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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

September 2020

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

Each month we monitor *Google Scholar* for the search terms "consent" and "informed consent" in title and available text. After careful consideration a selection of these results appear in the digest. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

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

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

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No new content identified for the following established categories:
BIOBANKING
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FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION

Please note that we maintain a glossary, tools for assessment and guidance documents on our website.

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COVID-19

Surgical consent during the COVID19 pandemic: Saving lives while in crisis editorial

Evander Meneses, Mark McKenney, Dessy Boneva, Adel Elkbuli

Annals of Medicine and Surgery, September 2020; (57) pp 163–165

Open Access

Excerpt

…At our institution, all patients who are admitted are tested for COVID-19 and results return usually within 24 hours. For emergent surgeries on trauma patients near death from hemorrhage, we proceed to the operating room without consent, as is the case at any trauma center. In this situation the patient is in extremis and lacks capacity due to exsanguination and altered mental status. For urgent surgeries, however we must obtain informed consent. We follow the ACS principles for informed consent, providing the patient information pertaining to the nature of their illness and consequence of no treatment, nature of proposed operation, commonly known complications, alternative forms of treatment, and a discussion of the different types of qualified medical providers who will participate in the care [5]. At our institution, the surgical resident and attending surgeon are the initial contact to the patient and/or family members when obtaining informed consent for surgical procedures. The attending surgeon provides information to the patient and/or family members and signs the physical consent form prior to the patient rolling into the operating suite. We now additionally speak with the patient and/or family members regarding COVID-19, explaining that we are unsure how it may impact their perioperative morbidity and possible mortality. We also explain that there is a risk for transmission within the hospital as well as further transmission after hospital discharge if they were to become infected in the hospital…

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.

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BIOMEDICAL RESEARCH

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.

Food and Drug Administration and Institutional Review Board Approval of a Novel Prehospital Informed Consent Process for Emergency Research

Jason McMullan,Christopher Droege,Col. Richard Strilka, Christopher Lindsell, Michael J. Linke

Prehospital Emergency Care, 13 August 2020

Abstract

Research on the management of acute pain in the prehospital setting is fraught with challenges. The prehospital setting is complex due to constrained time, resources, and training. Research activities must not interfere with the underlying clinical priorities of immediate patient stabilization and rapid transport to an appropriate hospital. The patient's pain, fear, and anxiety immediately after a traumatic event may interfere with undertaking an adequate informed consent process.

Pain management trials do not satisfy the criteria for application of the U.S. Food and Drug Administration (FDA) 21 CFR 50.24 exception from informed consent. While non-standard informed consent processes exist, waiver or alteration of informed consent may be limited if Institutional Review Boards or the FDA consider these studies to involve more than minimal risk related to the setting of the study, even if the interventions themselves might involve no more than minimal risk in other settings. In addition, any study requiring an Investigational New Drug application requires fully documented standard informed consent.

Emergency Medical Services agencies and fire departments become research institutions, and paramedics become study staff, but both the institutions and the staff often lack experience conducting human subjects research and are rarely formally affiliated with the academic institution overseeing the research. As such, additional administrative burdens must be overcome in interventional prehospital studies, including

additional training in the study protocol, research operations, and human subjects protections. Institutions conducting federally funded studies commit to regulations covering human subjects protections in the form of a Federalwide Assurance (FWA); prehospital organizations participating in research must either obtain an FWA or have coverage extended to them from an academic partner.

We describe how these challenges were addressed during Institutional Review Board review and approval of an FDA-regulated randomized placebo-controlled trial of intranasal ketamine (vs. placebo) in acutely injured patients receiving standard of care fentanyl for prehospital pain management (NCT02866071). To our knowledge, this trial is the first instance in the United States of paramedics screening, consenting, enrolling, and administering study medications to patients without direct, real-time support from a dedicated clinical research team.

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.

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.

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.

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SOCIAL SCIENCE RESEARCH

Evaluating survey consent to social media linkage in three international health surveys

Zeina N. Mneimneh, Ronny Bruffarets, Yasmin A. Altwaijri, Colleen McClain

Research in Social and Administrative Pharmacy, 10 August 2020

Abstract

Background

The use of Twitter data for health-related research has been increasing over time. While the organic nature of the data offer new opportunities, the limited understanding of how and by whom the data are generated poses a challenge for advancing health-related research. Individual-level data linkage could shed light into the data generation mechanism.

