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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

July 2020

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

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

No new content identified for the following established categories:
BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
RIGHTS/LEGAL/LEGISLATIVE
SOCIAL SCIENCE RESEARCH

Please note that we present a set of appendices, including a glossary, tools for assessment and guidance documents, on our website.

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COVID-19

Consent in the time of COVID-19

Helen Lynne Turnham, Michael Dunn, Elaine Hill, Guy T Thornburn, Dominic Wilkinson
Journal of Medical Ethics, 15 May 2020
Open Access
Abstract
The COVID-19 pandemic crisis has necessitated widespread adaptation of revised treatment regimens for both urgent and routine medical problems in patients with and without COVID-19. Some of these alternative treatments maybe second-best. Treatments that are known to be superior might not be appropriate to deliver during a pandemic when consideration must be given to distributive justice and protection of patients and their medical teams as well the importance given to individual benefit and autonomy. What is required of the doctor discussing these alternative, potentially inferior treatments and seeking consent to proceed? Should doctors share information about unavailable but standard treatment alternatives when seeking consent? There are arguments in defence of non-disclosure; information about unavailable treatments may not aid a patient to weigh up options that are available to them. There might be justified concern about distress for patients who are informed that they are receiving second-best therapies. However, we argue that doctors should tailor information according to the needs of the individual patient. For most patients that will include a nuanced discussion about treatments that would be considered in other times but currently unavailable. That will sometimes be a difficult conversation, and require clinicians to be frank about limited resources and necessary rationing. However, transparency and honesty will usually be the best policy.

Leveraging Tele-Critical Care Capabilities for Clinical Trial Consent

Commentary
Kristina M. Ieronimakis, Janell A. Cain, Michael S. Switzer, David D. Odineal, Thomas K. Deacy, Michael T. O. Stein, Rhonda E. Colombo, Christopher J. Colombo
Critical Care Explorations, July 2020; 2(7) e0167
Open Access
Abstract
A severe coronavirus disease 2019 patient admitted to our institution for medical management was enrolled in a randomized placebo-controlled trial of an investigational therapeutic for coronavirus disease 2019. We leveraged existing video-telecommunication equipment to obtain informed consent. We found video-telecommunication use closely mirrored person-to-person contact for research consent by maintaining engagement and ensuring understanding. Video-telecommunication use facilitated clinical research while minimizing unnecessary exposure to coronavirus disease 2019 and conserving personal protective equipment. Prior to the coronavirus disease 2019 pandemic, research regulatory agencies were essentially silent on the matter of video-telecommunication consent. Regulatory guidance became available during the pandemic in response to increased isolation and social distancing practices. Virtual health and telemedicine use expanded greatly during the pandemic, and this increase will likely persist after the pandemic ends. We anticipate video-telecommunication adoption and implementation for research consent will also continue to grow after the coronavirus disease 2019 pandemic is over.

Risks of COVID-19 for surgical cancer patients: The importance of the informed consent process

Alberto Julius Alves Wainstein, Ana Paula Drummond-Lage, Reitan Ribeiro, Héber Salvador de Castro Ribeiro, Rodrigo Nascimento Pinheiro, Glauco Baiocchi, Paulo Henrique de Sousa Fernandes, Marciano Anghinoni, Gustavo Andreazza Laporte, Manoel Jesus Coelho Junior, Vinicius Negri Dall'Inha, Alexandre Ferreira Oliveira

Journal of Surgical Oncology, 20 June 2020

Open Access

Excerpt

Since the World Health Organization (WHO) declared novel coronavirus disease-2019 (COVID-19) a global pandemic in March 2020, its rapidly spreading outbreak imposes an unprecedented burden on the effectiveness and sustainability of the health care system all over the world. The global debate regarding the safety and feasibility of continuing to perform elective surgery made most surgical societies suggest that nonessential elective surgery should be postponed. However, now, it is clear that cancer surgery, in general, should not be delayed for most patients. As part of the patients' preparation for surgery, the traditional informed consent now must also address the risks of COVID-19.

It is unquestioned that, despite the infection effect on practice, the consent process should keep the patient as the main focus. Taking that into consideration, it is the Brazilian Society of Surgical Oncology's (BSSO) objective to present the main aspects that must be covered in a surgical Informed Consent Form (ICF) to properly inform patients how this pandemic has influenced their cancer surgery and perioperative care. Supplement 1 provides the BSSO suggested ICF, adjusted to Brazilian laws and regulations…

Research on COVID-19 in South Africa: Guiding principles for informed consent

J de Vries, T Burgess, M Blockman, N A B Ntusi

South African Medical Journal, 5 June 2020

Open Access

Abstract

Research is imperative in addressing the COVID-19 epidemic, both in the short and long term. Informed consent is a key pillar of research and should be central to the conduct of COVID-19 research. Yet a range of factors, including physical distancing requirements, risk of exposure and infection to research staff, and multiple pressures on the healthcare environment, have added layers of challenges to the consent process in COVID-19 patients. Internationally, the recognition that consent for COVID-19 research may be imperfect has led to a range of suggestions to ensure that research remains ethical. Drawing on these guidelines, we propose a consent process for COVID-19 research in the South African context that combines individual consent with delayed and proxy consent for individuals who may be temporarily incapacitated, combined with key principles that should be considered in the design of a consent process for COVID-19 research.

Urological surgery in the COVID-19 era: Patient counselling and informed consent

Elsayed Desouky

Arab Journal of Urology, 17 May 2020; 18(2) pp 62-64

Open Access

Abstract

The current coronavirus disease 2019 (COVID-19) pandemic is massively affecting our daily practice. Elective surgical service has been significantly altered, i.e. reduced overall service provision, special operating theatres' precautions, as well as considerations for testing patients before surgery. The process of counselling patients and obtaining their consent is a must before any surgical intervention. Several factors can affect this process particularly amid the current pandemic crisis. Only with a full understanding of all the relevant facts, including risks and available alternatives, can patients give an 'informed consent'. Therefore, we urologists need to be aware of the impact of the current COVID-19 situation on how to consent our patients.

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POLICY GUIDANCE/PROGRAM ACTION

Protecting Privacy and Consent Online

News
Barnaby Lewis
International Standards Organisation, 23 June 2020
Excerpt
For everyone concerned about online privacy, ISO/IEC 29184 has just been published…

Devices such as these collect and process your personal data. That might include geographical and biometric data, or the frequency and timing of interactions with the device. That's legitimate, and useful for those who want to be able to get an objective insight into, say, their sleeping habits. But it also provides lucrative opportunities to companies who use such data to market their products and services, often without our informed consent…

The new standard, developed jointly by ISO and the IEC's committee on information security, cybersecurity and privacy protection1), provides details on the implementation of privacy principles from ISO/IEC 29100. Specifically, it addresses consent and choice (Principle 1), and openness, transparency and notice…

In addition to providing clearer information about what kind of PII is being collected and how it is being used, ISO/IEC 29184 will help people to better understand just what they're signing up to when they use connected services and, importantly, how to withdraw their consent…

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GENOMIC MEDICINE/GENE EDITING

A qualitative study on aspects of consent for genomic research in communities with low literacy

Research Article
Daima Bukini, Columba Mbekenga, Siana Nkya, Lisa Purvis, Sheryl McCurdy, Michael Parker, Julie Makani
BMC Medical Ethics, 12 June 2020; 21(48)
Open Access
Abstract
Background
Low literacy of study participants in Sub - Saharan Africa has been associated with poor comprehension during the consenting process in research participation. The concerns in comprehension are far greater when consenting to participate in genomic studies due to the complexity of the science involved. While efforts are made to explore possibilities of applying genomic technologies in diseases prevalent in Sub Saharan Africa, we ought to develop methods to improve participants' comprehension for genomic studies. The purpose of this study was to understand different approaches that can be used to seek consent from individuals with low literacy in Sub-Saharan African countries in genomic research to improve comprehension.
Methods
Using qualitative study design, we conducted focus-group discussions, in-depth interviews and participant observations as data collection methods. This study was embedded in a hospital based genomic study on Sickle Cell Disease at Muhimbili National Hospital in Tanzania. Thematic content analysis was used to analyse the transcripts and field notes.
Results
Findings from this study show that literacy level has little influence on understanding the research details. According to the participants of this study, the methods used to provide information, the language, and time

spent with the study participants were the key factors influencing understanding. The availability of group sessions held before individual consent to allow for a detailed questions and answers format was agreed to be the best method to facilitate the comprehension.

