ge²p² global

governance, ethics, evidence, policy, practice

human rights action :: humanitarian response :: health :: education :: heritage stewardship :: sustainable development

Informed Consent in the Genomic Medicine Era – Current Practice, Normative Frameworks, Effective Solutions

Initiative Vision

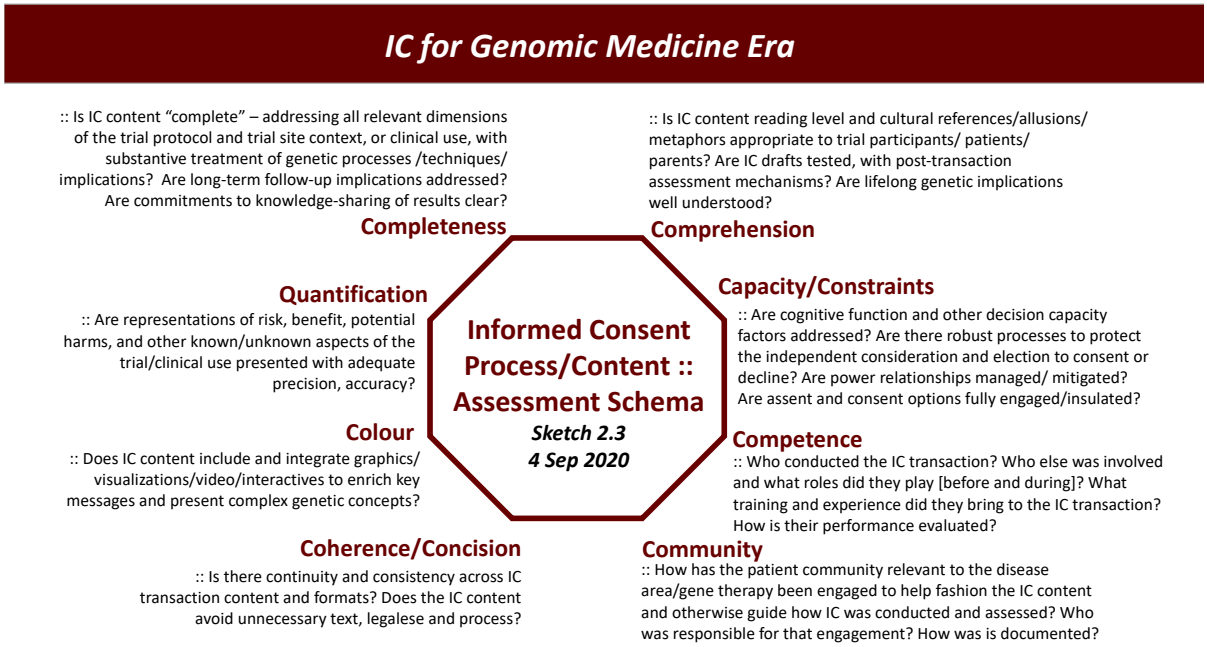
A global framework for informed consent practice across gene therapy development and clinical translation which is medically-responsible, operationally sound, and ethically-resilient – supported by a toolkit of open-source IC templates, content modules and assessment strategies which also address IC in the larger genomic medicine space and beyond.

Bibliographic Materials

draft at 3 September 2020

The following document is a set of bibliographic materials drawn from the GE2P2 Global Foundation publication *Informed Consent: A Month in Review.* These materials are intended to inform and support the ongoing development of a normative framework for informed consent practice in the genomic medicine era.

The document is organized as a set of chapters focused on eight individual elements in the informed consent assessment schema that is currently in development. Readers may note that some bibliographic items more than once throughout the document as they are relevant in more than one area of assessment.



Completeness [7]
Is IC content "complete" – addressing all relevant dimensions of trial/clinical use with substantive treatment of genetic implications?

Quantification [5]
Are representations of risk, benefit, potential harms, and other aspects of the trial/clinical use presented with adequate precision, accuracy?

Colour [22]
Does IC content include and integrate graphics/ visualizations/video/interactives to enrich key messages and present complex genetics concepts?

Coherence/Concision [3]
Is there continuity and consistency across IC transaction content and formats? Does the IC content avoid unnecessary text, legalese and process?

Comprehension [32]
Is IC content reading level appropriate to trial participants/patients/parents? Are IC drafts tested, with post-transaction assessment mechanisms? Are lifelong genetic implications well understood?

Capacity/Constraints [11]
Are there robust processes to protect the independent election of the persons involved to consent or decline? Are power relationships managed/mitigated? Are assent and consent options fully engaged and properly insulated?

Competence [26]
Who conducted the IC transaction? Who else was involved and what roles did they play [before and during]? What training and experience did they bring to the IC transaction? How is their performance evaluated? How is the IC process itself evaluated? How are these assessments communicated to patients and patient communities?

Community [17]
Was the patient community relevant to the disease area/gene therapy engaged to help fashion the IC content and otherwise guide how IC was conducted and assessed? Who was responsible for that engagement? How was is documented? Is this communicated in the IC transaction?

General [3]

Please note: Clicking on any of the headers above will take you to that position in the document.

Completeness

Is IC content "complete" – addressing all relevant dimensions of trial/clinical use with substantive treatment of genetic implications?

Evaluating the Quality of Research Ethics Review and Oversight: A Systematic Analysis of Quality Assessment Instruments

Holly Fernandez Lynch, Mohamed Abdirisak, Megan Bogia, Justin Clapp
American Journal of Bioethics, 21 August 2020
Abstract
Background
Research ethics review committees (RERCs) and Human Research Protection Programs (HRPPs) are responsible for protecting the rights and welfare of research participants while avoiding unnecessary inhibition of valuable research. Evaluating RERC/HRPP quality is vital to determining whether they are achieving these goals effectively and efficiently, as well as what adjustments might

be necessary. Various tools, standards, and accreditation mechanisms have been developed in the United States and internationally to measure and promote RERC/HRPP quality.

Methods

We systematically reviewed 10 quality assessment instruments, examining their overall approaches, factors considered relevant to quality, how they compare to each other, and what they leave out. For each tool, we counted the number of times each of 34 topics (divided into structure, process, and outcome categories) was mentioned. We generated lists of which topics are most and least mentioned for each tool, which are most prevalent across tools, and which are left unmentioned. We also conducted content analysis for the 10 most common topics.

Results

We found wide variability between instruments, common emphasis on process and structure with little attention to participant outcomes, and failure to identify clear priorities for assessment. The most frequently mentioned topics are Review Type, IRB Member Expertise, Training and Educational Resources, Protocol Maintenance, Record Keeping, and Mission, Approach, and Culture. Participant Outcomes is unmentioned in 8 tools; the remaining 2 tools include assessments based on adverse events, failures of informed consent, and consideration of participant experiences.

Conclusions

Our analysis confirms that RERC/HRPP quality assessment instruments largely rely on surrogate measures of participant protection. To prioritize between these measures and preserve limited resources for evaluating the most important criteria, we recommend that instruments focus on elements relevant to participant outcomes, robust board deliberation, and procedures most likely to address participant risks. Validation of these approaches remains an essential next step.

Surgical Consent during COVID Pandemic: COVID Times—Surgical Consent Checklist

Toney Jose, Arya Joy

Indian Journal of Surgery, 3 August 2020

Open Access

Abstract

COVID-19 caused many countries to stop their elective procedures to allow preservation of resources for COVID-19 care. With restriction being gradually lifted, the surgical services have to face the pending burden of elective cases alongside the pandemic. The true impact of the pandemic and the COVID-19 on perioperative outcomes is still being discovered. This demands a COVID-specific consenting process in addition to the routine surgical consent, to ensure that the patients are able to make informed decisions. The first ever COVID-specific checklist for surgical consent 'COVID times—surgical consent checklist' is introduced. This checklist enables the surgeon to ensure that a discussion detailing the impact of COVID-19 on surgical services is made. It also acts as a documentation of the discussions carried out during the consenting process.

Evaluating the Patient and Setting-Specific Factors That Influenced the Quality of Informed Consent in a Retrospective Cohort of Subtotal Cholecystectomy Patients

Mina Mesri, Ikemsinachi C. Nzenwa, Raimundas Lunevicius

Journal of Laparoendoscopic & Advanced Surgical Techniques, 13 July 2020

Abstract

Introduction

Cholecystectomy is the most frequently performed procedure in general surgery. The consent procedure for cholecystectomy needs to inform patients about the possibility of subtotal cholecystectomy (STC) as an alternative procedure used for "difficult gallbladders" as it is associated

with increased postoperative morbidity. We sought to determine the quality of informed consent for patients who were scheduled for cholecystectomy but underwent STC, and evaluate whether patient or procedural factors influenced the information discussed in consenting.

Materials and Methods

We classified 57 components of information necessary for a patient to give informed consent for cholecystectomy. We retrospectively reviewed the consent forms of patients scheduled for conventional cholecystectomy but instead undergoing STC between 2011 and 2017. Consent quality was measured as the percentage of components completed. Subgroup analyses were conducted to determine whether age, gender, American Society of Anesthesiologists grade, setting (elective/nonelective), operation mode (open/laparoscopic), or the responsible surgeon affected consent quality.

Results

Across 174 patients, just 9 (5.2%) had been informed about the possibility of undergoing STC, whereas the overall quality of consent was 37.5%. Patient and setting-specific factors affected the completion of specific consent components. Patients were more likely to receive a patient information leaflet if they were female (relative risk [RR] 2.76; 95% confidence interval [CI] 1.09–7.00), <60 years (RR 3.32; 95% CI 1.39–7.90) or undergoing laparoscopic surgery (RR 8.04; 95% CI 2.50–25.88).

Conclusion

The suboptimal quality of consent and multiple inconsistencies in the information disclosed to different patient cohorts emphasize the need for a more transparent and consistent consenting process.

The genomic data deficit: On the need to inform research subjects of the informational content of their genomic sequence data in consent for genomic research

Dara Hallinan

Computer Law & Security Review, July 2020; 37

Abstract

Research subject consent plays a significant role in the legitimation of genomic research in Europe – both ethically and legally. One key criterion for any consent to be legitimate is that the research subject is 'informed'. This criterion implies that the research subject is given all relevant information to allow them to decide whether engaging with a genomic research infrastructure or project would be normatively desirable and whether they wish to accept the risks associated with engagement. This article makes the normative argument that, in order to be truly 'informed', the research subject should be provided with information on the informational content of their genomic sequence data. Information should be provided, in the first instance, prior to the initial consent transaction, and should include: information on the fact that genomic sequence data will be collected and processed, information on the types of information which can currently be extracted from sequence data and information on the uncertainties surrounding the types of information which may eventually be extractable from sequence data. Information should also be provided, on an ongoing basis, as relevant and necessary, throughout the research process, and should include: information on novel information which can be extracted from sequence data and information on the novel uses and utility of sequence data. The article argues that current elaborations of 'informed' consent fail to adequately address the requirements set out in the normative argument and that this inadequacy constitutes an issue in need of a solution. The article finishes with a set of observations as to the fora best suited to deliver a solution and as to the substantive content of a solution.

Assessment of the quality of Patient Information Sheets and Informed Consent Forms for clinical trials at a Hospital Neurology Service

Andrea G Jaramillo Vélez, Margarita Aguas Compaired, Montserrat Granados Plaza, Eduardo L. Mariño, Pilar Modamio

European Journal of Neurology, 28 June 2020

Abstract

Background and purpose

Clinical trials (CTs) aimed at vulnerable groups such as patients with mental disorders create ethical complexity. The Patient Information Sheet (PIS) should provide all the information about the CT that is relevant to the subject's decision to participate. After being informed, the subject will decide freely whether to take part in the CT and will read and sign the Informed Consent Form (ICF). The objective was to assess the quality of PIS/ICFs from a Hospital Neurology Service (NS). The assessment was made using validated and reliable checklists of the information included in the PIS/ICFs of CTs with medicinal products.

Methods

Analyses of the compliance with the checklists of 21 PIS and ICFs reviewed/approved during 2016-2017 by a medicinal Research Ethics Committee.

Results

All PIS/ICFs were from multicenter CTs sponsored by pharmaceutical companies in different therapeutic areas, mainly Parkinson's (52.4%) and Alzheimer's (38.1%) diseases. The PISs from the NS demonstrated good compliance (≥ 80%) with the checklist, while ICFs should be improved. Sponsors omitted some relevant information such as study title or that the participant be informed of any information arising from the research that may be relevant to the subject's health, although this information may be in the PIS.

Conclusions

The PIS/ICFs of CTs of medicinal products currently used need improvement. PISs and ICFs should be separate documents for each CT. The PIS/ICFs should consider, in particular, those criteria related to the decision of participants, protect their rights and ensure that the information received is complete.

Informed Consent for Human Embryo Genome Editing

Erica C.Jonlin

Stem Cell Reports, 14 April 2020; 14(4) pp 530-537

Open Access

Abstract

In the event that human embryo genome editing is considered safe enough for the clinic, researchers will need to consider how to administer consent so that would-be recipients of edited embryos can make an informed decision. Informed consent will require truthfulness, sensitivity, regulatory compliance, and attention to the highest ethical standards.

Exploring broad consent in the context of the 100,000 Genomes Project: a mixed methods study

Lisa M. Ballard, Rachel H. Horton, Sandi Dheensa, Angela Fenwick & Anneke M. Lucassen

European Journal of Human Genetics, 9 January 2020

Abstract

The 100,000 Genomes Project (100kGP)—a hybrid clinical-research initiative—was set up to analyse whole-genome sequences (WGS) from patients living with a rare disease or cancer. The project

positioned participant consent as being of central importance, but consent in the context of genomic testing raises challenging issues. In this mixed method study, we surveyed 1337 100kGP participants regarding their experiences of taking part in the project and conducted in-depth interviews with 24 survey respondents to explore these findings further. Survey responses were analysed using descriptive statistics and interview data were analysed thematically. The consent approach of the 100kGP resulted in a proportion of our study's participants not understanding the complexities of the project and what types of results they might receive; for example, 20% of participants who we surveyed from the cancer arm did not recall what decisions they had made regarding additional findings. It is not surprising that a project such as this, with such diverse aims and participant groups, would throw up at least some challenges. However, participants reported being satisfied with their experience of the project to date. Our study highlights that in the context of consent for more complex endeavours, such as the 100kGP, it is important to assess (and document) an agreement to take part, but complicated decisions about what and when to communicate may need revisiting over time in response to changing contexts. We discuss the implications of our findings with reference to participants of the 100kGP and the newly formed NHS Genomic Medicine Service.

Quantification

Are representations of risk, benefit, potential harms, and other aspects of the trial/clinical use presented with adequate precision, accuracy?

Informed Consent, Therapeutic Misconception, and Unrealistic Optimism

Lynn A. Jansen

Perspectives in Biology and Medicine, Spring 2020; 63 (2) pp 359-373

Abstract

The Belmont Report attested to the cardinal importance of informed consent for ethical research on human subjects. Important challenges to securing informed consent have emerged since its publication more than 40 years ago. Among some of the most significant of these challenges are those that highlight social psychological factors that have the potential to impair the appreciation of relevant information disclosed in the informed consent process. Responding to these challenges requires us to think harder about the content of the principle of informed consent and the demands that it imposes on investigators. This article focuses on two challenges in particular, that presented by the so-called therapeutic misconception, and that presented by the psychological bias of unrealistic optimism. After outlining an account of the principle of informed consent as it applies to the research context, the article briefly reviews the empirical literature on the therapeutic misconception and the bias of unrealistic optimism. It then relates these phenomena to the principle of informed consent, paying special attention to the ethical demands they impose on investigators. The article concludes by considering how recent trends to integrate research and clinical care affect the main points it has advanced.

Towards Identifying an Upper Limit of Risk: A Persistent Area of Controversy in Research Ethics

Erin T. Paquette, Seema K. Shah

Perspectives in Biology and Medicine, Spring 2020; 63(2)

Abstract

Whether there is an upper limit of net risk that volunteers can consent to in research, and what that limit happens to be, has been the subject of persistent controversy in research ethics. This article defends the concept of an upper limit of risk in research against recent critics and supports the most promising approach for identifying this limit, that of finding comparator activities that are generally accepted in society and pose high levels of risk. However, high-risk activities that have been proposed as relevant comparators involve more certain benefits and confer considerable social esteem to those who take on the risks. This suggests that developing a robust approach to identifying social value, whether by developing a procedural safeguard or a systematic framework, could more effectively identify research with sufficient social value to justify high net risk. Additionally, the social status of research participants should be elevated to be more on par with others who laudably take on high risk for the benefit of others. By attending to the benefits necessary for the justification of high-risk research, the level of allowable risk will no longer be so controversial.

Parental Understanding of Research Consent Forms in the PICU: A Pilot Study

Shira Gertsman, Katharine O'Hearn, Jess Gibson, Kusum Menon

Pediatric Critical Care Medicine, 28 February 2020

Abstract

Objectives

To describe legal guardians' understanding of key concepts in a research consent form presented within 24 hours of their child's admission to the [Paediatric Intensive Care Unit] PICU and to explore legal guardians' opinions of the format (language, length) of the consent form and the overall consent process.

Design

Single-center, exploratory pilot study.

Setting

PICU at a tertiary-care hospital in Canada.

Subjects

Forty-one English- and French-speaking legal guardians of children less than 18 years old, who had been admitted to the PICU within the past 24 hours and were expected to stay at least 48 hours, between October 2018 and February 2019.

Interventions

The consent form from a previous PICU trial was given and explained to legal guardians within 24 hours of their child's admission to the PICU.

Measurements and main results

Legal guardians' understanding of key concepts in the consent form was evaluated using a questionnaire the day after the form was explained, and opinions were collected verbally and using an additional survey. The median number of questions answered incorrectly was three of seven (interquartile range = 2-4). Participants best understood the topic of the study (5% incorrect), but 80% of participants were unable to recall a single risk. The median rating of the language in the form was five of five (very easy to understand; interquartile range = 4-5), and 88% of participants said it was a reasonable length.

Conclusions

Despite positive opinions of the consent form, most legal guardians did not understand all key components of the consent information provided to them orally and in writing within 24 hours of their child's PICU admission. Future studies are required to determine barriers to understanding and explore alternative approaches to obtaining consent in this setting.

Unethical informed consent caused by overlooking poorly measured nocebo effects

J. Howick

Journal of Medical Ethics, 16 February 2020

Open Access

Abstract

Unlike its friendly cousin the placebo effect, the nocebo effect (the effect of expecting a negative outcome) has been almost ignored. Epistemic and ethical confusions related to its existence have gone
all but unnoticed. Contrary to what is often asserted, adverse events following from taking placebo interventions are not necessarily nocebo effects; they could have arisen due to natural history. Meanwhile, ethical informed consent (in clinical trials and clinical practice) has centred almost exclusively on the need to share intervention risks with patients to preserve their autonomy. Researchers have failed to consider the harm caused by the way in which such risk information is shared. In this paper, I argue that the magnitude of nocebo effects must be measured using control groups consisting of untreated patients. And, because the nocebo effect can produce harm, the principle of non-maleficence must be taken into account alongside the principle of autonomy when obtaining (ethical) informed consent.

Informed Consent in Fetal Hypoplastic Left Heart Syndrome [BOOK CHAPTER]

Constantine Mavroudis, Angira Patel, Rupali Gandhi

Bioethical Controversies in Pediatric Cardiology and Cardiac Surgery

Springer, 29 February 2020; pp 163-177

Abstract

Informed Consent in the setting of complex fetal congenital heart disease such as hypoplastic left heart syndrome involves many concerned individuals who include: the mother, the father, the obstetrician, the pediatric cardiologist, the pediatric cardiac surgeon, and many others. It is the duty of the physician to administer and perform informed consent under high risk pre- and postnatal circumstances that require high risk surgical options without which the newborn baby would most certainly die. We explore the intricate roll that physicians play in the informed consent process from prenatal to post-natal circumstances which include making decisions about pregnancy termination, comfort care, and staged palliation. Important considerations such as the importance of the woman's bodily integrity, autonomy, and the ethics of comfort care are discussed with reference to other complex congenital heart lesions. We conclude that informed consent for HLHS decisions is best practiced by a multi-disciplinary organized approach that will allow comprehensive counseling by multiple care-givers in a timely fashion. Ultimately, the obstetrician/pediatric cardiologist team continue to be the primary physicians that assist with shared decision-making.

Colour

Does IC content include and integrate graphics/ visualizations/video/interactives to enrich key messages and present complex genetics concepts?

