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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

August 2019

This digest aggregates and distills key content around 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. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

Informed Consent: A Monthly Review is a service of the GE2P2 Global Foundation's Center for Informed Consent Integrity, which is solely responsible for its content. Comments and suggestions should be directed to:

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

No new content identified for the following categories:
BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
HUMANITARIAN CONTEXT

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GENOMIC MEDICINE/GENE EDITING

Consent for clinical genome sequencing: considerations from the Clinical Sequencing Exploratory Research Consortium

Yu JH, Appelbaum PS, Brothers KB, Joffe S, Kauffman TL, Koenig BA, Prince AE, Scollon S, Wolf SM, Bernhardt BA, Wilfond BS

Personalized Medicine, 17 Jul 2019

Abstract

Implementing genome and exome sequencing in clinical practice presents challenges, including obtaining meaningful informed consent. Consent may be challenging due to test limitations such as uncertainties associated with test results and interpretation, complexity created by the potential for additional findings and high patient expectations. We drew on the experiences of research teams within the Clinical Sequencing Exploratory Research (CSER1) Consortium on informed consent for clinical genome and exome sequencing (CGES) to negotiate consensus considerations. We present six considerations for clinicians and 12 key points to communicate as they support patients in deciding whether to undergo CGES. These considerations and key points provide a helpful starting point for informed consent to CGES, grounded in the Clinical Sequencing Exploratory Research (CSER1) experience.

Informed consent and community engagement in open field research: lessons for gene drive science

Debate

Jerome Amir Singh

BMC Medical Ethics, 27 July 2019; 20(54)

Open Access

Abstract

Background

The development of the CRISPR/Cas9 gene editing system has generated new possibilities for the use of gene drive constructs to reduce or suppress mosquito populations to levels that do not support disease transmission. Despite this prospect, social resistance to genetically modified organisms remains high. Gene drive open field research thus raises important questions regarding what is owed to those who may not consent to such research, or those could be affected by the proposed research, but whose consent is not solicited. The precise circumstances under which informed consent must be obtained, and from whom, requires careful consideration. Furthermore, appropriate engagement processes should be central to any introduction of genetically modified mosquitos in proposed target settings.

Discussion

In this work, international guidance documents on informed consent and engagement are reviewed and applied to the genetically modified mosquito research context. Five analogous research endeavours that involve area-wide / open field experiments are reviewed. The approach of each in respect to the solicitation of individual informed consent and community engagement are highlighted.

Conclusions

While the solicitation of individual informed consent in host settings of gene drive field trials may not be possible or feasible in some instances, local community and stakeholder engagement will be key to building trust towards the proposed conduct of such research. In this regard, the approaches taken by investigators and sponsors of political science field research and weather modification field research should be avoided. Rather, proponents of gene drive field research should look to the Eliminate Dengue field trials, cluster randomised trials, and pragmatic clinical trials for guidance regarding how the solicitation of individual

informed consent of host communities ought to be managed, and how these communities ought to be engaged.

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YOUNG PERSONS

Optimising informed consent in school-based adolescent vaccination programmes in England: A multiple methods analysis

Tracey Chantler, Louise Letley, Pauline Paterson, Joanne Yarwood, Vanessa Saliba, Sandra Mounier-Jack
Vaccine, 24 July 2019
Open Access
Abstract
The process of obtaining informed consent for school-based adolescent immunisation provides an opportunity to engage families. However, the fact that parental consent needs to be obtained remotely adds complexity to the process and can have a detrimental effect on vaccine uptake. We conducted a multiple methods analysis to examine the practice of obtaining informed consent in adolescent immunisation programmes. This involved a thematic analysis of consent related data from 39 interviews with immunisation managers and providers collected as part of a 2017 service evaluation of the English adolescent girls' HPV vaccine programme and a descriptive statistical analysis of data from questions related to consent included in a 2017 survey of parents' and adolescents' attitudes to adolescent vaccination. The findings indicated that the non-return of consent forms was a significant logistical challenge for immunisation teams, and some were piloting opt-out consent mechanisms, increasing the proportion of adolescents consenting for their own immunisations, and introducing electronic consent. Communicating vaccine related information to parents and schools and managing uncertainties about obtaining adolescent self-consent for vaccination were the main practical challenges encountered. Survey data showed that parents and adolescents generally agreed on vaccine decisions although only 32% of parents discussed vaccination with their teenager. Parental awareness about the option for adolescents to self-consent for vaccination was limited and adolescents favoured leaving the decision-making to parents. From the interviews and variability of consent forms it was evident that health professionals were not always clear about the best way to manage the consent process. Some were also unfamiliar with self-consent processes and lacked confidence in assessing for 'Gillick competency'. Developing pathways and related interventions to improve the logistics and practice of consent in school-based adolescent immunisation programmes could help improve uptake.

Vaccination over Parental Objection — Should Adolescents Be Allowed to Consent to Receiving Vaccines?

Perspective
Ross D. Silverman, Douglas J. Opel, Saad B. Omer
New England Journal of Medicine, 11 July 2019; 381(2)
Excerpt
…Such cases raise the question of whether adolescent minors should be able to consent to vaccinations without parental permission. For minors to be able to choose to be vaccinated over parental objections, most states would need to make substantive changes to laws governing medical consent. Since children are generally considered nonautonomous under U.S. law, treatment of a child in a medical setting requires parental permission, typically until a child reaches 18 years of age. Parents are generally given broad discretion in making decisions on behalf of their children, in part because they know their child best, are positioned to weigh competing family interests, and are permitted to raise their child as they choose. Such discretion doesn't mean that adolescents have no role in decisions that affect them, however. Out of respect for adolescents' developing autonomy, clinicians routinely explore their understanding of health-related

issues, solicit their agreement on care plans, navigate discordance between parental and adolescent preferences, and protect adolescents' confidentiality interests.2

Both ethical principles and state laws also support independent decision making by adolescents in cases in which failing to grant adolescents autonomy could foreseeably result in substantial risk to the minor or to public health. For instance, all states have laws permitting minors to make independent, confidential clinical decisions regarding certain sensitive or stigmatized health care services, such as those related to sexual health, reproduction, mental health, and substance use disorders. Roughly 20% of jurisdictions require adolescents to be at least 12 or 14 years of age to make such decisions; others don't designate a minimum age of consent.3 A court may also grant an older adolescent (typically 16 years or older) legal emancipation or deem the adolescent to be a "mature minor" who is able to make certain decisions independently.

Most states, however, don't authorize adolescents to independently consent to vaccination…

Facilitating Informed Permission/Assent/Consent in Pediatric Clinical Trials

Susan M. Abdel-Rahman

Pediatric Drugs, 17 July 2019; pp 1-10

Abstract

Individuals approached to participate in human subjects research, irrespective of age, must be completely apprised of the study, and researchers must ensure that the information is understood to the fullest extent possible, prior to decision making. However, evolving regulatory and institutional requirements have led to permission/assent/consent (PAC) forms that are unnecessarily complex, serving only to exacerbate the challenges associated with communicating this important information to prospective participants. At greatest risk are children and other individuals with low literacy, limited English proficiency, and diminished mental capacity, populations all too often neglected in clinical research. This paper examines various strategies that have been evaluated to facilitate informed PAC, drawing on experiences across a broad array of populations whose needs overlap with those of children. These strategies range from simplifying PAC forms for readability and creating multimedia PAC delivery tools to actively engaging participants on their understanding of PAC elements by leveraging testing, rewards, and third-party communications. Notably, the findings from strategies that have been explored in more than one setting are uniformly mixed with respect to their ability to improve comprehension, underscoring the challenges that persist in designing, implementing, and objectively examining strategies intended to facilitate informed PAC. However, these studies do serve to highlight efforts that may reduce anxiety around, and increase the satisfaction of participants with, the PAC process. Ultimately, accommodating a diverse participant pool will require the consideration, and continual refinement, of various PAC strategies along with the engagement of team members who are intimately familiar with these populations.