Conclusion

The quality of the consenting process of participants will be influence by a number of factors. The type of research consented for, where the research will be implemented and who are the potential study participants are amongst the factors that need to be assessed during the consenting. Measures to improve participants' comprehension need to be developed when consenting participants with low literacy level in genomic studies.

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HUMANITARIAN CONTEXT

Research ethics and refugee health: a review of reported considerations and applications in published refugee health literature, 2015-2018

Research

Emma E. Seagle, Amanda J. Dam, Priti P. Shah, Jessica L. Webster, Drue H. Barrett, Leonard W. Ortmann, Nicole J. Cohen, Nina N. Marano

BMC Conflict and Health, 20 June 2020; 14(39)

Open Access

Abstract

Introduction

Public health investigations, including research, in refugee populations are necessary to inform evidence-based interventions and care. The unique challenges refugees face (displacement, limited political protections, economic hardship) can make them especially vulnerable to harm, burden, or undue influence. Acute survival needs, fear of stigma or persecution, and history of trauma may present challenges to ensuring meaningful informed consent and establishing trust. We examined the recently published literature to understand the application of ethics principles in investigations involving refugees.

Methods

We conducted a preliminary review of refugee health literature (research and non-research data collections) published from 2015 through 2018 available in PubMed. Article inclusion criteria were: participants were refugees, topic was health-related, and methods used primary data collection. Information regarding type of investigation, methods, and reported ethics considerations was abstracted.

Results

We examined 288 articles. Results indicated 33% of investigations were conducted before resettlement, during the displacement period (68% of these were in refugee camps). Common topics included mental health (48%) and healthcare access (8%). The majority (87%) of investigations obtained consent. Incentives were provided less frequently (23%). Most authors discussed the ways in which community stakeholders were engaged (91%), yet few noted whether refugee representatives had an opportunity to review investigational protocols (8%). Cultural considerations were generally limited to gender and religious norms, and 13% mentioned providing some form of post-investigation support.

Conclusions

Our analysis is a preliminary assessment of the application of ethics principles reported within the recently published refugee health literature. From this analysis, we have proposed a list of best practices, which include stakeholder engagement, respect for cultural norms, and post-study support. Investigations conducted among refugees require additional diligence to ensure respect for and welfare of the participants. Development of a refugee-specific ethics framework with ethics and refugee health experts that addresses the need for stakeholder involvement, appropriate incentive use, protocol review, and considerations of cultural practices may help guide future investigations in this population.

Barriers to Obtaining Informed Consent on Shortterm Surgical Missions

Urška Čebron, Calum Honeyman, Meklit Berhane, Vinod Patel, Dominique Martin, Mark McGurk

Plastic and Reconstructive Surgery - Global Open: May 2020; 8(5) e2823

Open Access

Abstract

Background

Short-term surgical missions (STSMs) enable visiting surgeons to help address inequalities in the provision of surgical care in resource-limited settings. One criticism of STSMs is a failure to obtain informed consent from patients before major surgical interventions. We aim to use collective evidence to establish the barriers to obtaining informed consent on STSMs and in resource-limited settings and suggest practical solutions to overcome them.

Methods

A systematic review was performed using PubMed and Web of Science databases and following Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines. In addition to the data synthesized from the systematic review, we also include pertinent data from a recent long-term follow-up study in Ethiopia.

Results

Of the 72 records screened, 11 studies were included in our review. The most common barrier to obtaining informed consent was a paternalistic approach to medicine and patient education. Other common barriers were a lack of ethics education among surgeons in low-income and middle-income countries, cultural beliefs toward healthcare, and language barriers between the surgeons and patients. Our experience of a decade of reconstructive surgery missions in Ethiopia corroborates this. In a long-term follow-up study of our head-and-neck patients, informed consent was obtained for 85% (n = 68) of patients over a 14-year period.

Conclusions

This study highlights the main barriers to obtaining informed consent on STSMs and in the resource-limited setting. We propose a checklist that incorporates practical solutions to the most common barriers surgeons will experience, aimed to improve the process of informed consent on STSMs.

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BIOMEDICAL RESEARCH

Potential research participants' use of information during the consent process: A qualitative pilot study of patients enrolled in a clinical trial

Research Article

Simon Paul Jenkins, Melanie J. Calvert, Heather Draper

PLOS One, 18 June 2020

Open Access

Abstract

There is increasing evidence that clinical trial participants are uninformed about the trials in which they participate, raising ethical concerns regarding informed consent. The aim of this pilot study was to explore clinical trial participants' use of consent discussions and information sheets when considering participating in clinical trials research. A qualitative, interview-based pilot study was designed in order to elicit, through dialogue, details of the reasons for participants' use of, and preferences regarding, different modes of information provision. Semi-structured interviews were undertaken with two different groups of patients who were participants in the Reinforcement of Closure of Stoma Site trial. The first group comprised newly-consented trial participants, who had been recruited up to 72 hours before our interview; the second group comprised patients attending a follow-up clinic 12 months after joining the trial. Thirteen participants were

recruited in total: three newly-consented patients, and ten follow-up patients. The study found that participants' use of consent discussions to gain information about clinical trials was varied, and that they only minimally used information sheets after providing initial consent for the trial. Participants demonstrated varying degrees of knowledge about the trial, with some having forgotten that they were still involved in the trial. Participants reported a high level of trust in medical staff as a reason for not seeking more information about the trial. Some participants reported dissatisfaction with the timing of information provision. Some were amenable to novel ways of receiving trial information, such as web-based methods. The pilot study demonstrated the feasibility of a larger study into the provision of information to prospective clinical trial participants. The results suggest that considering alternative ways of providing information and the appropriateness of existing information provision may be acceptable to and useful for potential trial participants.

Informed consent procedures in patients with an acute inability to provide informed consent: Policy and practice in the CENTER-TBI study

Roel P. J. van Wijk, Jeroen T. J. M. van Dijck, Marjolein Timmers, Ernest van Veen, Giuseppe Citerio, Hester F. Lingsma, Andrew I. R. Maas, David K. Menon, Wilco C. Peul, Nino Stocchetti, Erwin J. O. Kompanje

Journal of Critical Care, October 2020, 59; 6-15

Abstract

Purpose

Enrolling traumatic brain injury (TBI) patients with an inability to provide informed consent in research is challenging. Alternatives to patient consent are not sufficiently embedded in European and national legislation, which allows procedural variation and bias. We aimed to quantify variations in informed consent policy and practice.

