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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

January 2022

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 also monitor other research analysis and guidance beyond the journal literature globally. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

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

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

No new content identified for the following established categories:

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

HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION

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

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COVID-19

Consent or Public Reason? Legitimacy of Norms Applied in ASPD and COVID-19 Situations

Original Article
Elvio Baccarini
Philosophy and Society, 30 November 2021; 32(4) pp 674–694
Open Access
Abstract

This paper extends Alan John Simmons's conceptual distinction between Lockean (or consent) and Kantian (or justificatory) conceptions of legitimacy that he applied to the question of the legitimacy of states, to the issue of legitimacy of public decisions. I criticise the consent conception of legitimacy defended by Simmons, and I defend the Rawlsian version of the justificatory conception of legitimacy from his objection. The approach of this paper is distinctive because the two conceptions are assessed by investigating, using the method of reflective equilibrium, their respective prescriptions concerning the treatment of antisocial personality disorder (ASPD) and epidemiologic measures. I argue that the method of reflective equilibrium does not support the consent conception. Considering the issues of treatment of ASPD and of epidemiologic measures, I argue that the consent conception of legitimacy is not well-equipped for the evaluation of norms that are not strictly self-regarding. This causes a deficit of prescriptions for relevant social responses. Further, by considering the case of responses to epidemics, I argue that such a conception can avoid harmful consequences only by recurring to additional, and independent, premises. This does not cause incoherence but reduces the coherence of a normative system. Finally, the consent conception is not equipped to support social cooperation in an optimal way, which has proved to be necessary in critical conditions, like a pandemic. On the other hand, I argue that the method of reflective equilibrium supports the Rawlsian version of justificatory conception of legitimacy, because of its advantages in handling the indicated issues. In addition, I maintain that this justificatory conception is respectful of freedom and equality of agents as moral self-legislators, and, thus, it is not vulnerable to Simmons's main criticism.

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BIOMEDICAL RESEARCH

Implementing two-stage consent pathway in neonatal trials

Short Report
Eleanor Mitchell, Sam J Oddie, Jon Dorling, Chris Gale, Mark John Johnson, William McGuire, Shalini Ojha
Archives of Disease in Childhood - Fetal and Neonatal Edition, 23 December 2021
Abstract

Perinatal trials sometimes require rapid recruitment processes to facilitate inclusion of participants when interventions are time-critical. A two-stage consent pathway has been used in some trials and is supported by national guidance. This pathway includes seeking oral assent for participation during the time-critical

period followed by informed written consent later. This approach is being used in the fluids exclusively enteral from day one (FEED1) trial where participants need to be randomised within 3 hours of birth. There is some apprehension about approaching parents for participation via the oral assent pathway. The main reasons for this are consistent with previous research: lack of a written record, lack of standardised information and unfamiliarity with the process. Here, we describe how the pathway has been implemented in the FEED1 trial and the steps the trial team have taken to support sites. We provide recommendations for future trials to consider if they are considering implementing a similar pathway…

Informed consent and assent guide for paediatric clinical trials in Europe

Original Research

Pirkko Lepola, Maxine Kindred, Viviana Giannuzzi, Heidi Glosli, Martine Dehlinger-Kremer, Harris Dalrymple, David Neubauer, Geraldine B Boylan, Jean Conway, Jo Dewhurst, Diane Hoffman

Archives of Disease in Childhood, 1 December 2021

Abstract

Objective

Clinical trial sponsors spend considerable resources preparing informed consent (IC) and assent documentation for multinational paediatric clinical trial applications in Europe due to the limited and dispersed patient populations, the variation of national legal and ethical requirements, and the lack of detailed guidance. The aim of this study was to design new easy-to-use guide publicly available on European Medicines Agency's, Enpr-EMA website for all stakeholders.

Methods

Current EU legal, ethical and regulatory guidance for paediatric clinical trials were collated, analysed and divided into 30 subject elements in two tables. The European Network of Young Person's Advisory Group reviewed the data and provided specific comments. A three-level recommendation using 'traffic light' symbols was designed for four age groups of children, according to relevance and the requirements.

Results

A single guide document includes two tables: (1) general information and (2) trial-specific information. In the age group of 6–9 years old, 92% of the trial-specific subject elements can be or should be included in the IC discussion. Even in the youngest possible age group (2–5 years old children), the number of elements considered was, on average, 52%.

Conclusion

The EU Clinical Trial Regulation (2014) does not contain specific requirements exclusively for paediatric clinical trials. This work is the first to extensively collate all the current legal, regulatory and ethical documentation on the IC process, together with input from adolescents. This guide may increase the ethical standards in paediatric clinical trials.

Consent models in Canadian critical care randomized controlled trials: a scoping review

Review Article

Katie O'Hearn, Jess Gibson, Karla Krewulak, Rebecca Porteous, Victoria Saigle, Margaret Sampson, Anne Tsampalieros, Nick Barrowman, Saoirse Cameron, the Canadian Critical Care Trials Group

Canadian Journal of Anesthesia, 8 November 2021

Open Access

Abstract

Purpose

Our primary objective was to describe consent models used in Canadian-led adult and pediatric intensive care unit (ICU/PICU) randomized controlled trials (RCTs). Our secondary objectives were to determine the consent rate of ICU/PICU RCTs that did and did not use an alternate consent model to describe consent procedures.

Source

Using scoping review methodology, we searched MEDLINE, Embase, and CENTRAL databases (from 1998 to June 2019) for trials published in English or French. We included Canadian-led RCTs that reported on the effects of an intervention on ICU/PICU patients or their families. Two independent reviewers assessed eligibility, abstracted data, and achieved consensus.