A comparison of MITS counseling and informed consent processes in Pakistan, India, Bangladesh, Kenya, and Ethiopia

Commentary

Anam Shahil Feroz, Christina Paganelli, Milka Bunei, Beza Eshetu, Shahana Parveen, Sayyeda Reza, Chaitali Sanji, Shiyam Sunder Tikmani, Shivaprasad S. Goudar, Guruprasad Goudar, Sarah Saleem, Elizabeth M. McClure, Robert L. Goldenberg

Reproductive Health, 12 August 2020; 17(120)

Open Access

Abstract

Globally, more than 5 million stillbirths and neonatal deaths occur annually. For many, the cause of death (CoD) is unknown. Minimally invasive tissue sampling (MITS) has been increasingly used in postmortem examinations for ascertaining the CoD in stillbirths and neonates. Our study compared the counseling and consent methods used in MITS projects in five countries in Africa and south Asia. Key informant interviews were conducted with researchers to describe the characteristics and backgrounds of counselors, the environment and timing of consent and perceived facilitators and barriers encountered during the consent process. Counselors at all sites had backgrounds in social science, psychology and counseling or clinical expertise in obstetrics/gynecology or pediatrics. All counsellors received training about techniques for building rapport and offering emotional support to families; training duration and methods differed across sites. Counselling environments varied significantly; some sites allocated a separate room, others counselled families at the bedside or nursing stations. All counsellors had a central role in explaining the MITS procedure to families in their local languages. Most sites did not use visual aids during the process, relying solely on verbal descriptions. In most sites, parents were approached within one hour of death. The time needed for decision making by families varied from a few minutes to 24 h. In most sites, extended family took part in the decision making. Because many parents wanted burial as soon as possible, counsellors ensured that MITS would be conducted promptly after receiving consent. Barriers to consent included decreased comprehension of information due to the emotional and psychological impact of grief. Moreover, having more family members engaged in decision-making increased the complexity of counselling and achieving consensus to consent for the procedure. While each site adapted their approach to fit the context, consistencies and similarities across sites were observed.

Assessing Parent Decisions About Child Participation in a Behavioral Health Intervention Study and Utility of Informed Consent Forms

Stephanie A. Kraft, Kathryn M. Porter, Devan M. Duenas, Erin Sullivan, Maya Rowland, Brian E. Saelens, Benjamin S. Wilfond, Seema K. Shah

JAMA, 31 July 2020

Open Access

Abstract

Importance

Obtaining informed consent is an important ethical obligation for clinical research participation that is imperfectly implemented. Research on improving consent processes often focuses on consent forms, but little is known about consent forms' influence on decision-making compared with other types of engagement.

Objective

To evaluate whether parents decide whether to enroll their children in research before or after they receive the consent form.

Design, Setting, and Participants

An online survey of 88 parents who enrolled or declined to enroll their child in a weight management intervention study between January 2, 2018, and June 24, 2019, was conducted; surveys were completed between February 2, 2018, and July 9, 2019. A 31-item survey asked about impressions of the study throughout the enrollment process, timing of enrollment decisions, and

decision-making factors. Responses were summarized descriptively and subgroups were compared using the Fisher exact test or χ2 test.
Main Outcomes and Measures
Self-reported timing of enrollment decision.
Results
A total of 106 parents were approached and gave permission for their contact information to be shared with the study team; 22 additional parents declined to allow their information to be shared, and 24 lost contact with the partner study before they could be asked for permission. A total of 88 parents (67 enrollees, 21 decliners) completed the survey (83% participation rate); 79 of 88 reporting gender (instead of sex, as biological sex was not relevant to survey) information were women (91%), 66 participants (75%) were non-Hispanic White, and 63 participants (72%) had annual household incomes greater than or equal to $70 000. No significant differences in respondent characteristics between enrollees and decliners were identified. Fifty-nine parents (67%) responded that they decided whether to enroll in the weight management study before receiving the consent form. Only 17 of 69 parents (25%) who remembered receiving the consent form responded that it taught them new information.
Conclusions and Relevance
The findings of this study suggest that interventions to improve informed consent forms may have limited influence on decision-making because many research decisions occur before review of the consent form. It appears that regulatory review and interventions to improve decision-making should focus more on early engagement (eg, recruitment materials). Future studies should test timing of decisions in other types of research with different populations and clinical settings.

A Novel Framework Using Remote Telesimulation With Standardized Parents to Improve Research Staff Preparedness for Informed Consent in Pediatric Critical Care Research

Denise LaMarra, Jaclyn French, Christine Bailey, Martha T. Sisko, Kerry Coughlin-Wells, Michael S. Agus, Vijay Srinivasan, Vinay M. Nadkarni
Pediatric Critical Care Medicine, 28 July 2020
Open Access
Abstract
Objectives
The Heart And Lung Failure—Pediatric INsulin Titration study was experiencing poor subject enrollment due to low rates of informed consent. Heart And Lung Failure—Pediatric INsulin Titration investigators collaborated with the Perelman School of Medicine Standardized Patient Program to explore the novel use of telesimulation with standardized parents to train research staff to approach parents of critically ill children for informed consent. We describe the feasibility, learner acceptance, and financial costs of this novel intervention and performed a post hoc analysis to determine if this intervention improved study consent rates.
Design
Observational, comparative effectiveness study.
Setting
Heart And Lung Failure—Pediatric INsulin Titration study enrolling sites.
Subjects
Research staff (at the remote site).
Interventions
Individual 90-minute Skype telesimulation sessions with standardized parent and simulation facilitator (at the training site).
Measurements and Main Results

Forty telesimulation sessions with 79 Heart And Lung Failure—Pediatric INsulin Titration research staff (participants) at 24 remote sites were conducted. Despite some technical delays, 40 out of 40 simulations (100%) were completed. Based on feedback surveys, 100% of respondents agreed (81% strongly agreed) that telesimulation sessions achieved intended learning objectives to prepare research staff to approach parents of eligible critically ill children to obtain informed consent. Additionally, 100% of respondents agreed (74% strongly agreed) that they would use lessons from the telesimulation when approaching parents to obtain informed consent for research. Telesimulation with standardized parents achieved lower financial costs (approximately $85 per session) compared with traditional in-person site visits for training research staff. There was no significant improvement in study consent rates with the intervention (pre: 46% vs post: 48%; p = 0.78).

Conclusions

Remote telesimulation with standardized parents is feasible, acceptable, and associated with lower financial costs to prepare research staff to obtain informed consent from parents of critically ill children eligible for clinical research trials. Despite this novel approach, Heart And Lung Failure—Pediatric INsulin Titration study consent rates did not improve, suggesting that other factors influence parental consent and decision making in complex multicenter clinical research trials.

Adolescent Barriers to HIV Prevention Research: Are Parental Consent Requirements the Biggest Obstacle?

Original Article

Seema K. Shah, Zaynab Essack, Katherine Byron, Catherine Slack, Daniel Reirden, Heidi van Rooyen, Nathan R. Jones, David S. Wendler

Journal of Adolescent Health, 5 July 2020

Abstract

Purpose

One third of people newly living with HIV/AIDS are adolescents. Research on adolescent HIV prevention is critical owing to differences between adolescents and adults. Parental permission requirements are often considered a barrier to adolescent enrollment in research, but whether adolescents view this barrier as the most important one is unclear

Methods

Adolescents were approached in schools in KwaZulu-Natal, South Africa, and at a sexually transmitted infection clinic at the Children's Hospital of Aurora, Colorado. Surveys with a hypothetical vignette about participation in a pre-exposure prophylaxis trial were conducted on smartphones or tablets with 75 adolescents at each site. We calculated descriptive statistics for all variables, using 2-sample tests for equality of proportions with continuity correction. Statistical significance was calculated at $p < 0.05$. Multivariate analyses were also conducted.

Results

Most adolescents thought side effects (77%) and parental consent requirements (69%) were very important barriers to research participation. When asked to rank barriers, adolescents did not agree on a single barrier as most important, but the largest group of adolescents ranked parental consent requirements as most important (29.5%). Parental consent was seen as more of a barrier for adolescents in South Africa than in the United States. Concerns about being experimented on or researchers' mandatory reporting to authorities were ranked much lower. Finally, most (71%, n = 106) adolescents said they would want to extra support from another adult if parental permission was not required.

Conclusion

Adolescents consider both parental permission requirements and side effects important barriers to their enrollment in HIV prevention research. Legal reform and better communication strategies may help address these barriers.

A randomized controlled trial comparing video-assisted informed consent with standard consent for Mohs micrographic surgery

Original Article

Yueyue Miao, Victoria L. Venning, Kylie-Ann Mallitt, Julia E. J. Rhodes, Noah J. Isserman, Gilberto Moreno, Simon Lee, William Ryman, Gayle Fischer, Rebecca B. Saunderson

Journal of the American Academy of Dermatology International, July 2020; 1(1) pp 13-20

Open Access

Abstract

Background

There is a need for improvement in informed medical consent to address the lack of standardization and to increase patient engagement.

Objective

To investigate the use of a video to aid informed consent for Mohs micrographic surgery and evaluate patient understanding, satisfaction, anxiety, and time savings relative to verbal consent.

Methods

A 2-armed randomized controlled trial involving 102 patients compared video-assisted consent with a control group who underwent consent in the standard verbal manner. All participants underwent questionnaire-based testing of knowledge, satisfaction, and anxiety, and the time of each consultation was measured.

Results

Patients who watched the video performed significantly better in the knowledge questionnaire compared with the control group (P = .02), were more satisfied with their understanding of the risks of Mohs micrographic surgery (P = .013), and spent less time with their physician (P = .008). Additionally, 78.4% of video group patients reported that they preferred seeing the video before speaking with their physician.

Limitations

The study design may not replicate day-to-day clinical practice.

Conclusion

Video-assisted consent for Mohs micrographic surgery improves patient knowledge, leads to a better understanding of the risks, and saves physicians time without compromising patient satisfaction and anxiety levels in this study setting.

A multistage process leading to the development of a structured consent form and patient information leaflet for complex abdominal wall reconstruction (CAWR)

Original Article

M. Asarbakhsh, O. Smith, P. Chitsabesan, T. MacLeod, P. Lim, S. Chintapatla Hernia

Hernia, July 2020

Abstract

Purpose

Informed consent is vital in surgery. The General Medical Council, UK and Royal College of Surgeons of England provide clear guidance on what constitutes the process of informed patient consent. Despite this, evidence suggests that the consent process may not be performed well in surgery. We utilised a staged patient-centred approach and rigorous methodology to develop a standardised

patient information leaflet (PIL) and pre-written structured consent form for complex abdominal wall reconstruction (CAWR).

Methods

We utilised the principles of Deming's Plan-Do-Study-Act (PDSA) cycles to approach the process. Buzan's mind maps were used to identify the stakeholders and deficiencies in the consent process ('Plan' phase). The content of the PIL and pre-written consent form was then developed in collaboration with stakeholders ('Do' phase). Multidisciplinary and multidepartmental feedback was obtained on the proposed content and amendments were made ('Study' and 'Act' phases).

Results

We successfully produced a clear, focused PIL and structured consent form, in Plain English, presenting accurate, relevant and detailed information in a highly understandable way. The PIL had a Flesch Reading Ease score of > 80, demonstrating a high level of readability and comprehensibility, with positive implications for informed patient decision making and preparedness for surgery.

Conclusion

Through sharing the process that we undertook, we aim to support other abdominal wall units who wish to develop and improve their own consent process.

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 centered design and technical approach taken to resolve it.

Editor's note: Think about age gates for assent/consent and informed LTFU.

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.

Preoperative Patient Education Class during an Orthopaedic Mission Trip: Effects on Knowledge, Anxiety, and Informed Consent

Mitchell A. Solano, Kaaleswar K. Ramcharran, Lynne C. Jones, Robert S. Sterling, David R. Samaroo, Harpal S. Khanuja

The Journal of Arthroplasty, 1 May 2020

Abstract

Background

Patient knowledge about arthritis and risks, benefits, and outcomes of joint replacement in developing countries is unknown. We evaluated the effectiveness of a preoperative class on improving knowledge and decreasing anxiety during a surgical mission trip offering total joint replacement surgery.

Methods

A team of U.S. healthcare providers taught a preoperative class to 41 patients selected for total joint replacement during a surgical mission trip to Guyana. Participants completed a 32-point survey about arthritis; indications, risks, and benefits of joint replacement; and postoperative, in-patient rehabilitation expectations. The State-Trait Anxiety Inventory was used to measure participant anxiety. Participants completed identical surveys before and after class. Matched-pairs Student's t-tests were used to compare means between pre- and post-class surveys. Significance was accepted at $P < .05$.

Results

Seventy-eight percent of patients (31/41) scored less than 12 of 32 possible points (40%) on the pre-class knowledge questionnaire. Mean ± standard deviation knowledge scores improved from 14.0 ± 4.5 before the class to 16.5 ± 6.5 after the class ($P = .008$). Anxiety scores ($n = 33$) improved from 35 ± 13 before the class to 33 ± 12 after the class ($P = .047$).

Conclusion

On this surgical mission trip, underserved patients' knowledge about total joint replacement increased only modestly after taking a preoperative class. Greater understanding of how to educate patients and reduce their anxiety on medical missions is needed.

A rationale and framework for seeking remote electronic or phone consent approval in endovascular stroke trials – special relevance in the COVID-19 environment and beyond

Original Research

Ansaar T Rai, Donald Frei

Journal of NeuroInterventional Surgery, 28 April 2020

Open Access

Abstract

Background

Enrollment in time-sensitive endovascular stroke trials can be challenging because of an inability to consent a debilitated patient. Often the legally authorized representative is not on site. Remote consent procedures in the US are inconsistent with the majority of sites shunning these approaches. The current pandemic with visitor restrictions highlights the need for enhancing these options.

Methods

Remote electronic and phone consent procedures specifically for endovascular stroke trials from two comprehensive stroke centers (CSC) are presented. An overview of the genesis of informed consent
procedures in the US is also included. Results The two CSCs identified as Institution-1 and Institution-2 are large tertiary systems. Institution-1 is a non-profit university-affiliated academic medical center in rural geography. Institution-2 is an HCA hospital in an urban environment. Both serve patients through a
spoke-and-hub network, have participated in multiple randomized endovascular stroke trials, and have successfully used these remote options for enrollment. A tiered approach is employed at both institutions with an emphasis on obtaining informed consent in person and resorting to alternatives methods when efforts to that are unsuccessful. A rationale for electronic and phone consent is included, followed by step-by-step illustration of the process at each institution.

Conclusion

Two examples of remote electronic or phone consent procedures from institutions in different geographic
environments and organization structures demonstrate that these options can be successfully used for enrollment in stroke trials. The current pandemic highlights the need to enhance these approaches while maintaining appropriate adherence to ethical and legal frameworks.

Exploring solutions to the privacy paradox in the context of e-assessment: informed consent revisited

Original Paper

Ekaterina Muravyeva, José Janssen, Marcus Specht, Bart Custers

Ethics and Information Technology, 24 April 2020

Open Access

Abstract

Personal data use is increasingly permeating our everyday life. Informed consent for personal data use is a central instrument for ensuring the protection of personal data. However, current informed consent practices often fail to actually inform data subjects about the use of personal data. This article presents the results of a requirements analysis for informed consent from both a legal and usability perspective, considering the application context of educational assessment. The requirements analysis is based on European Union (EU) law and a review of current practices. As the main outcome, the article presents

a blueprint which will be the basis for the development of an informed consent template that supports data controllers in establishing an efective and efcient informed consent form. Because the blueprint, and subsequently, the template, distinguishes between legal and usability requirements, it also provides the basis for the mapping of legal requirements in other (non-European) contexts

The language and communication attributes of graphic symbol communication aids – a systematic review and narrative synthesis

Review Article

Simon Judge, Nicola Randall, Juliet Goldbart, Yvonne Lynch, Liz Moulam, Stuart Meredith, Janice Murray

Disability and Rehabilitation: Assistive Technology, 23 April 2019; pp 652-662

Abstract

Background

Symbol communication aids are used by children with little or no intelligible speech as an Augmentative and Alternative Communication strategy. Graphic symbols are used to help support understanding of language and used in symbol communication aids to support expressive communication. The decision making related to the selection of a symbol communication aid for a child is poorly understood and little is known about what language and communication attributes are considered in this selection.

Aim

To identify from the literature the language or communication attributes of graphic symbol communication aids that currently influence AAC practice.

Method and Procedure

A search strategy was developed and searches were performed on a range of electronic databases for papers published since 1970. Quality appraisal was carried out using the CCAT tool and papers rated as weak were not included in the review.

Results

Eleven studies were included in the review reporting data from 66 participants. Weaknesses were identified in most studies that would limit the validity of the results for application to practice. Included studies investigated aspects of vocabulary organization and design, the process of vocabulary selection, and the choice of the symbol system and encoding method. Two studies also evaluated innovative communication aid attributes.

Conclusions

Information from studies reported in the research literature provides a sparse source of information about symbol communication aids from which clinicians, children or family members may make informed decisions.

Evidence-Based Communication in Clinical, Mass Media, and Social Media Contexts to Enhance Informed Consent for Participation in Clinical Trials and Precision Medicine Initiatives [BOOK CHAPTER]

Susan E. Morgan, Aurora Occa, Wei Peng, Soroya J. McFarlane

The Handbook of Applied Communication Research

John Wiley & Sons, 17 April 2020; Chapter 49

Summary

This chapter explains that improved clinical trial communication will result in better informed patients who demonstrate greater willingness to participate in a system that is intended to produce significant advances in medical treatment. It centers on the factors where communication scholars

and practitioners can best apply their energy and insights. These include clinical communication interventions, including training of physicians, study nurses, and clinical research staff; public communication messages designed to inform a broad audience about scientific concepts that are central to meaningful and informed consent; and the use of social media platforms for participant recruitment and retention. The chapter discusses the implications of these findings for the development of new interventions designed to enroll members of the public in emerging precision medicine (PM) initiatives, particularly among minority populations. It also reviews communication-based interventions, including interpersonal communication trainings, public communication campaigns, persuasive message design, and targeted message delivery.

Educational Video Addition to the Bariatric Surgery Informed Consent Process: a Randomized Controlled Trial

Original Contributions

Saglam K, Kayaalp C, Aktas A, Sumer F

Obesity Surgery, 11 Apr 2020

Abstract

Objective

Bariatric surgery is not a risk-free procedure and requires lifelong patient compliance in the postoperative period. Although the risks involved in bariatric surgery and the importance of lifelong follow-ups in the postoperative period are explained to patients in detail through verbal and written informed consent, the strong desire for weight loss can sometimes cause patients and their families to be ignorant of the mentioned issues preoperatively. The objective of this study is to evaluate the effectiveness of preoperative informational videos at improving the comprehension of informed consent content in bariatric surgery candidates.

Materials and Methods

A total of 74 bariatric surgery candidates were randomized into two groups. The first group was given a usual verbal-written informed consent. The second group got an additional informing video presentation informed consent, in addition to the usual verbal-written informed consent. Then, both groups got a questionnaire evaluating their knowledge of bariatric surgery informed consent. The correct response scores and their relationship with patient demographics were analyzed.

Results

Both groups had similar demographic features. Video-presented group had higher scores in questionnaire (11.3 ± 2.3 versus 9.4 ± 1.7, p = 0.001). Subgroup analysis showed that health care workers (12.5 ± 1.9 versus 10.3 ± 2.2, p = 0.005) and university graduates (11.6 ± 2.4 versus 10.1 ± 2.1, p = 0.03) got better results in the questionnaire. In multivariate analysis, video-assisted informing was found to be the only independent variable for high questionnaire scores (p = 0.0001).

Conclusions

This study showed that video-assisted informed consent improves patients' comprehension prior to bariatric surgery. We recommend routine preoperative video-assisted informing for bariatric surgery candidates in addition to usual verbal-written informed consent.

Comparison of Video, App, and Standard Consent Processes on Decision-Making for Biospecimen Research: A Randomized Controlled Trial

Research Article

Erin Rothwell, Erin Johnson, Bob Wong, Aaron Goldenberg, Beth A. Tarini, Naomi Riches, Louisa A. Stark, Christina Pries, Carrie Langbo, Elizabeth Langen, Jeffrey Botkin

Journal of Empirical Research on Human Research Ethics, 3 April 2020

Abstract
Obtaining informed consent for bloodspot research from newborn screening is particularly challenging due to the hectic environment of the postnatal period and the relatively abstract nature of future, unspecified research on the biospecimens. A randomized controlled trial was conducted in three Michigan hospitals to compare two different consent processes (video and interactive tablet "app") with standard brochure-based consent in the Michigan BioTrust for Health. Results indicated higher knowledge scores for the video and app groups as well as significantly higher scores on satisfaction, amount of information, and clarity with the information provided. More research is needed to find the right amount of information for informed decision-making, and additional feasibility studies are needed to assess implementation strategies.