Consent in paediatric neurosurgery: adequacy of documentation and parental perspectives

Adikarige H. D. Silva, Haren Wijesinghe, Nilesh Mundil, William Lo, A. Richard Walsh, Guirish A. Solanki, Desiderio Rodrigues

Child's Nervous System, 9 July 2019; pp 1–7

Original Article

Abstract

Introduction

Consenting paediatric patients for surgical procedures remains inherently unique in that it is underpinned by principles such as parental responsibility, assessment of the child's capacity to consent, and adherence to national/legal guidelines. Quality record keeping is an important objective evidence to demonstrate the highest standards of medical care provided to our patients. The consent form is a crucial medical record encapsulating the attainment of informed consent from a parent/guardian for performing a procedure on their child. We aimed to prospectively evaluate the consenting process in our department to assess adequacy of documentation and parental perspectives.

Methods
A prospective study using qualitative descriptive design was conducted with parents of 50 children requiring neurosurgical procedures over a 3-month period.
Results
All patients understood the primary diagnosis and type of surgery. Procedure-specific risks were understood by 98% and 84% could remember the mentioning of general risks of surgery. Only a minority of parents (24%) could recollect that alternative options of management including no treatment were discussed. In cases where relevant, laterality was only documented in 56% of consent forms. All patients felt that an informed decision regarding consent to surgery was made. However, 12% suggested areas where further improvement could be made in the timing of consent and the way information could be better provided.
Discussion
Consent is more than a signature on a form. It provides objective evidence of a shared decision-making process between the surgeon, patient, and their parent/guardian. Our initial study highlights multiple areas for improvement.

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COGNITIVE CHALLENGES

Informed consent and ethical reporting of research in clinical trials recruiting participants with psychotic disorders

Guy M. Weissinger, Connie M. Ulrich
Contemporary Clinical Trials, 24 June 2019
Abstract
Informed consent is the foundation of modern biomedical research and it is vital for assuring the safety of vulnerable individuals, like those with psychotic disorders (e.g. schizophrenia, schizoaffective disorder, schizophreniform disorder, etc.). All individuals who are involved in clinical research must have consented to participate or had surrogate consent from a representative. As individuals with psychotic disorders may not always have capacity to consent, assessment of capacity before research participation is vital but there is little research on how these assessments are conducted in clinical research. The authors conducted a systematic review of high-risk trials, defined as randomized medication or device trials that specifically recruited individuals with psychotic disorders, to understand the use of capacity to consent assessment and their reporting. A total of 646 articles, which mostly recruited participants with schizophrenia and were medication trials, were coded using a standardized questionnaire on consent practices and ethical reporting of research. Only 34 (5.3%) of the studies reported an assessment of capacity to provide informed consent and less than half of those used a standardized assessment. Sixty-four (9.9%) of the articles had capacity to provide informed consent in the study inclusion/exclusion criteria. Additionally, 66 (10.2%) of the articles did not have a statement about IRB approval and 134 (20.7%) had no statements about potential conflicts of interest. Though limitations to the review exist, it is clear that both in conducting high-risk research with individuals with psychotic disorders and when reporting research findings, there are ethical issues that must be addressed.

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TECHNOLOGY/OTHER MEDIATION

Use of multimedia during informed consent: novelty or necessity

Henry H. Chill, Uri Dior, David Shveiky
International Urogynecology Journal, 13 July 2019; pp 1–3

Abstract
The process of informed consent is an integral part of the preoperative encounter. In theory, it has the potential to educate patients, enabling them to reach a true autonomous decision regarding the treatment offered. Unfortunately, in recent years informed consent has become overly complicated for the average patient. Questions have been raised regarding the ability of the process, as practiced nowadays, to actually increase knowledge and achieve its goals. In search of new ways to increase patient comprehension, researchers have suggested use of multimedia during the process of informed consent. Visualization of complex ideas, interactive learning and tailoring the procedure to fit patient needs are all advantages presented by use of multimedia during the process. Several randomized prospective trials have looked into this topic and have presented promising data in favor of multimedia use. Informed consent is a process with unfulfilled potential, and use of multimedia may be part of the solution. In our opinion, it is time to change the way we educate patients.

Electronic informed consent: the need to redesign the consent process for the digital age

Personal Viewpoint
Helen Lunt, Saxon Connor, Helen Skinner, Greg Brogden
International Medicine Journal, 11 July 2019
Abstract
The delivery of healthcare, which includes the informed consent process, is moving to a digital environment. This change in informed consent delivery will be associated with opportunities, risks and also unintentional consequences. Physicians are well placed to contribute to the ongoing dialogue about what is needed to make the informed consent process fit for purpose, in the digital age.

Recruitment and retention: A randomized controlled trial of video-enhanced versus standard consent processes within the E-OPTIMAL study

Research Article
Linda Brubaker, J Eric Jelovsek, Emily S Lukacz, Sunil Balgobin, Alicia Ballard, Alison C Weidner, Marie G Gantz, Ryan Whitworth, Donna Mazloomdoost
Clinical Trials, 26 July 2019
Abstract
Background/aims
In this study, we compared two research consent techniques: a standardized video plus usual consent and usual consent alone.
Methods
Individuals who completed 24-month outcomes (completers) in the Operations and Pelvic Muscle Training in the Management of Apical Support Loss study were invited to participate in an extended, longitudinal follow-up study (extended Operations and Pelvic Muscle Training in the Management of Apical Support Loss). Potential participants who were (1) able to provide consent and (2) not in long-term care facilities were randomized 1:1 to a standardized video detailing the importance of long-term follow-up studies of pelvic floor disorders followed by the usual institutional consent process versus the usual consent process alone. Randomization, stratified by site, used randomly permuted blocks. The primary outcome was the proportion of participants who enrolled in the extended study and completed data collection events 5 years after surgery. Secondary outcomes included the proportion enrolled in the extended study, completion of follow-up at each study year, completion of data collection points, completion of in-person visits, and completion of quality of life calls. Motivation and barriers to enrollment (study-level and personal-level) and satisfaction with the study consent process were measured by questionnaire prior to recruitment into extended Operations and Pelvic Muscle Training in the Management of Apical Support Loss. Groups were compared using an intention-to-treat principle, using unadjusted Student's t-test (continuous) and chi-square or Fisher's

exact (categorical) test. A sample size of 340 (170/group) was estimated to detect a 15% difference in enrollment and study completion between groups with $p < 0.05$.

Results

Of the 327 Operations and Pelvic Muscle Training in the Management of Apical Support Loss completers, 305 were randomized to the consent process study (153 video vs 152 no video). Groups were similar in demographics, surgical treatment, and outcomes. The overall rate of extended study enrollment was high, without significant differences between groups (video 92.8% vs no video 94.1%, $p = 0.65$). There were no significant differences in the primary outcome (video 79.1% vs no video 75.7%, $p = 0.47$) or in any secondary outcomes. Being "very satisfied" overall with study information (97.7% vs 88.5%, $p = 0.01$); "strong agreement" for feeling informed about the study (81.3% vs 70.8%, $p = 0.06$), understanding the study purpose (83.6% vs 71.0%, $p = 0.02$), nature and extent (82.8% vs 70.2%, $p = 0.02$), and potential societal benefits (82.8% vs 67.9%, $p = 0.01$); and research coordinator/study nurse relationship being "very important" (72.7% vs 63.4%, $p = 0.03$) were better in the video compared to the no video consent group.

Conclusion

The extended study had high enrollment; most participants completed most study tasks during the 3-year observational extension, regardless of the use of video to augment research consent. The video was associated with a higher proportion of participants reporting improved study understanding and relationship with study personnel.

Oxford Video Informed Consent Tool (OxVIC): a pilot study of informed video consent in spinal surgery and preoperative patient satisfaction

Research

Gerard Mawhinney, Chrishan Thakar, Victoria Williamson, Dominique A Rothenfluh, Jeremy Reynolds

BMJ Open, 24 July 2019; 9(7)

Open Access

Abstract

Objectives

The British Association of Spinal Surgeons recently called for updates in consenting practice. This study investigates the utility and acceptability of a personalised video consent tool to enhance patient satisfaction in the preoperative consent giving process.