Principal findings

We identified 48 RCTs of 17,558 patients. Included RCTs had ethics approval to use prior informed consent (43/48; 90%), deferred consent (13/48; 27%), waived consent (5/48; 10%), and verbal consent (1/48; 2%) models. Fifteen RCTs (15/48; 31%) had ethics approval to use more than one consent model. Twice as many trials used alternate consent between 2010 and 2019 (13/19) than between 2000 and 2009 (6/19). The consent rate for RCTs using only prior informed consent ranged from 54 to 91% (ICU) and 43 to 94% (PICU) and from 78 to 100% (ICU) and 74 to 87% (PICU) in trials using an alternate/hybrid consent model.

Conclusion

Alternate consent models were used in the minority of Canadian-led ICU/PICU RCTs but have been used more frequently over the last decade. This suggests that Canadian ethics boards and research communities are becoming more accepting of alternate consent models in ICU/PICU trials.

Race, Place, and The Federal Exception from Informed Consent (EFIC): A Semiotic Approach

[DISSERTATION]

Samantha Whitney Stein

UCLA, 2021

Abstract

The Exception from Informed Consent (EFIC) regulatory mechanism can be used to waive federal informed consent requirements for emergency medical research, pending satisfaction of pre-trial requirements. EFIC's most notoriously challenging pre-trial requirement is 'community consultation,' a process through which EFIC researchers solicit public feedback on their trials. Using a Peircean semiotic framework, this thesis unpacks the presuppositions undergirding the idea that community consultation can reduce friction between emergency clinical trials carried out without informed consent and the values of patients enrolled in them. I introduce a semiotics of prediction, showing how assumptions about race figure prominently in the commensuration-based tasks of selecting community consultation respondents and subsequently generalizing findings from these respondents to broader populations. I suggest that in practice the content and / or generalizability of feedback collected through community consultation has very limited utility for reducing friction. Rather, community consultation's primary function—as it is currently operationalized—is one of public relations, whereby the discursive processes through which community feedback is solicited have more bearing on EFIC trials' public acceptability than the content of community feedback and the ability of biomedical research actors to transpose this content across contexts. By examining who participates in / is affected by the discursive processes through which community feedback is solicited, I help explain otherwise untheorized yet nonetheless troubling disparities between the acceptability of EFIC as determined by community consultation respondents and the acceptability of EFIC as determined by EFIC trial participants and their surrogates.

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SOCIAL SCIENCE RESEARCH

Informed Consent as a Component of Online Research Ethics -- The Perspective of the Participants

Online Research

Nataša B. Matović, Kristinka Č. Ovesni

Globethics.net, 1 November 2021

Abstract
The paper discusses informed consent as a component of online research ethics. It begins from the analysis of understanding, from the preconditions on which the realization depends, and from the difficulties that accompany the application of the informed consent in practice. The aim of the empirical part of the research is to determine the characteristics of the process of obtaining the informed consent in online research and to examine the factors on which they depend. The sample included 153 teachers. Data were collected with the survey-type questionnaires and with the descriptive assessment scales. For data processing, besides the frequencies and percentages, the χ2 test and Kramer 's V correlation coefficient were performed. The results indicate that most of the respondents have had experience of giving informed consent in online surveys in which they have participated so far; that the text often contained information about the purpose and the goal of the research, apart from the tasks of the respondents in the research; that the majority of the teachers evaluate the content of the text as understandable and useful; and also that most of the characteristics depend on the environment of the school in which the teachers are employed. The results are discussed in the context of the possibility of improvement of the process of obtaining informed consent from the respondents in the online survey.

> *Editor's note: Globethics.net is a global network of teachers and institutions with the vision to embed ethics in higher education. It hosts a publishing house open to all the authors interested in applied ethics.*

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GENOMIC MEDICINE/GENE EDITING

Defining the Critical Components of Informed Consent for Genetic Testing

Kelly E. Ormond, Maia J. Borensztein, Miranda L. G. Hallquist, Adam H. Buchanan, William Andrew Faucett, Holly L. Peay, Maureen E. Smith, Eric P. Tricou, Wendy R. Uhlmann, Karen E. Wain, Curtis R. Coughlin, Clinical Genome CADRe Workgroup

Journal of Personalised Medicine, 5 December 2021

Open Access

Abstract

Purpose

Informed consent for genetic testing has historically been acquired during pretest genetic counseling, without specific guidance defining which core concepts are required.

Methods

The Clinical Genome Resource (ClinGen) Consent and Disclosure Recommendations Workgroup (CADRe) used an expert consensus process to identify the core concepts essential to consent for clinical genetic testing. A literature review identified 77 concepts that are included in informed consent for genetic tests. Twenty-five experts (9 medical geneticists, 8 genetic counselors, and 9 bioethicists) completed two rounds of surveys ranking concepts' importance to informed consent.

Results

The most highly ranked concepts included: (1) genetic testing is voluntary; (2) why is the test recommended and what does it test for?; (3) what results will be returned and to whom?; (4) are there other types of potential results, and what choices exist?; (5) how will the prognosis and management be impacted by results?; (6) what is the potential family impact?; (7) what are the test limitations and next steps?; and (8) potential risk of genetic discrimination and legal protections. *Conclusion*

Defining the core concepts necessary for informed consent for genetic testing provides a foundation for quality patient care across a variety of healthcare providers and clinical indications.