Informed Consent Through 3D Virtual Reality: A Randomized Clinical Trial

Alessandro Perin, Tommaso Francesco Galbiati, Roberta Ayadi, Enrico Gambatesa, Eleonora Francesca Orena, Nicole Irene Riker, Hagit Silberberg, Donatella Sgubin, Torstein Ragnar Meling, Francesco DiMeco

Acta Neurochirurgica, 3 April 2020

Abstract
Background
The informed consent is a defining moment that should allow patients to understand their condition, what procedure they are undergoing, and what consequences may follow. This process should foster trust and promote confidence, without increasing patients' anxiety. New immersive 3D imaging technologies may serve as a tool to facilitate this endeavor.
Methods
In a prospective, single-center, randomized controlled clinical trial (SPLICE Study: Surgical Planning and Informed Consent Study; ClinicalTrials.gov NCT03503487), 40 patients undergoing surgery for intracranial tumors were enrolled. After undergoing a traditional surgical informed consent acquisition, 33 patients were randomized 1:1:1 to 3 groups: in 2 experimental groups, patients underwent a 3D, immersive informed consent with two different surgical planners (group 1 and group 2); in the control group, patients underwent an informed consent supported by traditional 2D radiological images.
Results
Patients in the experimental groups appreciated this communication experience, while their objective comprehension was higher ((score mean (SD)): group 1 82.65 (6.83); group 2 77.76 (10.19)), as compared with the control group (57.70 (12.49); $P < 0.001$). Subjective comprehension and anxiety levels did not differ between experimental groups and control group.
Conclusions
3D virtual reality can help surgeons and patients in building a better relationship before surgery; immersive 3D-supported informed consent improves patients' comprehension of their condition without increasing anxiety. This new paradigm may foster trust between surgeons and patients, possibly restraining medical-legal acts.

Animation-supported consent for urgent angiography and angioplasty: a service improvement initiative

Original Research

David S Wald, Oliver Casey-Gillman, Katrina Comer, Josephine Sarah Mansell, Howie Teo, Kyriacos Mouyis, Matthew Kelham, Fiona Chan, Selda Ahmet, Max Sayers, Vincent McCaughan, Nito Polenio

Heart, 10 March 2020

Open Access

Abstract

Objective

Patient understanding of angiography and angioplasty is often incomplete at the time of consent. Language barriers and time constraints are significant obstacles, particularly in the urgent setting. We introduced digital animations to support consent and assessed the effect on patient understanding.

Methods

Multi-language animations explaining angiography and angioplasty (www.explainmyprocedure.com/heart) were introduced at nine district hospitals for patients with acute coronary syndrome before urgent transfer to a cardiac centre for their procedure. Reported understanding of the reason for transfer, the procedure, its benefits and risks in 100 consecutive patients were recorded before introduction of the animations into practice (no animation group) and in 100 consecutive patients after their introduction (animation group). Patient understanding in the two groups was compared.

Results

Following introduction, 83/100 patients reported they had watched the animation before inter-hospital transfer (3 declined and 14 were overlooked). The proportions of patients who understood the reason for transfer, the procedure, its benefits and risks in the no animation group were 58%, 38%, 25% and 7% and in the animation group, 85%, 81%, 73% and 61%, respectively. The relative improvement (ratio of proportions) was 1.5 (95% CI 1.2 to 1.8), 2.1 (1.6 to 2.8), 2.9 (2.0 to 4.2) and 8.7 (4.2 to 18.1), respectively ($p<0.001$ for all comparisons).

Conclusion

Use of animations explaining angiography and angioplasty is feasible before urgent inter-hospital transfer and was associated with substantial improvement in reported understanding of the procedure, its risks and its benefits. The approach is not limited to cardiology and has the potential to be applied to all specialties in medicine.

An assessment of provider satisfaction with the use of a standardized visual aid for informed consent for appendectomy in children

Brittany L. Johnson, Eric H. Rosenfeld, Brittany D. Carter, Monica E. Lopez, Annalyn S. DeMello, David E. Wesson, Mary L. Brandt

Journal of Pediatric Surgery, 1 February 2020

Abstract

Purpose

We previously validated a visual aid for the use in the consent process for an appendectomy showing improved parental satisfaction and understanding. In this study, we evaluated provider satisfaction and perceived value of using the visual aid.

Methods

An IRB approved survey was developed assessing provider experience with use of the visual aid. This was distributed and analyzed via Research Electronic Data Capture (RedCap) Database.

Results

We administered 58 surveys (45% response rate). Participants included faculty (n = 2), fellows (n = 1), residents (n = 6), and physician assistants (n = 17). The visual aid was used > 10 times by 50% of providers. The most common reason for not using the visual aid was not remembering it was available. Nearly half (40%) did not feel the visual aid added any time. 9/20 (45%) felt it added a small amount of time. Slightly over half of providers (52%) felt using the visual aid significantly

increased family ability to give informed consent and made the consenting process easier for both providers and families.
Conclusion
Using a visual aid in consenting families for appendectomy does not add significant time and subjectively improves the process for providers and increases provider perception of parental understanding.

The effects of a humorous video on memory for orthodontic treatment consent information

Original Article
Timothy P. Levine
American Journal of Orthodontics and Dentofacial Orthopedics, February 2020; 157(2) pp 240-244
Abstract
Introduction
Communication of treatment information is critical in orthodontics. The challenge lies in doing so effectively such that patients will understand and remember, which is the definition of true informed consent. Previous studies have established that information is more readily remembered when presented using multimedia presentations. Likewise, humor has been shown to increase information retention.
Methods
Two videos, 1 humorous (H) and 1 unhumorous (U), were produced with identical information about orthodontic treatment consent. Thirty-eight new orthodontic patients were randomly selected and divided into H (n = 20) and U (n = 18) video groups. Identical questionnaires with multiple-choice responses to judge memory of the content were completed by both groups immediately after watching the video (T1) and 6 weeks later (T2). A one-tailed Welch's t test was used to analyze the scores.
Results
At T1, there was no significant difference in the scores of the questionnaire between H and U groups, whereas at T2, there was a significant difference between groups. The intragroup score difference was also analyzed, with a significant decrease from T1 to T2 in the U, but not H, group. Subjective questions were also asked regarding content. No significant differences were found between the groups regarding the informativeness of each video; however, willingness to watch again and memorability of the content were significantly higher in the H group.
Conclusions
Patients who received orthodontic treatment information presented with humor retained significantly more of that information after 6 weeks compared with patients who received the same information without humor. Patients who received the humorous content subjectively stated they were more likely to rewatch the video and also found the information presented in this manner to be more memorable.

Remote Consent Clinical Research

Commentary
Sriram Preethi
Clinical Trials and Practice, 30 October 2019; 1(1) pp 39-41
Open Access
Abstract

Recruitment in clinical research trials can be challenging in trials that are time-sensitive and/or are rare disease and critical care trials. One of the hurdles for recruitment in these types of clinical trials is due to the consent process, and the need to have consent of the patient within a certain timeframe, or the patient unable to consent for themselves. This paper will discuss the usage of the utilization of remote consent options for these trials.

Coherence/Concision

Is there continuity and consistency across IC transaction content and formats? Does the IC content avoid unnecessary text, legalese and process?

A multistage process leading to the development of a structured consent form and patient information leaflet for complex abdominal wall reconstruction (CAWR)

Original Article

M. Asarbakhsh, O. Smith, P. Chitsabesan, T. MacLeod, P. Lim, S. Chintapatla Hernia

Hernia, July 2020

Abstract

Purpose

Informed consent is vital in surgery. The General Medical Council, UK and Royal College of Surgeons of England provide clear guidance on what constitutes the process of informed patient consent. Despite this, evidence suggests that the consent process may not be performed well in surgery. We utilised a staged patient-centred approach and rigorous methodology to develop a standardised patient information leaflet (PIL) and pre-written structured consent form for complex abdominal wall reconstruction (CAWR).

Methods

We utilised the principles of Deming's Plan-Do-Study-Act (PDSA) cycles to approach the process. Buzan's mind maps were used to identify the stakeholders and deficiencies in the consent process ('Plan' phase). The content of the PIL and pre-written consent form was then developed in collaboration with stakeholders ('Do' phase). Multidisciplinary and multidepartmental feedback was obtained on the proposed content and amendments were made ('Study' and 'Act' phases).

Results

We successfully produced a clear, focused PIL and structured consent form, in Plain English, presenting accurate, relevant and detailed information in a highly understandable way. The PIL had a Flesch Reading Ease score of > 80, demonstrating a high level of readability and comprehensibility, with positive implications for informed patient decision making and preparedness for surgery.

Conclusion

Through sharing the process that we undertook, we aim to support other abdominal wall units who wish to develop and improve their own consent process.

Eliciting consent from patients with dementia in general X-ray departments: Law, ethics and interpretation of context [CONFERENCE PAPER]

Katie Kelly, Lisa Booth, Paul K. Miller

United Kingdom Imaging and Oncology Congress 2020: Pathways and Communication, 1-3 June 2020; ACC, Liverpool

Open Access

Abstract

Background

While the numbers of individuals suffering from dementia syndromes in the UK steadily increase, many practitioners in the allied healthcare professions, and particularly junior staff, still feel ill-equipped for face-to-face communicative encounters with such individuals (Miller et al., 2019; Tullo et al., 2016). An elemental feature of effective communication in healthcare contexts is the seeking of proper consent to perform given procedures. The propositions above, however, raise questions regarding how 'properly' consent is being acquired when dementia is at stake. This paper, thus, reports findings from a qualitative study of general radiographers' experiences of acquiring consent from patients with dementia, specifically exploring participants' interpretations of correct legal and ethical practice therein.

Methods

With institutional ethical approval, N=6 general radiographers with less than ten years of clinical experience were recruited to sit for extended interviews. Verbatim transcripts were analysed using the domain-established techniques of Interpretative Phenomenological Analysis (Miller et al., 2017).

Results

Four key areas of extremely variable interpretation and practice were identified. (1) How to assess capacity for informed consent; (2) How to effectively modify communication when gaining consent; (3) Managing carer involvement during consent-acquisition and; (4) Constituting the 'best interest' of the patient.

Conclusion

Participants' own accounts often indicated that they were often not lawfully implementing the Mental Capacity Act (MCA) when acquiring consent. Moreover, as previously identified by Miller et al. (2019), the situational confusion did little for participants' confidence, with prospectively damaging import for future encounters. Stronger training in practical application of the MCA is recommended.

The role of institutional review boards, and hospital pharmacists as members, in the informed consent process in clinical research: a retrospective observational study

E Villamañán, C Sobrino, M Freire, JN Inmaculada, SR Luis, L Patricia, C Lara, E Fernández De Uzquiano, A Herrero, M Moreno

European Journal of Hospital Pharmacy, 24 March 2020; 27(suppl 1:6ER-023)

Open Access

Abstract

Background and importance

It is the responsibility of institutional review boards (IRBs) and hospital pharmacists, as members of these boards, to review a research proposal and ensure that adequate informed consent procedures are implemented in an ethical way, promoting participant autonomy and protecting them from potential harm. In this context, informed consent forms (ICFs) have become increasingly complex and difficult for patients to understand.

Aim and objectives

To analyse non-approval of clinical research by IRBs, related to deficiencies found in the ICFs. Secondary outcomes were type of objections in terms of readability, length, description of study purpose, design, expected benefits and foreseeable risks. Other ethical and legal aspects, such as voluntary agreement to participate, right to withdraw, biological sample management and access to personal data were also analysed.

Material and methods

This was a retrospective observational study of the clinical studies evaluated by the IRB in a tertiary hospital. We evaluated the IRB resolutions of all clinical studies over 4 years, including interventional studies (clinical trials) and non-interventional research assessed by the IRB where a hospital

pharmacist was a member of the board. The committee's decisions on approval were registered in the minutes of the meetings. The pharmacists reviewed the minutes, evaluating the final opinion of the committee (approval/non-approval of the study) in the first review.

Results

A total of 91 sets of minutes, corresponding to the IRB meetings over 4 years, were analysed. In these meetings, 1858 clinical trials were evaluated (1057 clinical trials and 801 non-interventional studies). Of these, 1558 required informed consent for participation (83.9%, 95% CI 82.1–85.5) and 987 were not approved at first review due to deficiencies detected in the ICF (63.3%, 95% CI 60.9–65.7). The main reasons for non-approval were unreadability (11.7%), inadequate information given about access to personal data rights (9.2%), biological sample management (7.8%) and expected benefits (7.6%).

Conclusion and relevance

There was a high proportion of deficiencies in the ICFs for clinical research. They were an important reason for non-approval of protocols evaluated by IRBs. Taken together, there are three fundamental weaknesses in ICFs where IRBs in hospitals play a key role: improving their readability, adapting them to regulations concerning data protection or biological sample management, and avoiding misleading information concerning enrolment.

Comprehension

Is IC content reading level appropriate to trial participants/patients/parents? Are IC drafts tested, with post-transaction assessment mechanisms? Are lifelong genetic implications well understood?

Evaluating the Quality of Research Ethics Review and Oversight: A Systematic Analysis of Quality Assessment Instruments

Holly Fernandez Lynch, Mohamed Abdirisak, Megan Bogia, Justin Clapp

American Journal of Bioethics, 21 August 2020

Abstract

Background

Research ethics review committees (RERCs) and Human Research Protection Programs (HRPPs) are responsible for protecting the rights and welfare of research participants while avoiding unnecessary inhibition of valuable research. Evaluating RERC/HRPP quality is vital to determining whether they are achieving these goals effectively and efficiently, as well as what adjustments might be necessary. Various tools, standards, and accreditation mechanisms have been developed in the United States and internationally to measure and promote RERC/HRPP quality.

Methods

We systematically reviewed 10 quality assessment instruments, examining their overall approaches, factors considered relevant to quality, how they compare to each other, and what they leave out. For each tool, we counted the number of times each of 34 topics (divided into structure, process, and outcome categories) was mentioned. We generated lists of which topics are most and least mentioned for each tool, which are most prevalent across tools, and which are left unmentioned. We also conducted content analysis for the 10 most common topics.

Results

We found wide variability between instruments, common emphasis on process and structure with little attention to participant outcomes, and failure to identify clear priorities for assessment. The most frequently mentioned topics are Review Type, IRB Member Expertise, Training and Educational Resources, Protocol Maintenance, Record Keeping, and Mission, Approach, and Culture. Participant

Outcomes is unmentioned in 8 tools; the remaining 2 tools include assessments based on adverse events, failures of informed consent, and consideration of participant experiences.
Conclusions
Our analysis confirms that RERC/HRPP quality assessment instruments largely rely on surrogate measures of participant protection. To prioritize between these measures and preserve limited resources for evaluating the most important criteria, we recommend that instruments focus on elements relevant to participant outcomes, robust board deliberation, and procedures most likely to address participant risks. Validation of these approaches remains an essential next step.

The capacity to consent to treatment in amyotrophic lateral sclerosis: a preliminary report

Original Communication
Rossella Spataro, Vincenzo La Bella
Journal of Neurology, 6 August 2020
Abstract
Background
Facing the relentless worsening of their condition, ALS patients are required to make decisions on treatments and end-of-life care. A cognitive impairment showed to be a negative prognostic factor in ALS patients, perhaps affecting the ability to make informed decisions. Notwithstanding its crucial role, the capacity to consent to treatment (CCT) has never been evaluated in these patients.
*Ob*jectives
To assess the CCT in an ALS cohort in comparison to a control group, and to study the effects of demographic and clinical variables on this high-level cognitive function.
Methods
102 ALS patients and 106 healthy controls (HC) were enrolled. CCT was assessed using the MacArthur Competence Assessment Tool for Treatment (MAC-CAT-T) and the performance was classified into the three CCT outcomes (full credit, partial credit, no credit). Cognitive and psychological variables were assessed by MMSE, phonemic fluencies, Frontal System Behavioural Scale (FrSBe), and ALS Depression Inventory (ADI). Clinical and demographic variables were analyzed as possible predictors of the MAC-CAT-T outcomes. After a 1-year follow-up, CCT and neuropsychological assessments were repeated.
Results
Most ALS patients (i.e., from 75 to 83% according to the different sub-items) retain full CCT. However, a subpopulation of the ALS patients showed a reduced CCT with respect to the HC. Age, education, phonemic fluency, and depression appeared related to the CCT outcomes. After 1 year, only the reasoning items worsened.
Conclusions
This is a preliminary report suggesting that the large majority of ALS patients can retain full ability to choose between treatment options. However, demographic and neuropsychological variables may affect CCT, pointing to the need for special attention to the consent disclosure in this disease.

Informed consent approaches for clinical trial participation of infants with minor parents in sub-Saharan Africa: A systematic review

Research Article
Angela De Pretto-Lazarova, Domnita Oana Brancati-Badarau, Christian Burri
PLOS One, 4 August 2020
Abstract
Background

Regulations are vague regarding the appropriate decision-maker and authority to consent for children of minor parents participating in clinical trials. In countries with high rates of underage mothers, such as in sub-Saharan Africa, this lack of guidance may affect the rights of potential paediatric participants already bearing increased vulnerability. It can also influence the recruitment and generalizability of the research. We provide evidence and discuss informed consent management in such cases to inform best practice.

Materials and methods

We searched PubMed/MEDLINE, Embase, CINAHL, and Google Scholar for articles published up to March 2019. In total, 4382 articles were screened, of which 16 met our inclusion criteria. Studies addressing informed consent in clinical trials involving children with minor parents in sub-Saharan Africa were included. We performed descriptive and qualitative framework analyses. The review was registered in PROSPERO: CRD42018074220.

Results

Various informed consent approaches were reported. Articles supporting individual consent by minor parents based on emancipation or "mature minor" status lacked evidence in the context of research. National laws on medical care guided consent instead. When no laws or guidance existed an interpretation of the local decision-making culture, including community engagement and collaboration with local ethics committees, defined the informed consent approach.

Conclusions

The review emphasises that the implementation of informed consent for children with minor parents may be variable and hampered by absent or ambiguous clinical trial regulations, as well as divergent local realities. It may further be influenced by the research area and study-specific risks. Clear guidance is required to help address these challenges proactively in clinical trial planning. We provided a set of questions to be considered in the development of an ethically acceptable informed consent approach and proposed information that should be integrated into international clinical trial guidelines.

Influence of a Preadmission Procedure-Specific Consent Document on Patient Recall of Informed Consent at 4 Weeks After Total Hip Replacement: A Randomized Controlled Trial

Fiachra Richard Power, Aine McClean, James Cashman

Journal of Patient Safety, 29 July 2020

Abstract

Objectives

Consent is a legal and ethical requirement for undertaking surgical procedures; however, the literature suggests that there continues to be poor recall among patients of the surgical risks discussed during the consent process. The aim of this study was to evaluate whether the addition of a preadmission procedure-specific consent document would improve patient recall of surgical risks at 4 weeks after total hip replacement in patients consented with a procedure-specific consent form.

Methods

A prospective randomized controlled trial allocated seventy adult patients who were undergoing a primary total hip replacement to either receive (intervention group) or not receive (control group) a preadmission procedure-specific consent document. All patients were also consented with a procedure-specific consent form on the morning of surgery and were contacted 4 weeks later to assess recall of surgical risks.

Results

There was a very poor recall rate seen in both the intervention group (16%) and the control group (13%), with no statistically significant difference between them (P = 0.49). A large number (30%) of

patients could not recall a single risk. A subgroup analysis excluding these "consent nonresponders" did show a significantly increased recall rate in the intervention group (24.5% versus 18.25%, P = 0.02).
Conclusions
Patient recall of potential complications of total hip replacement was poor despite the intervention. Although not effective overall, the use of a preadmission procedure-specific consent document did improve recall of potential complications of surgery in a subset of patients. The phenomenon of consent nonresponders is worth exploring in future research.

