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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

May 2023 :: Issue 53

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.

In preparing this digest, we monitor *Google Scholar* using the search terms "consent", "informed consent", and "assent" in title and available text. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic 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 to areas of interest. We expect that these categories will evolve over time. We also include a spotlight section which highlights articles appearing in each edition which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
TECHNOLOGY/OTHER MEDIATION

Please note that while we strive to identify the primary subject area for the categorization of the monthly digest we also recognize that many articles are relevant across other subject areas. We encourage readers to gloss over the entire digest or search the website where articles are cross tagged. We maintain a glossary, an inventory of tools for assessment, as well as standards and guidance documents on the website.

SPOTLIGHT ARTICLES

In **Exploring the Ethical and Moral Implications of Requiring Informed Consent to Determine Death by Neurologic Criteria** Hibbs et al. discuss the role of consent in the declaration of brain death. While assessing and declaring brain death have been widely discussed, consent has been largely absent from this conversation to date.

In the article **Explanation before Adoption: Supporting Informed Consent for Complex Machine Learning and IoT Health Platforms** Eardley et al. write about explaining complex health technology platforms to non-technical audiences. A sufficiently comprehensive understanding of these systems is integral to gaining informed consent, and is becoming increasingly important with continuous technological integration in routine healthcare.

Jeyabalan et al. discuss consent for the use of drones in healthcare in their article **To Obtain Informed Consent or Not to Obtain Informed Consent? Drones for Health Programs in the Grey Zone between Research and Public Health**. In this article, the authors consider consent at both an individual and community level when using drones to map remote communities for health hazards, risks and safety concerns.

And finally, in **Practical issues in pragmatic trials: the implementation of the Diuretic Comparison Project** Ferguson et al. highlight the work of the US Department of Veterans Affairs Point of Care Clinical Trial Program. This study had a large patient population and worked to customize procedures to align with local clinical practice.

Exploring the Ethical and Moral Implications of Requiring Informed Consent to Determine Death by Neurologic Criteria

Matthew J. Hibbs, Morgan C. Arnold, Mark S. Beveridge
Journal of Pain and Symptom Management, May 2023; 65(5)
Abstract
Background
The American Academy of Pediatrics published guidelines in 1987 providing criteria for the declaration of brain death for children. Multiple societies, including neurology and critical care, renewed these guidelines in 2011 to further standardize the brain-death exam. Despite clear guidelines, laws regarding brain death vary among states, including whether consent is required to perform neurologic testing.

Objective
To examine the role of parental consent in brain-death testing from an ethicolegal perspective as well as its potential to create clinician distress.
Design/Method
Case report
Results
Patient is a 3-year-old, previously healthy male who suffered a tragic submersion injury requiring prolonged cardiopulmonary resuscitation. During the subsequent hospitalization, his clinical exam, head CT scan, and electroencephalogram demonstrated devastating, irreversible neurologic injury concerning for brain death. The family refused formal brain-death testing, instead requesting more time to allow for a miraculous recovery. The patient remains on life support after 5 weeks and is beginning to experience multiorgan dysfunction.
Discussion
Many physicians feel that brain-death testing should not require parental consent. Despite this, states vary in their requirements for parental consent for brain-death testing. When legally permissible, there are competing ethical principles governing a family's request to delay or refuse brain-death testing.The principle of informed consent reflects the culture change from a paternalistic physician-patient relationship to a collaborative, family-centered approach. However, the argument remains that brain-death testing offers no therapeutic benefit and has the potential to cause harm via apnea testing, thereby requiring informed consent. This case presentation will illustrate the varied legal landscape surrounding pediatric brain-death testing, the ethical principles involved, and the moral injury that can result.

Explanation before Adoption: Supporting Informed Consent for Complex Machine Learning and IoT Health Platforms

Research Article
Rachel Eardley, Emma L. Tonkin, Ewan Soubutts, Amid Ayobi, Gregory J. L. Tourte, Rachael Gooberman-Hill, Ian Craddock, Aisling Ann O'Kane
Association for Computing Machinery: Human-Computer Interaction, 16 April 2023
Open Access
Abstract
Explaining health technology platforms to non-technical members of the public is an important part of the process of informed consent. Complex technology platforms that deal with safety-critical areas are particularly challenging, often operating within private domains (e.g. health services within the home) and used by individuals with various understandings of hardware, software, and algorithmic design. Through two studies, the first an interview and the second an observational study, we questioned how experts (e.g. those who designed, built, and installed a technology platform) supported provision of informed consent by participants. We identify a wide range of tools, techniques, and adaptations used by experts to explain the complex SPHERE sensor-based home health platform, provide implications for the design of tools to aid explanations, suggest opportunities for interactive explanations, present the range of information needed, and indicate future research possibilities in communicating technology platforms.