Objectives

This paper investigates whether consent to link survey data with Twitter public data is associated with socio-demographic and Twitter use pattern factors and whether consenters and non-consenters differ on health-related outcomes.

Methods

Data from three health related surveys that use probability samples of the target population were used: 1) A college population web survey in KU Leuven University, 2) An adult population web survey of the US population, and 3) A population face-to-face survey in the Kingdom of Saudi Arabia (KSA). In all surveys, respondents reported whether they have a Twitter account, and Twitter users were asked to provide consent for linking their survey responses to their public Twitter data.

Results

Consent rate estimates from the two web surveys in Belgium and the US were 24% and 27% respectively. The face-to-face survey in KSA yielded a higher consent rate of 45%. In general, respondent's sociodemographic characteristics were not significantly associated with consent to link. However, more use of social media and reporting sensitive information in the survey were found to be significantly correlated with higher consent. Consenters and non-consenter were not found to be statistically different on any of the health related measures.

Conclusions

Very few differences were found between those who consented to link their survey data with their Twitter public data and those who did not. Modifiable design variables need to be investigated to maximize consent while maintaining balance between consenters and non-consenters.

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TECHNOLOGY/OTHER MEDIATION

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.

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.

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CAPACITY TO CONSENT

Who Has the Ability to Consent?

La Vonne Ann Downey, Les Zun

Primary Care Companion for Central Nervous System Disorders, 20 August 2020; 22(4)

Abstract

Objective

Previous studies have shown no consistent examinations for testing the ability of patients to consent in hospital emergency departments (EDs). The primary objective of this study was to compare providers' opinions with 3 capacity assessment tools to determine the ability of medical and psychiatric patients to consent in the ED.

Method

The study was conducted at a level 1 inner-city general hospital ED from June 2016 to October 2017. The study participants comprised a random sample of English-speaking patients aged ≥ 18 years who presented with any medical or psychiatric complaint. Each patient was administered 3 tools: the standard ED consent form, the Aid to Capacity Evaluation (ACE), and the Mini-Mental State Examination. The results of these assessments were then compared to the provider's opinion of the patient's ability to provide consent.

Results

A total of 283 patients participated in the study, and 84.4% were able to consent according to providers. There was a high level of consistency with the provider's assessment and the other assessment tools on the patient's ability to consent. Most patients, both medical and psychiatric, showed the ability to consent. However, this was less true for psychiatric patients with schizophrenia, as 32.6% (n = 14) were unable to consent.

Conclusions

The study revealed that the ACE capacity assessment was highly consistent with the providers' assessment for medical (88.3%) and psychiatric patients (80.3%), but not for psychiatric patients with schizophrenia. Using the ACE, patients with schizophrenia presenting to the ED were significantly less able to understand their illnesses (0.01) and treatments (0.04) and thus were less able to give consent.

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.

Objectives

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.

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.

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YOUNG PERSONS

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 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.

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 $\chi 2$ 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.

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RIGHTS/LEGAL/LEGISLATIVE

Contributory factors to the evolution of the concept and practice of informed consent in clinical research: A narrative review

Review Article

Lydia O'Sullivan, Rachel Crowley, Éilish McAuliffe, Peter Doran

Contemporary Clinical Trials Communications, 13 August 2020

Abstract

Informed consent can be defined as a freely-given decision or agreement following disclosure of relevant information. This review explores how legislation surrounding informed consent has impacted upon clinical research practices, with a focus on clinical trials involving individuals with the capacity to give consent in the

non-emergency setting. We also highlight the challenges which remain with the informed consent process, including those which exist in the era of data protection legislation and genetic research.

Modern ethicists agree that informed consent encompasses three principal factors: disclosure of information, capacity for decision making, and voluntariness. In the context of clinical research, informed consent is now required by regulatory and ethical frameworks as well as by law, and various guidelines govern the practice of informed consent, including the Declaration of Helsinki and the Good Clinical Practice Guidelines. Historically, however, researchers acted paternalistically and, included participants in research without their knowledge or consent. Following societal and political revolution, an autonomy model of consent became prevalent, and individuals become free to make individual choices about whether to participate. Despite this, it is also recognized that an individual's community has a role in supporting their decision making, and this may be a strong influence, particularly within some societies. Research scandals and controversies and whistle-blowers which exposed unethical practices in the area of informed consent also contributed to changes in societal attitudes and legislation changed as a result. Medical journals also have an established, although indirect, role in strengthening good practices surrounding informed consent.