A Novel Framework Using Remote Telesimulation With Standardized Parents to Improve Research Staff Preparedness for Informed Consent in Pediatric Critical Care Research

Denise LaMarra, Jaclyn French, Christine Bailey, Martha T. Sisko, Kerry Coughlin-Wells, Michael S. Agus, Vijay Srinivasan, Vinay M. Nadkarni
Pediatric Critical Care Medicine, 28 July 2020
Open Access
Abstract
Objectives
The Heart And Lung Failure—Pediatric INsulin Titration study was experiencing poor subject enrollment due to low rates of informed consent. Heart And Lung Failure—Pediatric INsulin Titration investigators collaborated with the Perelman School of Medicine Standardized Patient Program to explore the novel use of telesimulation with standardized parents to train research staff to approach parents of critically ill children for informed consent. We describe the feasibility, learner acceptance, and financial costs of this novel intervention and performed a post hoc analysis to determine if this intervention improved study consent rates.
Design
Observational, comparative effectiveness study.
Setting
Heart And Lung Failure—Pediatric INsulin Titration study enrolling sites.
Subjects
Research staff (at the remote site).
Interventions
Individual 90-minute Skype telesimulation sessions with standardized parent and simulation facilitator (at the training site).
Measurements and Main Results
Forty telesimulation sessions with 79 Heart And Lung Failure—Pediatric INsulin Titration research staff (participants) at 24 remote sites were conducted. Despite some technical delays, 40 out of 40 simulations (100%) were completed. Based on feedback surveys, 100% of respondents agreed (81% strongly agreed) that telesimulation sessions achieved intended learning objectives to prepare research staff to approach parents of eligible critically ill children to obtain informed consent. Additionally, 100% of respondents agreed (74% strongly agreed) that they would use lessons from the telesimulation when approaching parents to obtain informed consent for research. Telesimulation with standardized parents achieved lower financial costs (approximately $85 per session) compared with traditional in-person site visits for training research staff. There was no significant improvement in study consent rates with the intervention (pre: 46% vs post: 48%; p = 0.78).
Conclusions
Remote telesimulation with standardized parents is feasible, acceptable, and associated with lower financial costs to prepare research staff to obtain informed consent from parents of critically ill

children eligible for clinical research trials. Despite this novel approach, Heart And Lung Failure—Pediatric INsulin Titration study consent rates did not improve, suggesting that other factors influence parental consent and decision making in complex multicenter clinical research trials.

Readability of the informed consent forms in Flanders using the Douma index: Analyzing the documents that help patients make decisions

Research Article

María del Valle Ramírez-Durán, María del Valle Coronado-Vázquez, María Isabel Mariscal-CrespoFirst **Clinical Ethics, 9 July 2020**

Abstract

Informed consent forms have been useful in clinical practice and they constitute a part of the shared decision making in the informed consent process. They provide information to patients about clinical procedures and techniques. They also act as a remainder of the information discussed after the medical interview. Sometimes these documents are not readable to everybody. Belgian law specifies that all information that patients receive has to be proportionate verbally, but written information is also handled. The present research analyzes the readability of the Flemish informed consent forms located in the webs of all General Hospitals using a simple random sample of 75 informed consent forms.

By using the Douma tool, which bases its analysis in the length of words and sentences, the readability mean of the sample was 46, level “Difficult”. The 59% of them had a difficult level. The 11% were normal. It is a fact, then, that the 59% of the informed consent forms evaluated in this study are not suitable for everybody in Flanders, especially those people with low literacy. There were some researches made in other countries that agreed with these results. Written clinical information was poorly written so the informed consent forms were not working helping patients to recall information nor helping patients to become a part in the shared decision making about their health. The use of readability formulas represented a simple way to discriminate those informed consent forms that had normal readability scores from those that should be adapted.

Improving knowledge and decision readiness to participate in cancer clinical trials: Effects of a plain language decision aid for minority cancer survivors

Short Communication

Aisha Langford, Jamie L. Studts, Margaret M. Byrne

Patient Education and Counseling, 7 July 2020

Abstract

Objective

To evaluate the impact of a web-based, plain language decision aid (CHOICES DA) on minority cancer survivors’ knowledge of cancer clinical trials (CCTs), readiness for making decisions about clinical trial participation, and willingness to participate in a clinical trial.

Methods

Participants were 64 Black and Hispanic cancer survivors from Miami, Florida. In a single arm intervention study, participants completed self-report assessments of CCT knowledge, decision readiness regarding clinical trial participation, and willingness to participate at three time points.

Results

Black and Hispanic participants did not differ on demographic characteristics. Post-test and follow-up measures of CCT knowledge and decision readiness were significantly greater than pre-test measures for the sample overall, and for Black and Hispanic participants separately. Few significant

differences were observed between Black and Hispanic participant outcomes at each survey time point, and willingness to participate did not change overall and for either group independently.
Conclusions
Reviewing the CHOICES DA was associated with significantly improved knowledge and decision readiness to participate in a CCT immediately and at 2-week follow-up.
Practical Implications
These findings suggest that CHOICES DA may support informed decision making about CCT participation within an acute, yet clinically relevant window of time for minority cancer patients who are substantially under-represented in cancer research.

Evaluation of donor informed consents and associated predonation educational materials in the United States and Canada: variability in elements of consent and measures of readability and reading burden

Original Research
Mary Townsend, Terri Buccino, Louis Katz
Transfusion, 4 July 2020
Abstract
Background
Every day, approximately 30,000 donors present to blood collection establishments in the United States or Canada, where they are provided information about donation and asked to sign a consent before donating. We evaluated elements of informational and consent documents and measures of readability that may influence their comprehension.
Materials and Methods
Consents for whole blood (WB) and automated collections and predonation reading materials (PRMs) representing over 93% of WB collections in the United States and Canada were evaluated. Elements, including risks of donation, were cataloged. Word count, Flesch-Kinkaid (F-K) reading ease/grade level scores, Simple Measure of Gobbledygook grade, and percentage of complex words were measured.
Results
F-K grade levels ranged from 9.2 to 16.9 for WB consents, 7.8 to 16.0 for apheresis consents, and 6.7 to 10.9 for PRMs, above the recommended level of eighth grade or lower for general audiences. F-K reading ease scores were below the cutoff of 60 for readability. Reading burden was substantial, with word count ranging from 131 to 885, 131 to 996, and 649 to 2743 for WB and apheresis consents and PRMs, respectively. Use of jargon and the absence of consent elements such as confidentiality, voluntariness, ability to withdraw consent, and risks of deferral were common.
Conclusions
Donor consent documents and associated materials vary widely, are written at challenging grade levels, present considerable reading burden, contain substantial jargon, and are missing key elements of consent. The authors recommend an organized effort, including blood donors, legal experts, and blood collection experts, to reach consensus on the minimal requirements for standardized clear and concise consent documents in an optimized format.

Study within a trial protocol: Same-day consent vs. delayed consent in a randomized trial

Marah Elfghi, Fionnuala Jordan, Sherif Sultan, Wael Tawfick
Journal of Evidence-Based Medicine, 15 June 2020
Abstract
Background

Randomized trials are designed to evaluate the effects of health care interventions. The recruitment process in a randomized trial can be challenging. Poor recruitment can have a negative impact on the allocated budget and estimated completion date of the study and may result in an underpowered research that will not adequately answer the original research question.
Aim
We aim to perform a Study Within A Trial (SWAT) to evaluate the impact of same-day consent or delayed consent on recruitment and retention in the host trial.
Methods
This SWAT is designed as an observational study. However, the host trial is a randomized controlled trial evaluating the effectiveness of an intensive lifestyle modification program in patients with peripheral arterial disease. For this trial and SWAT, same-day consent is defined as the patient giving consent on the same day, after the investigator has fully explained the predesigned information leaflet for the host trial. Delayed consent is defined as the patient feeling they still need further time to consider their decision to participate or not.

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.

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.

Informed Consent in Patients With Frailty Syndrome

Brendan Silbert, David Scott

Anesthesia & Analgesia, June 2020; 130(6) pp 1474–1481

Abstract

Frailty is present in more than 30% of individuals older than 65 years of age presenting for anesthesia and surgery, and poses a number of unique issues in the informed consent process. Much attention has been directed at the increased incidence of poor outcomes in these individuals, including postoperative mortality, complications, and prolonged length of stay. These material risks are not generally factored into conventional risk predictors, so it is likely that individuals with frailty are never fully informed of the true risk for procedures undertaken in the hospital setting. While the term "frailty" has the advantage of alerting to risk and allowing appropriate care and interventions, the term has the social disadvantage of encouraging objectivity to ageism. This may encourage paternalistic behavior from carers and family encroaching on self-determination and, in extreme cases, manifesting as coercion and compromising autonomy. There is a high prevalence of neurocognitive disorder in frail elderly patients, and care must be taken to identify those without capacity to provide informed consent; equally important is to not exclude those with capacity from providing consent. Obtaining consent for research adds an extra onus to that of clinical consent. The informed consent process in the frail elderly poses unique challenges to the busy clinical

anesthesiologist. At the very least, an increased time commitment should be recognized. The gap between theoretical goals and actual practice of informed consent should be acknowledged.

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.

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.

Editor's note: We note the aggregation for comparative review of informed consent forms in the oncology space. Consideration should be given to using other readability tools to review informed consent content for the ICGenMed project.

The Importance of Engaging Children in Research Decision-Making: A Preliminary Mixed-Methods Study

Erin Talati Paquette, Hannah Palac, Elizabeth Bair, Blake Schultz, Nicole Stenquist, Steven Joffe, Avani Shukla

Ethics & Human Research, 18 May 2020

Abstract

Studies demonstrate deficiencies in parents' and children's comprehension of research and lack of child engagement in research decision-making. We conducted a cross-sectional and interview-based study of 31 parent-child dyads to describe decision-making preferences, experiences, and comprehension of parents and children participating in research. Parents and children reported that parents played a greater role in decisions about research participation than either parents or children preferred. The likelihood of child participation was associated with the extent of input the parent permitted the child to have in the decision-making process, the child's comprehension, whether the study team asked the child about participation, whether the child read study-related materials, the parent's marital status, and the child's race. Children had lower comprehension than adults. Comprehension was related to age, education, verbal intelligence, and reading of study-related information. Parent understanding was associated with prospect for benefit and illness severity. Child participation may be improved by increasing parent-child communication, emphasizing

important relational roles between parent and child, respecting the developing autonomy of the child, increasing engagement with the study team, providing appropriate reading materials, and assessing comprehension.

IRB Policies for Obtaining Informed Consent from Non-English-Speaking People

Gianna McMillan

Ethics & Human Research, 18 May 2020

Abstract

United States regulations for the protection of human research subjects prescribe parameters for documentation of valid informed consent, which include the stipulation that the process be in a "language understandable to the subject." While significant energy has been devoted to improving

the readability of consent documents, supplemental educational tools, and nuanced measurements of individual decisional capacity, there is little guidance about how to best meet the informational needs of adults with decisional capacity who do not speak English. This article reviews the institutional review board policies from the twenty-one research centers that received the most funding from the National Institutes of Health in 2018 and compares their guidelines for obtaining informed consent from non-English speakers. Inconsistent practices suggest the need for more assertive federal direction on what parameters constitute valid consent for this population. These practices also indicate a reluctance to directly engage the ethical underpinnings of consent policies for non-English speakers.

Preoperative Patient Education Class during an Orthopaedic Mission Trip: Effects on Knowledge, Anxiety, and Informed Consent

Mitchell A. Solano, Kaaleswar K. Ramcharran, Lynne C. Jones, Robert S. Sterling, David R. Samaroo, Harpal S. Khanuja

The Journal of Arthroplasty, 1 May 2020

Abstract

Background

Patient knowledge about arthritis and risks, benefits, and outcomes of joint replacement in developing countries is unknown. We evaluated the effectiveness of a preoperative class on improving knowledge and decreasing anxiety during a surgical mission trip offering total joint replacement surgery.

Methods

A team of U.S. healthcare providers taught a preoperative class to 41 patients selected for total joint replacement during a surgical mission trip to Guyana. Participants completed a 32-point survey about arthritis; indications, risks, and benefits of joint replacement; and postoperative, in-patient rehabilitation expectations. The State-Trait Anxiety Inventory was used to measure participant anxiety. Participants completed identical surveys before and after class. Matched-pairs Student's t-tests were used to compare means between pre- and post-class surveys. Significance was accepted at $P < .05$.

Results

Seventy-eight percent of patients (31/41) scored less than 12 of 32 possible points (40%) on the pre-class knowledge questionnaire. Mean ± standard deviation knowledge scores improved from 14.0 ± 4.5 before the class to 16.5 ± 6.5 after the class ($P = .008$). Anxiety scores ($n = 33$) improved from 35 ± 13 before the class to 33 ± 12 after the class ($P = .047$).

Conclusion

On this surgical mission trip, underserved patients' knowledge about total joint replacement increased only modestly after taking a preoperative class. Greater understanding of how to educate patients and reduce their anxiety on medical missions is needed.

Communicating genetic information to family members: analysis of consent forms for diagnostic genomic sequencing

Article

Amicia Phillips, Emilia Niemiec, Heidi Carmen Howard, Kalliopi Kagkelari, Pascal Borry & Danya F. Vears

European Journal of Human Genetics, 27 April 2020

Abstract

Communicating results from genomic sequencing to family members can play an essential role allowing access to surveillance, prevention, treatment or prophylactic measures. Yet, many patients struggle with communication of these results and it is unclear to what extent this is discussed during the consent process. We conducted an online systematic search and used content analysis to explore how consent forms for genomic sequencing address communication of genetic information to family members. Our search yielded 68 consent forms from 11 countries. Although 57 forms alluded to the familial nature of results, forms varied in their discussion of the potential familial implications of results. Only 11 addressed communication of genetic information with family members, with differences in who would be responsible for this process. Several forms offered patients options regarding communication, even in countries where national guidelines and legislation allow for the disclosure of results in the absence of patient consent. These findings are concerning because they show how forms may potentially mislead patients and health care professionals about whether communication is permissible in cases where the patient does not consent. We suggest that providers and health care professionals reconsider how consent forms address communicating genetic information to family members.

Children's ability to consent to medical management in South Africa

J van Heerden, R Delport, M Kruger

South African Journal of Child Health, 23 April 2020; 14(1) pp 25-29

Open Access

Abstract

Background

The South African Children's Act No. 38 of 2005 requires paediatric medical consent from 12 years of age.

Objective

To determine children's ability to provide informed consent for medical treatment.

Methods

Assessment used hypothetical treatment storyboards and structured interviews for assessment of 100 children (aged 10 -17 years), and 25 adult controls, using a 35tandardized scoring tool to test understanding, ability to deliberate treatment choices, and provide rational reasons. Statistical analysis involved multivariate analyses of variance (MANOVAs) and analysis of variance (ANOVA).

Results

The female:male ratios for children and adults were 1:0.92 and 1:0.98, respectively. Children ≥12 years were competent with regard to treatment choices ($p<0.001$), while 10-year-olds could deliberate reasonable outcomes, similar to adults ($p<0.001$). However, only children 12 years and older could provide rational reasons, where abstract concepts were not involved, whereas children who were ≥14 years old were able to provide rational reasons involving abstract concepts. The actual understanding of choices, compared with adults, was only observed in children older than 14 years ($p<0.001$). Gender was not a statistically significant denominator.

Conclusion

Children of 12 years and older are competent to make medical decisions, but the understanding of medical treatment choices under the age of 14 years is not clear.

Trust trumps comprehension, visceral factors trump all: A psychological cascade constraining informed consent to clinical trials: A qualitative study with stable patients

Original Research

Michael Rost, Rebecca Nast, Bernice S Elger, David Shaw

Research Ethics, April 2020

Open Access

Abstract

This paper addresses psychological factors that might interfere with informed consent on the part of stable patients as potential early-phase clinical trial participants. Thirty-six semistructured interviews with patients who had either diabetes or gout were conducted. We investigated stable patients' attitudes towards participating in a fictitious first-in-human trial of a novel intervention. We focused on an in-depth analysis of those statements and explanations that indicated the existence of psychological factors impairing decision-making capacity. Three main themes emerged: insufficient comprehension of the inherent logic of clinical trials (actual comprehension), the recourse to trust over comprehension (prioritization of trust), and visceral factors that override deliberative process (visceral factors). Overall, our results indicate a limited psychological capacity on the part of stable patients to meet the requirements of informed consent as set by Declaration of Helsinki. A redesigned informed consent procedure should take account of these psychological realities.

Approaches for assessing decision-making capacity in older adults a scoping review protocol

Systematic Review Protocols

Ruth Usher, Tadhg Stapleton

JBI Evidence Synthesis, April 2020; 18(4) pp 832-840

Open Access

Abstract

Objective

This review will identify and map existing evidence on current approaches to determining decision-making capacity in older adults. It will provide a summary of available evidence and policies and identify gaps in research.

Introduction

Assessment of decision-making capacity is emerging as an important issue in society and healthcare. It is considered an ethically challenging area of clinical practice, and issues with implementation have been identified internationally. With the aging population increasing globally, approaches to assess and support decision-making are becoming more pertinent.

Inclusion criteria

This scoping review will consider studies on assessment approaches and procedures that are used to evaluate the decision-making capacity of older adults, aged 60 years and over. It will include those with age-related cognitive impairment, dementia, and neurodegenerative conditions. Quantitative, qualitative, and mixed-methods studies along with gray literature, including expert opinions, policies reports, and practice guides, will be included.

Methods

The JBI scoping review methodological framework will be used. The review will also be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist for scoping reviews. The following major healthcare databases will be searched: MEDLINE, PsycINFO, Embase, CINAHL, Cochrane Databases, Web of Science, and Scopus. The search will cover studies published in English from January 2000 to the present date. Titles and abstracts will be screened against inclusion criteria. Data will be extracted using a form developed for this review. A stakeholder consultation meeting will be held to provide feedback on the findings.

Literacy as a Distinct Developmental Domain in Children

Viewpoint

Perri Klass, John S. Hutton, Thomas G. DeWitt

JAMA Pediatrics, 30 March 2020; 174(5) pp 407-408

Abstract

The acquisition of literacy, from earliest emergent stages to full fluency with understanding and self-expression in written language, represents a distinct developmental trajectory. Unlike other developmental arenas, achieving literacy combines environmental stimulation and informal interaction in the preschool years with formal school-based instruction in decoding print and reflects the integration of multiple neuronal networks. Skills children acquire along this literacy trajectory powerfully influence life course, from early school achievement to earning potential to lifelong self-expression and civic engagement. Recognizing this, many pediatric health care professionals have incorporated literacy promotion into primary care, often through Reach Out and Read, an evidence-based model (supported by a national network) that provides parental guidance and children's books at health supervision visits.

Reflecting on three creative approaches to informed consent with children under six

Lorna Arnott, Loreain Martinez, Kate Wall, Caralyn Blaisdell, Ioanna Palaiologou

British Educational Research Journal, 10 March 2020

Abstract

In an era where children's rights are paramount, there are still few practical examples to guide us when seeking informed consent from children. This paper therefore makes a significant contribution to the field by examining three practical approaches to negotiating informed consent with young children under 6 years old. We draw on researcher field notes, images and observations from four research projects that employed creative methods for seeking informed consent from young children. We take a reflexive approach, considering how successful the three techniques have been in facilitating young children's decision making around research participation. Our findings suggest that innovative approaches to informed consent create spaces for children to engage in dialogue and questioning about the research project. However, in order for the approaches to be meaningful they need to be pedagogically-appropriate to the maturity and capabilities of the children. We also demonstrate that irrespective of the approach devised, researchers have a responsibility to ensure consent is continuously negotiated throughout the project through reflexive questioning.

Capacity to Consent to Research Participation in Adults with Metastatic Cancer: Comparisons of Brain Metastasis, Non-CNS Metastasis, and Healthy Controls

Kyler Mulhauser, Dario A Marotta, Adam Gerstenecker, Gabrielle Wilhelm, Terina Myers, Meredith Gammon, David E Vance, Burt Nabors, John Fiveash, Kristen Triebel

Neuro-Oncology Practice, 9 March 2020

Abstract

Background

To evaluate the ability of persons with metastatic cancer to provide informed consent to research participation, we used a structured vignette-based interview to measure four consenting standards across three participant groups.

Methods

Participants included 61 persons diagnosed with brain metastasis, 41 persons diagnosed with non-CNS metastasis, and 17 cognitively intact healthy controls. All groups were evaluated using the Capacity to Consent to Research Instrument (CCRI), a performance-based measure of research

consent capacity. The ability to provide informed consent to participate in research was evaluated across four consent standards: expressing choice, appreciation, reasoning, and understanding. Capacity performance ratings (intact, mild/moderate impairment, severe impairment) were identified based on control group performance.