Methods

Variation was explored in the CENTER-TBI study. Policies were reported by using a questionnaire and national legislation. Data on used informed consent procedures were available for 4498 patients from 57 centres across 17 European countries.

Results

Variation in the use of informed consent procedures was found between and within EU member states. Proxy informed consent (N = 1377;64%) was the most frequently used type of consent in the ICU, followed by patient informed consent (N = 426;20%) and deferred consent (N = 334;16%). Deferred consent was only actively used in 15 centres (26%), although it was considered valid in 47 centres (82%).

Conclusions

Alternatives to patient consent are essential for TBI research. While there seems to be concordance amongst national legislations, there is regional variability in institutional practices with respect to the use of different informed consent procedures. Variation could be caused by several reasons, including inconsistencies in clear legislation or knowledge of such legislation amongst researchers.

Advances and challenges in conducting ethical trials involving populations lacking capacity to consent: A decade in review

Victoria Shepherd

Contemporary Clinical Trials, August 2020; 95

Abstract

Informed consent is an essential requirement prior to clinical trial participation, however some 'vulnerable' groups, such as people with cognitive impairments and those in medical emergency situations, may lack decisional capacity to consent. This raises ethical and practical challenges when designing and conducting clinical trials involving these populations, who are frequently excluded as a result. Despite recent advances in

improving informed consent processes, there has been far less attention paid to the enrolment of adults lacking capacity.

Exclusion criteria are an important determinant of the external validity of clinical trial results. The exclusion of these populations, and consent-based recruitment biases which arise from the challenges of identifying and involving surrogate decision-makers, leads to trials which are not representative of the clinical population.

This article discusses the involvement of adults who lack decisional capacity to consent in clinical trials and presents the advances over the previous decade and the remaining ethical challenges for the inclusion of this under-represented population in research.

Informing Informed Consent for HIV Research

Research Article

Laura M. Campbell, Emily W. Paolillo, Robert Bryan, Jennifer Marquie-Beck, David J. Moore, Camille Nebeker, Raeanne C. Moore

Journal of Empirical Research on Human Research Ethics, 19 June 2020

Abstract

"Respect for Persons" is an ethical principle demonstrated through the informed consent process. Participants at a large HIV research center were surveyed to identify important aspects of the consent process. Persons with and without HIV (n = 103) completed a short pre/post questionnaire with both open-ended and forced choice response options. Qualitative analysis resulted in eleven themes about the most important consent elements which did not differ by HIV serostatus. Overall, participants rated the informed consent content and presentation by research staff as "extremely informative" and found the consent information to be "extremely consistent" with their study experience. Study results support the value of an interactive process and can be used to inform the design of a standardized, digital consent process.

Communication Training for Obtaining Informed Consent for Medical Research [BOOK CHAPTER]

N. Ananthakrishnan

Effective Medical Communication

Springer, 17 June 2020; pp 63-76

Abstract

Medical practice requires constant interaction between health care providers and those who seek care at these facilities. In addition, modern medicine also requires a strong focus on continued research for the benefit of mankind. It is estimated that the doubling time of medical knowledge in 1950 was 50 years; in 1980, 7 years; and in 2010, 3.5 years. In 2020, it is projected to be 0.2 years—just 73 days [1]. According to an estimate, students who join medicine in 2010 would experience three doublings before they complete the course, and those who join in 2020 would experience four doublings [1]. Medical research on either patients or other subjects/volunteers has, therefore, become an undeniable existential fact of medical practice.

An under-represented and underserved population in trials: methodological, structural, and systemic barriers to the inclusion of adults lacking capacity to consent

Commentary

Victoria Shepherd

BMC Trials, 29 May 2020; 21(445)

Open Access

Abstract

Background

There is increasing international recognition that populations included in trials should adequately represent the population treated in clinical practice; however, adults who lack the capacity to provide informed

consent are frequently excluded from trials. Addressing the under-representation of groups such as those with impaired capacity to consent is essential to develop effective interventions and provide these groups with the opportunity to benefit from evidence-based care. While the spotlight has been on ensuring only appropriate and justifiable exclusion criteria are used in trials, barriers to the inclusion of adults lacking capacity are multifactorial and complex, and addressing their under-representation will require more than merely widening eligibility criteria. This commentary draws on the literature exploring the inclusion of adults lacking the capacity to consent in research and a number of recent studies to describe the methodological, structural, and systemic factors that have been identified.

Main text

A number of potentially modifiable factors contributing to the under-representation of adults lacking the capacity to consent in trials have been identified. In addition to restrictive eligibility criteria, methodological issues include developing appropriate interventions and outcome measures for populations with impaired capacity. Structurally determined factors include the resource-intensive nature of these trials, the requirement for more appropriate research infrastructure, and a lack of interventions to inform and support proxy decision-makers. Systemic factors include the complexities of the legal frameworks, the challenges of ethical review processes, and paternalistic attitudes towards protecting adults with incapacity from the perceived harms of research.

Conclusions

Measures needed to address under-representation include greater scrutiny of exclusion criteria by those reviewing study proposals, providing education and training for personnel who design, conduct, and review research, ensuring greater consistency in the reviews undertaken by research ethics committees, and extending processes for advance planning to include prospectively appointing a proxy for research and documenting preferences about research participation. Negative societal and professional attitudes towards the inclusion of adults with impaired capacity in research should also be addressed, and the development of trials that are more person-centred should be encouraged. Further work to conceptualise under-representation in trials for such populations may also be helpful.

Cancer clinical trial consent forms: A readability analysis

Health Services Research and Quality Improvement

Mohana Roy, Lidia Schapira

Journal of Clinical Oncology, 25 May 2020; 38(15) supplement e19075

Abstract

Background: The National Cancer Institute (NCI) provides a template for cancer clinical trial consent forms and recommends a reading grade level of eighth grade or lower for such forms. This recommendation aligns with the goal of making clinical trials accessible to more patients. Methods: We surveyed clinical trial leaders at a large tertiary academic cancer center, to provide consent forms for active or recently closed, interventional cancer clinical trials (as of 2019). We requested forms that were preferably from multi-center trials and those perceived to have the highest accruals. We received 26 consent forms representing nine disease groups. Results: The average Flesh-Kincaid reading grade level was 11.2 (reflecting a 11th grade reading level), and no single form met the 8th grade reading level mark. The grade levels were assessed with three additional readability analyses (SMOG, FORCAST, and Raygor, see Table). The average Flesch reading ease was 50.7, rated as “fairly difficult”, with a scale of 0-100 (100 =“very easy” to read). The general HIPAA consent followed similar patterns, with a reading level of 10.9 and a reading ease of 49.2. There was an average of 18-20 words used per sentence. The reading levels and ease did not significantly vary with disease group or phase of trial. Conclusions: The overall readability level of cancer clinical trial forms, at our center, still require at least at least a 10th grade reading level. These forms may be difficult to understand for those with lower English proficiency and/or health literacy. We recommend a basic readability screen of such forms, and use of shorter sentences and simplified writing structure, to aid in comprehension.