Responding from the Place of Suffering: Informed Consent and Non-invasive Prenatal Genetic Screening [BOOK CHAPTER]

Michael McCarthy

Suffering in Theology and Medical Ethics, 3 December 2021; pp 179–187 [Brill]

Introduction

…Informed consent after a positive screen for Trisomy 21, Down syndrome, should move from an individualist model of autonomy to a principled autonomy that allows the patient to explore the decision from her reality. This shift would need to incorporate the medical facts, understanding the risks and benefits, and learning from those faced previously with similar decisions. This chapter begins, first, by describing non-invasive prenatal genetic screening. Secondly, it explores what constitutes informed consent through an individual/utilitarian model of autonomy and juxtaposes that with principled autonomy grounded in Ada María Isasi-Díaz's mujerista hermeneutic, *lo cotidiano*. The chapter concludes by drawing on both insights from minority participants in clinical research and parents of a child with Trisomy 21 in order to enhance the process for informed consent. Better understanding the reality of the patient and explaining the potential options in a way that prioritizes the patient's reality allows her to make a responsible and informed decision…

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BIOBANKING

Biobank Participants' Attitudes toward Requiring Understanding for Biobank Consent

T.J. Kasperbauer, Colin Halverson, Abigail Garcia, Karen K. Schmidt, Peter H. Schwartz

Ethics & Human Research, 22 December 2021

Abstract

Biobank participants often do not understand the information they are provided during the informed consent process. Ethicists and other stakeholders have disagreed, however, on the appropriate response to these failures in understanding. This paper describes an attempt to address this issue by conducting knowledge tests with 22 recent biobank enrollees, followed by in-depth, semistructured interviews about the goal of understanding in biobank consent. The interviews revealed that while biobank enrollees thought the information on the knowledge test was important, they did not think that performance on the test should affect whether individuals are permitted to enroll in a biobank. Three main themes emerged from the interviews: helping others by contributing to research is more important than understanding consent forms, less understanding is required because biobank-based research is low risk, and only a small amount of information in the consent form is really essential. These perspectives should be considered in discussing the ethics and governance of biobank consent processes.

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HEALTH DATA

Dynamic Consent for Sensor-Driven Research

Hyunsoo Lee

Graduate School of Knowledge Service Engineering [Daejeon, South Korea], 2021

Open Access

Abstract

Dynamic consent is a term initially emerged in biomedical research that involves a large-scale, long-term participant engagement for continuous data collection (e.g., biosamples, health records). Dynamic consent is a wider concept of informed consent that enables granular consent in dealing with personal data. Dynamic consent is typically incorporated into a personalized digital platform that allows participants to tailor and manage their own consent preferences. This feature leads to improved transparency and proactive privacy management. Due to such benefits, dynamic consent offers potential applications in other domains that collect diverse data that require multiple consents over time. One possible testbed is digital health, where there have been several attempts to track symptoms and diagnose mental illnesses (e.g., depression) with data collected from mobile and wearable devices (i.e., digital phenotyping). As these sensors continuously collect personal data, users may feel uncomfortable in certain private contexts. However, the current status of the studies only provides one-off informed consent without consideration of specific user contexts, which calls for context-aware fine-grained control. Thus, this paper explores the feasibility of dynamic consent in sensor-driven research and suggests a future outlook of dynamic consent usage in mobile and ubiquitous computing.

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TECHNOLOGY/OTHER MEDIATION

Using Hyperrealistic Simulations to Improve Digital Informed Consent for Endourological Procedures

Original Article

Víctor Galve Lahoz, David Corbatón Gomollón, Federico Rodríguez-Rubio Cortadellas, Pedro Gil Martínez, Maria Jesús Gil Sanz, Jorge Rioja Zuazu

BJUI International, 25 December 2021

Abstract

Objectives

To show that digital informed consent (DIC) improves the subjective understanding of information and, therefore, informed consent.

Patients and Methods

A nonblinded randomized controlled trial was performed with 84 patients who had undergone a transurethral resection of bladder, transurethral resection of prostate, or ureterorenoscopy between July 2017 to March 2018. The DIC group watched a hyperrealistic simulation on a tablet device before surgery. After surgery and again 30 days later, both groups completed a validated questionnaire that measured subjective understanding, anxiety, and utility of and need for information.

Results

The mean±SD age of participants was 68.7±11.1 years. Nine of 84 patients (10.7%) did not complete the questionnaire. 42 patients were allocated to the DIC group and 42 to the control group. The mean±SD score on immediate subjective understanding in the DIC group was 14.5% higher than in control group (72%±17.5% vs 57.5%±23.5%, respectively; p=0.006). There was no statistical difference among anxiety, utility of and need for information relative to delayed subjective understanding. In subgroup analysis, subjective understanding scores were higher, but not significantly so, among patients with low and higher education levels in the DIC group than in the control group (68%±18.1% vs 54%±22.5%, respectively, p=0.06; and 76%±18.3% vs and 66%±21.9%, respectively, (p=0.89).

Conclusion

Hyperrealistic simulations improved subjective understanding of information and, therefore, informed consent for endourological procedures.

Cognitive Testing of an Electronic Consent Platform: Researcher Perspectives

Daniel Robins, Rachel Brody, Irena Parvanova, Joseph Finkelstein

Studies in Health Technology and Informatics, 15 December 2021; 284 pp 457-462

Abstract

This study focuses on feedback from domain experts to assess usability and acceptance of the E-Consent electronic consent platform. Quantitative and qualitative data were captured throughout the usability inspection, which was structured around a cognitive walkthrough with heuristics evaluation. Additional surveys measured biobanking knowledge and attitudes and familiarity with informed consent. A semi-structured qualitative interview captured open-ended feedback. 23 researchers of various ages and job titles were included for analysis. The System Usability Scale (SUS) provided a standardized reference for usability and satisfaction, and the mean result of 86.7 corresponds with an 'above average' usability rating in the >90th percentile. Overall, participants believe that electronic consenting using this platform will be faster than previous workflows while enhancing patient understanding, and human rapport is still a key component of the consent process. Expert review has provided valuable insight and actionable information that will be used to further enhance this maturing platform.