Design

A single-centre, prospective pilot study using questionnaires to assess acceptability of video consent and its impacts on preoperative patient satisfaction.

Setting

A single National Health Service centre with individuals undergoing surgery at a regional spinal centre in the UK.

Outcome measure

As part of preoperative planning, study participants completed a self-administered questionnaire (CSQ-8), which measured their satisfaction with the use of a video consent tool as an adjunct to traditional consenting methods.

Participants

20 participants with a mean age of 56 years (SD=16.26) undergoing spinal surgery.

Results

Mean patient satisfaction (CSQ-8) score was 30.2/32. Median number of video views were 2–3 times. Eighty-five per cent of patients watched the video with family and friends. Eighty per cent of participants reported that the video consent tool helped to their address preoperative concerns. All participants stated they would use the video consent service again. All would recommend the service to others requiring surgery. Implementing the video consent tool did not endure any significant time or costs.

Conclusions

Introduction of a video consent tool was found to be a positive adjunct to traditional consenting methods. Patient–clinician consent dialogue can now be documented. A randomised controlled study to further evaluate the effects of video consent on patients' retention of information, preoperative and postoperative anxiety, patient reported outcome measures as well as length of stay may be beneficial.

Obtaining Informed Consent Using Patient Specific 3D Printing Cerebral Aneurysm Model

Pil Soo Kim, Chang Hwa Choi, In Ho Han, Jung Hwan Lee, Hyuk Jin Choi, Jae Il Lee

Journal of Korean Neurosurgical Society, 1 July 2019; 62(4) pp 398-404

Open Access

Abstract

Objective

Recently, three-dimensional (3D) printed models of the intracranial vascular have served as useful tools in simulation and training for cerebral aneurysm clipping surgery. Precise and realistic 3D printed aneurysm models may improve patients' understanding of the 3D cerebral aneurysm structure. Therefore, we created patient-specific 3D printed aneurysm models as an educational and clinical tool for patients undergoing aneurysm clipping surgery. Herein, we describe how these 3D models can be created and the effects of applying them for patient education purpose.

Methods

Twenty patients with unruptured intracranial aneurysm were randomly divided into two groups. We explained and received informed consent from patients in whom 3D printed models-(group I) or computed tomography angiography-(group II) was used to explain aneurysm clipping surgery. The 3D printed intracranial aneurysm models were created based on time-offlight magnetic resonance angiography using a 3D printer with acrylonitrile-butadiene-styrene resin as the model material. After describing the model to the patients, they completed a questionnaire about their understanding and satisfaction with aneurysm clipping surgery.

Results

The 3D printed models were successfully made, and they precisely replicated the actual intracranial aneurysm structure of the corresponding patients. The use of the 3D model was associated with a higher understanding and satisfaction of preoperative patient education and consultation. On a 5-point Likert scale, the average level of understanding was scored as 4.7 (range, 3.0–5.0) in group I. In group II, the average response was 2.5 (range, 2.0–3.0).

Conclusion

The 3D printed models were accurate and useful for understanding the intracranial aneurysm structure. In this study, 3D printed intracranial aneurysm models were proven to be helpful in preoperative patient consultation.

Ethical Tensions Resulting from Interpreter Involvement in the Consent Process

Amelia Barwise, Richard Sharp, and Jessica Hirsch

Ethics & Human Research, July 2019; 41(4) pp 31-35

Open Access

Abstract

We describe how our institution responded when an interpreter who participated in the consent process involving an individual with limited English proficiency refused to cosign consent documents attesting that the individual enrolling in the study understood the consent information and that her consent to enroll was voluntary. In developing our approach, our institution took into account ethical tensions between the Belmont principles of respect for persons, beneficence, and justice that apply to the protection of research participants and the professional principles of beneficence, fidelity, and respect for the importance of culture that are outlined in ethical guidelines for medical interpreters.

Editor's note: The Belmont principles referred to above can be found in the Belmont Report here.

Evaluation of a REDCap-based Workflow for Supporting Federal Guidance for Electronic Informed Consent

Cindy Chen, Scott P. Turner, Evan T. Sholle, Scott W. Brown, Vanessa L.I. Blau, Julianna P. Brouwer, Alicia N. Lewis, Curtis L. Cole, David M. Nanus, Manish A. Shah, John P. Leonard, Thomas R. Campion, Jr.

AMIA Joint Summits on Translational Science Proceedings, 6 May 2019; pp163–172

Open Access

Abstract

Adoption of electronic informed consent (eConsent) for research remains low despite evidence of improved patient comprehension, usability, and workflow processes compared to paper. At our institution, we implemented an eConsent workflow using REDCap, a widely used electronic data capture system. The goal of this study was to evaluate the extent to which the REDCap eConsent solution adhered to federal guidance for eConsent. Of 29 requirements derived from sixteen recommendations from the United States Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA), the REDCap eConsent solution supported 24 (86%). To the best of our knowledge, this is among the first studies to evaluate an eConsent approach's support for federal guidance. Findings suggest use of REDCap may help other institutions overcome barriers to eConsent adoption, and that OHRP and FDA expand guidance to recommend eConsent solutions integrate with enterprise clinical and research information systems.

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BIOMEDICAL RESEARCH

Public Approval of Exception From Informed Consent in Emergency Clinical Trials: A Systematic Review of Community Consultation Surveys

Original Investigation

William B. Feldman, Spencer P. Hey, Jessica M. Franklin, Aaron S. Kesselheim

JAMA Network Open, 24 July 2019; 2(7)

Open Access

Abstract

Importance

The US Food and Drug Administration (FDA) created the exception from informed consent (EFIC) pathway in 1996 to allow some emergency trials to enroll patients without informed consent. To protect individual autonomy and preserve public trust, the FDA requires that EFIC trial investigators consult with community members before a trial may begin.

Objectives

To analyze data from surveys conducted as part of community consultation ahead of EFIC trials and assess levels of public approval.

Data Sources

All trials granted an EFIC must submit documentation of compliance with EFIC regulations to a publicly available docket at the FDA. Submissions between November 1, 1996, and October 23, 2017, were reviewed.

Study Selection

Trials with survey data were included.

Data Extraction and Synthesis

Data were extracted between January 2018 and June 2018 and were analyzed between June 2018 and August 2018. The quality and validity of data were assessed according to Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. A random-effects metaregression was used to assess the association of demographic characteristics with EFIC approval.

Main Outcomes and Measures

The primary study outcome was EFIC approval.

Results

The FDA docket contained 15 958 pages of material with survey data for 42 448 individuals submitted by 27 trials. Public approval of EFIC varied by question type, with more people willing to approve initiation of EFIC trials in their community (86.5%) than personal enrollment (73.0%), enrollment of a family member (68.6%), or the principle of enrollment without consent (58.4%) (P < .001 for all comparisons). In the United States, African American individuals made up 29.3% of those enrolled in EFIC trials that reported data on race (5064 of 17 302) but only 16.7% of those surveyed as part of community consultation. In the United States and Canada, men made up 42.9% of the surveyed population but 65.6% of those eventually enrolled in EFIC trials (29 961 of 45 694). Groups surveyed with higher proportions of African American and male respondents had lower rates of EFIC approval.

Conclusions and Relevance

Public approval of EFIC trials varied by question type and by the respondents' reported race and sex. The demographic characteristics of those surveyed did not match the demographic characteristics of EFIC enrollees. The FDA could strengthen community consultation by standardizing survey instruments and reporting, requiring broader inclusion of African American and male respondents, clarifying the function of surveys in the development and modification of trial protocols, and building more public consensus around the acceptable use of EFIC.

How Should We Apply the Wisdom of the Crowd to Clinical Trials With Exception From Informed Consent?

Invited Commentary

Michael J. Lanspa, Eddy Fan, Alan H. Morris

JAMA Network Open, 24 July 2019; 2(7)

Open Access

Excerpt

In emergency trials applying for an exception from informed consent (EFIC), the US Food and Drug Administration (FDA) requires transparency, achieved through consultation with community members, before clinical investigators can enroll patients without informed consent. Feldman et al1 provide a review of surveys intended to achieve these consultations. Their results contribute to the literature by indicating the persistent gap between our goals and the imperfect surveys that have been reported….