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CULTURAL/COUNTRY CONTEXT

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.

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 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.

Local customs and implications for informed consent process in research in African low and middle income countries. Challenges in information disclosure, understanding and voluntariness. [THESIS]

C. Miguel Paulo

Utrecht University Repository, Faculty of Humanities Theses, 2020

Abstract

The process of requesting informed consent for participation in research has been widely addressed in various international guidelines, such as the Belmont Report, the Nuremberg code and the Declaration of Helsinki. Currently, the Declaration of Helsinki is the predominant ethical guideline for conducting research with human subjects. It has an extensive section dedicated to informed consent, meant to embed in researchers the understanding of the importance and underlying core values of informed consent. While the predominant justification for informed consent requirement rests on respect for autonomy, I will argue for prevention of deception and coercion as the core value to substantiate informed consent in collaborative research in African low and middle income countries (henceforth LMIC). By using principlism as a framework, I will explore how the conflict between respect for autonomy and nonmaleficence provide support for my stance. In this paper, I scrutinize how local customs intertwined in the historical and socio-cultural context of LMIC in Africa, shape underlying dynamics in the informed consent communication process by disrupting information disclosure, understanding and voluntariness. Those aspects intersect with underlying pillars of autonomous choice, resulting in presumably undermined autonomy. Consequently, I argue that the researcher-research subject ought to be based on grounds of trust and trustworthiness in order to still validate the relevance of informed consent as currently applied. I end by arguing that a deliberative approach should be attained in improving the quality of informed consent in those settings. To this end, the intuitionist model by Heidt could be conducive for deliberations on identifying moral grounds for justifying informed consent requirements when meeting the presuppositions of the rational choice theory is not attainable.

Patients Perception of the Quality of Consent for Caesarean Sections in Tertiary Health Facility in Port Harcourt, Southern Nigeria

Kenneth Eghuan Okagua, Joyce Okagua

The Nigerian Health Journal, 2019; 19(4)

Open Access

Abstract

Background

Informed consent should be viewed as a process and not just a signature on a form as is commonly seen in most cases. It is very important not just to minimise conflict/medico-legal issues but as a tool for better communication between the physician and the patient on diagnosis, treatment risk, etc. In order to improve acceptance/minimise conflicts from Caesarean Deliveries, which are increasingly being performed globally, it is important to determine patients perception of the quality of consents obtained, more so, as previous studies have demonstrated poor quality of consent for various surgical procedures.

Materials and Method

A cross-sectional study was carried out in Braithwaite Memorial Specialist Hospital, between January 2016 to June 2016, using an interviewer based structured questionnaire on women who had caesarean section.

Results

Three hundred and forty eight women who had caesarean section were recruited for the study. They were aged between 20 and 42 years with a mean age of 31.74 ± 4.39 years. Majority (67.5%) of the women had tertiary level of education and 94.8% of the women were married. Of the 348 women, 220 (63.2%) had emergency caesarean section. 89.9% had knowledge of the diagnosis and the same number, were not aware of possible complications. 55.7% of the consents were obtained by a nurse. Only 52% of the women were satisfied with the consent.

Conclusion

The quality of consent for obstetric surgeries is still poor. Doctors especially consultants need to be more involved in the process to improve its quality.

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MEDICAL/SURGICAL

Ethical and legal challenges of informed consent applying artificial intelligence in medical diagnostic consultations

Kristina Astromskė, Eimantas Peičius, Paulius Astromskis

AI & Society, 27 August 2020

Abstract

This paper inquiries into the complex issue of informed consent applying artificial intelligence in medical diagnostic consultations. The aim is to expose the main ethical and legal concerns of the New Health phenomenon, powered by intelligent machines. To achieve this objective, the first part of the paper analyzes ethical aspects of the alleged right to explanation, privacy, and informed consent, applying artificial intelligence in medical diagnostic consultations. This analysis is followed by a legal analysis of the limits and requirements for the explainability of artificial intelligence. Followed by this analysis, recommendations for action are given in the concluding remarks of the paper.