To draw or not to draw: Informed consent dilemma

Research Article

Santovito D, Cena G, Tattoli L, Di Vella G, Bosco C

Health and Primary Care, 14 May 2021

Open Access

Abstract

Background

Informed consent is a worldwide standard medical practice. The purpose of this study was to determine whether surgical freehand-drawings do facilitate surgeons in the communication process.

Methods

Authors carried out a questionnaire survey aimed at exploring physicians' perceptions of the usefulness of drawings, in terms of level of understanding in consent acquisition procedures. A total of 90 anonymous questionnaires were distributed for doctors to fill in, in surgical and interventional medicine wards of the University Hospital of Turin.

Results

Out of the 90 questionnaires delivered, 37.8% (n=34) were filled out. 93.8% (n=30) of the physicians interviewed consider freehand-drawings a useful tool, 90% (n=27) of the surgeons, who confirmed to routinely use drawing for informed consent acquisition purposes. 96.3% (n=26) of the physicians who draw themselves illustrative images of proposed treatments asserted to perceive a real benefit in patients' comprehension of the information when visually provided. Many respondent surgeons stated to consider drawing an effective means of information for consent acquisition. Nonetheless, just in 7.4% of the cases, personally drawn explicative images are then added in patients' medical records, with possible detrimental effects on a medico legal point of view.

Conclusions

Graphical representation is useful for breaking down comprehension barriers resulting not only from the modality in which the information is conveyed but also from patients' relational, social, and psychological factors, ensuring bi-directionalness of communication and prove in Italy, a Civil Law Country, the communicative effort of physicians in the best interest of the patients.

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CAPACITY TO CONSENT

Capacity to consent to treatment in psychiatry inpatients – a systematic review

Review Article

Aoife Curley, Carol Watson, Brendan D. Kelly

International Journal of Psychiatry in Clinical Practice, 23 December 2021

Abstract

Background

Mental capacity for treatment decisions in psychiatry inpatients is an important ethical and legal concern, especially in light of changes in mental capacity legislation in many jurisdictions.

Aims

To conduct a systematic review of literature examining the prevalence of mental capacity for treatment decisions among voluntary and involuntary psychiatry inpatients, and to assess any correlations between research tools used to measure mental capacity and binary judgements using criteria such as those in capacity legislation.

Method

We searched PsycINFO, Ovid MEDLINE and EMBASE for studies assessing mental capacity for treatment decisions in people admitted voluntarily and involuntarily to psychiatric hospitals.

Results

Forty-five papers emanating from 33 studies were identified. There was huge variability in study methods and often selective populations, but the prevalence of decision-making capacity varied between 5% and 83.7%. These figures resulted from studies using cut-off scores or categorical criteria only. The prevalence of decision-making capacity among involuntary patients ranged from 7.7% to 42%, and among voluntary patients ranged from 29% to 97.9%. Two papers showed positive correlations between clinicians' judgement of decision-making capacity and scores on the MacArthur Competence Assessment Tool for Treatment; two papers showed no such correlation.

Conclusions

Not all voluntary psychiatry inpatients possess mental capacity and many involuntary patients do. This paradox needs to be clarified and resolved in mental health legislation; supported decision-making can help with this task.

Doing research with intellectually disabled participants: reflections on the challenges of capacity and consent in socio-legal research

Rosie Harding

Journal of Law and Society, 16 December 2021

Abstract

In this article, I reflect on the praxis of doing qualitative interview research involving intellectually disabled people as participants. I explore the ways in which ethical and legal norms work together to shape what is possible in research with intellectually disabled participants. I use stories from the field to explore issues of recruitment and sampling, working with 'gatekeeper' organizations, accessible information and informed consent, and data sharing and open access. As these reflections demonstrate, undertaking fieldwork involving intellectually disabled participants presents multiple challenges for socio-legal researchers. They also show that many of the challenges are surmountable, offering concerns, considerations, and solutions that can, and perhaps should, be considered by all socio-legal researchers who wish to ensure that all of the voices of society are included and reflected in their research.

Doctors' knowledge regarding decision-making capacity: A survey of anesthesiologists

Research Article

Alastair Moodley, Ames Dhai

Clinical Ethics, 6 December 2021

Abstract

Informed consent for anesthesia is an ethical and legal requirement. A patient must have adequate decision-making capacity (DMC) as a prerequisite to informed consent. In determining whether a patient has sufficient DMC, anesthesiologists must draw on their knowledge of DMC. Knowledge gaps regarding DMC may result in incorrect assessments of patients' capacity. This could translate to an informed consent process that is ethically and legally unsound. This study examined the DMC-related knowledge of anesthesiologists in a group of four university-affiliated hospitals. The findings suggest that anesthesiologists have several areas of knowledge deficiency regarding DMC and DMC assessment. These findings could inform the development of undergraduate and postgraduate curricula.