Public Deliberation as a Novel Method for an Exception from Informed Consent Community Consultation

Original Contribution

Patricia E. Powers, Karen K. Shore, Susan Perez, Dominique Ritley, Nathan Kuppermann, James F. Holmes, Leah S Tzimenatos, Hiwote Shawargga, Daniel K. Nishijima

Academic Emergency Medicine, 4 July 2019

Abstract

Objectives

Community consultation is required for clinical trials considering federal exception from informed consent (EFIC) procedures. Questions remain about the value of the community consult process and whether it adds intended protections to study subjects. Public deliberation methods that provide baseline participant education and elicit values and opinions about consent options is a novel approach for community consultation. This study evaluated the use of structured public deliberation methods to assess a community's values and opinions about informed consent procedures for a pediatric trauma trial.

Methods

This was a mixed-methods descriptive study of public deliberation sessions assessing participants' opinions about informed consent procedures for a pediatric trauma randomized controlled trial (RCT). Participants

from communities with high rates of pediatric trauma were recruited via community-based organizations and social media. Deliberation focused on three consent options for a proposed RCT: 1) enrollment using EFIC procedures with no attempt to obtain informed consent; 2) enrollment using EFIC procedures after attempting to reach a parent; or 3) enrollment only with informed consent. Participant demographic data and their opinions about the proposed study and deliberative session were also collected.

Results

There were 102 participants across eight sessions (range of 9 to 15/session, average of 13). Most participants were female (n=78, 76%) and a plurality black (n=48, 47%). The majority of participants preferred enrollment using EFIC procedures only after an attempt was made to reach a parent and informed consent was not possible (n=56, 55%), followed by enrollment using EFIC procedures with no attempt to obtain informed consent (n=32, 32%), and enrollment only with written informed consent (n=13, 13%). One participant declined all options. 84 participants (82%) agreed or strongly agreed that the RCT was important to do, and 79 participants (77%) said the sessions provided enough information to make an informed decision about the proposed RCT.

Conclusions

Structured public deliberation is an effective approach when consulting communities for trials considering EFIC procedures. Future studies are needed to evaluate whether public deliberation methods provide participants with enhanced understanding of clinical trials compared to other community consultation methods.

The impact of central IRB's on informed consent readability and trial adherence in SPRINT

Leonardo Tamariz, Mitscher Gajardo, Carolyn H.Still, Lisa H.Gren, Elizabeth Clark, Sandy Walsh, Jeff Whittle, John Nord, Thomas Ramsey, Gabriel Contreras

Contemporary Clinical Trials Communications, September 2019; 15

Open Access

Abstract

Background

Federal agencies have encouraged the use of central institutional review boards (CIRBs) for multi-site clinical trials. There is limited evidence supporting the use of CIRBs. Our aim is to evaluate how SPRINT sites regulated by CIRBs performed regarding informed consent readability and participant trial adherence compared to those regulated by local IRBs.

Methods

We conducted a cohort study using the SPRINT clinical trial. We collected the IRB of record from the stamped and approved 2012 informed consents from each of the sites. We defined CIRB as an IRB for more than one SPRINT site. Our outcomes were informed consent readability measured using the Flesch-Kincaid readability scale and trial adherence defined as a loss to follow-up, consent withdrawal, and missed last 3-month visit.

Results

Sixty-one percent of all SPRINT sites used a CIRB as their IRB of record. The adjusted mean grade reading level for CIRB consents was 13.4 (95% CI 12.6–13.8) compared to 12.3 (95% CI 12.1–13.1) for non CIRB consents ($p = 0.07$). CIRB sites had similar rates of withdrawal of consent and loss to follow-up as non-CIRB sites; subjects missing the last appointment of the study were more likely to come from sites regulated by a CIRB. The Veterans Affairs CIRB had the lowest rate of withdrawal of consent (1.9%) and the lowest rate of missed appointments (1.9%) among CIRBs.

Conclusions

Niether CIRB-regulated sites nor IRB regulated sites enforce the recommended readability level of the informed consent documents. Sites regulated by both IRBs had similar participant trial adherence.

> *Editor's note: SPRINT refers to the Systolic Blood Pressure Intervention Trial (SPRINT), a multisite randomized controlled trial.*

What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research? A qualitative review

Review

Pauline Brown, Alistair Hewison, Roger Newham

Journal of Clinical Nursing, 26 June 2019

Abstract

Introduction

If studies are to be valid, recruitment of representative samples is essential. In 2012, 28% of UK emergency departments met the 80% standard for recruitment to trials set by the National Institute for Health Research. Research nurses play a vital role in the conduct of high-quality research, and it has been argued that dedicated research nurses are needed if clinical trials are to recruit successfully to target.

Review question

What are research nurses' experiences of obtaining consent from or for patients participating in emergency care research? A qualitative evidence review.

Methods

A qualitative integrative literature review with a narrative synthesis of the evidence. PRISMA guidelines for reporting systematic qualitative reviews (Appendix S1) were followed. A search of five electronic databases was performed in December 2018 along with a hand search which yielded 125 citations: 10 papers and one PhD thesis met the review eligibility criteria. Methodological quality of the selected studies was evaluated, and data were extracted and synthesised.

Results

Three themes were identified: Access, Organisation and Timing. Research nurses encountered both general and specific barriers when seeking to obtain consent for participation in research. In particular, it was found there was lack of experience among staff of working in emergency research and with securing deferred consent. The distinction between nurse researchers with a clinical role and those dedicated to solely to research only is often not clear and warrants further investigation.

Conclusion

Nurse researchers with and without a clinical role can make a positive difference in recruitment to trials in emergency care. The involvement of dedicated research nurses in the consent process can increase recruitment to emergency care research. Experience of recruiting to clinical trials in nonemergency settings does not seem to help when recruiting for trials in emergency care.

Relevance to clinical practice

There is a need for greater understanding of the experiences of dedicated research nurses in emergency care settings and in particular with regard to deferred consent.

Health literacy and informed consent for clinical trials: a systematic review and implications for nurses

Allison C Burks, Jessica Keim-Malpass

Nursing Research and Reviews, 2019; 9 pp 31-40

Open Access

Abstract

The informed consent process for consideration of clinical trials is a complex process that requires the understanding of the potential trial risk, benefits, and alternatives of treatment. The aim of this systematic review was to explore the available literature related to health literacy and the informed consent process for clinical trials. Articles were included if they focused on health literacy and patient comprehension of informed consent, had perceptions related to the informed consent process, or assessed the impact of health literacy on patients' willingness to participate in clinical trials. Eight articles were selected for this review. Limited health literacy was determined to be related to a lack of comprehension of clinical trial consent documents and heightened anxiety surrounding the informed consent process. Conflicting evidence exists

around the relationship between health literacy and clinical trial enrollment. Limited health literacy levels may impact the ability for nurses to have effective informed consent processes.

Improvement of Informed Consent Document Management in Clinical Trials Using an Electronic Medical Record System

Takahiro Kawakami, Katsuhiko Nagase, Yuko Yokoi, Yoshimichi Sai, Toshinori Murayama

Clinical Pharmacology, 2019; 50(3) pp 81-86

Abstract

Background

This study aims to systematize quality assurance and document management support to ensure the smooth implementation of investigator-initiated clinical trials (IITs).

Methods

A sample survey was performed to investigate whether and how signed original informed consent (IC) documents for IITs were stored at Kanazawa University Hospital. Based on the findings, initiatives were implemented utilizing an electronic medical record (EMR) system: 1) The latest versions of IC forms were issued directly from the EMRs for version control. Forms were printed with a 2D barcode to facilitate their re-entry into subjects' medical records. 2) A new management protocol was introduced in the clinical trial support office to ensure consistent uploading processes for signed IC documents and the archiving of paper records. 3) Patients were registered to trials individually using their EMRs, enabling investigators to access their consent and progress statuses in one place. After implementing these initiatives, the storage of signed original IC documents was re-assessed.