"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.

Updated GMC guidance on decision-making and consent: implications for urologists

Research Article

Siobhan Duffy, Catriona Barlow, Mark Underwood, Elizabeth Day

Journal of Clinical Urology, 30 July 2020

Abstract

We summarise the updated General Medical Council guidance on consent and decision-making. We explore the emphasis on enabling supported decision-making and the implications this has in day to day urological practice. In particular, we address some of the issues encountered in one-stop clinics, on pooled elective lists and with pre-written consent forms. The new guidance will emphasise the importance of sharing information relevant to your patient in light of the Montgomery ruling. Every decision is unique. We must appreciate the importance of the process of decision-making and understand our role as the clinician. Here we suggest some practical considerations to address the updated General Medical Council guidance.

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.

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.

Informed Consent Guidelines for Optimizing the Use of Telomerase-Positive Stem Cells

Henry E Young, Mark O Speight

Journal of Regenerative Medicine & Biology Research, 22 July 2020

Open Access

Abstract

The objectives of the work, based on previous characterization studies, pre-clinical animal models of induced diseases, e.g., Parkinson disease, cardiovascular disease, pulmonary disease, and type-I diabetes mellitus, and early clinical human studies of Parkinson disease, cardiovascular disease, and pulmonary diseases, were to established a set of criteria that needed to be followed for using telomerase-positive stem cells in future human clinical trials. From this set of criteria, informed consent guidelines were established to optimize the safety and efficacy of using endogenous adult-derived telomerase-positive stem cells to restore organ function by either repair and/or regeneration of cells and tissues resulting from tissue damage and/or loss. Inclusion criteria were any male or female, 18 to 120 years of age, with preferably no serious comorbidities. Exclusion criteria were use of alcohol, tobacco products, vaping, recreational drugs, lidocaine, and/or

chemotherapeutic drugs. We also cautioned use of caffeine and corticosteroids, as well as limiting moderate to strenuous physical activity within a two week window before and after stem cell treatment. Following these inclusion and exclusion criteria, endogenous adult-derived autologous and/or allogeneic telomerase-positive stem cells have proven to be both safe and effective at restoring (up to 50% above pre-treatment values in compliant individuals) organ function for diseases and/or disorders caused by trauma or chronic diseases. Conditions treated thus far, within IRB-approved human study protocols, include neurodegenerative, cardiovascular, pulmonary, autoimmune, renal, and orthopedic disorders.

Medicaid Sterilization Consent Forms: Variation in Rejection and Payment Consequences

Research Letter

Neena Qasba, Baystate HealthFollow

American Journal of Obstetrics and Gynecology, July 2020

Open Access

Abstract

Objective

In 1974, the federal Sterilization Consent Form (SCF) was created for those with publicly funded insurance to document appropriate informed consent by a clinician for sterilization procedures. This form must be signed by the clinician and patient at least 30 days before the procedure and expires 180 days after being signed. While there are numerous barriers to desired sterilization, the Medicaid consent process is a major cause of unfulfilled sterilization requests. As long as they comply with federal statutes, states may modify the Medicaid SCF, further complicating this process. However, data regarding this state-level variability is largely unavailable. Federal policy dictates that the global obstetrical fee should not be affected by SCF rejection. We sought to describe how individual state Medicaid policies differed in terms of what constitutes proper SCF completion and the payment ramifications of a rejected SCF.

Study design

A 25-question survey was administered with Qualtrics XM® to 50 United States state Medicaid Directors or the most appropriate state official based on a review of the state website. The survey assessed state officials' knowledge of criteria used to assess completion and validity of SCFs, SCF rejection rate, and payment ramifications for rejected SCFs. Data were collected from January to May 2020. Deidentified data were analyzed and reported in aggregate. This study was given Exempt Status by the Tufts Health Sciences Institutional Review Board.