Results

Results revealed that the brain metastasis group performed significantly lower than healthy controls on the consent standard of understanding, while both metastatic cancer groups performed below controls on the consent standard of reasoning. Both metastatic cancer groups performed similar to controls on the standards of appreciation and expressing choice. Approximately 60% of the brain metastasis group, 54% of the non-CNS metastasis group, and 18% of healthy controls showed impaired research consent capacity.

Conclusions

Our findings, using a performance-based assessment, are consistent with other research indicating that the research consent process may be overly cumbersome and confusing. This, in turn, may lead to research consent impairment not only in patient groups but also in some healthy adults with intact cognitive ability.

NIH-funded effort may help people with intellectual disability participate in clinical studies

Media Advisory

National Institues of Health, 24 February 2020

Open Access

What

The NIH Toolbox Cognitive Battery — an assessment of cognitive functioning for adults and children participating in neuroscience research —can be adapted to people with intellectual disabilities by modifying some test components and making accommodations for the test-takers' disabilities, according to researchers funded by the National Institutes of Health. The adaptations ensure that the battery can be used to assess the cognitive ability of people with intellectual disabilities who have a mental age of 5 years and above, providing objective measures that could be used in a wide variety of studies.

The research team, led by David Hessl, Ph.D., of the University of California Davis Medical Center, published their findings in Neurology. The work was funded by NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and National Center for Advancing Translational Sciences, as well as the Administration for Community Living.

The battery is administered on a computer tablet and measures memory, vocabulary, reading and executive functioning, which includes skills such as the ability to shift from one thought to another, pay attention and control impulses. The researchers adapted the battery by reducing the complexity of the instructions and including developmentally appropriate starting points. They also developed a structured manual to guide test administrators.

The researchers validated the battery and its modifications by assessing 242 people ages 6 through 25 with fragile X syndrome, Down syndrome or other disabilities. They found that the battery produced reliable and valid results for those with a mental age of 5 years and above. The authors called for additional research to adapt the battery to people with lower mental ages and to older adults with intellectual disability who may be experiencing cognitive decline or dementia.

> *Editor's note: Think about toolbox to asses capacity to consent in children/legal guardians under times of stress?*

Trust and consent: a prospective study on parents' perspective during a neonatal trial

Original Research

Sonia Dahan, Camille Jung, Gilles Dassieu, Xavier Durrmeyer, Laurence Caeymaex

Journal of Medical Ethics, 20 February 2020

Abstract

Objective

This study aimed to describe how parents and physicians experienced the informed consent interview and to investigate the aspects of the relationship that influenced parents' decision during the consent process for a randomised clinical trial in a tertiary neonatal intensive care unit (NICU). The secondary objective was to describe the perspectives of parents and physicians in the specific situation of prenatal informed consent.

Setting

Single centre study in NICU of the Centre Hospitalier Intercommunal de Créteil, France, using a convenience period from February to May 2016.

Design

Ancillary study to a randomised clinical trial: Prettineo. Records of interviews for consent. Population: parents and physicians. Mixed study including qualitative and quantitative interview data about participants' recall and feelings about the consent process. Interviews were reviewed using thematic discourse analysis.

Results

Parents' recall and understanding of the study's main goal and design was good. Parents and physicians had a positive experience, and trust was one of the main reasons for parents to consent. Misunderstanding (bad comprehension) was the main reason for refusal. Before birth, three situations can compromise parents' consent: the mother already consented to participate in other studies, the absence of the father during the interview and the feeling that the baby's birth is not an imminent possibility.

Conclusions

Confronting parents and physicians' perspectives in research can help us reach answers to sensitive issues such as content and timing of information. Each different types of study raises different ethical dilemmas for consent that might be discussed in a more individual way.

Facilitators, barriers, and recommendations related to the informed consent of Marshallese in a randomized control trial

Research Article

Rachel S Purvis, Leah R Eisenberg, Christopher R Trudeau, Christopher R Long, Pearl A McElfish

Clinical Ethics, 2 February 2020

Abstract

Background

The Pacific Islander population is the second fasting growing population in the United States and Arkansas is home to the largest Marshallese population in the continental US. The Marshallese community have significant health disparities with high prevalence of diabetes, heart disease, and obesity compared to the general US population. Using a community-based participatory research approach, researchers and Marshallese community stakeholders identified diabetes as the top health issue for research.

Methods

From 2014 to 2018, a randomized control trial was conducted comparing standard diabetes management education with a culturally adapted family model of standard diabetes management education delivered in participants' homes by Marshallese community health workers and certified

diabetes educators. Interviews were held with Marshallese participants to document their experiences with and perceptions of the informed consent process for this randomized control trial.

Results

Participants provided feedback on the process of enrolling in the study, describing barriers and facilitators to giving informed consent from their perspective, and offering recommendations for improving the informed consent process.

Conclusion

Findings suggest that informed consent with underserved communities, including immigrant and migrant populations who do not speak English or have limited English proficiency, is possible, and that using a community-based participatory research approach can help facilitate the informed consent process.

Exploring broad consent in the context of the 100,000 Genomes Project: a mixed methods study

Lisa M. Ballard, Rachel H. Horton, Sandi Dheensa, Angela Fenwick & Anneke M. Lucassen

European Journal of Human Genetics, 9 January 2020

Abstract

The 100,000 Genomes Project (100kGP)—a hybrid clinical-research initiative—was set up to analyse whole-genome sequences (WGS) from patients living with a rare disease or cancer. The project positioned participant consent as being of central importance, but consent in the context of genomic testing raises challenging issues. In this mixed method study, we surveyed 1337 100kGP participants regarding their experiences of taking part in the project and conducted in-depth interviews with 24 survey respondents to explore these findings further. Survey responses were analysed using descriptive statistics and interview data were analysed thematically. The consent approach of the 100kGP resulted in a proportion of our study's participants not understanding the complexities of the project and what types of results they might receive; for example, 20% of participants who we surveyed from the cancer arm did not recall what decisions they had made regarding additional findings. It is not surprising that a project such as this, with such diverse aims and participant groups, would throw up at least some challenges. However, participants reported being satisfied with their experience of the project to date. Our study highlights that in the context of consent for more complex endeavours, such as the 100kGP, it is important to assess (and document) an agreement to take part, but complicated decisions about what and when to communicate may need revisiting over time in response to changing contexts. We discuss the implications of our findings with reference to participants of the 100kGP and the newly formed NHS Genomic Medicine Service.

Ageism in Consent? In a decision-making capable geriatric orthopaedic trauma patient population, does increased age impact who physicians consent for surgical fixation?

Madeline M McGovern, Michael F McTague, Marilyn Heng

Jefferson Digital Commons, January 2020

Open Access

Abstract

Introduction

Persistent misconceptions of frailty and dementia in geriatric patients impact physician-patient communication and leave patients vulnerable to disempowerment. Our study examines the consenting process in an orthogeriatric trauma patient population to determine if there is a

relationship between increased age at presentation and utilization of health care proxies (HCPs) for surgical procedure consent.
Methods
We retrospectively reviewed medical records of patients aged 65 and older admitted for an operative fracture between 2013 and 2016. Patients were considered decision-making capable if there was absence of history of cognitive impairment prior to surgical consent and if the patients screened negative in a pre-surgical Confusion Assessment Method (CAM) and Mini-Cog Assessment. Data was analyzed via chi-squared and t-test analysis in SPSS.
Results
510 patients were included, and 276 (54.1%) patients were deemed capable of consent. 27 (9.8%) decision-making capable patients had HCPs consent for surgery. 20 of the 27 (74.1%) were 80 years of age or older and 7 patients between 70 and 79 had HCP consent. ($p=0.07$). HCP consent was significant for age ($p<0.001$), income level ($p=0.03$), and HCP physically present at consult ($p<0.001$). Additionally, language other than English was found to be a significant predictor of HCP consent ($p=0.035$).
Conclusion
It is concerning that cognitively intact geriatric orthopaedic trauma patients are not always consented for their own surgical procedures. Factors including age, income, and language contribute to increased risk of HCP consent. Increased physician vigilance and adoption of institutional consenting guidelines can reinforce appropriate respect of geriatric patients' consenting capacity.

Researcher and study participants' perspectives of consent in clinical studies in four referral hospitals in Vietnam

Nguyen Thi Thanh Thuy, Le Nguyen Thanh Nhan, Nguyen Van Vinh Chau, Nguyen Thi Phuong Dung
BMC Medical Ethics, 2020; pp 1-12
Abstract
Background
Within the research community, it is generally accepted that consent processes for research should be culturally appropriate and tailored to the context, yet researchers continue to grapple with what valid consent means within specific stakeholder groups. In this study, we explored the consent practices and attitudes regarding essential information required for the consent process within hospital-based trial communities from four referral hospitals in Vietnam.
Methods
We collected surveys from and conducted semi-structured interviews with study physicians, study nurses, ethics committee members, and study participants and family members regarding their experiences of participating in research, their perspectives toward research, and their views about various elements of the consent process.
Results
In our findings, we describe three interrelated themes related to the consent process: (1) words and regulation; (2) reimbursement, suspicions, and joining; and (3) responsibilities. In general, stakeholders had highly varied perspectives of nghiên cứu (Eng.: research) and researchers used varying levels of detail regarding all aspects of the study in the consent process to build trust with and/or promote potential research participants' choices about taking part in research. Findings additionally highlight how researchers felt that offering financial reimbursements in a hospital setting, where payment for services was routine, would be unfamiliar to participants and could raise suspicions about the research. Participants, however, focused their discussions on reimbursement or alternative reasons for joining the study, such as health related benefits or altruism. Finally, participants often relied on their physician to help them decide about joining a study or not.

Conclusion

Further research is needed to understand how researchers and participants make sense of and practice consent, and how that impacts participants' decision-making about research participation. To promote valid consent within this context, it is important to engage with hospital-based trial communities as a whole. The data from this study will inform future research on consent, guide the revisions of consent related policies within our research sites and point to several larger issues surrounding researcher-participant expectations, communication, and trust.

Translations of informed consent documents for clinical trials in South Africa: are they readable? [MA DISSERTATION]

Makiti Thelma Leopeng

University of Cape Town, Maternal and Child Health in the Department of Pediatrics and Child Health, February 2019

Open Access

Abstract

Introduction

Obtaining Informed consent is an ethical prerequisite for enrollment in clinical research. There is a perception that Informed consent documents used in biomedical research are lengthy, overly complex and above the reading capability of typical research participants. In South Africa, ethical committees regulating research on human participants (HRECs) are mandated by the Department of Health's National Health Research Ethics Council's (NHREC) guidelines to ensure that researchers have made special considerations for vulnerable groups when conducting research. This includes considerations made for populations with low literacy. For example, the Standard Operating Procedure (SOP) of the University of Cape Town's Human Research Ethics Committee (UCTHREC), requires that the language used in Informed consent documents should be directed at a reading level of grade 6 to 8 and that common, everyday words should be used rather than complex language syntax. The HREC expects researchers to translate the approved English version documents into local languages such as isiXhosa and Afrikaans. Since ethics committee focus approval on the English language consent documents and only acknowledge translated versions, a potential gap in this process is whether the translated versions meet the same required readability levels. This study aims to investigate whether translated versions of English language informed consent documents used at a single busy clinical research site are readable and meet the readability levels specified by UCTHREC. 14

Methodology

A quantitative descriptive statistical design was used to explore readability levels of informed consent documents used at a single clinical research facility based in a semi-rural community. Informed consent documents approved by UCTHREC over the past thirteen years (2004 to 2017) that met the inclusion criteria were analysed for readability. The LIX readability test tool was used to calculate readability scores and the levels of reading difficulty. These scores were then matched to a grade level conversion chart to determine the equivalent number of education years required to be able to easily understand the information. Readability levels were determined for isiXhosa and Afrikaans translations of the documents and compared to the levels of the English document.

Results

The results indicate that informed consent documents used at this single clinical research facility, independent of language type, are difficult to read. A total of 259 sub-sections of informed consent documents from 10 different studies were analysed. The analysis showed that informed consent documents were classified as "very difficult to read" according to the LIX readability tool in a large proportion of English, isiXhosa and Afrikaans languages: 41 (16%), 255 (98%), and 85 (33%) of

informed consent sections respectively. Of all the subsections of English, isiXhosa and Afrikaans documents respectively, 98 (38%), 0 (0%) and 126 (49%) were classified as “difficult to read”, while 79 (31%), 3 (1%) and 38 (15%) were found to have an “average” readability level. Twenty eight (11%), 1 (0%) and 10 (4%) were found to be “easy to read” and 13 (5%), 0 (0%) and 0 (0%) had a “very easy” readability level. The mean LIX readability scores across English, isiXhosa, and Afrikaans languages were respectively 42.27 (95% CI 41.20 – 43.34) corresponding to a readability level of “average”, 74.64 (95% CI 73.79-75.49), corresponding to “very difficult to read” and 46.73 (95% CI 15 45.66-47.8) “difficult to read”. These findings suggest a high level of difficulty in reading of the text in the Informed consent documents.

Conclusion

Translations of Informed consent documents used at a single busy clinical research site are difficult to read and are written at high school to tertiary reading level. These reading levels are above the recommended level prescribed by the site’s research ethics committee (UCTHREC). Local ethics committees should employ more stringent guidelines and checks to ensure readability of translated informed consent documents. Researchers and Sponsors should include readability outcomes in the design and with submissions of new protocols.

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.

Capacity/Constraints

Are there robust processes to protect the independent election of the persons involved to consent or decline? Are power relationships managed/mitigated? Are assent and consent options fully engaged and properly insulated?

Ethical considerations cited in child health research published in leading nursing journals : 2015-2019

Y Wu, ML Howarth, C Zhou, L Yang, X Ye, R Wang, C Li, M Hu, W Cong

International Journal Of Nursing Practice, 24 August 2020

Abstract

Background: Child health research comprises complex ethical considerations. Understanding the extent to which the ethical process is reported in child health research is needed to improve reporting. Aims: To identify reportage of ethical considerations in child health research in leading nursing and paediatric journals. Methods: All child health research published between 2015 and 2019 in ten leading nursing journals and two paediatric journals were retrieved and critically appraised for the reportage of informed consent and ethical approval. Results: Eight hundred and fifty-one child health research papers were included. Whilst 544 (79.9%) of the prospective studies mentioned informed consent, only 300 (55.2%) reported that written informed consent was obtained from the participants. Overall, 748 (87.9%) of child health research papers noted obtaining research ethics committee approval. Articles that mentioned financial support were significantly more likely to report informed consent and ethical approval than unfunded studies (all P<0.001). Prospective studies showed higher rates of reportage of ethical approval compared to retrospective studies (P=0.027). Rates of child consent (assent) obtained in different age groups of children ranged from 29.6% to 66.3%. Conclusion: Despite improvements in the reportage of ethical review and approval processes in child health research, consistent and transparent reports are still lacking.

Opt-out consent in children's emergency medicine research

T Long, A Rowland, S Cotterill, SR Woby

Comprehensive Child and Adolescent Nursing, 17 August 2020

Abstract

There is global acceptance that individuals should be allowed to decide whether or not to take part in research studies, and to do so after being informed about the nature of the research and the risk that might attach to participation. The process of providing detailed information before seeking

consent (formalised by signatures) in advance of undertaking research procedures may not be possible in some circumstances, and sometimes an amended approach may be adopted. The use of opt-out consent has been recognised as a valid and ethical means of recruiting participants to studies particularly with large samples and where the risk to participants is small. However, it is sometimes misunderstood and can be a problematic factor in being accepted by research ethics committees and governing authorities. This may be due partly to differing expectations of the amount of information and support offered, together with the nature of the process that is adopted to ensure that a decision has been made rather than consent simply being assumed. In accordance with ongoing discussions with young people, and following consultation with parents, an opt-out consent strategy including varied means of providing information was employed in a large study of 44,501 cases of children attending emergency or urgent care departments. The study was conducted over more than 12 months in dissimilar emergency departments and an urgent care unit, and was designed to support better decision-making in paediatric emergency departments about whether children need to be admitted to hospital or can be discharged home safely. Robust analysis of the factors that exerted the greatest impact on predicting the need to admit or the safety of discharging children led to a revised version of a an existing tool. In this article we review approaches to consent in research, the nature and impact of opt-out consent, the factors that made this an effective strategy for this study, but also more recent concerns which may make opt-out consent no longer acceptable.

Informed consent for controlled human infection studies in low- and middle-income countries: Ethical challenges and proposed solutions

Vina Vaswani, Abha Saxena, Seema K. Shah, Ricardo Palacios, Annette Rid

Bioethics, 10 August 2020

Abstract

In controlled human infection studies (CHIs), participants are deliberately exposed to infectious agents in order to better understand the mechanism of infection or disease and test therapies or vaccines. While most CHIs have been conducted in high-income countries, CHIs have recently been expanding into low- and middle-income countries (LMICs). One potential ethical concern about this expansion is the challenge of obtaining the voluntary informed consent of participants, especially those who may not be literate or have limited education. In some CHIs in LMICs, researchers have attempted to address this potential concern by limiting access to literate or educated populations. In this paper, we argue that this practice is unjustified, as it does not increase the chances of obtaining valid informed consent and therefore unfairly excludes illiterate populations and populations with lower education. Instead, we recommend that investigators improve the informed consent process by drawing on existing data on obtaining informed consent in these populations and interventions aimed at improving their understanding. Based on a literature review, we provide concrete suggestions for how to follow this recommendation and ensure that populations with lower literacy or education are given a fair opportunity to protect their rights and interests in the informed consent process.

The capacity to consent to treatment in amyotrophic lateral sclerosis: a preliminary report

Original Communication

Rossella Spataro, Vincenzo La Bella

Journal of Neurology, 6 August 2020

Abstract

Background

Facing the relentless worsening of their condition, ALS patients are required to make decisions on treatments and end-of-life care. A cognitive impairment showed to be a negative prognostic factor in ALS patients, perhaps affecting the ability to make informed decisions. Notwithstanding its crucial role, the capacity to consent to treatment (CCT) has never been evaluated in these patients.
*Ob*jectives
To assess the CCT in an ALS cohort in comparison to a control group, and to study the effects of demographic and clinical variables on this high-level cognitive function.
Methods
102 ALS patients and 106 healthy controls (HC) were enrolled. CCT was assessed using the MacArthur Competence Assessment Tool for Treatment (MAC-CAT-T) and the performance was classified into the three CCT outcomes (full credit, partial credit, no credit). Cognitive and psychological variables were assessed by MMSE, phonemic fluencies, Frontal System Behavioural Scale (FrSBe), and ALS Depression Inventory (ADI). Clinical and demographic variables were analyzed as possible predictors of the MAC-CAT-T outcomes. After a 1-year follow-up, CCT and neuropsychological assessments were repeated.
Results
Most ALS patients (i.e., from 75 to 83% according to the different sub-items) retain full CCT. However, a subpopulation of the ALS patients showed a reduced CCT with respect to the HC. Age, education, phonemic fluency, and depression appeared related to the CCT outcomes. After 1 year, only the reasoning items worsened.
Conclusions
This is a preliminary report suggesting that the large majority of ALS patients can retain full ability to choose between treatment options. However, demographic and neuropsychological variables may affect CCT, pointing to the need for special attention to the consent disclosure in this disease.

Informed consent approaches for clinical trial participation of infants with minor parents in sub-Saharan Africa: A systematic review

Research Article
Angela De Pretto-Lazarova, Domnita Oana Brancati-Badarau, Christian Burri
PLOS One, 4 August 2020
Abstract
Background
Regulations are vague regarding the appropriate decision-maker and authority to consent for children of minor parents participating in clinical trials. In countries with high rates of underage mothers, such as in sub-Saharan Africa, this lack of guidance may affect the rights of potential paediatric participants already bearing increased vulnerability. It can also influence the recruitment and generalizability of the research. We provide evidence and discuss informed consent management in such cases to inform best practice.
Materials and methods
We searched PubMed/MEDLINE, Embase, CINAHL, and Google Scholar for articles published up to March 2019. In total, 4382 articles were screened, of which 16 met our inclusion criteria. Studies addressing informed consent in clinical trials involving children with minor parents in sub-Saharan Africa were included. We performed descriptive and qualitative framework analyses. The review was registered in PROSPERO: CRD42018074220.
Results
Various informed consent approaches were reported. Articles supporting individual consent by minor parents based on emancipation or “mature minor” status lacked evidence in the context of research. National laws on medical care guided consent instead. When no laws or guidance existed

an interpretation of the local decision-making culture, including community engagement and collaboration with local ethics committees, defined the informed consent approach.