Results

The EMR system presented a simpler IC document management compared to the conventional approach. The updated post-consent document handling procedure improved and consolidated signed original IC document archiving. In addition to the separate registration of trial subjects, investigators responsible for the trial were explicitly identified in the EMR system in the event of uncertainty in other departments. This approach allows for easy confirmation of subjects' consent status when preparing and administering trial drugs.

Conclusions

Our approach of consolidated document and trial process management can improve the reliability of clinical research.

Editor's note: This a Japanese language publication. Kanazawa University Hospital operates in Kanazawa, Ishikawa, Japan.

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SOCIAL SCIENCE RESEARCH

Ethical dilemmas in social media health research [CONFERENCE ABSTRACT]

Dan Wolf Meyrowitsch, Jacob Lauge Thomassen, Flemming Konradsen, Natasja Kingod, Jane Brandt Sørensen

The Digitally Engaged Patient, 11-12 June 2019; Copenhagen, Denmark

Abstract

An increasing number of individuals worldwide engage in online communication concerning human health and researchers have identified the need to gain further insights on how individuals and communities engage and respond to particular health topics discussed on social media. However, this type of research is not without ethical dilemmas. Though ethical guidelines on the conduct of online research do exist, there is a lack of practical tools and procedures for the initiation and implementation of research on social media platforms in a thoughtful and respectful manner. When carrying out research involving human subjects, three ethical concepts are central: 1) confidentiality; 2) anonymity; and 3) informed consent. These

dimensions need rethinking when conducting research on social media platforms. For instance, a researcher stepping into a social media community would initially present herself, the objective of the research, and implications for participants – as in any other research project. However, it is a challenge to maintain informed consent to a study in a rapidly changing online community with a changing composition of members. Based on hands-on experiences from an ongoing research project in a Danish Facebook group of users and group administrators living with suicidal thoughts, we have encountered a range of challenges related to all three ethical concepts. These challenges have lead us to explore new paths and solutions. In this presentation, we will share our experiences and reflections.

Ethics and Consent in the (Sociotechnical) Wild [BOOK CHAPTER]

Ewa Luger, Tom Rodden

Into the Wild: Beyond the Design Research Lab, 4 July 2019; pp 149-172

Abstract

When we speak of ethics, we refer to the articulation of moral principles intended to promote societal and individual good. Derived of moral philosophy, they describe the codified process by which we determine how and why specific human conduct might be deemed right or wrong, good or bad. This is especially critical in the context of human-subjects research, where ill-considered interventions may otherwise result in harm to participants. Socio-technical studies conducted in naturalistic settings, what HCI terms 'in the wild' research, present some tensions with our current approaches to ethical practice. In particular, the ways in which we inform, secure and support participant consent. This chapter explores these emerging tensions and, through the voices of interviewed experts, highlights some of the issues arising around user consent and sociotechnical systems.

> *Editor's note: Emery's (1969) sociotechnical systems model of organizations speaks to when the technological, social, and managerial components interact. The technological system includes all the equipment, infrastructure, and technology in the workplace. The social system includes cultural and other diverse groups and individuals, and the social processes and informal channels used to communicate and negotiate in the workplace. The managerial system is concerned with power and authority within the organization, including decision making and formal lines of communication.*

Government Policy Experiments and Informed Consent

Douglas MacKay, Averi Chakrabarti

Public Health Ethics, July 2019; 12(2) pp 188–201

Abstract

Governments are increasingly making use of field experiments to evaluate policy interventions in the spheres of education, public health and welfare. However, the research ethics literature is largely focused on the clinical context, leaving investigators, institutional review boards and government agencies with few resources to draw on to address the ethical questions they face regarding such experiments. In this article, we aim to help address this problem, investigating the conditions under which informed consent is required for ethical policy research conducted or authorized by government. We argue that investigators need not secure participants' informed consent when conducting government policy experiments if: (i) the government institution conducting or authorizing the experiment possesses a right to rule over the spheres of policy targeted by the research; and (ii) data collection does not involve the violation of participants' autonomy rights.

Philosophical Basis of Informed Consent, Informed Refusal and Documentation of Medical Information into Medical Record

Ismijatie Jenie, Ahdiana Yuni Lestari

Journal Media Hukum, June 2019; 26(1) pp 60-70

Open Access

Abstract

Information delivered by the medical professionals to the patients in their initial communication is crucial in establishing the therapeutic contract (transaction). Based on that information, the patient will decide whether to accept or to refuse the proposed medical treatment. This paper discusses the philosophical basis of the Informed Consent, Informed Refusal and the documentation of medical information into Medical Record. This normative legal research is carried out by library-based study on primary and secondary legal materials. Besides descriptive-analytical approach, the study also employs comparative approach. The comparison is made between continental legal system, common law system, and the Islamic legal system. It is found that philosophical basis of informed consent, informed refusal and documentation of medical information into medical record is basically to protect the patients' dignity and to maintain their trust and cooperation. Furthermore, from the Islamic perspective the establishment of informed consent is to respect the privacy to blood, property, and family. In addition, the documentation of medical information into the medical record is to give legal protection in the form of strong evidence both for the health providers and health receivers in the event of a medical dispute.

Editor's note: MEDIA HUKUM (JMH) is journal published by Faculty of Law Universitas Muhammadiyah Yogyakarta. JMH publishes scientific articles that related in law, development and harmonization of Shariah and positive law in Indonesia.

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CULTURAL/COUNTRY CONTEXT

Overvaluing individual consent ignores risks to tribal participants

Comment

Krystal S. Tsosie, Joseph M. Yracheta, Donna Dickenson

Nature Reviews Genetics, 15 July 2019

Excerpt

Genomic studies often rely on individual-based consent approaches for tribal members residing outside of their communities. This consent model fails to acknowledge the risks to small groups such as tribes, which can implicate the community as a whole.

The challenge of community engagement and informed consent in rural Zambia: an example from a pilot study

Research Article

Joseph Mumba Zulu, Ingvild Fossgard Sandøy, Karen Marie Moland, Patrick Musonda, Ecloss Munsaka, Astrid Blystad

BMC Medical Ethics, 4 July 2019; 20(45)

Open Access

Abstract

Background

There is a need for empirically based research on social and ethical challenges related to informed consent processes, particularly in studies focusing on adolescent sexual and reproductive health. In a pilot study of a school-based pregnancy prevention intervention in rural Zambia, the majority of the guardians who were asked to consent to their daughters' participation, refused. In this paper we explore the reasons behind the

low participation in the pilot with particular attention to challenges related to the community engagement and informed consent process.

Methods

The pilot was implemented in two schools and examined the acceptability of a package of interventions including economic support to families to keep their girls in school, pocket money for girls, youth club meetings on reproductive health, and community meetings to sensitize the community. Focus group discussions (4) were conducted with girls who participated in the pilot, boys in their class and with parents. Individual semi-structured interviews (11) were conducted with teachers, peer educators and community health workers involved in the coordination of the intervention as well as with religious and traditional leaders. Data were analyzed through thematic analysis.

Results

The findings indicate that inadequate use of recognized community communication channels during the community engagement process and dissemination of information about the pilot resulted in limited understanding of the pilot concept by the community. This surfaced through uncertainty and fear that the intervention may result in loss of control over daughters, worries about why money was provided unconditionally to girls, and suspicion of links to satanism. The sense of insecurity appeared to be exacerbated by low literacy levels, poverty, fear of loss of bride wealth, perceived disregard for local perceptions of social status, and scanty trust in the actors implementing the pilot.

Conclusions

Inadequate use of locally appropriate channels in the dissemination of information created room for interpretation and facilitated development of mistrust, undermining the conditions for community engagement and actual informed consent. A key lesson learnt is the importance of taking seriously the complexity of local values and structures that may impact people's capability to consent or not consent to a study in an informed manner.