The use of patient health information outside the circle of care: Consent preferences of patients from a large academic cancer centre

Care Delivery and Regulatory Policy

Fei Fei Liu, Sarah Tosoni, Indu S Voruganti, Rebecca Wong, Carl Virtanen, Donald Willison, Ann Heesters

Journal of Clinical Oncology, 25 May 2020; 38(15) supplement e14122

Abstract

Background: Massive volumes of patient health information (PHI) are required to realize the anticipated benefits of artificial intelligence in future clinical medicine. To maintain public trust in medical research however, consent policies must evolve to reflect contemporary patient preferences. Methods: From January-December 2019, patients attending clinics at a large academic cancer centre were invited to complete a 27-item iPad survey on consent preferences. Survey items focused on: (a) broad vs. specific consent; (b) opt-in vs. opt-out approaches for research contact; (c) comfort sharing with different recipients; (d) perceptions on commercialization; and (e) options to track information use and study results. Demographic questions addressed cancer type, treatment stage, age, gender, ethnicity, education level, and household income. Results: A total of 222 participants were included in the analysis (112 males, 108 females; 2 rather not say); 83% were comfortable sharing PHI with researchers at their own hospital. While 56% of patients preferred broad consent, 38% preferred to be contacted with study details and asked to consent every time (specific consent); 6% prefer not to share at all. Younger patients (< 49 years) most often chose specific consent (50%); significantly more than those 75+ years (24%; $p < .05$). Younger patients (< 49 years) were also significantly more uncomfortable than older patients (50+ years) sharing even within their own hospital (13% uncomfortable vs. 1% uncomfortable; $p < .05$). A significant majority of patients (63%, $p = .0001$) preferred to be asked for permission before being entered into a contact pool vs. automatic entry with opportunity to opt-out. The majority of patients were uncomfortable sharing PHI with commercial enterprises (51% uncomfortable, 27% comfortable, 22% neutral). A significant majority expressed the desire to track who is using their PHI (61%, $p < .0001$), and be notified regarding study results (70%, $p < .0001$). Conclusions: While most patients were willing to share their PHI with researchers at their own hospital, many preferred a transparent and reciprocal consent process. These data also suggest a generational shift, wherein younger patients preferred more informed consent options. Modernizing consent policies to reflect increased patient interest in the exercise of their autonomy is crucial in fostering sustained public engagement in medical research.

Informed consent in phase I clinical trials: Implications for trends in design

Care Delivery and Regulatory Policy

Paul Henry Frankel, Susan G. Groshen

Journal of Clinical Oncology, 25 May 2020; 38(15) supplement e14077

Abstract

Background: Informed Consent (IC) is a critical aspect of human subjects protection. Institutional Review Boards are tasked with insuring proper IC as one aspect of protecting participants in clinical trials. Phase I trials in oncology present special issues with IC, as often neither the risks nor the benefits are well-known. This has resulted in carefully worded IC templates for Phase I studies based on the traditional use of dose-finding designs that are geared towards finding the “Maximum Tolerated Dose (MTD)”. As the definition of this term varies by study, the implication for patient risk and informed consent are rarely discussed. Methods: We reviewed Phase I designs to present options for improving the informed consent process for Phase I oncology trials. Results: Phase I studies have seen an increase in designs based on work from the early 1990s seeking a dose that results in a targeted percent of patients experiencing a “Dose Limiting Toxicity (DLT)” to define the MTD. The most common definition of a DLT is a treatment-related toxicity that results in a particularly concerning severe toxicity (grade 3 or higher) in the first cycle of therapy and the most common rate targeted (in designs that define toxicity as a goal) is 25%. In that setting, while lower doses may have a lower likelihood of DLT, higher doses or the expansion cohort are likely to have a 25%

chance of DLT if the target is pursued. This information is rarely quantitatively communicated in the informed consent. Conclusions: IRBs and investigators should consider communicating through informed consent the quantitative summary of goals of the study and related risk. For example, transparency suggests conveying when the goal (target) of the study is to find the dose where there is a one in four chance of experiencing a severe adverse event in the first cycle.

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TECHNOLOGY/OTHER MEDIATION

Towards a Highly Usable, Mobile Electronic Platform for Patient Recruitment and Consent Management

Daniel Robins, Rachel Brody, In Cheol Jeong, Irena Parvanova, Jiazhen Liu, Joseph Finkelstein Abstract
Studies in health technology and informatics, 16 June 2020; 270 pp 1066-1070
Abstract
This study seeks to assess usability and acceptance of E-Consent on mobile devices such as tablet computers for collecting universal biobank consents. Usability inspection occurred via cognitive walkthroughs and heuristics evaluations, supplemented by surveys to capture health literacy, patient engagement, and other metrics. 17 patients of varied ages, backgrounds, and occupations participated in the study. The System Usability Scale (SUS) provided a standardized reference for usability and satisfaction, and the mean result of 84.4 placed this mobile iteration in the top 10th percentile. A semi-structured qualitative interview provided copious actionable feedback, which will inform the next iteration of this project. Overall, this implementation of the E-Consent framework on mobile devices was considered easy-to-use, satisfying, and engaging, allowing users to progress through the consent materials at their own pace. The platform has once again demonstrated high usability and high levels of user acceptance, this time in a novel setting.

Video Consent Improves Satisfaction in a Safety-Net Multi-Lingual Population

Gabriel Castillo, Zoe Lawrence, Janice Jang, Timothy A. Zaki, Adam J. Goodman, Demetrios Tzimas, Andrew Dikman, Renee Williams
Gastrointestinal Endoscopy, 2020; 91(6S) Tu1095
Open Access
Introduction
Informed consent for endoscopy is traditionally done verbally, which places an emphasis on auditory comprehension. Language discordance between providers and patients can negatively impact this process. Studies have shown that patients with low health literacy may prefer other methods of information delivery, such as visual media which may be more meaningful. The use of videos during
informed consent for procedures may improve patient satisfaction and more sufficiently address pre-procedural concerns in comparison to verbal consent. Data on the use of video consent for endoscopy is limited, with recent studies focusing on the pediatric population. Our quality improvement project aimed to assess if the addition of an educational video to the consent process for endoscopy and colonoscopy improves patient comprehension and satisfaction in a safety-net setting with a diverse, underserved population.
Methods
We identified English and Spanish-speaking outpatients presenting for upper endoscopy and colonoscopy in our inner-city, public hospital. Videos detailing the procedures, risks, benefits, and alternatives were produced in both languages. All participants underwent a traditional verbal consent process, and a subset were randomly chosen to watch the video in their preferred language. All patients completed a questionnaire

in their preferred language to assess comprehension and satisfaction. Unpaired t-test analysis was applied to the data.

Results

156 questionnaires were collected: 83 colonoscopy specific (58 English, 25 Spanish) and 73 endoscopy specific questionnaires (37 English, 36 Spanish). 80 patients provided education data, 64% reported an education level of high school or less. Among participants who viewed the colonoscopy video, 79% rated the information provided as excellent compared to 38% of participants who underwent only the traditional verbal consent (p Z <0.05). Among participants who viewed the endoscopy video, 88% rated the information provided as excellent compared to 35% of participants who did not watch the video (p < 0.05). In both cohorts, video consent patients reported improved satisfaction. Our prior results demonstrate a significant improvement in comprehension scores in video consent patients compared to traditional verbal consent (77% vs. 51%, p <0.0001).

Discussion

Our results demonstrate a significant improvement in patient satisfaction with the use of video consent for endoscopic procedures in a multi-lingual population with low educational levels and health literacy. Including a video in the consent process may satisfy multiple learning needs this population. Based on this data, we have obtained a patient care grant which will be used to incorporate this process within our endoscopy suite and compose videos in other languages in order to improve care for our patients.