Conclusions

The review emphasises that the implementation of informed consent for children with minor parents may be variable and hampered by absent or ambiguous clinical trial regulations, as well as divergent local realities. It may further be influenced by the research area and study-specific risks. Clear guidance is required to help address these challenges proactively in clinical trial planning. We provided a set of questions to be considered in the development of an ethically acceptable informed consent approach and proposed information that should be integrated into international clinical trial guidelines.

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.

Adolescent Barriers to HIV Prevention Research: Are Parental Consent Requirements the Biggest Obstacle?

Original Article

Seema K. Shah, Zaynab Essack, Katherine Byron, Catherine Slack, Daniel Reirden, Heidi van Rooyen, Nathan R. Jones, David S. Wendler

Journal of Adolescent Health, 5 July 2020

Abstract

Purpose

One third of people newly living with HIV/AIDS are adolescents. Research on adolescent HIV prevention is critical owing to differences between adolescents and adults. Parental permission requirements are often considered a barrier to adolescent enrollment in research, but whether adolescents view this barrier as the most important one is unclear

Methods

Adolescents were approached in schools in KwaZulu-Natal, South Africa, and at a sexually transmitted infection clinic at the Children's Hospital of Aurora, Colorado. Surveys with a hypothetical vignette about participation in a pre-exposure prophylaxis trial were conducted on smartphones or tablets with 75 adolescents at each site. We calculated descriptive statistics for all

variables, using 2-sample tests for equality of proportions with continuity correction. Statistical significance was calculated at $p < 0.05$. Multivariate analyses were also conducted.
Results
Most adolescents thought side effects (77%) and parental consent requirements (69%) were very important barriers to research participation. When asked to rank barriers, adolescents did not agree on a single barrier as most important, but the largest group of adolescents ranked parental consent requirements as most important (29.5%). Parental consent was seen as more of a barrier for adolescents in South Africa than in the United States. Concerns about being experimented on or researchers' mandatory reporting to authorities were ranked much lower. Finally, most (71%, n = 106) adolescents said they would want to extra support from another adult if parental permission was not required.
Conclusion
Adolescents consider both parental permission requirements and side effects important barriers to their enrollment in HIV prevention research. Legal reform and better communication strategies may help address these barriers.

Understanding voluntariness of consent in first-in-human cell therapy trials

Perspective
Kristina Hug
Regenerative Medicine, 1 July 2020
Abstract
Consensus about contents of voluntariness in informed consent is lacking. Core criteria for voluntary consent are needed to ensure voluntariness. This article outlines the multidimensionality of voluntariness and identifies what could reduce voluntariness, especially in first-in-human clinical trials involving cell therapies. In such trials, truly voluntary consent is especially important because: such trials may involve risk of serious harm, while in case of some diseases, eligible patients often have potentially effective therapeutic alternatives; patients considering participation in high-risk first-in-human trials may feel more desperate and some may be dependent on their caregivers, including those in the family; implanted cells cannot be taken out of the patient's body if the patient wants to withdraw.

Evaluation of an Innovative Informed Consent Support Program for Individuals Considering a Living Kidney Donation

Chantal Fortin, Deitan Bourget
Nephrology Nursing Journal, May-June 2020; 47(3) pp 245-251
Abstract
Regulations require that consent be obtained before accepting a kidney donation, and respect for the competent adult requires the living donor to think, decide, and act freely, without any form of pressure or coercion. This article describes the results of a program, Les Compagnons de la Donation (Donation Companions), that attempts to meet these needs. A descriptive, non-experimental study was conducted to evaluate the degree of participant satisfaction and the program's influence on consent. Thirty-nine (n = 39) potential donors took part in the study. For each of the items evaluated, the mean change of participants pre- and post-intervention perception was statistically significant. The change was even more marked for feeling informed or prepared compared to being convinced or confident about the decision. Almost all participants strongly agreed the program was satisfactory. This study demonstrated a structured program, such as the Les Compagnons de la

Donation program, meets the needs of the target audience and appears to provide significant support to the decision-making process.

Communicating genetic information to family members: analysis of consent forms for diagnostic genomic sequencing

Article

Amicia Phillips, Emilia Niemiec, Heidi Carmen Howard, Kalliopi Kagkelari, Pascal Borry & Danya F. Vears

European Journal of Human Genetics, 27 April 2020

Abstract

Communicating results from genomic sequencing to family members can play an essential role allowing access to surveillance, prevention, treatment or prophylactic measures. Yet, many patients struggle with communication of these results and it is unclear to what extent this is discussed during the consent process. We conducted an online systematic search and used content analysis to explore how consent forms for genomic sequencing address communication of genetic information to family members. Our search yielded 68 consent forms from 11 countries. Although 57 forms alluded to the familial nature of results, forms varied in their discussion of the potential familial implications of results. Only 11 addressed communication of genetic information with family members, with differences in who would be responsible for this process. Several forms offered patients options regarding communication, even in countries where national guidelines and legislation allow for the disclosure of results in the absence of patient consent. These findings are concerning because they show how forms may potentially mislead patients and health care professionals about whether communication is permissible in cases where the patient does not consent. We suggest that providers and health care professionals reconsider how consent forms address communicating genetic information to family members.

A Review of Socio-Cultural Factors Affecting Patients' Right to Informed Consent and Autonomy in Medical Practice in Nigeria

Chinemelum Nelson Arinze-Umobi, Godwin N Okeke

African Journal Of Law And Human Rights, 2020; 4(1)

Open Access

Abstract

Today, the fundamental principle of medical law and ethics is that a medical professional should obtain the informed consent of a competent patient before administering any form of treatment on such a patient. This is in tandem with the principle of autonomy (self-determination) which is intrinsic in every individual save for circumstances wherein the observance of this principle can legally be departed from. In clinical context, 'autonomy' connotes a patient's 'right to refuse and right to participate in every decision regarding medical treatment'. This study reviewed the socio-cultural factors inhibiting patients' right to autonomy in medical practice in Nigeria. The study found that striking a balance between the opposing interests may be a difficult tasks as patients' right to autonomy is case-specific and that a whole lot of factors operate in the social space and as a result, alter, from time to time, the standard, such that it becomes nearly impossible to apply the same standard in all instances. The study found that certain circumstances exist in the doctor-patient relationship wherein a patient lacks capacity to grant such consent to the medical professional – hence the need for such consent to be given on his/her behalf towards his/her best interests.

Competence

Who conducted the IC transaction? Who else was involved and what roles did they play [before and during]? What training and experience did they bring to the IC transaction? How is their performance evaluated? How is the IC process itself evaluated? How are these assessment communicated to patients and patient communities?

Ethical considerations cited in child health research published in leading nursing journals : 2015-2019

Y Wu, ML Howarth, C Zhou, L Yang, X Ye, R Wang, C Li, M Hu, W Cong

International Journal Of Nursing Practice, 24 August 2020

Abstract

Background: Child health research comprises complex ethical considerations. Understanding the extent to which the ethical process is reported in child health research is needed to improve reporting. Aims: To identify reportage of ethical considerations in child health research in leading nursing and paediatric journals. Methods: All child health research published between 2015 and 2019 in ten leading nursing journals and two paediatric journals were retrieved and critically appraised for the reportage of informed consent and ethical approval. Results: Eight hundred and fifty-one child health research papers were included. Whilst 544 (79.9%) of the prospective studies mentioned informed consent, only 300 (55.2%) reported that written informed consent was obtained from the participants. Overall, 748 (87.9%) of child health research papers noted obtaining research ethics committee approval. Articles that mentioned financial support were significantly more likely to report informed consent and ethical approval than unfunded studies (all P<0.001). Prospective studies showed higher rates of reportage of ethical approval compared to retrospective studies (P=0.027). Rates of child consent (assent) obtained in different age groups of children ranged from 29.6% to 66.3%. Conclusion: Despite improvements in the reportage of ethical review and approval processes in child health research, consistent and transparent reports are still lacking.

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*Ob*jectives

To assess the CCT in an ALS cohort in comparison to a control group, and to study the effects of demographic and clinical variables on this high-level cognitive function.

Methods

102 ALS patients and 106 healthy controls (HC) were enrolled. CCT was assessed using the MacArthur Competence Assessment Tool for Treatment (MAC-CAT-T) and the performance was classified into the three CCT outcomes (full credit, partial credit, no credit). Cognitive and psychological variables were assessed by MMSE, phonemic fluencies, Frontal System Behavioural Scale (FrSBe), and ALS Depression Inventory (ADI). Clinical and demographic variables were analyzed

as possible predictors of the MAC-CAT-T outcomes. After a 1-year follow-up, CCT and neuropsychological assessments were repeated.

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Conclusions

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"Let's Get the Consent Together": Rethinking How Surgeons Become Competent to Discuss Informed Consent

Erin M. White, Samuel M. Miller, Andrew C. Esposito, Peter S. Yoo

Journal of Surgical Education, 1 August 2020

Objective

Eliciting informed consent is a clinical skill that many residents are tasked to conduct without sufficient training and before they are competent to do so. Even senior residents and often attending physicians fall short of following best practices when conducting consent conversations.

Design

This is a perspective on strategies to improve how residents learn to collect informed consent based on current literature.

Conclusions

We advocate that surgical educators approach teaching informed consent with a similar framework as is used for other surgical skills. Informed consent should be defined as a core clinical skill for which attendings themselves should be sufficiently competent and residents should be assessed through direct observation prior to entrustment.

Parents'/Patients' Perception of the Informed Consent Process and Surgeons Accountability in Corrective Surgery for Adolescent Idiopathic Scoliosis (AIS): A Prospective Study

Chris Yin Wei Chan, Jessamine Sze Lynn Chong, Sin Ying Lee, Pei Ying Ch'ng, Weng Hong Chung , Chee Kidd Chiu, Mohd Shahnaz Hasan, Manes, Mun Keong Kwan

Spine, 1 August 2020

Abstract

Objective

To determine the parents'/patients' perception on the informed consent process prior to posterior spinal fusion (PSF) for Adolescent Idiopathic Scoliosis (AIS) patients.

Summary of Background Data

Understanding parents/patients perspective on the process is important in order to achieve the goal of consent and prevent medico legal implications.

Methods

50 AIS patients operated between Aug 2019 to Nov 2019 were prospectively recruited. Parents'/patients' perceptions on three sections were evaluated: the process of the informed consent, specific operative risk which they were most concerned with and the accountability of surgeons for the surgical risks. These data were ranked and scored using a 5-point Likert Scale.

Preferences were reported in mean and standard deviation. Differences in terms of preferences were studied using One-way ANOVA analysis and deemed significant when $p < 0.05$.

Results

There were 30 females (60.0%) and 20 males (40.0%) with a mean age of 41.8 ± 10.6 years. Majority of parents/patients preferred the inform consent to be explained more than once ($p = 0.021$), once during clinic consultation and once during admission (4.2 ± 1.0). Consent taking by both attending surgeons was preferred (4.5 ± 0.6) compared to other healthcare providers, $p < 0.001$. Death (60.0%) and neurological deficit (30.0%) were the two most concerned surgical risks. Parents/patients would still hold the surgeon accountable for any complications despite signing the informed consent and they felt that surgeons were directly responsible for screw-related injuries (3.9 ± 0.9), neurological injury (3.8 ± 0.9) and intraoperative bleeding (3.7 ± 0.9).

Conclusions

Parents/patients preferred the attending surgeons to personally explain the informed consent, more than once with the use of visual aid. They would still hold the surgeons accountable when complications occur despite acceptance of the informed consent.

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.

Training Surgeons and the Informed Consent Discussion in Paediatric Patients: A Qualitative Study Examining Trainee Participation Disclosure

J. Chang, K. Bhanot, S. Grant, A. Fecteau, M. Camp

Orthopaedic Proceedings, 17 July 2020; 102-B supplement 6

Open Access

Excerpt

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.

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…

Exploring the concept of 'informed consent' within the context of paramedic practice

Helen Taylor, James Brogan

Journal of Paramedic Practice, 7 July 2020; 12(7)

Abstract

The phrase 'informed consent' is used widely in healthcare. Practitioners ask their patients for their consent to a treatment or a diagnostic or monitoring procedure and, if consent is given, will document this. There is a general understanding that consent is a prerequisite for care and signifies the patient's permission for the paramedic to proceed with assessments and other therapeutic interventions. Obtaining the patient's informed consent is fundamental to contemporary healthcare: what is informed consent and why is it so important? This article explores the meaning of consent in practice and the purpose it serves. It will then go on to consider complex circumstances, including emergencies, young people aged under 18 years, when a patient is unable to give consent or where a person has capacity to consent but refuses.

Can incoming United States pediatric interns be entrusted with the essential communication skills of informed consent?

Research Article

Nicholas Sevey, Michelle Barratt, Emma Omoruyi

Journal of Educational Evaluation for Health Professions, 29 June 2020; 17(18)

Open Access

Abstract

Purpose

According to the Entrustable Professional Activities (EPA) for Entering Residency by the Association of American Medical Colleges, incoming residents are expected to independently obtain informed consent for procedures they are likely to perform. This requires residents to not only inform their patients but to ensure comprehension of that information. We assessed the communication skills demonstrated by 372 incoming pediatric interns between 2007 and 2018 at the University of Texas Health Science Center at Houston, obtaining informed consent for a lumbar puncture.

Methods

During a simulated case in which interns were tasked with obtaining informed consent for a lumbar puncture, a standardized patient evaluated interns by rating 7 communication-based survey items using 5-point Likert scale from "poor" to "excellent." We then converted the scale to a numerical system and calculated intern proficiency scores (sum of ratings for each resident) and average item performance (average item rating across all interns).

Results

Interns received an average rating of 21.6 per 28 maximum score,) of which 227 interns (61.0%) achieved proficiency by scoring 21 or better. Notable differences were observed when comparing groups before and after EPA implementation (76.97% vs 47.0% proficient, respectively). Item-level analysis showed that interns struggled most to conduct the encounter in a warm and friendly manner and encourage patients to ask questions (average ratings of 2.97/4 and 2.98/4, respectively). Interns excelled at treating the patient with respect and actively listening to questions (average ratings of 3.16, each). Both average intern proficiency scores and each average item ratings were significantly lower following EPA implementation (P<0.001).

Conclusion

Interns demonstrated moderate proficiency in communicating informed consent, though clear opportunities for improvement exist such as demonstrating warmth and encouraging questions.

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.

Informed Consent in Patients With Frailty Syndrome

Brendan Silbert, David Scott

Anesthesia & Analgesia, June 2020; 130(6) pp 1474–1481

Abstract

Frailty is present in more than 30% of individuals older than 65 years of age presenting for anesthesia and surgery, and poses a number of unique issues in the informed consent process. Much attention has been directed at the increased incidence of poor outcomes in these individuals, including postoperative mortality, complications, and prolonged length of stay. These material risks are not generally factored into conventional risk predictors, so it is likely that individuals with frailty are never fully informed of the true risk for procedures undertaken in the hospital setting. While the term “frailty” has the advantage of alerting to risk and allowing appropriate care and interventions, the term has the social disadvantage of encouraging objectivity to ageism. This may encourage paternalistic behavior from carers and family encroaching on self-determination and, in extreme cases, manifesting as coercion and compromising autonomy. There is a high prevalence of neurocognitive disorder in frail elderly patients, and care must be taken to identify those without capacity to provide informed consent; equally important is to not exclude those with capacity from providing consent. Obtaining consent for research adds an extra onus to that of clinical consent. The informed consent process in the frail elderly poses unique challenges to the busy clinical

anesthesiologist. At the very least, an increased time commitment should be recognized. The gap between theoretical goals and actual practice of informed consent should be acknowledged.

Enabling data sovereignty for patients through digital consent enforcement

Arno Appenzeller, Ewald Rode profile imageEwald Rode, Erik Krempel profile imageErik Krempel, Jürgen Beyerer profile imageJürgen Beyerer

PETRA '20: Proceedings of the 13th ACM International Conference on PErvasive Technologies Related to Assistive Environments, June 2020; 33 pp 1-4

Abstract

Digital medical data offers an opportunity to improve medical diagnosis and caregiving. While a single doctor might not have enough patients to spot significant factors, data becomes much more evaluable once different doctors combine their data. Data evaluation across multiple data sources will be more practical with the increasing level of digitalization. While the potential benefits of a broad data analysis are enormous, there is a huge potential privacy impact for patients. To cope with legal regulations, for example the European General Data Protection Regulation (GDPR) and to give patients more control over the usage of their data, new tools are needed. Digital distributed patient records need a mechanism to manage a digital declaration of consent. There are some concepts how to digitize medical consent, but still there is no complete workflow that automatically evaluates and enforces consent for the usage of personal medical data. In this paper we will present a continuous digital consent enforcement workflow. Patients can define a detailed declaration of consent for their medical data and researchers can request data through a dedicated interface that enforces that consent. We show the feasibility of this workflow by presenting a prototype implementation and evaluating the system against defined requirements for informed consent.

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.

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.

To explore the experience of research nurses who obtain consent from adults in emergency settings to participate in clinical trials, either prospectively or post enrolment

Brown P, Newham R, Hewison A

Journal of Clinical Nursing, 22 May 2020

Abstract

Aim

To explore the understanding and experiences of research nurses who obtain informed consent from adult patients participating in emergency care research.

Design

Qualitative phenomenographic descriptive study.

Methods

Ten research nurses from six hospitals in England were recruited. Data were collected using semi-structured face-to-face and telephone interviews between January 2019 and March 2019. Interviews were transcribed verbatim and analysed thematically, informed by phenomenography. COREQ was followed.

Results

Three main themes were identified (1) Emergency research is different (2) Protecting the patient and (3) Experience and confidence with recruitment. It was found that obtaining patient consent in emergency care research was challenging and timing of the process was crucial. Nurses with more experience of emergency care were more confident in approaching patients and their families. There was variability in out-of-hours recruitment which was a consequence of the range of informed consent processes used and the different levels of engagement of clinical teams.

Conclusion

There is a variety of organisational cultures, processes and procedures which affect the way consent is obtained in emergency care research. A team approach was evident in the hospitals where consent rates were high and was more successful than those reliant solely on the presence of a research nurse. Organisations were able to recruit successfully to emergency care research studies irrespective of size and configuration. Further investigation of their models of working and strategies for engagement is needed. Experienced research nurses made a positive difference to recruitment and were more likely to approach patients to obtain consent.

Relevance to Clinical Practice

The understanding and experiences of recruitment to clinical trials in emergency care research by research nurses can help identify barriers to recruitment. This study provides useful insights for healthcare practitioners, clinical trials coordinators and sponsors about how best to develop protocols and policies to increase recruitment to emergency care research.

The Importance of Engaging Children in Research Decision-Making: A Preliminary Mixed-Methods Study

Erin Talati Paquette, Hannah Palac, Elizabeth Bair, Blake Schultz, Nicole Stenquist, Steven Joffe, Avani Shukla

Ethics & Human Research, 18 May 2020

Abstract

Studies demonstrate deficiencies in parents' and children's comprehension of research and lack of child engagement in research decision-making. We conducted a cross-sectional and interview-based study of 31 parent-child dyads to describe decision-making preferences, experiences, and comprehension of parents and children participating in research. Parents and children reported that parents played a greater role in decisions about research participation than either parents or children preferred. The likelihood of child participation was associated with the extent of input the parent permitted the child to have in the decision-making process, the child's comprehension, whether the study team asked the child about participation, whether the child read study-related materials, the parent's marital status, and the child's race. Children had lower comprehension than adults. Comprehension was related to age, education, verbal intelligence, and reading of study-related information. Parent understanding was associated with prospect for benefit and illness severity. Child participation may be improved by increasing parent-child communication, emphasizing

important relational roles between parent and child, respecting the developing autonomy of the child, increasing engagement with the study team, providing appropriate reading materials, and assessing comprehension.

Children's ability to consent to medical management in South Africa

J van Heerden, R Delport, M Kruger

South African Journal of Child Health, 23 April 2020; 14(1) pp 25-29

Open Access

Abstract

Background

The South African Children's Act No. 38 of 2005 requires paediatric medical consent from 12 years of age.

Objective

To determine children's ability to provide informed consent for medical treatment.