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YOUNG PERSONS

The introduction of electronic consent for the school aged immunization program

Rebecca Footer, Owen Foster

Public Health Nursing, 8 December 2021

Abstract

Historically, consent for treatment in the United Kingdom's National Health Service has been collected using traditional paper forms. For public health services, such as immunizations, this process involved significant time, space, paper, and staff resources. In a bid to provide a more modern, secure, cost-effective and paperless service, an electronic consent (eConsent) form for the routine school aged immunization program was designed and successfully piloted for the HPV 1 vaccine in 25 schools during the summer of 2019, with an average of 80% return rate. This was not only significantly higher than paper consent returns, there was also a significantly quicker return rate. These factors resulted in the clinical record being updated more quickly than ever before which reduced clinical risk. Following the pilot, the program was launched countywide for all school aged immunizations in September 2020. Since its launch some minor issues have been identified but resolved quickly and efficiently. Although still in its early days it is felt that the eConsent system has promoted a more informed and easier collaboration across sectors and has reduced operating costs. Although the use of electronic consent needs to be used more widely, it is felt that this new practice is a success.

The ethical-legal requirements for adolescent self-consent to research in sub-Saharan Africa: A scoping review

Busisiwe Nkosi, Brian Zanoni, Janet Seeley, Ann Strode

Bioethics, 14 October 2021

Open Access

Abstract

Support for the enrolment of adolescents in research has been constrained by uncertainties in parental involvement, and the lack of clarity in the ethical and legal frameworks. We conducted a scoping review to examine articles that explored the opinion of scholars on the question of adolescent consent and conditions for parental waivers in research in sub-Saharan Africa (SSA). Guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) tool, we searched electronic databases (PubMed, EMBASSE, EBSCOHOST) and also reviewed the references of articles identified for additional relevant literature. We included full text English articles focusing on adolescent consent and parental waivers in SSA that were published between 2004 and 2020. We excluded studies focusing on healthcare, theses, and reviews. We reviewed a total of 21 publications from South Africa (n = 12), Kenya (n = 4) and Botswana, Malawi, Nigeria, Uganda and Zimbabwe (n = 1 each). We identified four broad thematic issues: the current

position regarding parental waivers and self-consent; parental involvement in the consent process; the role of community approval or consent when adolescent self-consent approaches were used; and complexities and ambiguities in legal requirements and ethical guidelines on adolescent consent. Our findings show inconsistencies and ambiguities in the existing legal and ethical frameworks within and across different countries, and underscore the need for consistent and clearer guidance on parental waivers and adolescent self-consent. Harmonization of the legal and ethical frameworks taking into account varying contexts is critically important to ensure research on adolescents in SSA meets adolescents' specific unmet needs.

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RIGHTS/LEGAL/LEGISLATIVE

Bell v Tavistock: Rethinking informed decision-making as the practical device of consent for medical treatment

Research Article

Abeezar I. Sarela

Clinical Ethics, 27 December 2021

Abstract

The decision of the High Court in Bell v Tavistock has excited considerable discussion about lawful consent for puberty-blocking drug treatment for children with gender dysphoria. The present paper draws attention to a wider question that surfaces through this case: is informed decision-making an adequate practical tool for seeking and obtaining patients’ consent for medical treatment? Informed decision-making engages the premises of the rational choice theory: that people will have well-crystallised health goals; and, if they are provided with sufficient information about medical treatments, then they will be able to choose the treatment that satisfies their goals. Whilst appealing, the informed decision-making paradigm is assailed by various fallacies, which apply not only to children but also to adults. In Bell v Tavistock, the High Court seems to have recognised such fallacies, and it rejected informed decision-making as an adequate tool for consent from children with gender dysphoria. Similar considerations apply to adults in various situations. Thus, Bell v Tavistock can be seen as an attempt to refine the views on the consent that were expressed by the Supreme Court in Montgomery. It can be inferred that the Supreme Court did recognise the limitations of informed decision-making, but it did not develop this point. Further work is required to formulate an adequate model of decision-making, and Bell v Tavistock serves as a useful reminder to rethink informed decision-making as the device for consent.

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CULTURAL/COUNTRY CONTEXT

Informed Consent for Surgical Care in East Africa

Richard Wismayer

Journal of Advances in Medicine and Medical Research, 13 December 2021

Open Access

Abstract

In the developed world one of the pillars of ethical conduct in surgical practise is informed surgical consent. In low income developing countries only a few researchers have explored the practise of surgical consent pre-operatively. During the informed consent process, the patient has a right to make an autonomous and independent decision about his/her surgical treatment after having been provided the necessary information by the surgeon caring for the patient. Patient autonomy and independent decision-making is recommended by the World Medical Association (WMA) Declaration of Lisbon. Family and cultural background, education,

religion and socioeconomic status may all influence informed consent in surgical practise. In East Africa, few studies have reviewed consent practises among surgeons to document best surgical practise and identify areas that need improvement in the East African setting. This review reports the author's personal experience of the practise of surgical consent among surgeons in Uganda and reviews the specific challenges faced in East Africa. In Uganda, the administration and documentation of informed consent is still inadequate. Better medical ethics education and proper communication skills training in medical schools needs to be addressed. Refresher courses on medical ethics and communication skills may also be necessary for fully trained surgeons.

Patient's knowledge, attitudes and practices on informed consent in a clinical setting; A study done at Colombo North Teaching Hospital in Sri Lanka

Research Article

W. N. S. Perera, B. P. P. Perera, P. Paranitharan

Sri Lanka Journal of Forensic Medicine, Science & Law, 3 December 2021; 12(2) pp 11-18

Abstract

Introduction

The signing of a consent form is a process with legal and ethical implications. It is required that informed written consent be obtained from a patient for an invasive procedure after proper explanation of the risks, benefits and alternative procedures.

Objective

To determine knowledge, attitudes and practices related to informed consent among patients.

Materials and Methods

A cross sectional descriptive study was carried out over a period of one year in a Tertiary care hospital in Sri Lanka. The participants were medical or surgical inward patients who were 18 years or above, who had consented to invasive procedure or surgery. The quantitative data of 420 patients were analyzed.