Replacing Paper Informed Consent with Electronic Informed Consent for Research in Academic Medical Centers: A Scoping Review

Cindy Chen, Pou-I Lee, Kevin J. Pain, Diana Delgado, Curtis L. Cole, Thomas R. Campion Jr.

AMIA Joint Summits on Translational Science Proceedings, 30 May 2020; pp 80-88

Open Access

Abstract

Although experts have identified benefits to replacing paper with electronic consent (eConsent) for research, a comprehensive understanding of strategies to overcome barriers to adoption is unknown. To address this gap, we performed a scoping review of the literature describing eConsent in academic medical centers. Of 69 studies that met inclusion criteria, 81% (n=56) addressed ethical, legal, and social issues; 67% (n=46) described user interface/user experience considerations; 39% (n=27) compared electronic versus paper approaches; 33% (n=23) discussed approaches to enterprise scalability; and 25% (n=17) described changes to consent elections. Findings indicate a lack of a leading commercial eConsent vendor, as articles described a myriad of homegrown systems and extensions of vendor EHR patient portals. Opportunities appear to exist for researchers and commercial software vendors to develop eConsent approaches that address the five critical areas identified in this review.

MSK eConsent: Digitalizing the informed consent process to improve participant engagement and understanding

Care Delivery and Regulatory Policy

Michael T. Buckley, Joseph M. Lengfellner, Matthew J. Koch, Benjamin Search, Carol Hoidra, Mary Lin, Sangeeta Kundu, Roy Cambria, Molly O'Shea, Jesse Galle, Jennifer Wang, Ann Rodavitch, Karima Yataghene, Jaclyn Pember, Stephanie Lucia Terzulli, Collette Houston, Eric Cottington, Paul Sabbatini

Journal of Clinical Oncology, 25 May 2020; 38(15)suppl.2066

Abstract

Background: eConsent was developed to digitize the research participant consenting experience with an educational engagement model. The eConsent platform tiers consent document content in an easy-to-navigate format, using videos, images, and access to supplementary information. We hypothesize that enhancing the consenting experience improves participant engagement and comprehension. Methods: Here we present two projects: 1) qualitative assessment of patient engagement in the eConsent process using a

standardized 5-question survey sent to all patients who used it during 9 months in 2019, and 2) a report of our preliminary findings from exempt protocol, Assessing Participant Engagement and Protocol Education in the Consent Process (X19-055) that quantitatively compares paper and electronic consenting and a) assesses patient agency and b) tests comprehension of key consent elements in 2 protocols: Storage and Research Use of Human Biospecimens (06-107) and Genomic Profiling in Cancer Patients (12-245). Results: 1) 940 patients completed the qualitative experience survey (27% response). Most respondents (777; 83%) indicated that electronic consenting was very easy (371) or easy (406) to use. Only 25 (3%) said electronic consenting was somewhat difficult to use, 3 indicated it was difficult (0.3%), and 64 were neutral. Most (896; 95%) recommended electronic consenting to other MSK patients. Those who reported a 1 unit increase in technology discomfort, only reported a .48 unit increase in eConsent discomfort (P< .001). 2)Quantitative 10-question electronic tests were sent to each patient's portal account within 72h after consenting via paper or eConsent to protocols 06-107 and 12-245. To date, for 06-107: 18 paper consenters completed the test with a score of 76% vs 23 eConsent users who scored 80%. For 12-245: 43 paper consenters scored 69% vs 13 eConsent users scoring 80%. Scores are a surrogate marker for patient comprehension and show that 12-245 protocol participants' average testing scores are higher when participants are consented with eConsent vs paper (P < .01). 06-107 protocol participants' average test scores are trending toward eConsent improving patient understanding (P= .11). We will follow this trend as our sample size increases to a total of 500 participants. Patient agency questions received favorable responses from most patients (100%-84%). Conclusions: eConsent enhances participant engagement and understanding and does not impose a digital burden on participants.

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COGNITIVE CHALLENGES

Capacity, consent and compulsion [BOOK CHAPTER]

Margaret Brazier, Emma Cave
Medicine, patients and the law (sixth edition)
Manchester University Press, 29 May 2020; Chapter 6
Abstract/Excerpt
Capacity, Consent and Compulsion examines the Mental Capacity Act 2005 ten years on. This visionary piece of legislation has led to a substantial body of case law. Its rejection of a pure substituted judgement test in favour of a modified best interests test and its adoption of a two part test for (in)capacity have excited much academic debate. In 2007 the Act was amended to introduce new Deprivation of Liberty Safeguards (DoLS). The DoLS have been widely criticised. We consider measures to support those lacking capacity such as advance directives, lasting powers of attorney and court-appointed deputies. Central to the Act is the Court of Protection which adjudicates on disputes in both health care and welfare matters.

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YOUNG PERSONS

Designing a Solution to Manage Electronic Consent for Children

Gary Leeming , Sarah Thew, John Ainsworth
Studies in health technology and informatics, 16 June 2020; 270 pp 1103-1107
Abstract
Electronic systems for managing consent do exist but are generally only able to record consent from the research subject directly. Consent for research is also challenging to integrate into many electronic patient record systems. The Born In Bradford study is a large, from birth cohort study in the North of England which

requires consent to be recorded by the pregnant mother of a child who will be included in the study from birth. This creates a complex challenge for consent management that has previously been achieved through paper-based processes. As the study begins a new phase with the objective of inviting all new parents within the Bradford region to participate in the study the solution also needs to work with existing maternity systems. This paper considers the specific challenges of converting the often grey rules around consent of children into an electronic system that is transparent and supports the trust of both the family and the clinical and care teams recruiting research subjects into a large cohort study, and describes the user centred design and technical approach taken to resolve it.

Is consent causing confusion for clinicians? A survey of child and adolescent Mental health professional's confidence in using Parental Consent, Gillick Competence and the Mental Capacity Act

Research Article

Clare Fenton

Clinical Child Psychology and Psychiatry, 6 June 2020

Abstract

All professionals engaged in clinical work should be competent to assess consent for the interventions they provide. This study assesses CAMHS clinicians confidence and knowledge in the various forms of consent and the number of minors admitted to mental health units in England under parental consent alone.

An online questionnaire using vignettes of possible scenarios was sent to child and adolescent mental health practitioners in Tees Esk and Wear Valleys Trust. A freedom of information request was used to determine the number of young people admitted through parental consent.

Thirteen of the 20 trusts contacted had no knowledge of the number of young people admitted under parental consent. A total of 93 participants completed the survey. Out of six vignettes, there were two where the majority of responses were discordant with current legal advice. Both of these vignettes considered the use of parental consent for admission to a mental health unit.

This study provides further evidence to indicate that the current consent processes in CAMHS causes confusion for clinicians. There continues to be very few safeguards for children admitted under parental consent, with most trusts in England and Wales having no centralised knowledge of whether this is occurring and the numbers involved if it is.

Racial/ethnic, language, and health literacy disparities on perception of voluntariness during informed consent for pediatric cancer clinical trials

Paula Aristizabal, Arissa MA, Bianca Perdomo, Jesse Nodora, Maria E. Martinez

Eleventh AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved, 2-5 November 2018; New Orleans, LA

Open Access

Abstract

Background

Valid consent for research requires that the decision for participation be both fully informed and voluntary. Previous studies on informed consent have shown that when presented with a clinical trial for their child, parents often do not understand the many components of informed consent, including voluntariness of participation. In addition, individuals with limited English proficiency have reported lower understanding and satisfaction during informed consent. There is limited research on factors associated with perception of voluntariness during participation in pediatric cancer clinical trials. Our aim was to examine contextual factors associated to perception of voluntariness in parents who had consented to participation of their child in a clinical trial for cancer treatment, focused on characterizing differences between non-Hispanics and Hispanics, as the latter is the fastest-growing ethnic group in the U.S.