Results

There were 41 responses from 36 states for a 72% participation rate. Four states had submitted multiple nonidentical responses. Criteria for SCF rejection included an incomplete form (35, 85%), mismatching or incorrect dates/times on the SCF (28, 68%), and that greater than 180 days had passed since the patient's signature rendering the form expired (27, 66%) (Figure 1A). Ten respondents (24%) estimated a SCF rejection rate of less than or equal to 10% while four respondents (10%) indicated a greater than 30% rejection rate (Figure 1B). The majority of respondents indicated that the ramification of a rejected SCF included the loss of payment for the postpartum sterilization procedure for the provider (32, 78%) as well as facility (29, 71%). Five respondents stated that a rejected SCF resulted in loss of the entire obstetrical global payment for provider and facility (5, 12% provider; 5, 12% facility).

Conclusion

From our survey, it is clear that wide variation exists between states or within individual states, in the criteria used by state Medicaid offices to assess SCF completion, rate of rejections, and subsequent payment ramifications for providers and facilities. While the majority of respondents identified objective measures (e.g. incorrect dates) as major reasons to reject SCFs, many also used subjective reasons (e.g. signature legibility). Though federal policy dictates that the global fee should not be affected by SCF rejection, our study found 12% of respondents indicated a loss of the global fee. The fear of payment loss can be a significant barrier to desired sterilization. Ensuring greater transparency and consistency in the Title XIX

sterilization consent process within and between states is a key step to ensuring equitable access to postpartum sterilization.

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GENERAL/OTHER

Why 'understanding' of research may not be necessary for ethical emergency research

Dan Kabonge Kaye
Philosophy, Ethics, and Humanities in Medicine, 26 August 2020; 15(6)
Open Access
Abstract
Background
Randomized controlled trials (RCTs) are central to generating knowledge about effectiveness of interventions as well as risk, protective and prognostic factors related to diseases in emergency newborn care. Whether prospective participants understand the purpose of research, and what they perceive as the influence of the context on their understanding of the informed consent process for RCTs in emergency obstetric and newborn care are not well documented.
Methods
Conceptual review.
Discussion
Research is necessary to identify how the illnesses may be prevented, to explore the causes, and to investigate what medications could be used to manage such illness. Voluntary informed consent requires that prospective participants understand the disclose information about the research, and use this to make autonomous informed decision about participation, in line with their preferences and values. Yet the emergency context affects how information may be disclosed to prospective research participants, how much participants may comprehend, and how participants may express their voluntary decision to participate, all of which pose a threat to the validity of the informed consent. I challenge the claim that the 'understanding' of research is always necessary for ethical informed consent for research during emergency care. I argue for reconceptualization of the value of understanding, through recognition of other values that may be equally important. I then present a reflective perspective that frames moral reflection about autonomy, beneficence and justice in research in emergency research.
Conclusion
While participant 'understanding' of research is important, it is neither necessary nor sufficient for a valid informed consent, and may compete with other values with which it needs to be considered.

In Defence of informed consent for health record research - why arguments from 'easy rescue', 'no harm' and 'consent bias' fail

Thomas Ploug
BMC Medical Ethics, 20 August 2020; 21(75)
Open Access
Abstract
Background
Health data holds great potential for improved treatments. Big data research and machine learning models have been shown to hold great promise for improved diagnostics and treatment planning. The potential is tied, however, to the availability of personal health data. In recent years, it has been argued that data from health records should be available for health research, and that individuals have a duty to make the data

available for such research. A central point of debate is whether such secondary use of health data requires informed consent.

Main body

In response to recent writings this paper argues that a requirement of informed consent for health record research must be upheld. It does so by exploring different contrasting notions of the duty of easy rescue and arguing that none of them entail a perfect duty to participate in health record research. In part because the costs of participation cannot be limited to 1) the threat of privacy breaches, but includes 2) the risk of reduced trust and 3) suboptimal treatment, 4) stigmatization and 5) medicalisation, 6) further stratification of solidarity and 7) increased inequality in access to treatment and medicine. And finally, it defends the requirement of informed consent by arguing that the mere possibility of consent bias provides a rather weak reason for making research participation mandatory, and that there are strong, independent reasons for making.

Conclusion

Arguments from the duty of easy rescue in combination with claims about little risk of harm and potential consent bias fail to establish not only a perfect duty to participate in health record research, but also that participation in such research should be mandatory. On the contrary, an analysis of these arguments indicates that the duty to participate in research is most adequately construed as an imperfect duty, and reveals a number of strong reasons for insisting that participation in health records research is based on informed consent.