Free, Prior and Informed Consent (FPIC) in Mexico: Elements for its construction and challenges

Jose Israel Herrera

The Age of Human Rights Journal, June 2019; 12 pp.62-83

Open Access

Abstract

Free, Prior and Informed Consent (FPIC) - Consultation has become one of the most powerful tools indigenous people and minorities have to generate a dialogue and begin a negotiation in the country to face Government decisions, private companies seeking to carry out any work or when legislative measures are about to be implemented on their territories with a possibility of damaging them. In Mexico, this right is based over a group of not articulated among themselves normative foundations. This end up causing confusion and uncertainty on its application. This article presents elements to review the FPIC - Consultation foundations in Mexico for discussion and theoretical deepening in the light of human rights.

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RIGHTS/LEGAL/LEGISLATIVE

Consent for data processing under the General Data Protection Regulation: could 'dynamic consent' be a useful tool for researchers?

J. Kaye, H. Teare, J. Bell

Journal of Data Protection and Privacy, 19 July 2019

Abstract

The General Data Protection Regulation (GDPR) sets a high bar for consent for the processing of personal data. In the UK, researchers have been directed to rely on legal bases other than consent for processing

personal data for research purposes. Informed consent nonetheless, and despite certain shortcomings, holds a central position in ethical research practice, as well as at common law, and in a range of other legislation dealing with research involving humans.

This paper evaluates the place of informed consent in research following the GDPR's implementation, arguing that a fresh approach to consent – specifically the concept known as 'dynamic consent' – could provide a way for researchers to meet the new European regulatory requirements for data processing whilst adhering to the highest ethical standards for research conduct. It analysis dynamic consent according to specific GDPR requirements and reflects on practical examples that could inform future implementation of the approach, while remaining aware of the need for further empirical research.

Key Information in the New Common Rule: Can It Save Research Consent?

Research Article

Nancy M. P. King

The Journal of Law, Medicine & Ethics, 12 July 2019

Abstract

Informed consent in clinical research is widely regarded as broken, but essential nonetheless. The most recent attempt to reform it comes as part of the first revisions to the Common Rule since it became truly "common" in 1991. This change, the addition of a "key information" requirement for most consent forms, is intended to support and promote a reasoned decision-making process by potential subjects. The key information requirement is both promising and problematic. It is promising because it encourages clarity and honesty about research participation, creativity in information disclosure, and mutual learning through the investigator-subject relationship. It is problematic because those goals — which have remained aspirational since the beginning — may be difficult to achieve in what has become an excessively compliance-oriented regulatory regime.

Implementing Regulatory Broad Consent Under the Revised Common Rule: Clarifying Key Points and the Need for Evidence

Research Article

Holly Fernandez Lynch, Leslie E. Wolf, Mark Barnes

The Journal of Law, Medicine & Ethics, 12 July 2019

Abstract

The revised Common Rule includes a new option for the conduct of secondary research with identifiable data and biospecimens: regulatory broad consent. Motivated by concerns regarding autonomy and trust in the research enterprise, regulators had initially proposed broad consent in a manner that would have rendered it the exclusive approach to secondary research with all biospecimens, regardless of identifiability. Based on public comments from both researchers and patients concerned that this approach would hinder important medical advances, however, regulators decided to largely preserve the status quo approach to secondary research with biospecimens and data. The Final Rule therefore allows such research to proceed without specific informed consent in a number of circumstances, but it also offers regulatory broad consent as a new, optional pathway for secondary research with identifiable data and biospecimens. In this article, we describe the parameters of regulatory broad consent under the new rule, explain why researchers and research institutions are unlikely to utilize it, outline recommendations for regulatory broad consent issued by the Secretary's Advisory Committee on Human Research Protections (SACHRP), and sketch an empirical research agenda for the sorts of questions about regulatory broad consent that remain to be answered as the research community embarks on Final Rule implementation.

Blockchain Based Informed Consent with Reputation Support

Advances in Intelligent Systems and Computing book series

Hélder Ribeiro de Sousa, António Pinto

International Congress on Blockchain and Applications, 25 June 2019; pp 54-61

Abstract

Digital economy relies on global data exchange flows. On May 25th 2018 the GDPR came into force, representing a shift in data protection legislation by tightening data protection rules. This paper introduces an innovative solution that aims to diminish the burden resulting from new regulatory demands on all stakeholders. The presented solution allows the data controller to collect the consent, of a European citizen, in accordance to the GDPR and persist proof of said consent on public a blockchain. On the other hand, the data subject will be able to express his consent conveniently through his smartphone and evaluate the data controller's performance. The regulator's role was also contemplated, meaning that he can leverage certain system capabilities specifically designed to gauge the status of the relationships between data subjects and data controllers.

Speech as Speech: "Professional Speech" and Missouri's Informed Consent for Abortion Statute

Michael J. Essma

Missouri Law Review, Spring 2019; 84(2)

Open Access

Excerpt

Does life begin at conception? Do women need to see a sonogram to make an informed decision about whether they want an abortion? Some state legislatures believe so.[1] Laws mandating politically driven doctor-patient dialogue affect one of the hallmarks of the physician-patient relationship: a patient's trust in the physician's expertise. The common law and statutory requirement that a patient provide informed consent for a medical procedure facilitates the development of trust between patient and physician by allowing the patient to understand the procedure and discuss her options with her physician.[2] However, provisions of abortion-specific informed consent statutes that require physicians to communicate to the patient messages with which the physician disagrees undermine this trust…

Consent, capacity and the law [BOOK CHAPTER]

Jonathan Waite

The ECT Handbook, Cambridge University Press, Online 2018; chapter 22

Summary

All medical procedures, be they therapeutic or investigative, touch on the issue of consent – that is a measure of willingness on the part of the patient to undertake the procedure proposed. In this, ECT is no different to other therapeutic interventions. However, ECT has a particular status both within psychiatry and within the law that makes specific discussion of issues with regard to consent necessary.

> *Editor's note: The Cambridge university Press summarizes The ECT Handbook as "present[ing] the latest clinical guidelines on the prescription and practical administration of electroconvulsive therapy (ECT). It clarifies the place of ECT in contemporary practice and reviews the evidence for its efficacy. The ECT Handbook is an essential reference manual for all psychiatrists, for anaesthetists and nurses who work in ECT clinics, for everyone professionally involved in caring for patients for whom ECT may be recommended, and for second-opinion appointed doctors working for the Care Quality Commission."*

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GENERAL/OTHER

Informed Consent: an Update

Biermann E.

Anasthesiol Intensivmed Notfallmed Schmerzther, 25 Jul 2019; 54(7-8) pp 457-473

Abstract

An indication for a medical intervention alone is not sufficient to justify its implementation. In addition, consent has to be obtained from the patient who has been given relevant information by a doctor. If, instead of the patient, other persons are entitled to decide for him (parents for children incapable of consent, authorised representatives, carers), they must be informed. If the patient, who is aware of the significance of his decision, refuses to consent to the measure as a whole or to parts of it, the physician is bound by it - even if the patient's refusal is based on religious, ideological or other reasons which are not comprehensible to the physician. In urgent cases, and in the case of a patient unable to give consent, the doctor can initiate treatment according to the principle of so-called presumed consent. The physician must inform the patient about all circumstances essential for the consent in a timely and comprehensible manner, i.e. also in the language of the patient in the case of patients who do not understand German. The patient must be informed about alternatives if there are other common treatment methods that are medically equally indicated, but which carry substantially different burdens, risks or chances of recovery. From a medical and forensic point of view, risk education is of the greatest importance, in particular information about the typical risks specific to interventions which are unknown to the patient and which, if they materialise, might have a lasting adverse effect on the patient's lifestyle. The extent of risk disclosure is influenced by the urgency of the intervention; the scope of risk disclosure is in inverse proportion to its urgency. An enlightened or otherwise adequately informed patient (e.g. in the case of a series of dressing changes under general anaesthesia) does not have to be enlightened every time, provided that the risk spectrum for the patient has not changed. Consent and clarification are also verbally effective, written form is strongly recommended for reasons of preserving evidence. However, the patient's right to self-determination also means that the patient can expressly dispense with more detailed information. Such a waiver should be carefully documented.

Editor's note: This is a German language publication.