Methods
Parents (n=97) of children aged 0-17 years with newly diagnosed cancer, who had consented to participation of their child in a clinical trial for treatment at Rady Children's Hospital-San Diego, were prospectively recruited. Participants completed questionnaires assessing sociodemographics, health literacy, perception of voluntariness, decisional regret, satisfaction, and acculturation level, if Hispanic. Outcomes and their correlates were analyzed using logistic regression.
Results
Fifty participants (51.5%) were Hispanic and 47 (48.5%) non-Hispanic. We found that parents who were Hispanic compared to non-Hispanics ($p<0.001$), Spanish-speaking compared to English-speaking ($p=0.048$), and those with lower health literacy ($p<0.001$) had lower perception of voluntariness. Decisional regret was overall low and satisfaction was overall high across all subgroups and neither measure was significantly impacted by sociodemographics, health literacy or acculturation.
Conclusions
In this study, with equivalent numbers of Hispanics and non-Hispanics, we found that Hispanic parents of children with newly diagnosed cancer, and particularly Spanish-speakers and those with low health literacy, had inadequate perception of voluntariness. To our knowledge, this is the first study to associate lower health literacy with lower perception of voluntariness in parents of children with newly diagnosed cancer despite overall high rates of satisfaction with the informed consent process for pediatric cancer clinical trials. True voluntariness of participation is essential to the ethical practice of informed consent, and our study suggests that many participants with low health literacy, particularly Hispanics and Spanish-speaking individuals, are not making truly informed decisions. Tailored interventions can improve decision-making, reduce clinical trial participation inequities and, ultimately, eliminate survival disparities by effectively and equally translating discoveries and treatment benefits to diverse populations.

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CULTURAL/COUNTRY CONTEXT

Egyptians' social acceptance and consenting options for posthumous organ donation; a cross sectional study

Research Article
Ammal M. Metwally, Ghada A. Abdel-Latif, Lobna Eletreby, Ahmed Aboulghate, Amira Mohsen, Hala A. Amer, Rehan M. Saleh, Dalia M. Elmosalami, Hend I. Salama, Safaa I. Abd El Hady, Raefa R. Alam, Hanan A. Mohamed, Hanan M. Badran, Hanan E. Eltokhy, Hazem Elhariri, Thanaa Rabah, Mohamed Abdelrahman, Nihad A. Ibrahim, Nada Chami
BMC Medical Ethics, 15 June 2020; 21(49)
Open Access
Abstract
Background
Organ donation has become one of the most effective ways to save lives and improve the quality of life for patients with end-stage organ failure. No previous studies have investigated the preferences for the different consenting options for organ donation in Egypt. This study aims to assess Egyptians' preferences regarding consenting options for posthumous organ donation, and measure their awareness and acceptance of the Egyptian law articles regulating organ donation.
Methods
A cross sectional study was conducted among 2743 participants over two years. Each participant was required to rank eleven consenting options from 1 (most preferred) to 11 (least preferred), and to report his awareness and acceptance of the seven articles of the Egyptian law of organ donation.
Results

47% of the participants expressed willingness to donate their organs after death. This percentage increased to 78% when consenting options were explained to participants. “Informed consent by donor only” was the most preferred type of consent for one third of respondents. Awareness of the law articles regulating organ donation was relatively low ranging from 56% to 23%.

Conclusion

Currently, around half of the Egyptian population agree to posthumous organ donation. This percentage could be increased significantly by raising the awareness about how the process of donation could be regulated and how the patient’s right of decision could be protected.

Empirical Investigation on the Contents of the Patients Informed Consent Forms for Medical Imaging Services in the Government Hospitals in Nairobi City County, Kenya

Victoria Otysula Koi, Dr. Andrea Yitambe, Dr. Peterson Warutere

International Academic Journal of Health, Medicine and Nursing, 5 June 2020; 2(1) pp 66-79

Open Access

Abstract

Informed consent is a requirement by the law to allow patients to make decisions with respect to their health and well-being. It is an ethical and legal requirement that patients seeking medical imaging services should give an informed consent prior to seeking treatment with respect from healthcare providers. However, the extent of usage of the informed consent process vary across medical procedures. The study therefore seeks to assess the contents of the patients Informed Consent Forms for medical imaging services in the government hospitals in Nairobi City County, Kenya. The study adopted a descriptive cross-sectional study design. The study specifically focused on administration of informed consent, contents of the patients Informed Consent Forms and modes of informed consent used among patients for medical imaging services. Imaging departments in Kenyatta National hospital, Mbagathi, Mama Lucy, National spinal injury and National Mathare Hospitals in Nairobi City County were chosen as the area of study. Patients in the imaging departments of the selected hospitals were recruited for study. The sample size selected was 307 respondents. The respondents were selected using systematic random sampling at a predetermined interval of 3. Collected data was coded for analysis by use of SPSS. Analysis was conducted on descriptive and inferential statistics. Frequency tables, pie charts and graphs were used to present the quantitative data. Inferential statistics were done using Chi Square tests to determine the association between study variables at 95% confidence interval ($p<0.05$). The ethical considerations were strictly followed during data collection. It was further revealed that age ($\chi2=3.782$; df= 4; $p=0.016$;), level of education ($\chi2=3.89$; df= 4; $p=0.030$), revelation of reason for referral ($\chi2=26.081$; df=1; $p=0.001$), provision of right to refuse or defer imaging ($\chi2=33.468$; df= 1; $p=0.001$), giving consent for treatment ($\chi2=70.733$; df=1; $p=0.001$), decision making for wellbeing ($\chi2=12.056$; df=1; $p=0.001$), preoperative counseling ($\chi2=9.533$; df=1; $p=0.002$), cases of negligence from clinicians ($\chi2=22.414$; df=1; $p=0.001$), understanding information provided by clinicians ($\chi2=4.394$; df=1; $p=0.036$), adaptation of informed consent doctrine meeting physicians and patients ($\chi2=7.648$; df=1; $p=0.006$), performance of diagnosis from patients’ past medical history ($\chi2=9.788$; df=1; $p=0.002$), advice on alternative treatment options available ($\chi2=8.065$; df=1; $p=0.005$), disclosure of information by practitioners ($\chi2=19.406$; df=1; $p=0.001$) and physical examination done before medication ($\chi2=9.006$; df=1; $p=0.003$) were significantly associated with informed consent administration among respondents. The study concludes majority of the domains of the contents of informed consent had a significant statistical association with administration of informed consent among respondents. These research findings provide a great insights and information to leaders, managers, law makers, governing and oversight authorities in decision making, policy formulation, strategic planning and regulation in a context specific to provide a conducive environment for practicing medical imaging procedures in an ethical and legal manner.