Consenting and ethical considerations in embryo cryopreservation

Arian Khorshid, Ruben Alvero

Current Opinion in Obstetrics and Gynecology, 27 July 2020

Abstract

Purpose of review

An emerging body of literature has elucidated the growing burden of surplus embryos left in storage without any clear disposition. An out dated consent process is a significant but easily remedied contributor to this problem. We propose a novel approach to consenting for disposition of surplus embryos.

Recent findings

Decisional conflicts that stem from the moral status of embryos and from evolving personal values contribute to surplus embryos being left in storage. Barriers to donation of embryos to research or to other patients also discourage embryo disposition decisions. A flawed informed consent process compromises the physician--provider relationship and complicates decision-making.

Summary

Centralizing the process of donating embryos to research and to patients would lower barriers to these disposition options. The informed consent protocol must be redesigned as a longitudinal, narrative process compatible with the evolving values and fertility outcomes of patients. Counselors should be integrated into all discussions regarding embryo disposition from the onset of fertility treatment through its conclusion to facilitate the decision-making process.

Desperate Times: Protecting the Public From Research Without Consent or Oversight During Public Health Emergencies

Ideas and Opinions

Mary Catherine Beach, Howard M. Lederman, Megan Singleton, Roy G. Brower, Joseph Carrese, Daniel E. Ford, Bhakti Hansoti, Craig W. Hendrix, Ellen Verena Jorgensen, Richard D. Moore, Philip Rocca, Jonathan M. Zenilman

Annals of Internal Medicine, 27 July 2020; (57) pp 163–165

Open Access

Excerpt

…Obtaining informed consent may be impracticable in some public health surveillance activities. The ethical basis for using surveillance data without consent, particularly in emergency situations, is that it serves a compelling common good. Many—including the authors—agree that public health activities should proceed without informed consent when it is not possible or would undermine effective public health response. However, in the absence of a legal requirement, consent should be considered if possible. Obtaining consent may not be difficult, especially when data are collected prospectively. Even if informed consent is impracticable, information about the scope and purpose of the surveillance should be available to participants and to the public…

20th Anniversary Update of the Ottawa Decision Support Framework Part 1: A Systematic Review of the Decisional Needs of People Making Health or Social Decisions

Review Article

Lauren Hoefel, Annette M. O'Connor, Krystina B. Lewis, Laura Boland, Lindsey Sikora, Jiale Hu, Dawn Stacey

Medical Decision Making, 13 July 2020

Abstract

Background. The Ottawa Decision Support Framework (ODSF) has been used for 20 years to assess and address people's decisional needs. The evidence regarding ODSF decisional needs has not been synthesized. Objectives. To synthesize evidence from ODSF-based decisional needs studies, identify new decisional needs, and validate current ODSF decisional needs. Methods. A mixed-studies systematic review. Nine electronic databases were searched. Inclusion criteria: studies of people's decisional needs when making health or social decisions for themselves, a child, or a mentally incapable person, as reported by themselves, families, or practitioners. Two independent authors screened eligibility, extracted data, and quality appraised studies using the Mixed Methods Appraisal Tool. Data were analyzed using narrative synthesis. Results. Of 4532 citations, 45 studies from 7 countries were eligible. People's needs for 101 unique decisions (85 health, 16 social) were reported by 2857 patient decision makers (n = 36 studies), 92 parent decision makers (n = 6), 81 family members (n = 5), and 523 practitioners (n = 21). Current ODSF decisional needs were reported in 2 to 40 studies. For 6 decisional needs, there were 11 new (manifestations): 1) information (overload, inadequacy regarding others' experiences with options), 2) difficult decisional roles (practitioner, family involvement, or deliberations), 3) unrealistic expectations (difficulty believing outcome probabilities apply to them), 4) personal needs (religion/spirituality), 5) difficult decision timing (unpredictable), and 6) unreceptive decisional stage (difficulty accepting condition/need for treatment, powerful emotions limiting information processing, lacking motivation to consider delayed/unpredictable decisions). Limitations. Possible publication bias (only peer-reviewed journals included). Possible missed needs (non-ODSF studies, patient decision aid development studies, 3 ODSF needs added in 2006). Conclusion. We validated current decisional needs, identified 11 new manifestations of 6 decisional needs, and recommended ODSF revisions.

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