained were not based on previous experiences with the procedure.

Conclusion

When employed correctly by surgeons in the perioperative setting, the teach-back method enhances shared decision-making, comprehension, and surgeon trust. Incorporating the teach-back method into risk and benefit disclosures effectively informs and more fully engages patients in the informed consent process. Notably, the added benefits from using teach-back can be obtained without a burdensome increase in the length of visit.

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GENERAL/OTHER

Explanation before Adoption: Revealing Methods Used to Support Informed Consent for Complex Platforms

Rachel Eardley, Emma L. Tonkin, Ewan Soubutts, Amid Ayobi, Gregory J. L. Tourte, Rachael Gooberman-Hill, Ian J Craddock, Aisling Ann O'Kane

Proceedings of the ACM on Human-Computer Interaction [Bristol, UK], April 2023

Abstract

Explaining health technology platforms to non-technical members of the public is an important part of the process of informed consent. Complex technology platforms that deal with safety-critical areas are particularly challenging, often operating within private domains (eg health services within the home) and used by individuals with various understandings of hardware, software, and algorithmic design. Through two studies, the first an interview and the second an observational study, we questioned how experts (eg those who designed, built, and installed a technology platform) supported provision of informed consent by participants. We identify a wide range of tools, techniques, and adaptations used by experts to explain the complex SPHERE sensor-based home health platform, provide implications for the design of tools to aid

explanations, suggest opportunities for interactive explanations, present the range of information needed, and indicate future research possibilities in communicating technology platforms.

Consent: A Research and Design Lens for Human-Computer Interaction

Douglas Zytko, Jane Im, Jonathan Zong

Computer Supported Cooperative Work and Social Computing Conference Companion, 8 November 2022; pp 205–208

Open Access

Abstract

Consent has become an important concept across multiple areas within HCI/CSCW, community advocacy work, and the tech industry, for understanding social computing problems and designing safe and agentic computer-mediated communication. Recent research has studied consent in various topics, such as online-to-offline interaction and harm, data privacy and security, research ethics, and human-robot interaction. The goal of this panel is to bring together researchers and practitioners to discuss how consent has been defined and studied within HCI and adjacent fields, and how cross-field discourse around consent can inform future work that pursues safe and equitable computing. We aim to introduce consent as a multifaceted research and design lens to the HCI and CSCW community and illuminate ways that consent can contribute to better understanding or re-imagination of contemporary research interests. Lastly, the panel aims to spark cross-field communication around consent to identify latent connections across research topics and foster synergistic collaborations.

Editor's note: In this abstract, HCI refers to human-computer interaction, and CSCW refers to Computer Supported Cooperative Work.

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