Examination of Informed Consent Forms in Masters and Doctorate Theses of Educational Sciences

Ozgur Onen, Funda Eryilmaz Balli

International Online Journal of Educational Sciences, May 2020; 12(2) pp 119-131

Abstract

The purpose of this study is to examine the informed consent forms of the master's theses and doctorate dissertations in educational sciences departments in Turkey; and to reach a conclusion about whether the informed consent forms have the related informed consent criteria (competence, voluntariness, disclosure, recommendation, understanding, decision and authorization) as proposed by previous studies. This study is designed as documentary analysis, and the data was obtained from master and doctorate theses which have been approved by social sciences and educational sciences institutions, and submitted to the National Theses Center founded by the Council of Higher Education (CoHE). Results indicated some deficiencies on consent forms, and some studies even did not report consent forms in master thesis and doctorate dissertations. The results of the study are discussed in the light of the existing literature. Finally, for ensuring responsible research conduct, some recommendations were provided.

Knowledge about informed consent among doctors in postgraduate courses in Bangladesh

Original Article

Kazi Taib Mamun, Nabeela Mahboob, Mohammad Abdullah Al Mahmud, K. Zaman

Ibrahim Medical College Journal of Medical Science, 7 March 2020; 14(1)

Open Access

Abstract

Background and objectives

Informed consent is now accepted as the cornerstone of medical practice and research. Concept of consent is an endeavor by which the patient can take part in clinical judgment concerning their treatment and protects patient and doctors against any litigation. However, in research informed consent is not merely a form that is signed, but is a process in which the participant has an understanding of the research and its risks. In view of this, the objective of the study was to assess the knowledge regarding informed consent among the doctors pursuing postgraduate courses in a medical institute in Bangladesh.

Methodology

A descriptive cross sectional study was carried out among 160 postgraduate medical students in Dhaka city. A self-administered structured questionnaire consisting of 36 questions was used to assess their knowledge regarding informed consent. The response format was based on a 3-point Likert scale. Frequency distribution was used for statistical analysis.

Results

The age range of the participants was from 25-40 years. Of the total participants, 48% were males and 42% were females. Majority of the respondents acknowledged the importance of an informed consent and 86.3% of the doctors agreed that only verbal consent was not adequate. Only 66.2% agreed that consent for participation in research should always be voluntary and informed. Majority (76.9%) agreed not to recruit individuals with mental or behavioral disorders not capable of giving adequately informed consent. Only 27.5% were aware that assent should be taken from children participating in a research. Out of total participants, 71.2% and 81.2% agreed that the participants should be informed about the laboratory test results. Management/referral must be ensured in case of abnormal test results respectively. For genetic research, 88.1% and 81.3% agreed for pre- and post-counseling respectively.

Conclusion

There is need to initiate further educational programs to aware the doctors of the importance of informed consent in research, clinical practice and patient care.

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MEDICAL/SURGICAL

Recall of consent information by day care prostate biopsy patients: An assessment of the role of a third-party check

Original Article

II Nnabugwu, FO Ugwumba, EI Udeh, SK Anyimba

Nigerian Journal of Clinical Practice, 11 June 2020

Open Access

Abstract

Background: To evaluate the extent of recall of consent information by daycare prostate biopsy patients in our low-literacy setting. And to evaluate the role of a 3rd party check on patient's recall of consent information. Subjects and Methods: As part of our standard of care, a formal informed consent session for day care prostate biopsy takes place 3 days prior to the procedure. For this study, before leaving the outpatient clinic the same day, the patient acknowledged before a third-party that his concerns were or were not satisfactorily addressed. The extent of recall of consent information was assessed on the morning of the procedure using a researcher-administered questionnaire. Consecutive patients participated in this cross-sectional study for day care prostate biopsy at a tertiary hospital in southeast Nigeria from February to November 2015 after obtaining due consent. Results: The recall of the risks associated with the planned procedure was poorer than the recall of the nature of the disease condition or the nature of the planned procedure. However, it was observed that aggregate recall was significantly poorer among patients who negatively attested to a satisfying consent session (OR 0.125; P < 0.0005). Conclusion: The use of a third-party in determining patient satisfaction after a consent session may be a better indicator of patient comprehension and subsequent recall of consent information, especially in low-literacy settings. Using a third-party, in this manner, may assist in checking paternalism inherent in the patient-doctor relationship.

Women's experiences of decision-making and informed choice about pregnancy and birth care: a systematic review and meta-synthesis of qualitative research

Research Article

Cassandra Yuill, Christine McCourt, Helen Cheyne, Nathalie Leister

BMC Pregnancy and Childbirth, 10 June 2020; 20(343)

Open Access

Abstract

Background

The purpose of this systematic review (PROSPERO Ref: CRD42017053264) was to describe and interpret the qualitative research on parent's decision-making and informed choice about their pregnancy and birth care. Given the growing evidence on the benefits of different models of maternity care and the prominence of informed choice in health policy, the review aimed to shed light on the research to date and what the findings indicate.

Methods

a systematic search and screening of qualitative research concerning parents' decision-making and informed choice experiences about pregnancy and birth care was conducted using PRISMA guidelines. A meta-synthesis approach was taken for the extraction and analysis of data and generation of the findings. Studies from 1990s onwards were included to reflect an era of policies promoting choice in maternity care in high-income countries.

Results

Thirty-seven original studies were included in the review. A multi-dimensional conceptual framework was developed, consisting of three analytical themes ('Uncertainty', 'Bodily autonomy and integrity' and 'Performing good motherhood') and three inter-linking actions ('Information gathering,' 'Aligning with a birth philosophy,' and 'Balancing aspects of a choice').

Conclusions
Despite the increasing research on decision-making, informed choice is not often a primary research aim, and its development in literature published since the 1990s was difficult to ascertain. The meta-synthesis suggests that decision-making is a dynamic and temporal process, in that it is made within a defined period and invokes both the past, whether this is personal, familial, social or historical, and the future. Our findings also highlighted the importance of embodiment in maternal health experiences, particularly when it comes to decision-making about care. Policymakers and practitioners alike should examine critically current choice frameworks to ascertain whether they truly allow for flexibility in decision-making. Health systems should embrace more fluid, personalised models of care to augment service users' decision-making agency.

Informed consent in obstetrics – a survey of pregnant women to set a new standard for consent in emergency obstetric interventions

Original Article
Tracey E. Sturgeon, Huma Ayaz, Kirsty McCrorie, Kate Stewart
Journal of Obstetrics and Gynaecology, 10 June 2020
Abstract
Informed consent is necessary for all medical, surgical and obstetric interventions. Whilst informed consent can be obtained for elective procedures, it is much more challenging to obtain for emergency interventions. It can be difficult for women to understand the need for emergency intervention when pregnancy has been low risk. This can lead to problems with psychological trauma from the delivery being foremost in their minds in the postnatal period and in future pregnancies. The Montgomery ruling of 2015 encouraged informing women about risks and benefits of interventions and letting the women take responsibility for their own decision-making. Here, a patient-focused survey collected information on pregnant women's knowledge and wishes regarding emergency interventions. The responses were analysed in relation to local and Scottish national delivery data. We have initiated a novel programme to ensure all of our pregnant women are empowered to give informed consent for emergency interventions.