Results

Majority (96%) agreed that consent is important in medical practice. Many (61%) were of the view that it helps to make an informed decision. Majority (92%) preferred a doctor, who can explain more in the consent process than a nursing officer (11%). However, 61% were of the view that consent should be taken from the patient and relatives both, even if the patient is competent of giving consent. Majority of the participants (84%) wanted to discuss with family members before giving consent.

Conclusion

Majority of patients were aware of the concept of consent in medical practice and preferred the doctor and family members to be involved in the decision-making process. This finding is important to adopt a doctor-patient-family model in the consent taking process while respecting the patient's wishes.

Virtual consent and the use of electronic informed consent form in clinical research in Brazil

Original Article

Juliana Carvalho Rocha Alves da Silva, Helaine Carneiro Capucho

Revista da Associação Médica Brasileira, November 2021; 67(11)

Summary

Objective

In view of the need to apply term free and informed consent (IC) in clinical research involving humans, in accordance with the Brazilian ethical standards (CNS Resolution No. 466/2012), it is necessary to assess whether this practice is being effective and can be improved. The aim of this study was to evaluate the use of the IC in electronic format (e-IC), regarding its feasibility and suitability, as a complement to the written/physical consent form.

Methods

Quantitative-qualitative research with a questionnaire instrument.

Results

Greater retention of information and fewer wrong answers were observed after the application of the e-IC.

Conclusions

The use of e-IC is of great value to research participants in Brazil.

Knowledge on Informed Consent for Blood Transfusion Among Patients in Hospital Melaka and Its Associated Factors

Original Article

Mohd Hilmi Senin, Bakiah Shaharuddin, Nor Amiza Mat Amin, Mastura Sopian

Malaysian Journal of Medicine and Health Sciences, November 2021; pp 22-31

Open Access

Abstract

Introduction

To perform blood transfusion, a physician should obtain informed consent from the patient. However, previous studies have shown a poor transfer of knowledge from the doctor to the patient regarding blood transfusion, with conflicting information as recollected by patients from informed consent discussions. This study aims to describe knowledge of informed consent for blood transfusion from the patients' perspective.

Methods

A cross-sectional study was performed from October 2019 to May 2020 at Hospital Melaka. The instrument used in this study was a structured, validated questionnaire written in the Malaysian language. Respondents aged 18 and above, who had given their consent for blood transfusion within three days, were recruited using purposive sampling. Logistic regression was used to investigate potential predictors for good knowledge.

Results

Data analysis was performed on 239 sets of returned questionnaires, which showed that 85.8% of the respondents had good knowledge scores. Additionally, 94.1% of them were aware that informed consent is mandatory before the blood transfusion procedure. The lowest percentage of correct responses (43.9%) was regarding the timing of the informed consent. Respondents with a history of undergoing transfusion more than once (AOR = 2.18; 95% CI = 1.02, 4.65; p = 0.04), and practicing Buddhism as a religion (AOR = 0.36; 95% CI = 0.15–0.86; p = 0.02) showed significant associations with knowledge.

Conclusion

The respondents in this study were relatively knowledgeable about informed consent for blood transfusion. However, further analysis revealed the deficiency of knowledge among the respondents in several aspects of this topic. The findings can help Malaysian health authority plan for interventions that would improve knowledge of informed consent on blood transfusion among patients and the public.

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MEDICAL/SURGICAL

Patient and Clinician Perceptions of Informed Consent and Decision Making About Accepting KDPI > 85 Kidneys

Karolina Schantz, Elisa J. Gordon, Unsun Lee, Maria Rocha, John Friedewald, Daniela P. Ladner, Yolanda Becker, Richard Formica, Peter P. Reese, Dixon Kaufman, Masoud Barah, Marissa Walker, Om Mehrotra, Dania Viveros, Sanjay Mehrotra

Transplantation Direct, January 2022; 8(1) pp e1254

Abstract

Background

Although the impact of the kidney donor profile index (KDPI) on kidney discard is well researched, less is known about how patients make decisions about whether to give consent for KDPI > 85 kidney offers.
Methods
We conducted in-depth, semistructured interviews with 16 transplant recipients, 15 transplant candidates, and 23 clinicians (transplant surgeons, nephrologists, and nurse coordinators) to assess and compare perceptions of transplant education, informed consent for KDPI > 85 kidneys, and the decision-making process for accepting kidney offers. Thematic analysis was used to analyze qualitative data.
Results
Four themes emerged: (1) patients reported uncertainty about the meaning of KDPI or could not recall information about KDPI; (2) patients reported uncertainty about their KDPI > 85 consent status and a limited role in KDPI > 85 consent decision making; (3) patients' reported willingness to consider KDPI > 85 kidneys depended on their age, health status, and experiences with dialysis, and thus it changed over time; (4) patients' underestimated the survival benefit of transplantation compared with dialysis, which could affect their KDPI > 85 consent decision making.
Conclusions
To better support patients' informed decision making about accepting KDPI > 85 kidneys, centers must ensure that all patients receive education about the trade-offs between accepting a KDPI > 85 kidney and remaining on dialysis. Additionally, education about KDPI and discussions about informed consent for KDPI > 85 kidneys must be repeated at multiple time points while patients are on the waiting list.

Should medical students perform pelvic exams on anaesthetised patients without explicit consent?