Methods

Assessment used hypothetical treatment storyboards and structured interviews for assessment of 100 children (aged 10 -17 years), and 25 adult controls, using a 57tandardized scoring tool to test understanding, ability to deliberate treatment choices, and provide rational reasons. Statistical analysis involved multivariate analyses of variance (MANOVAs) and analysis of variance (ANOVA).

Results

The female:male ratios for children and adults were 1:0.92 and 1:0.98, respectively. Children ≥12 years were competent with regard to treatment choices ($p<0.001$), while 10-year-olds could deliberate reasonable outcomes, similar to adults ($p<0.001$). However, only children 12 years and

older could provide rational reasons, where abstract concepts were not involved, whereas children who were ≥14 years old were able to provide rational reasons involving abstract concepts. The actual understanding of choices, compared with adults, was only observed in children older than 14 years ($p<0.001$). Gender was not a statistically significant denominator.

Conclusion

Children of 12 years and older are competent to make medical decisions, but the understanding of medical treatment choices under the age of 14 years is not clear.

A Survey of Current Practices of Informed Consent by Pediatric Anesthesiologists

Short Report

Allison M Fernandez, Scott C Watkins, David J Clendenin, Erik B Smith, Jenny E Dolan, Ernest Amankwah, Ali Jalali, Luis Ahumada, Anh Thy H Nguyen, Mohamed Rehman, Richard A Elliott

Pediatric Anesthesia, 22 April 2020

Abstract

Informed consent is fundamental to the ethical practice of medicine and carries important legal implications. Of particular relevance to pediatric anesthesia is the Food and Drug Administration's Drug Safety Communication (DSC), which highlights potential yet theoretical adverse effects on brain development of repeated or prolonged anesthesia administration to children younger than 3 years of age.

Informed Consent for Human Embryo Genome Editing

Erica C.Jonlin

Stem Cell Reports, 14 April 2020; 14(4) pp 530-537

Open Access

Abstract

In the event that human embryo genome editing is considered safe enough for the clinic, researchers will need to consider how to administer consent so that would-be recipients of edited embryos can make an informed decision. Informed consent will require truthfulness, sensitivity, regulatory compliance, and attention to the highest ethical standards.

Dynamic-informed consent: A potential solution for ethical dilemmas in population sequencing initiatives

Review

Fida K Dankar, Marton Gergely, Bradley Malin, Radja Badji, Samar K Dankar, Khaled Shuaib

Computational and Structural Biotechnology Journal, 2 April 2020

Open Access

Abstract

While the majority of population-level genome sequencing initiatives claim to follow the principles of informed consent, the requirements for informed consent have not been-well defined in this context. In fact, the implementation of informed consent differs greatly across these initiatives - spanning broad consent, blanket consent, and tiered consent among others. As such, this calls for an investigation into the requirements for consent to be "informed" in the context of population genomics. One particular strategy that claims to be fully informed and to continuously engage participants is called "dynamic consent". Dynamic consent is based on a personalised communication platform that aims to facilitate the consent process. It is oriented to support continuous two-way communication between researchers and participants. In this paper, we

analyze the requirements of informed consent in the context of population genomics, review various current implementations of dynamic consent, assess whether they fulfill the requirement of informed consent, and, in turn, enable participants to make autonomous and informed choices on whether or not to participate in research projects.

Informing MS Patients on Treatment Options: A Consensus on the Process of Consent Taking

Brief Communication

C Tortorella, C Solaro, P Annovazzi, L Boffa, M C Buscarinu, F Buttari, M Calabrese, P Cavalla, E Cocco, C Cordioli, G De Luca, M Di Filippo, R Fantozzi, D Ferraro, A Gajofatto, A Gallo, R Lanzillo, A Laroni, S Lo Fermo, S Malucchi, G T Maniscalco, M Moccia, V Nociti, D Paolicelli, I Pesci, L Prosperini, P Ragonese, V Tomassini, V L A Torri Clerici, M Rodegher, M Gherardi, C Gasperini, RIReMS Group

Neurological sciences, 2 Apr 2020

Abstract

In the last years, change in multiple sclerosis (MS) therapeutic scenario has highlighted the need for an improved doctor-patient communication in advance of treatment initiation in order to allow patient's empowerment in the decision-making process. AIMS: The aims of our project were to review the strategies used by Italian MS specialists to inform patients about treatment options and to design a multicentre shared document that homogenizes the information about disease-modifying treatment (DMTs) and the procedure of taking informed consent in clinical practice. RESULTS: The new resource, obtained by consensus among 31 neurologists from 27 MS Centres in Italy with the supervision of a medico-legal advisor, received the aegis of Italian Neurological Society (SIN) and constitutes a step toward a standardized decision process around DMTs in MS.

Approaches for assessing decision-making capacity in older adults a scoping review protocol

Systematic Review Protocols

Ruth Usher, Tadhg Stapleton

JBI Evidence Synthesis, April 2020; 18(4) pp 832-840

Open Access

Abstract

Objective

This review will identify and map existing evidence on current approaches to determining decision-making capacity in older adults. It will provide a summary of available evidence and policies and identify gaps in research.

Introduction

Assessment of decision-making capacity is emerging as an important issue in society and healthcare. It is considered an ethically challenging area of clinical practice, and issues with implementation have been identified internationally. With the aging population increasing globally, approaches to assess and support decision-making are becoming more pertinent.

Inclusion criteria

This scoping review will consider studies on assessment approaches and procedures that are used to evaluate the decision-making capacity of older adults, aged 60 years and over. It will include those with age-related cognitive impairment, dementia, and neurodegenerative conditions. Quantitative, qualitative, and mixed-methods studies along with gray literature, including expert opinions, policies reports, and practice guides, will be included.

Methods

The JBI scoping review methodological framework will be used. The review will also be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist for scoping reviews. The following major healthcare databases will be searched: MEDLINE, PsycINFO, Embase, CINAHL, Cochrane Databases, Web of Science, and Scopus. The search will cover studies published in English from January 2000 to the present date. Titles and abstracts will be screened against inclusion criteria. Data will be extracted using a form developed for this review. A stakeholder consultation meeting will be held to provide feedback on the findings.

Literacy as a Distinct Developmental Domain in Children

Viewpoint

Perri Klass, John S. Hutton, Thomas G. DeWitt

JAMA Pediatrics, 30 March 2020; 174(5) pp 407-408

Abstract

The acquisition of literacy, from earliest emergent stages to full fluency with understanding and self-expression in written language, represents a distinct developmental trajectory. Unlike other developmental arenas, achieving literacy combines environmental stimulation and informal interaction in the preschool years with formal school-based instruction in decoding print and reflects the integration of multiple neuronal networks. Skills children acquire along this literacy trajectory powerfully influence life course, from early school achievement to earning potential to lifelong self-expression and civic engagement. Recognizing this, many pediatric health care professionals have incorporated literacy promotion into primary care, often through Reach Out and Read, an evidence-based model (supported by a national network) that provides parental guidance and children's books at health supervision visits.

Reflecting on three creative approaches to informed consent with children under six

Lorna Arnott, Loreain Martinez, Kate Wall, Caralyn Blaisdell, Ioanna Palaiologou

British Educational Research Journal, 10 March 2020

Abstract

In an era where children's rights are paramount, there are still few practical examples to guide us when seeking informed consent from children. This paper therefore makes a significant contribution to the field by examining three practical approaches to negotiating informed consent with young children under 6 years old. We draw on researcher field notes, images and observations from four research projects that employed creative methods for seeking informed consent from young children. We take a reflexive approach, considering how successful the three techniques have been in facilitating young children's decision making around research participation. Our findings suggest that innovative approaches to informed consent create spaces for children to engage in dialogue and questioning about the research project. However, in order for the approaches to be meaningful they need to be pedagogically-appropriate to the maturity and capabilities of the children. We also demonstrate that irrespective of the approach devised, researchers have a responsibility to ensure consent is continuously negotiated throughout the project through reflexive questioning.

Mainstream consent programs for genetic counseling in cancer patients: A systematic review

Review

Tahlia Scheinberg, Alison Young, Henry Woo, Annabel Goodwin, Kate L. Mahon, Lisa G. Horvath

Asia-Pacific Journal of Clinical Oncology, 29 February 2020; pp 1–15

Open Access

Abstract

As demand for germline genetic testing for cancer patients increases, novel methods of genetic counseling are required. One such method is the mainstream consent pathway, whereby a member of the oncology team (rather than a genetic specialist) is responsible for counseling, consenting, and arranging genetic testing for cancer patients. We systematically reviewed the literature for evidence evaluating mainstream pathways for patients with breast, ovarian, colorectal, and prostate cancer. Medline, EMBASE, and Cochrane Library were searched for studies that met inclusion and exclusion criteria. Article references were checked for additional studies. Trial databases were searched for ongoing studies. Of the 13 papers that met inclusion criteria, 11 individual study groups were identified (two study groups had two publications each). Ten of the 11 studies evaluated the acceptability, feasibility, and impact of BRCA testing for patients and/or clinicians in different clinical settings in breast and ovarian cancer, while the final study explored the attitudes of colorectal specialists toward genetic testing for colorectal cancer. None involved prostate cancer. Overall, mainstream pathways were acceptable and feasible. Medical oncologistand nurse-driven pathways were particularly successful, with both patients and clinicians satisfied with this process. Although the content of pretest counseling was less consistent compared with counseling via the traditional model, patients were largely satisfied with the education they received. Further research is required to evaluate the mainstream pathway for men with prostate cancer.

Ageism in Consent? In a decision-making capable geriatric orthopaedic trauma patient population, does increased age impact who physicians consent for surgical fixation?

Madeline M McGovern, Michael F McTague, Marilyn Heng

Jefferson Digital Commons, January 2020

Open Access

Abstract

Introduction

Persistent misconceptions of frailty and dementia in geriatric patients impact physician-patient communication and leave patients vulnerable to disempowerment. Our study examines the consenting process in an orthogeriatric trauma patient population to determine if there is a relationship between increased age at presentation and utilization of health care proxies (HCPs) for surgical procedure consent.

Methods

We retrospectively reviewed medical records of patients aged 65 and older admitted for an operative fracture between 2013 and 2016. Patients were considered decision-making capable if there was absence of history of cognitive impairment prior to surgical consent and if the patients screened negative in a pre-surgical Confusion Assessment Method (CAM) and Mini-Cog Assessment. Data was analyzed via chi-squared and t-test analysis in SPSS.

Results

510 patients were included, and 276 (54.1%) patients were deemed capable of consent. 27 (9.8%) decision-making capable patients had HCPs consent for surgery. 20 of the 27 (74.1%) were 80 years of age or older and 7 patients between 70 and 79 had HCP consent. (p=0.07). HCP consent was significant for age (p<0.001), income level (p=0.03), and HCP physically present at consult (p<0.001). Additionally, language other than English was found to be a significant predictor of HCP consent (p=0.035).

Conclusion

It is concerning that cognitively intact geriatric orthopaedic trauma patients are not always consented for their own surgical procedures. Factors including age, income, and language contribute to increased risk of HCP consent. Increased physician vigilance and adoption of institutional consenting guidelines can reinforce appropriate respect of geriatric patients' consenting capacity.

The Importance of Physician Directed Informed Consent

Neena Oza

Journal of Health Care Finance, 2020

Open Access

Abstract

The process and scope of procedural/surgical informed consent has changed dramatically with emerging technologies, expanding medical knowledge, updated outcomes data and increased recognition of patient autonomy. With the paradigm shifting towards ethical considerations of patient care and active involvement of patient's in their treatment, medical practices and laws have evolved to guide communication standards between the patient and physician. The delivery of all relevant information should enable the patient to make an informed decision regarding the procedure, while preserving the core principles of patient understanding and free consent, devoid of coercion or manipulation.[1],3 Additionally, education and counseling delivered during the informed consent should relieve the patient's safety concerns related to procedures and to address patient knowledge deficiencies, present other alternative plans or procedures, as well as any possible perceived coercion related to noninvasive and invasive procedures. The intent of this article will be to further explain the rationale for the performing provider, attending physician or surgeon, to be the sole person ultimately responsible for providing the patient with the goals, risks and benefits of the proposed treatment or intervention; and for the words and actions of any other medical team member (such as medical students or residents) that may assisting during the informed consent process.

Community

Was the patient community relevant to the disease area/gene therapy engaged to help fashion the IC content and otherwise guide how IC was conducted and assessed? Who was responsible for that engagement? How was is documented? Is this communicated in the IC transaction?

The Standard of Disclosure in Informed Consent Decision Making in Medical Practice in Malaysia

Ambikai S Thuraisingam

Asian Journal of Law and Governance, 10 August 2020; 2(1) pp 1-14

Abstract

This is a conceptual paper to analyse the standard of disclosure in informed consent decision making in the medical practice in Malaysia. This study reviews literature on the history of the standard applied in the informed consent requirement among patients and its consequences in healthcare practice. It aims to evaluate the crucial elements of patient centricness particularly the factors that affect the voluntariness and competency of the patient in giving consent. This paper reviews the existing literature surrounding the phenomenon of giving consent for medical treatment in the healthcare, particularly on how the concept of shared decision making affects the consent requirement. This study provides an overview of the perplexing nature of disclosure in shared decision making and the various concerns that have surrounded the topic leading to its recognition.

Hence in Malaysia, there is no specific law which governs the provisions for shared decision making in informed consent in the healthcare practice. This study aims to explore the Malaysian Medical Council Guideline on Consent for Treatment of Patients by Registered Medical Practitioner (MMC Guideline on Consent) and the current Malaysian laws to determine whether they are sufficient to address the principle of shared decision making requirement patients. The study reviews the existing case laws and literature on the historical development of the elements of shared decision making, subsequently, the findings of the perusal of the MMC Guideline on Consent and the current statutory laws are presented and discussed. Finally, lack of empirical evidence is recognised in this paper and several suggestions are made for future research and recommendation for enactment of a new law pertaining to shared decision making in informed consent to medical treatment.

Informed consent approaches for clinical trial participation of infants with minor parents in sub-Saharan Africa: A systematic review

Research Article

Angela De Pretto-Lazarova, Domnita Oana Brancati-Badarau, Christian Burri

PLOS One, 4 August 2020

Abstract

Background

Regulations are vague regarding the appropriate decision-maker and authority to consent for children of minor parents participating in clinical trials. In countries with high rates of underage mothers, such as in sub-Saharan Africa, this lack of guidance may affect the rights of potential paediatric participants already bearing increased vulnerability. It can also influence the recruitment and generalizability of the research. We provide evidence and discuss informed consent management in such cases to inform best practice.

Materials and methods

We searched PubMed/MEDLINE, Embase, CINAHL, and Google Scholar for articles published up to March 2019. In total, 4382 articles were screened, of which 16 met our inclusion criteria. Studies addressing informed consent in clinical trials involving children with minor parents in sub-Saharan Africa were included. We performed descriptive and qualitative framework analyses. The review was registered in PROSPERO: CRD42018074220.

Results

Various informed consent approaches were reported. Articles supporting individual consent by minor parents based on emancipation or “mature minor” status lacked evidence in the context of research. National laws on medical care guided consent instead. When no laws or guidance existed an interpretation of the local decision-making culture, including community engagement and collaboration with local ethics committees, defined the informed consent approach.

Conclusions

The review emphasises that the implementation of informed consent for children with minor parents may be variable and hampered by absent or ambiguous clinical trial regulations, as well as divergent local realities. It may further be influenced by the research area and study-specific risks. Clear guidance is required to help address these challenges proactively in clinical trial planning. We provided a set of questions to be considered in the development of an ethically acceptable informed consent approach and proposed information that should be integrated into international clinical trial guidelines.

Parents'/Patients' Perception of the Informed Consent Process and Surgeons Accountability in Corrective Surgery for Adolescent Idiopathic Scoliosis (AIS): A Prospective Study

Chris Yin Wei Chan, Jessamine Sze Lynn Chong, Sin Ying Lee, Pei Ying Ch'ng, Weng Hong Chung , Chee Kidd Chiu, Mohd Shahnaz Hasan, Manes, Mun Keong Kwan

Spine, 1 August 2020

Abstract

Objective

To determine the parents'/patients' perception on the informed consent process prior to posterior spinal fusion (PSF) for Adolescent Idiopathic Scoliosis (AIS) patients.

Summary of Background Data

Understanding parents/patients perspective on the process is important in order to achieve the goal of consent and prevent medico legal implications.

Methods

50 AIS patients operated between Aug 2019 to Nov 2019 were prospectively recruited. Parents'/patients' perceptions on three sections were evaluated: the process of the informed consent, specific operative risk which they were most concerned with and the accountability of surgeons for the surgical risks. These data were ranked and scored using a 5-point Likert Scale. Preferences were reported in mean and standard deviation. Differences in terms of preferences were studied using One-way ANOVA analysis and deemed significant when $p < 0.05$.

Results

There were 30 females (60.0%) and 20 males (40.0%) with a mean age of 41.8 ± 10.6 years. Majority of parents/patients preferred the inform consent to be explained more than once ($p = 0.021$), once during clinic consultation and once during admission (4.2 ± 1.0). Consent taking by both attending surgeons was preferred (4.5 ± 0.6) compared to other healthcare providers, $p < 0.001$. Death (60.0%) and neurological deficit (30.0%) were the two most concerned surgical risks. Parents/patients would still hold the surgeon accountable for any complications despite signing the informed consent and they felt that surgeons were directly responsible for screw-related injuries (3.9 ± 0.9), neurological injury (3.8 ± 0.9) and intraoperative bleeding (3.7 ± 0.9).

Conclusions

Parents/patients preferred the attending surgeons to personally explain the informed consent, more than once with the use of visual aid. They would still hold the surgeons accountable when complications occur despite acceptance of the informed consent.

What Matters to Patients and Families: A Content and Process Framework for Clarifying Preferences, Concerns, and Values

Research Article

Rhéa Rocque, Selma Chipenda Dansokho, Roland Grad, Holly O. Witterman

Medical Decision Making, 22 July 2020

Abstract

Background. Values clarification, or sorting out what matters to a patient or family relevant to a health decision, is a fundamental part of shared decision making. We aimed to describe how values clarification occurs in routine primary care. Methods. Using framework analysis and an established taxonomy, 2 independent researchers analyzed 260 consultations in 5 family medicine clinics across Quebec. Two questions guided our analyses: 1) What categories exist regarding what matters to patients? 2) What patterns exist in discussions of what matters to patients? Results. 1) Five distinct categories of what matters to patients and families were discussed during values clarification: preferences, concerns, treatment-specific values, life goals or philosophies, and broader contextual

or sociocultural values. Preferences and concerns were the matters most commonly raised. 2) Diverse patterns of values clarification emerged based on 3 analytical questions: Who initiates the discussion about what matters to patients? When? What information is discussed? The most frequent pattern was clinicians soliciting patients' concerns and preferences during the information-gathering phase. The second most common pattern was similar, except that patients' spontaneously raised what matters to them. Limitations. The study was descriptive and based on audio-recorded visits. We did not interview patients and clinicians to elicit their perspectives. Conclusions. There are 5 distinct categories of what matters to patients and families as well as clear patterns of how values clarification occurs in routine primary care consultations. Clinicians could be sensitive to these categories when engaging in the process of values clarification and may wish to pay particular attention to the opening minutes of a consultation. This study provides a structure for future identification of best practices in values clarification.

Processes of consent in research for adults with impaired mental capacity nearing the end of life: systematic review and transparent expert consultation (MORECare_Capacity statement)

Research Article

C. J. Evans, E. Yorganci, P. Lewis, J. Koffman, K. Stone, I. Tunnard, B. Wee, W. Bernal, M. Hotopf, I. J. Higginson, Deborah Tanner, Claire Henry, Gunn Grande, Steve Dewar, Gareth Owen, Rachel Burman, Dimitrios Adamis, Michael Dunn, Scott Kim, Simon Woods & Rowena Vohora

BMC Medicine, 22 July 2020; 18(221)

Open Access

Abstract

Background

Involving adults lacking capacity (ALC) in research on end of life care (EoLC) or serious illness is important, but often omitted. We aimed to develop evidence-based guidance on how best to include individuals with impaired capacity nearing the end of life in research, by identifying the challenges and solutions for processes of consent across the capacity spectrum.