How Do We Really Communicate? Challenging the Assumptions behind Informed Consent Interventions

Article

Stephanie Solomon Cargill

Ethics & Human Research, 23 July 2019

Abstract

It is generally accepted that ethical research requires valid informed consent and that current informed consent practice frequently fails to attain it. Interventions concerning the content and methods of communication in informed consent have met with limited success. One explanation is that they reflect an outdated and limited model of how communication functions, the transmission model of communication. This model assumes that communication is linear, is limited in time, and succeeds when the content of a message is passed from one person to another without distortion. Later communication models have challenged the limitations and inaccuracies of this model, emphasizing the continuous, contextual, and relational nature of communication. Looking beyond these assumptions behind current interventions can open multiple paths of research and intervention that have the potential to affect and improve the informed consent process in much greater ways than have been achieved previously.

Bioethical reflexivity and requirements of valid consent: conceptual tools

Debate

John Barugahare

BMC Medical Ethics, 4 July 2019; 20(44)

Open Access

Abstract

Background

Despite existing international, regional and national guidance on how to obtain valid consent to health-related research, valid consent remains both a practical and normative challenge. This challenge persists despite additional evidence-based guidance obtained through conceptual and empirical research in specific localities on the same subject. The purpose of this paper is to provide an account for why, despite this guidance, this challenge still persist and suggest conceptual resources that can help make sense of this problem and eventually mitigate it'.

Main body

This paper argues that despite the existence of detailed official guidance and prior conceptual and empirical research on how to obtain valid consent, the question of 'how to obtain and ascertain valid consent to participation in health-related research' cannot always be fully answered by exclusivereference to pre-determined criteria/guidance provided by the guidelines and prior research'. To make intelligible why this is so and how this challenge could be allayed, the paper proposes six concepts. The first five of these are intended to account for the persistent seeming inadequacies of existing guidelines. These are fact-skepticism; guideline insufficiency; generality; context-neutrality and presumptiveness. As an outcome of these five, the paper analyzes and recommends a sixth, called bioethical reflexivity. Bioethical reflexivity is reckoned as a handy tool, skill, and attitude by which, in addition to guidance from context-specific research, the persisting challenges can be further eased.

Conclusions

Existing ethical guidelines on how to obtain valid consent to health-related research are what they ought to be – general, presumptive and context-neutral. This explains their seeming inadequacies whenever they are being applied in concrete situations. Hence, the challenges being encountered while obtaining valid consent can be significantly eased if we appreciate the guidelines' nature and what this means for their implementation. There is also a need to cultivate reflexive mindsets plus the relevant skills needed to judiciously close the unavoidable gaps between guidelines and their application in concrete cases. This equally applies to the gaps which cannot be filled by reference to additional guidance from prior conceptual and empirical research in specific contexts.

Attitudes Regarding Enrollment in a Genetic Research Project: An Informed Consent Simulation Study Comparing Views of People With Depression, Diabetes, and Neither Condition

Research Article

Jane Paik Kim, Katie Ryan, Laura Weiss Roberts

Journal of Emirical Research on Human Research Ethics, 22 July 2019

Abstract

In this study, participants with a self-reported history of depression, diabetes, or no illness underwent a simulated informed consent process for a hypothetical genetic study related to depression or diabetes. Participants completed a survey assessing their perceived understanding of the research process, perceptions of its risks and benefits, their satisfaction with the informed consent process, and their readiness to make a hypothetical enrollment decision. All participants indicated strong readiness to make an enrollment decision regarding the research characterized in the simulation. Participants reported understanding the consent process relatively well and being generally satisfied with it. Greater concerns were expressed regarding psychosocial risks than biological risks for genetic studies on mental disorders. Our study documented positive attitudes toward volunteering for research that involved the collection of genetic data.

How to Strengthen Patients' Meaning Response by an Ethical Informed Consent in Psychotherapy

Conceptual Analysis Article

Manuel Trachsel, Martin grosse Holtforth

Frontiers in Psychology, 31 July 2019

Open Access

Abstract

Healthcare professionals including psychotherapists are legally and ethically obliged to ensure informed consent for the provided treatments comprising type and duration or potential benefits and possible risks (e.g., side effects) among others. In the present contribution, we argue that as potential benefit, informed consent can foster the patient's meaning response. Moerman's notion of the meaning response as the physiological or psychological effects of meaning in the course and treatment of an illness is a useful concept in explaining the effects of communicating a treatment rationale as part of the informed consent procedure. The more compelling the rational explanation of the targeted treatment effects including an explanatory model and a model of unique and common change mechanisms, the stronger the meaning response is expected to be resulting in increased hope and positive expectations with regard to the treatment.

Privacy, Sensitive Questions, and Informed Consent: Their Impacts on Total Survey Error, and the Future of Survey Research

Eric Plutzer

Public Opinion Quarterly, 28 June 2019; 83(1) pp 169-184

Abstract

Survey science is driven to maximize data quality and reduce Total Survey Error (TSE). At the same time, survey methodologists have ethical and professional obligations to protect the privacy of respondents and ensure their capacity to provide informed consent for their participation, for data linkage, passive data collection, and the archiving of replication data. We have learned, however, that both sensitive topics and the consent process can contribute to errors of representation and errors of measurement. These compound threats to data quality that arise due to broader concerns about privacy, the intrusiveness of surveys, and the increasing number of participation requests directed to the same respondents. This article critically assesses the extant literature on these topics—including six original articles in this issue—by viewing these challenges through the lens of the TSE framework. This helps unify several distinct research programs and provides the foundation for new research and for practical innovations that will improve data quality.

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MEDICAL/SURGICAL

Association of Preoperative Disclosure of Resident Roles With Informed Consent for Cataract Surgery in a Teaching Program

Original Investigation

Alicia M. Corwin, Jonathan N. Rajkumar, Bruce J. Markovitz, Avrey Thau, Douglas M. Wisner, John M. Spandorfer, Benjamin E. Leiby, Robert Bailey, George L. Spaeth, Alex V. Levin

JAMA Ophthalmology, 25 July 2019

Abstract

Importance

Cataract surgery is the most commonly performed intraocular surgery. Academic centers have mandates to train the next surgeon generation, but resident roles are often hidden in the consent process.

Objective

To investigate associations of full preoperative disclosure of the resident role with patient consent rates and subjective experience of the consent process.

Design, Setting, and Participants

Full scripted disclosure of residents' roles in cataract surgery was delivered by the attending surgeon. Qualitative analysis was conducted from recorded interviews of patients postoperatively regarding consent process experience and choice of whether to allow resident participation. Associations were sought regarding demographic characteristics and consent rates. Patients were recruited though a private community office. Surgery was performed at a single hospital where resident training was routinely conducted. The study included systemically well patients older than 18 years with surgical cataract. They had no previous eye surgery, English fluency, and ability to engage in informed consent decision-making and postsurgery interview. Patients were ineligible if they had monocular cataracts, required additional simultaneous procedures, had history of ocular trauma, or had cataracts that were surgically technically challenging beyond the usual resident skill level.

Interventions

Eligible patients received an informed consent conversation by the attending physician in accordance with a script describing projected resident involvement in their cataract surgery. Postoperatively, patients were interviewed and responses were analyzed with a quantitative and thematic qualitative approach.

Main Outcomes and Measures

Consent rates to resident participation and qualitative experience of full disclosure process.

Results

Ninety-six patients participated. Participants were between ages 50 and 88 years, 53 were men (55.2%), and 75 were white (85.2%). A total of 54 of 96 participants (56.3%; 95% CI, 45.7%-66.4%) agreed to resident involvement. There were no associations between baseline characteristics and consent to resident involvement identified with any confidence, including race/ethnicity (60% [45 of 75] in white patients vs 30.8% [4 of 13] in nonwhite patients; difference, 29.2%; 95% CI, −0.7% to 57.3%; Fisher exact P = .07). Thematically, those who agreed to resident involvement listed trust in the attending surgeon, contributing to education, and supervision as contributing factors. Patients who declined stated fear and perceived risk as reasons.

Conclusions and Relevance

Our results suggest 45.7% to 66.4% of community private practice patients would consent to resident surgery. Consent rates were not associated with demographic factors. Because residents are less often offered the opportunity to do surgery on private practice patients vs academic center patients, this may represent a resource for resident education.