Research Article
Chloe Bell, Nathan Emmerich
Clinical Ethics, 28 December 2021
Abstract
There have been many reports of medical students performing pelvic exams on anaesthetised patients without the necessary consent being provided or even sought. These cases have led to an ongoing discussion regarding the need to ensure informed consent has been secured and furthermore, how it might be best obtained. We consider the importance of informed consent, the potential harm to both the patient and medical student risked by the suboptimal consent process, as well as alternatives to teaching pelvic examinations within medical school. The subsequent discussion focuses on whether medical students should perform pelvic examinations on anaesthetised patients without personally ensuring that they have given their explicit consent. Whilst we question the need to conduct pelvic examinations on anaesthetised patients in any circumstance, we argue that medical students should not perform such exams without personally securing the patients informed consent.

Perceptions and practices regarding the process of obtaining informed consent from surgical patients at a tertiary care hospital

Cross-sectional Study
Muhammad Asharib Arshad, Naureen Omar, Muhammad Zaid Amjad, Khalid Bashir, Muhammad Irfan, Irfan Ullah
Annals of Medicine and Surgery, 22 December 2021
Abstract
Background
Proper informed consent is essential for patients to have sound knowledge about the indication, risks, and benefits of a proposed surgical procedure. The study aim was to assess the perceptions of postoperative patients about the informed consent process and identify various influential factors in a tertiary care hospital.

Methods
A cross-sectional study was conducted from February to August 2018 at a tertiary care hospital in Lahore, Pakistan. A validated questionnaire was used to conduct interviews of 101 patients planning to undergo elective surgery after fulfilling all ethical considerations. A purposive sampling technique was employed to enroll and the data analysis was performed by using SPSS version 23.

Results
Out of total 101 patients, 50 (49.5%) of them were males and the mean age of total sample was 36.98 ± 14.23 years. The majority 92 (91.1%) considered informed consent to be important and that it did not influence their surgical decision 85 (84.2%). Consent was obtained by the consulting surgeon from 41 (40.6%) patients and by the residents/house officer from 60 (59.4%) patients. Fifteen (14.8%) patients signed the consent form themselves, and 86 (85.1%) relatives of patients signed. Ninety-eight (97.0) patients were told about indications of the surgery, and 54 (53.5%) were told about possible complications. Seventy-five (74.3%) patients were informed about alternatives to surgery. Significant reasons for not signing were language (p = 0.03), educational status (p = 0.002), and not being informed by relatives before signing (p = 0.02).

Conclusion
The patients had adequate knowledge about the process of informed consent and considered it important. Factors identified as barriers to signing the consent form by the patients themselves included language, better educational status, and not being asked by relatives. It is imperative to involve the patients in the process of consent, especially in signing by them or in their presence by their surrogate.

Upgrading the Chemotherapy Consent: Trading in Paper for Tablet

Lesley Wu, Cardinale B. Smith, Jessica Parra, Mark Liu, Haley Hines Theroux, Aarti S. Bhardwaj

JCO Oncology Practice, 15 December 2021

Abstract

Purpose
Our institution participated in the Oncology Care Model, which required us to include many of the 13 elements of the National Academy of Medicine (NAM) care plan into care pathways for our patients. We optimized our existing chemotherapy consent process to meet this need and maximized completion.

Methods
Our multidisciplinary committee developed a three-phase Plan-Do-Study-Act process in our breast cancer clinic: (1) update and educate providers on our paper chemotherapy form with multiple components of the NAM care plan including prognosis and treatment effects on quality of life; (2) piloted an electronic chemotherapy consent form to decrease the administrative burden; and (3) autopopulated fields within the electronic consent. We assessed feedback after cycle 1 and created a Pareto chart. The outcome measure was percent completion of chemotherapy consent documents.

Results
Baseline monthly random chart audit of 40 patients revealed 20% of paper chemotherapy consent forms were completed in their entirety among patients. When we re-educated clinicians about the new paper consent containing the NAM elements, compliance rose to nearly 30%. A Pareto chart confirmed that content redundancy and wordiness were leading to under-completion. After creating and piloting the electronic consent, compliance increased to 90%. Finally, autopopulation with drop-down selections increased and sustained completion to 100%.

Conclusion
Incorporating regulatory requirements into an existing workflow using Plan-Do-Study-Act methodology can reduce administrative burden on clinicians. Additional use of innovative technology can further increase clinician compliance with regulatory requirements while delivering high-value quality care to patients with cancer.

A survey on current practice of informed consent process in surgical specialties of a tertiary teaching hospital center: What is the state of play?

Research Article

Ana Luísa Vieira, Cândida Infante, Sérgio Santos, Mariana Asseiro, Celine Ferreira

Research Square, 1 December 2021

Abstract

Background

Informed consent is essential in current medical practice and should be a global standard to be sought at all instances when doctors interact with patients. The aim of this study was to evaluate compliance to the guidelines of the Portuguese health entity regarding the correct filling process of informed consent.

Methods

A prospective observational survey was conducted upon arrival of the patient at the operating room of a tertiary teaching hospital center in Portugal, in march 2021, to verify the presence of informed consent in the clinical process. A sample of 202 clinical files was randomly collected.

Results

Only 47% of the patients had the informed consent document in the clinic process and only 45% of the total clinical files had the informed consent signed by the patient. Merely 21.8% of the informed consents respected all the items recommended by the guidelines of the Portugal health entity. Most of the surgical informed consent (SIC) had only basic information and only a lower percentage had reports about the surgical procedure, information regarding the treatment, possible consequences of a missed treatment or complications and possible treatment alternatives. Those results didn’t conform to the standard regulations of the Portuguese health guidelines regarding SIC.

Conclusion

Even though improvements in SIC were attained in recent years, our study suggests that the implementation of SIC is still suboptimal in surgical practice. It is important to raise awareness for the obtention of SIC by the healthcare team, because complete information before an invasive procedure is an ethical requirement.