Methods

Methods Of Researching End of Life Care_Capacity (MORECare_C) furthers the MORECare statement on research evaluating EoLC. We used simultaneous methods of systematic review and transparent expert consultation (TEC). The systematic review involved four electronic databases searches. The eligibility criteria identified studies involving adults with serious illness and impaired capacity, and methods for recruitment in research, implementing the research methods, and exploring public attitudes. The TEC involved stakeholder consultation to discuss and generate recommendations, and a Delphi survey and an expert 'think-tank' to explore consensus. We narratively synthesised the literature mapping processes of consent with recruitment outcomes, solutions, and challenges. We explored recommendation consensus using descriptive statistics. Synthesis of all the findings informed the guidance statement.

Results

Of the 5539 articles identified, 91 met eligibility. The studies encompassed people with dementia (27%) and in palliative care (18%). Seventy-five percent used observational designs. Studies on research methods (37 studies) focused on processes of proxy decision-making, advance consent, and deferred consent. Studies implementing research methods (30 studies) demonstrated the role of family members as both proxy decision-makers and supporting decision-making for the person with impaired capacity. The TEC involved 43 participants who generated 29 recommendations, with consensus that indicated. Key areas were the timeliness of the consent process and maximising an individual's decisional capacity. The think-tank (n = 19) refined equivocal recommendations

including supporting proxy decision-makers, training practitioners, and incorporating legislative frameworks.

Conclusions

The MORECare_C statement details 20 solutions to recruit ALC nearing the EoL in research. The statement provides much needed guidance to enroll individuals with serious illness in research. Key is involving family members early and designing study procedures to accommodate variable and changeable levels of capacity. The statement demonstrates the ethical imperative and processes of recruiting adults across the capacity spectrum in varying populations and settings.

Improving knowledge and decision readiness to participate in cancer clinical trials: Effects of a plain language decision aid for minority cancer survivors

Short Communication

Aisha Langford, Jamie L. Studts, Margaret M. Byrne

Patient Education and Counseling, 7 July 2020

Abstract

Objective

To evaluate the impact of a web-based, plain language decision aid (CHOICES DA) on minority cancer survivors' knowledge of cancer clinical trials (CCTs), readiness for making decisions about clinical trial participation, and willingness to participate in a clinical trial.

Methods

Participants were 64 Black and Hispanic cancer survivors from Miami, Florida. In a single arm intervention study, participants completed self-report assessments of CCT knowledge, decision readiness regarding clinical trial participation, and willingness to participate at three time points.

Results

Black and Hispanic participants did not differ on demographic characteristics. Post-test and follow-up measures of CCT knowledge and decision readiness were significantly greater than pre-test measures for the sample overall, and for Black and Hispanic participants separately. Few significant differences were observed between Black and Hispanic participant outcomes at each survey time point, and willingness to participate did not change overall and for either group independently.

Conclusions

Reviewing the CHOICES DA was associated with significantly improved knowledge and decision readiness to participate in a CCT immediately and at 2-week follow-up.

Practical Implications

These findings suggest that CHOICES DA may support informed decision making about CCT participation within an acute, yet clinically relevant window of time for minority cancer patients who are substantially under-represented in cancer research.

Evaluation of donor informed consents and associated predonation educational materials in the United States and Canada: variability in elements of consent and measures of readability and reading burden

Original Research

Mary Townsend, Terri Buccino, Louis Katz

Transfusion, 4 July 2020

Abstract

Background

Every day, approximately 30,000 donors present to blood collection establishments in the United States or Canada, where they are provided information about donation and asked to sign a consent

before donating. We evaluated elements of informational and consent documents and measures of readability that may influence their comprehension.
Materials and Methods
Consents for whole blood (WB) and automated collections and predonation reading materials (PRMs) representing over 93% of WB collections in the United States and Canada were evaluated. Elements, including risks of donation, were cataloged. Word count, Flesch-Kinkaid (F-K) reading ease/grade level scores, Simple Measure of Gobbledygook grade, and percentage of complex words were measured.
Results
F-K grade levels ranged from 9.2 to 16.9 for WB consents, 7.8 to 16.0 for apheresis consents, and 6.7 to 10.9 for PRMs, above the recommended level of eighth grade or lower for general audiences. F-K reading ease scores were below the cutoff of 60 for readability. Reading burden was substantial, with word count ranging from 131 to 885, 131 to 996, and 649 to 2743 for WB and apheresis consents and PRMs, respectively. Use of jargon and the absence of consent elements such as confidentiality, voluntariness, ability to withdraw consent, and risks of deferral were common.
Conclusions
Donor consent documents and associated materials vary widely, are written at challenging grade levels, present considerable reading burden, contain substantial jargon, and are missing key elements of consent. The authors recommend an organized effort, including blood donors, legal experts, and blood collection experts, to reach consensus on the minimal requirements for standardized clear and concise consent documents in an optimized format.

Distributed consent and its impact on privacy and observability in social networks

Juniper Lovato, Antoine Allard, Randall Harp, Laurent Hebert-Dufresne
Cornell University, Physics and Society, 29 June 2020
Open Access
Abstract
Personal data is not discrete in socially-networked digital environments. A single user who consents to allow access to their own profile can thereby expose the personal data of their network connections to non-consented access. The traditional (informed individual) consent model is therefore not appropriate in online social networks where informed consent may not be possible for all users affected by data processing and where information is shared and distributed across many nodes. Here, we introduce a model of “distributed consent” where individuals and groups can coordinate by giving consent conditional on that of their network connections. We model the impact of distributed consent on the observability of social networks and find that relatively low adoption of even the simplest formulation of distributed consent would allow macroscopic subsets of online networks to preserve their connectivity and privacy. Distributed consent is of course not a silver bullet, since it does not follow data as it flows in and out of the system, but it is one of the most straightforward non-traditional models to implement and it better accommodates the fuzzy, distributed nature of online data.

Level of education and preferred language of informed consent for clinical research in a multi-lingual community

Grace Muzanyi, Isaac Sekitoleko, John L Johnson, Jane Lunkuse, Gladys Nalugwa, Joanita Nassali, David Kaawa Mafigiri
African Health Sciences, June 2020; 20(2)
Open Access

Abstract

Background

Low education levels and language barriers present challenges in obtaining informed consent for clinical research.

Objective

To describe and correlate the association between the level of education and the participant's preferred language of consent.

Design

Descriptive-analytical cross-sectional study.

Participants

Adults being consented for participation in tuberculosis (TB) research studies in an East African community with varying levels of education.

Procedures

We analyzed data on demographic and educational characteristics collected from adults being consented for participation in TB studies. Only participants who could understand and speak Luganda (the main local language) or English (the official language of Uganda) were included in this analysis.

Results

A total of 523 participants were consented between April 2015 and December 2017 and included in this analysis; 250 below Senior four (< 11yrs of education), 114 senior four (at 11yrs of education),73 senior five-senior six (12-13yrs of education) and 86 beyond senior six (> 13yrs of education). We noted that the preference for English rises with the rising levels of education and peaked at beyond senior six (83%Vs17%,OR=49,95%CI:22.8-106.3,p<0.001).Participants below senior four preferred Luganda Vs senior four and above(OR=16.9,95%CI:9.9-28.8,p<0.001)

Conclusion

Rising education levels of participants were associated with preference for English language usage during initial consent for clinical research studies.

Consensus on Language for Advance Informed Consent in Health Care–Associated Pneumonia Clinical Trials Using a Delphi Process

Original Investigation

Amy Corneli, Sara B. Calvert, John H. Powers III, Teresa Swezey, Deborah Collyar, Brian Perry, John J. Farley, Jonas Santiago, Helen K. Donnelly, Carisa De Anda, Katelyn Blanchard, Vance G. Fowler Jr, Thomas L. Holland

JAMA, 22 May 2020

Open Access

Abstract

Importance

Information to be included in advance informed consent forms for health care–associated pneumonia treatment trials remains to be determined.

Objective

To identify and determine how to describe information to be included in an advance informed consent form for an early-enrollment noninferiority hospital-acquired and/or ventilator associated bacterial pneumonia (HABP/VABP) clinical trial.

Design, Setting and Participants

A Delphi consensus process with stakeholders in HABP/VABP clinical trials was conducted using qualitative semistructured telephone interviews from June to August 2016, followed by 2 online surveys, the first from April to May 2017, and the second from September to October 2017. All

stakeholders who participated in the interview were invited to participate in the first survey. Stakeholders who participated in the first survey were invited to participate in the second survey. Stakeholders were patients at risk of pneumonia, caregivers, representatives of institutional review boards, investigators, and study coordinators.
Main Outcomes and Measures
Description and consensus of information to be included in advance informed consent forms for early enrollment in noninferiority HABP/VABP clinical trials.
Results
Suggestions from 52 stakeholders about what key informed consent concepts to include and how to explain them were used to create 3 categories to be included in an advance consent form: (1) reassurances on patient health and treatment, (2) rationale for advance consent and early enrollment, and (3) an explanation of noninferiority. At the end of the Delphi process, at least 80% consensus was reached among the 40 stakeholders who participated in the second online survey on each of the statements to include in the proposed consent text. Throughout the process, however, describing and reaching consensus on statements about noninferiority was more problematic than the other categories.
Conclusions and Relevance
The stakeholders endorsed consent language to be used in combination with a strategy for enrolling patients at highest risk for pneumonia before infection onset. Data-driven consent language may help potential participants make informed decisions about their involvement in clinical research and improve enrollment rates, which are necessary to evaluate new treatments and improve patient care. The proposed consent language may be adapted for other trials using an early enrollment strategy and for noninferiority trials.

Developing model biobanking consent language: what matters to prospective participants?

Research Article
Laura M. Beskow, Catherine M. Hammack-Aviran, Kathleen M. Brelsford
BMC Medical Research Methodology, 15 May 2020; 20(119)
Open Access
Abstract
Background
Efforts to improve informed consent have led to calls for providing information a reasonable person would want to have, in a way that facilitates understanding of the reasons why one might or might not want to participate. At the same time, advances in large-scale genomic research have expanded both the opportunities and the risks for participants, families, and communities. To advance the use of effective consent materials that reflect this landscape, we used empirical data to develop model consent language, as well as brief questions to assist people in thinking about their own values relative to participation.
Methods
We conducted in-person interviews to gather preliminary input on these materials from a diverse sample (n = 32) of the general population in Nashville, Tennessee. We asked them to highlight information they found especially reassuring or concerning, their hypothetical willingness to participate, and their opinions about the values questions.
Results
Consent information most often highlighted as reassuring included the purpose of the biobank, the existence and composition of a multidisciplinary oversight committee, the importance of participants' privacy and efforts to protect it, and controlled access to a scientific database.

Information most often highlighted as concerning included the deposition of data in a publicly accessible database, the risk of unintended access to data, the potential for non-research use of data, and use of medical record information in general. Seventy-five percent of participants indicated initial willingness to participate in the hypothetical biobank; this decreased to 66% as participants more closely considered the information over the course of the interview. A large majority rated the values questions as helpful.

Conclusions

These results are consistent with other research on public perspectives on biobanking and genomic cohort studies, suggesting that our model language effectively captures commonly expressed reasons for and against participation. Our study enriches this literature by connecting specific consent form disclosures with qualitative data regarding what participants found especially reassuring or concerning and why. Interventions that facilitate individuals' closer engagement with consent information may result in participation decisions more closely aligned with their values.

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.

Partnering With Patients to Bridge Gaps in Consent for Acute Care Research

Neal W. Dickert, Amanda Michelle Bernard ,JoAnne M. Brabson, Rodney J. Hunter, Regina McLemore, Andrea R. Mitchell, Stephen Palmer, Barbara Reed, Michele Riedford, Raymond T. Simpson, Candace D. Speight, Tracie Steadman, Rebecca D. Pentz

The American Journal of Bioethics, 4 May 2020; 5 pp 7-14

Abstract

Clinical trials for acute conditions such as myocardial infarction and stroke pose challenges related to informed consent due to time limitations, stress, and severe illness. Consent processes should be sensitive to the context in which trials are conducted and to needs of patients and surrogate decision-makers. This manuscript describes a collaborative effort between ethicists, researchers, patients, and surrogates to develop patient-driven, patient-centered approaches to consent for clinical trials in acute myocardial infarction and stroke.

Our group identified important ways in which existing consent processes and forms for clinical trials fail to meet patients' and surrogates' needs in the acute context. We collaborated to create model forms and consent processes that are substantially shorter and, hopefully, better-matched to patients' and surrogates' needs and expectations from the perspective of content, structure, and tone. These changes, however, challenge some common conventions regarding consent.

Assessing the stability of biobank donor preferences regarding sample use: evidence supporting the value of dynamic consent

Joel E. Pacyna, Jennifer B. McCormick, Janet E. Olson, Erin M. Winkler, Josh T. Bublitz, Matthew A. Hathcock & Richard R. Sharp

European Journal of Human Genetics, 23 April 2020

Abstract

Dynamic consent has been proposed as a strategy for addressing the limitations of traditional, broad consent for biobank participation. Although the argument for dynamic consent has been made on theoretical grounds, empirical studies evaluating the potential utility of dynamic consent are needed to enhance deliberations about the merits of dynamic consent. Few studies have assessed such considerations as whether donor preferences may change over time or if participants would use a dynamic consent mechanism to modify preferences when they change. We administered a 66-item survey to participants in a large DNA biobank. The survey sought to gauge the stability of donor preferences specified at the time of biobank enrollment, specifically the stability of donors' preference regarding posthumous availability of biospecimens to next-of-kin. We received 1164 completed surveys for a response rate of 72%. Forty percent of respondents indicated a preference regarding sample availability on the survey (T2) that was inconsistent with the preference they had expressed when they enrolled in the biobank (T1). Most (94%) individuals with inconsistent preferences regarding sample availability had initially restricted sample availability at T1 but were comfortable with broader availability when asked at the time of the survey (T2). Our findings demonstrate that preferences regarding sample use expressed at the time of enrollment in a DNA biobank may not be reliable indicators of donor preferences over time. These findings lend empirical support to the case for a dynamic consent model in which biobank participants are approached over time to clarify their views regarding sample use.

Patient perspectives on research use of residual biospecimens and health information: On the necessity of obtaining societal consent by creating a governance structure based on value-sharing

Original Research
Mayumi Yamanaka, Mika Suzuki, Keiko Sato
Research Ethics, April 2020
Open Access
Abstract
Very few attempts have been made to survey patient opinions, particularly regarding the use of residual biospecimens and health information in research, to clarify their values. We conducted a questionnaire survey that targeted outpatients of a university hospital to gauge their awareness levels and understand patient perspectives on research that uses these items. Few patients felt that obtaining individual consent for each research study was necessary. Most patients expressed the view that researchers should be obligated to inform them about the research use of their items and be subject to self-directed rules (including sanctions). The research community should try to obtain "societal consent regarding an opt-out system" from the public. A salient value-sharing-based governance structure is necessary for obtaining public trust.

Towards Identifying an Upper Limit of Risk: A Persistent Area of Controversy in Research Ethics

Erin T. Paquette, Seema K. Shah
Perspectives in Biology and Medicine, Spring 2020; 63(2)
Abstract
Whether there is an upper limit of net risk that volunteers can consent to in research, and what that limit happens to be, has been the subject of persistent controversy in research ethics. This article defends the concept of an upper limit of risk in research against recent critics and supports the most promising approach for identifying this limit, that of finding comparator activities that are generally accepted in society and pose high levels of risk. However, high-risk activities that have been proposed as relevant comparators involve more certain benefits and confer considerable social esteem to those who take on the risks. This suggests that developing a robust approach to identifying social value, whether by developing a procedural safeguard or a systematic framework, could more effectively identify research with sufficient social value to justify high net risk. Additionally, the social status of research participants should be elevated to be more on par with others who laudably take on high risk for the benefit of others. By attending to the benefits necessary for the justification of high-risk research, the level of allowable risk will no longer be so controversial.

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.

General

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).

An instrument for assessing the quality of informed consent documents for elective procedures: development and testing

Original Research

Erica S Spatz, Lisa G Suter, Elizabeth George, Mallory Perez, Leslie Curry, Vrunda Desai, Haikun Bao, Lori L Geary, Jeph Herrin, Zhenqiu Lin, Susannah M Bernheim, Harlan M Krumholz

BMJ Open: Ethics, 19 May 2020; 10(5)

Open Access

Abstract

Objective

To develop a nationally applicable tool for assessing the quality of informed consent documents for elective procedures.

Design

Mixed qualitative-quantitative approach.

Setting

Convened seven meetings with stakeholders to obtain input and feedback on the tool.

Participants

Team of physician investigators, measure development experts, and a working group of nine patients and patient advocates (caregivers, advocates for vulnerable populations and patient safety experts) from different regions of the country.

Interventions

With stakeholder input, we identified elements of high-quality informed consent documents, aggregated into three domains: content, presentation and timing. Based on this comprehensive taxonomy of key elements, we convened the working group to offer input on the development of an abstraction tool to assess the quality of informed consent documents in three phases: (1) selecting the highest-priority elements to be operationalised as items in the tool; (2) iteratively refining and testing the tool using a sample of qualifying informed consent documents from eight hospitals; and (3) developing a scoring approach for the tool. Finally, we tested the reliability of the tool in a subsample of 250 informed consent documents from 25 additional hospitals.

Outcomes

Abstraction tool to evaluate the quality of informed consent documents.

Results

We identified 53 elements of informed consent quality; of these, 15 were selected as highest priority for inclusion in the abstraction tool and 8 were feasible to measure. After seven cycles of iterative development and testing of survey items, and development and refinement of a training manual, two trained raters achieved high item-level agreement, ranging from 92% to 100%.

Conclusions

We identified key quality elements of an informed consent document and operationalised the highest-priority elements to define a minimum standard for informed consent documents. This tool

is a starting point that can enable hospitals and other providers to evaluate and improve the quality of informed consent.

Quality of informed consent documents among US. hospitals: a cross-sectional study

Original Research

Erica S Spatz, Haikun Bao, Jeph Herrin, Vrunda Desai, Sriram Ramanan, Lynette Lines, Rebecca Dendy, Susannah M Bernheim, Harlan M Krumholz, Zhenqiu Lin, Lisa G Suter

BMJ Open: Cardiovascular Medicine, 19 May 2020; 10(5)

Open Access

Abstract

Objective

To determine whether informed consent for surgical procedures performed in US hospitals meet a minimum standard of quality, we developed and tested a quality measure of informed consent documents.

Design

Retrospective observational study of informed consent documents.

Setting

25 US hospitals, diverse in size and geographical region.

Cohort

Among Medicare fee-for-service patients undergoing elective procedures in participating hospitals, we assessed the informed consent documents associated with these procedures. We aimed to review 100 qualifying procedures per hospital; the selected sample was representative of the procedure types performed at each hospital.

Primary outcome

The outcome was hospital quality of informed consent documents, assessed by two independent raters using an eight-item instrument previously developed for this measure and scored on a scale of 0–20, with 20 representing the highest quality. The outcome was reported as the mean hospital document score and the proportion of documents meeting a quality threshold of 10. Reliability of the hospital score was determined based on subsets of randomly selected documents; face validity was assessed using stakeholder feedback.

Results

Among 2480 informed consent documents from 25 hospitals, mean hospital scores ranged from 0.6 (95% CI 0.3 to 0.9) to 10.8 (95% CI 10.0 to 11.6). Most hospitals had at least one document score at least 10 out of 20 points, but only two hospitals had >50% of their documents score above a 10-point threshold. The Spearman correlation of the measures score was 0.92. Stakeholders reported that the measure was important, though some felt it did not go far enough to assess informed consent quality.

Conclusion

All hospitals performed poorly on a measure of informed consent document quality, though there was some variation across hospitals. Measuring the quality of hospital's informed consent documents can serve as a first step in driving attention to gaps in quality.

From "Informed" to "Engaged" Consent: Risks and Obligations in Consent for Participation in a Health Data Repository

Research Article

Elizabeth Bromley, Alexandra Mendoza-Graf, Sandra Berry, Camille Nebeker, Dmitry Khodyakov

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Abstract

The development and use of large and dynamic health data repositories designed to support research pose challenges to traditional informed consent models. We used semi-structured interviewing (n=44) to elicit diverse research stakeholders' views of a model of consent appropriate to participation in initiatives that entail collection, long-term storage, and undetermined future research use of multiple types of health data. We demonstrate that, when considering health data repositories, research stakeholders replace a concept of consent as informed with one in which consent is engaged. In engaged consent, a participant's ongoing relationship with a repository serves as a substitute or adjunct to information exchange at enrollment. We detail research stakeholders' views of the risks of engaged consent and suggest questions for further study about engagement and consent procedures in initiatives that aim to store data for future unspecified research purposes.

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