The effect of positively framing side-effect risk in two different formats on side-effect expectations, informed consent and credibility: A randomised trial of 16-75 year olds in England

R. Webster, G.J. Rubin
Springer Nature, 2 June 2020
Abstract
Background
Reframing side-effect information in patient information leaflets (PILs) in terms of those who remain side-effect free may reduce negative expectations and side-effects, although there are concerns this may impact informed consent. This study compared two versions of positively framed PILs to current practice to see which reduces side-effect expectations whilst maintaining informed consent and credibility.
Methods
We commissioned Ipsos MORI to conduct an online survey of 16-75s in England. 1067 people completed the study and were randomised to receive a PIL for a hypothetical new antibiotic that either communicated side-effects following current practice (n=356), used positive framing with natural frequencies (n=356), or positive framing with percentages (n=355). After reading the leaflet participants completed measures of their side-effect expectations, absolute risk perceptions, and satisfaction and credibility of the leaflet.
Results
Both positively framed PILs resulted in significantly lower side-effect expectations compared to the current PIL for all side-effects (p's<.001), apart from seizure. Pairwise comparisons showed no difference in side-effect expectations between the two positively framed PILs (p's>.626). The positively framed PIL using natural frequencies produced more accurate risk perceptions than the same leaflet using percentages; but

performed equally to the current PIL. There was no difference between the leaflets in terms of satisfaction with or credibility of the PILs

Conclusion

Positively framed PILs using natural frequencies significantly reduced side-effect expectations and provided the most accurate risk perceptions without impacting satisfaction or credibility. Replication is needed with patients prescribed new medication and those with lower educational status.

The Practice of Obtaining Informed Consent for Elective Surgery and Anesthesia from Patients' Perspective: An Institutional based Cross-Sectional Study

Tadese Tamire Negash, Aragaw Tesfaw

Research Square, June 2020

Open Access

Abstract

Background

Informed consent is a body of shared decision making process and voluntary authorization of patients to receive medical or surgical intervention. There are limited studies conducted so far to examine the practice of informed consent in Ethiopia. The aim of the study was to assess the practice of informed consent for surgery and Anesthesia from patients' perspective.

Method

An institutional-based cross-sectional study was conducted from March to May 2019. The data were collected using an interviewer-administered structured questionnaire and entered and analyzed using Microsoft Excel and SPSS version 23.

Results

A total of 139 patients were interviewed in this study. Most 42(30.2%) of patients were in the age group of 29-38 years. The majority 74(53.2%) of the population were females and most 85 (61.2%) were from a rural residence. Nearly half 68 (48.9%) of the patients were informed of the benefits of the surgical procedure and 78(56.1%) of the patients were informed on the type of anesthesia to be administered while 65 (46.8%) were not informed on any complications related to the anesthesia. About 66 (47.5%) of the patients interviewed were informed on alternatives to the surgery done. Of these patients, 39(59%) were not informed of any benefits and possible risks associated with the alternative modes of treatment. More than half 75 (54%) of the patients reported as they were understood the information provided during the pre-operative counseling and about 114 (82%) of the patients interviewed satisfied with the current process of obtaining informed consent.

Conclusions and recommendation

The current practice of obtaining informed consent addressed only certain aspects of the informed consent component which reflects that patients were inadequately informed on complications related to surgery and anesthesia, alternative forms of treatment and their risks and benefits.

Patient-centered care using a single consent for planned serial procedures

Brenda G. Fahy, Terrie Vasilopoulos, Susan Ford, F. Kayser Enneking

Perioperative Care and Operating Room Management, September 2020; 20

Abstract

Background

The purpose of this study was to measure the satisfaction of patients and families with the use of a single anesthesia consent form for multiple-related treatments and procedures.

Methods

A six-question survey was developed to ascertain the satisfaction of this consent process. Chi-square tests were used to evaluate how responses differed by procedure. $P < 0.05$ was considered statistically significant.

Results

Fifty-two surveys were obtained with all (100%) aware consent entailed more than one procedure and was preferred. Nearly all respondents (98%) agreed or strongly agreed that they were well informed about the consent process.

Conclusion

In this study, a single consent encompassing multi-related procedures was understood and preferred by patients. This could be applied more broadly for other services when a series of procedures are anticipated as part of the patient's care plan. There may be opportunity to apply a single consent form for other areas that have a series of planned procedures as part of care (e.g. multi-related surgical procedures).

Analysis of the Influence of Clinical and Demographic Factors on the Understandig of Cataract Informed Consent

Antonio Barreiro-González, Miriam Rahhal-Ortuño, Alex S. Fernández-Santodomingo, Jose I. Bueso-Bordils, Antonio J. Cañada-Martínez, María J. López-Prats, Mercedes Hurtado-Sarrió

Acta Bioethica, 2020; 26(1) pp 91-100

Open Access

Abstract

Purpose: To estimate the influence of clinical and demographical information in the understanding of cataract surgery informed consent, identifying less understandable areas. To assess informed consent document concept. Methods: Multiple-choice questionnaire was designed to collect information and to evaluate the understanding of cataract surgery and informed consent. An ordinary regression model was adjusted to express the effect of clinical and demographic variables to the questionnaire score. Results: The study comprised 180 patients. Sex (female, p=0.404), non-ophthalmologist source of information (p=0.397), previous surgical history (p=0.571), not having a companion (p=0.396) nor the days since the signing of informed consent form (p=0.535) had no influence in the understanding of cataract surgery informed consent. Age (r=-0.083, p<0.001) and educational level (secondary studies r=1.845, p<0.001; tertiary studies r=4.289, p<0.001) showed statistical significance with greater strength of association educational level (OR secondary studies = 6.33, OR tertiary studies = 72.86) than age had (OR = 0.92). Conclusion: Patient's knowledge about cataract informed consent is influenced by age and educational level. The purpose and the risks, consequences of not performing surgery and postoperative indications are the least understood topics. Informed consent is seen as a forced legal obligation.

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GENERAL/OTHER

'Relative consent' or 'presumed consent'? Organ donation attitudes and behaviour

Joan Costa-I-Font , Caroline Rudisill, Maximilian Salcher-Konrad

European Journal of Health Economics, 26 June 2020

Abstract

Legislation, in the form of presumed consent, has been argued to boost organ donation but most evidence disregards the practice of seeking relative's consent, which can either 'veto' donation decisions, or 'legitimize them', by removing any possible conflict with the donor's family. We study the effect of presumed consent alongside family consent on indiviuals' willingness to donate (WTD) one's own and relatives' organs, and on actual organ donation behaviours. Using data from 28 European countries for the period 2002-2010, we found that presumed consent (PC) policies are associated with increased willingness to donate organs, but this effect was attenuated once internal family discussions on organ donation were controlled for. Our findings indicate that relative's consent acts as a veto of donation intentions and attenuates the effect of regulation on actual donations. More specifically, PC increases WTD one's own and relatives' organs in countries where no family consent is required. In contrast, family consent attenuates by 23% the influence of

regulatory environment on actual donations. The effect is driven by the influence of family discussions which increased WTD, and in combination with presumed consent translated into higher organ donation rates.

Ethical and Legal Manifestations of Informed Consent

Peter Kalina

Technium Social Sciences Journal, 23 May 2020; 8

Open Access

Abstract

Informed consent to medical or surgical treatment, or "permission granted in the knowledge of the possible consequences" is an important, and sometimes contentious and controversial component of clinical practice. From an ethical, legal and philosophical perspective; informed consent has significant implications for health care providers. The three principal elements of informed consent are 1) thorough presentation of information, 2) patient's capacity to comprehend (competence), 3) patient's voluntary willingness to undergo or refuse treatment. The history of informed consent is highlighted by precedent-setting legal cases, the atrocities of World War II and subsequent 1947 Nuremberg Trials and, current HIPAA regulations and guidelines. Informed consent involves shared decision-making between provider and patient. Including patients acknowledges and safeguards patient autonomy such that health care decisions are made based on respecting individual preferences, goals, values, beliefs, objectives, and desires. Providers act as advocates for patients' rights. These are fundamental premises of today's patient-centered care.

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