Exploring the Adequacy of Obtaining Informed Consent for Caesarean Deliveries - A Patient Perspective

P. Theletsane, T. Cronje, B.G Lindeque, S. Adam

Obstetrics and Gynaecology Forum, 30 November 2021; 31(2)

Abstract

Obstetrics

The objective of this study was to assess the adequacy of informed consent obtained from patients prior to caesarean delivery.

Design

Descriptive study

Setting

Tertiary level hospitals in a major South African center in Pretoria, South Africa Subjects: Two-hundred-and-fifty patients who underwent elective and emergency caesarean deliveries

Outcome Measures

The assessment of the adequacy of the informed consent was assessed via a questionnaire that the participants answered on day 2-3 post caesarean delivery.

Results

Average age of participants was 28.8 years (28.75 ± 5.92). Twenty three percent (23.2%) of the participants underwent elective and 76.8% underwent emergency caesarean deliveries. Seventy five percent (75.6%) of the participants knew the name of the procedure, although only 29.2% were aware of the associated risks, and 59.2% of participants knew of their right to refuse the procedure.

Conclusion

Adequate communication is essential to all aspects of medicine and this study has highlighted the inadequacy of the informed consent process that takes place at our institution. Information regarding risks and complications was not adequately communicated. A standardized informed consent document that healthcare professionals can use for counseling, starting antenatally, should be considered.

Is informed consent practice in a general surgery unit adequate? An audit report

Original Article

Sameeah Hanif, Muhammad Nawaz, Sumera Naseem

Pakistan Journal of Medical Sciences, 29 June 2021; 37(3) pp 192-195

Open Access

Abstract

Objective

To obtain an informed consent is essential part of surgical practice. It not only ensures patients rights but also decreases the chances of legal proceedings against surgeons in case of any issue from procedure. The objective of this study is to evaluate the prevailing practices of getting informed consent and documentation in case of general surgical patients.

Material and Methods

This cross sectional (audit) study was carried out in department of Surgery District Head Quarter (DHQ), Abbottabad from December 2020 till February 2021 in general surgical unit. 132- patients chosen randomly were included. Both cases of elective as well as emergency cases were included. Patient operated on General and spinal anesthesia were interviewed according to questionnaire relating to informed surgical practices. Data of interviewed patients were analysed using spss 17.

Results

132 patients were included in study. Mean age was 34.98±16.1 years. Study comprised of 70 female(53%) and 62(47%) male. 117(88.6%) consent were taken by house officers while 15(11.4%) consent were taken by operating surgeon. 84(63.6%) consent were signed by patients themselves while 48(36.4%) were signed by relatives. All 132(100%) consent were written consent.

Conclusion

The quality of obtaining consent is below optimal and needs improvement. Education amongst health care workers is required so that they realize the importance of patients right's so they make their own independent decision in the light of knowledge given. Also knowing that to have a complete and up to mark consent is beneficial for clinician in case of legal issues.

The Microethics of Informed Consent for Early Feminizing Surgery in Congenital Adrenal Hyperplasia

Katharine B. Dalke, Arlene B. Baratz

Journal of Pediatric Ethics, Spring 2021

Open Access

Abstract

Early surgery for genital difference in 46,XX congenital adrenal hyperplasia (CAH) is highly controversial, with contested evidence of benefits and risks. While professional urological societies and a parent-led CAH advocacy group maintain that families should have the option to consent for surgery for their child, former patients, intersex-led advocacy groups, and human rights and medical organizations denounce surgery on unconsenting infants for non-life-threatening genital variations. In the absence of clear data, clinicians are encouraged to engage in shared decision making with parents to obtain their fully informed consent. Unexplored microethics issues regarding clinicians' implicit bias for treatments may interfere with their ability to obtain parents' fully informed consent in this setting. Implicit bias may be inferred from parents' experiences and from official and unofficial communications from clinicians.

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GENERAL/OTHER

Interactive Media-Based Community Consultation for Exception From Informed Consent Trials

Jan O. Jansen, Shannon W. Stephens, Brandon Crowley, Kenji Inaba, Sara F. Goldkind, John B. Holcomb
The Journal of Trauma and Acute Care Surgery, 29 November 2021
Abstract
Community consultation (CC) is a requirement for exception from informed consent (EFIC) research. This article explores the issue of how representative such consultations can and should be, with particular reference to the use of media-based activities. Interactive, media-based CC strategies are gaining traction, because they have much greater reach than traditional methods, but the increasing use of such methods has also led to calls to ensure that those contacted are representative of the community at risk. However, this is more complex than at first apparent. This article examines the question of how the “trauma community” should be defined, and what characteristics might be used to assess whether a sample of this community is representative. It also considers what data are actually available in order to satisfy such requirements.

The Problem of Consent in Feminist Practical Ethics

Laura Avakyan, Galina Tsimmerman, Alexander Zimmermann, Vladimir Shcherbakov
Wisdom, 2021; 4(20)
Open Access
Abstract
The article analyzes the topical problem of consent in modern feminist theory as a way of achieving public consensus on the goals and forms of women’s emancipation. The emancipation of women is one of the most important achievements of modern society and an ongoing process. Therefore, the issues that are being discussed within the framework of feminist ethics are appropriate. For example, the extent to which men who hold power and dominance for thousands of years can genuinely liberate women and share with them equal rights and opportunities. There is also an acute problem of the extent to which women themselves are willing to show solidarity and their consent on social and political issues. These issues and discussions by contemporary feminists, who deserve the attention of a wide range of experts in applied ethics, argumentation theory, social and political theory, are addressed in this study.

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