Training surgeons and the informed consent discussion in paediatric patients: a qualitative study examining trainee participation disclosure

Original Article

Kunal Bhanot, Justin Chang, Samuel Grant, Annie Fecteau, Mark Camp

BMJ, 19 July 2019

Open Access

Abstract

Background

The process of obtaining informed consent is an important and complex pursuit, especially within a paediatric setting. Medical governing bodies have stated that the role of the trainee surgeon must be explained to patients and their families during the consent process. Despite this, attitudes and practices of surgeons and their trainees regarding disclosure of the trainee's participation during the consent process has not been reported in the paediatric setting.

Methods

Nineteen face-to-face interviews were conducted with surgical trainees and staff surgeons at a tertiary-level paediatric hospital in Toronto, Canada. These were transcribed and subsequently thematically coded by three reviewers.

Results

Five main themes were identified from the interviews. (1) Surgeons do not consistently disclose the role of surgical trainees to parents. (2) Surgical trainees are purposefully vague in disclosing their role during the consent discussion without being misleading. (3) Surgeons and surgical trainees believe parents do not fully understand the specific role of surgical trainees. (4) Graduated responsibility is an important aspect of training surgeons. (5) Surgeons feel a responsibility towards both their patients and their trainees. Surgeons do not explicitly inform patients about trainees, believing there is a lack of understanding of the training process. Trainees believe families likely underestimate their role and keep information purposely vague to reduce anxiety.

Conclusion

The majority of surgeons and surgical trainees do not voluntarily disclose the degree of trainee participation in surgery during the informed consent discussion with parents. An open and honest discussion should occur, allowing for parents to make an informed decision regarding their child's care. Further patient education regarding trainees' roles would help develop a more thorough and patient-centred informed consent process.

Ethical challenges of obtaining informed consent from surgical patients

Research Article

Sanaz Moeini, Mohsen Shahriari, Mahdi Shamali

Nursing Ethics, 11 July 2019

Abstract

Background

Informed consent can be obtained by various methods, by various people, and with use of various types of consent forms. Persistent effort is necessary to reveal the practical realities of informed consent to improve ethical and legal standards.

Objective

To determine the ethical challenges of obtaining informed consent from surgical patients.

Methods

The present study was a descriptive cross-sectional study using two researcher-made questionnaires and a checklist for data collection. Data were collected from nursing personnel (n = 95) and surgical patients (n = 203) on the surgical wards of three university hospitals in Isfahan, Iran. Data were analyzed using descriptive statistics, Spearman's rank correlation, Pearson's correlation coefficient, and the t-test.

Ethical considerations

The study was approved by the Ethics Committee of Isfahan University of Medical Sciences (No: 396478).

Results

The mean scores (maximum 100) of awareness, competency, and authority were 36.3, 67.7, and 57.6, respectively. The overall quality of the informed consent was poor (score 53.9 of 100). The higher educational level in patients was correlated with lower awareness of and less authority to give informed consent. Only 12.6% of the nurses stated that patients were given sufficient information to assure informed consent. In 89.2% of the consent forms, the risks of the treatment were mentioned. However, alternative methods and risks and advantages of rejecting the treatment were not mentioned in any of the forms.

Conclusion

Ethical challenges to obtaining informed consent include patients' poor awareness of their rights, a failure to provide adequate information to patients, absence of consideration of patients' educational level, an unclear definition of who is responsible for obtaining informed consent from the patients, time constraints, and use of unclear language and medical jargon. Constructing an ethical framework may guide nursing staff in dealing with the ethical challenges involved in obtaining informed consent.

Implementation of a Bundled Consent Process in the ICU; A Single-Center Experience

Asha M. Anandaiah, Jennifer P. Stevens, Amy M. Sullivan

Critical Care Medicine, 11 July 2019

Abstract

Objectives

A bundled consent process, where patients or surrogates provide consent for all commonly performed procedures on a single form at the time of ICU admission, has been advocated as a method for improving both rates of documented consent and patient/family satisfaction, but there has been little published literature about the use of bundled consent. We sought to determine how residents in an academic medical center with a required bundled consent process actually obtain consent and how they perceive the overall value, efficacy, and effects on families of this approach.

Design

Single-center survey study.

Setting

Medical ICUs in an urban academic medical center.

Subjects

Internal medicine residents.

Interventions

We administered an online survey about bundled consent use to all residents. Quantitative and qualitative data were analyzed.

Measurements and Main Results

One-hundred two of 164 internal medicine residents (62%) completed the survey. A majority of residents (55%) reported grouping procedures and discussing general risks and benefits; 11% reported conducting a complete informed consent discussion for each procedure. Respondents were divided in their perception of the value of bundled consent, but most (78%) felt it scared or stressed families. A minority (26%) felt confident that they obtained valid informed consent for critical care procedures with the use of bundled consent. An additional theme that emerged from qualitative data was concern regarding the validity of anticipatory consent.

Conclusions

Resident physicians experienced with the use of bundled consent in the ICU held variable perceptions of its value but raised concerns about the effect on families and the validity of consent obtained with this strategy. Further studies are necessary to further explore what constitutes best practice for informed consent in critical care.

Valid consent and orthodontic treatment

Maurice J Meade, Annalene Weston, Craig W Dreyer

Australasian Orthodontic Journal, May 2019; 35(1)

Abstract

Valid patient consent is a legal and ethical principle that is fundamental to healthcare provision. Oral health practitioners (OHPs) must understand the principles that need to be addressed to ensure that the consent given by a patient is valid. Failure to obtain consent may result in a negligence claim or a complaint of professional misconduct against the OHP. Orthodontic treatment is mostly elective but is not without risk to the patient. Obtaining and maintaining valid consent for orthodontic treatment presents additional challenges in comparison with other dental procedures as the treatment lasts over a longer time and is most commonly performed in adolescents. In addition, prospective patients need to be informed regarding 'lifelong' management in the retention phase to minimise the risk of relapse. The present paper outlines the principles of valid consent with particular regard to orthodontic treatment in the adolescent patient. OHPs must ensure that they are satisfied that the competent patient has the capacity to voluntarily consent.

Clinicians must also recognise that valid consent is not a one-off 'tick the box' procedural exercise but an ongoing process of effective information sharing in light of changing laws and an ever-changing scientific evidence base within a patient-centred model of healthcare.

Perceptions and Perspectives of Patients regarding process of informed consent in a tertiary care hospital

Original Article

Shanaz Kouser, Tahira Fatima, Zunaira Tabassum, Khushbakht Anwar

Pakistan Journal of Medical and Health Sciences, January - March 2019

Open Access

Abstract

Aim

To analyze the patient's perceptions and perceptive about different components and procedure of taking informed consent in a tertiary care hospital

Methods

This was a cross sectional study conducted with a predesigned interview based questionnaire form. 150 patients who underwent cesarean section, were randomly selected for study at Jinnah Hospital, Lahore, which is a tertiary care multidisciplinary hospital. Patients who had some emergency surgical procedures, patients who belonged to a medical profession and the patients who refused to be interviewed were excluded from the study. Data was analyzed in SPSS Ver:17.0. Frequencies and percentages were calculated for demographic and perception process regarding informed consent.

Results

A total of 150 patients were included in the study. Age range of the patients, who were interviewed was 18-44 years. Majority of the patients were primipara 89(59.3%).Out of all cases, 64(42.7%) of patients were from rural areas and 88 patients (58.7%) belonged to poor socioeconomic class. Almost half of the patients 77(57.3%) were uneducated. It was observed that husbands, parents in law and patient's own parents were somehow or other were involved in the decision making process. In 107 cases (71.3%), the consent form was signed by the husband. The other forms were signed by mother in law 12(8%) and by patient's own parents 31(20.7%), surprisingly none of the patients signed her own consent form as primary consenting person though they were told about the reasons for cesarean section (n=134, 89.3%) by the signatory.

Conclusion

Majority of the patients in our set-up were satisfied with the process of informed consent, though at times, some of them were not fully aware about indications, risks and benefits of the surgery.

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