To Obtain Informed Consent or Not to Obtain Informed Consent? Drones for Health Programs in the Grey Zone between Research and Public Health

Vyshnave Jeyabalan, Lorie Donelle, Patrick Meier, Elysée Nouvet
Drones 2023, 2 April 2023; 7(4)
Abstract
Drones are increasingly being introduced to support healthcare delivery around the world. Most *Drones for Health* projects are currently in the pilot phase, where frontline staff are testing the feasibility of implementing drones into their healthcare system. Many of these projects are happening in remote localities

where populations have been historically under-served within national healthcare systems. Currently, there exists limited drone-specific guidance on best practices for engaging individuals in decision-making about drone use in their communities. Towards supporting the development of such guidance, this paper focuses on the issue of obtaining community and individual consent for implementing *Drones for Health* projects. This paper is based on original qualitative research involving semi-structured interviews (N = 16) with program managers and implementation staff hired to work on health-related projects using drone technologies. In this paper, we introduce a scenario described by one participant to highlight the ethical and practical challenges associated with the implementation and use of drones for health-related purposes. We explore the ethical and practical complexities of obtaining informed consent from individuals who reside in communities where *Drones for Health* projects are implemented.

Practical issues in pragmatic trials: the implementation of the Diuretic Comparison Project

Research Article

Ryan E Ferguson, Sarah M Leatherman, Patricia Woods, Cynthia Hau, Robert Lew, William C Cushman, Mary T Brophy, Louis Fiore, Areef Ishani

Society for Clinical Trials, 29 March 2023

Abstract

Background/Aims

The US Department of Veterans Affairs Point of Care Clinical Trial Program conducts studies that utilize informatics infrastructure to integrate clinical trial protocols into routine care delivery. The Diuretic Comparison Project compared hydrochlorothiazide to chlorthalidone in reduction of major cardiovascular events in subjects with hypertension. Here we describe the cultural, technical, regulatory, and logistical challenges and solutions that enabled successful implementation of this large pragmatic comparative effectiveness Point of Care clinical trial.

Methods

Patients were recruited from 72 Veterans Affairs Healthcare Systems using centralized processes for subject identification, obtaining informed consent, data collection, safety monitoring, site communication, and endpoint identification with minimal perturbation of the local clinical care ecosystem. Patients continued to be managed exclusively by their clinical care providers without protocol specified study visits, treatment recommendations, or data collection extraneous to routine care. Centralized study processes were operationalized through the application layer of the electronic health record via a data coordinating center staffed by clinical nurses, data scientists, and statisticians without site-based research coordinators. Study data was collected from the Veterans Affairs electronic health record supplemented by Medicare and National Death Index data.

Results

The study exceeded its enrolled goal (13,523 subjects) and followed subjects for the 5-year study duration. The key determinant of program success was collaboration between researchers, regulators, clinicians, and administrative staff at the site level to customize study procedures to align with local clinical practice. This flexibility was enabled by designation of the study as minimal risk and determination that clinical care providers were not engaged in research by the Veterans Affairs Central Institutional Review Board. Cultural, regulatory, technical, and logistical problems were identified and solved through iterative collaboration between clinical and research entities. Paramount among these problems was customization of the Veterans Affairs electronic health record and data systems to accommodate study procedures.

Conclusions

Leveraging clinical care for large-scale clinical trials is feasible but requires a rethinking of traditional clinical trial design (and regulation) to better meet requirements of clinical care ecosystems. Study designs must accommodate site-specific practice variation to reduce the impact on clinical care. A tradeoff thus exists between designing trial processes tailored to expedite local study implementation versus those to produce a more refined response to the research question. The availability of a uniform and flexible electronic health record in the Department of Veterans Affairs played a major role in the success of the trial. Conducting Point

of Care research in other healthcare systems without such research-friendly infrastructure presents a more formidable challenge.

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BIOMEDICAL RESEARCH

Piloting a tool for informed consent comprehension in a cardiovascular clinical trial in South Africa: An IMPI-2 pilot trial substudy (ICC Study)

G C Isiguzo, M A Familusi, K Sliwa, L Thabane, M Ntsekhe, B M Mayosi, J de Vries
South African Medical Journal, 12 April 2023
Abstract
Background
Informed consent is a key requirement in research. However, the comprehension of information presented is rarely evaluated prior to or during the research. Ensuring that participants understand the key issues in trials is important, not just for ethical reasons, but also because it can help set patient expectations. We evaluated the feasibility of using the University of California Brief Assessment of Capacity to Consent (UBACC) questionnaire to guide informed consent comprehension in the pilot study for the second Investigation of the Management of Pericarditis in Africa (IMPI-2) trial. IMPI-2 is a randomised controlled trial (RCT) on the use of alteplase-facilitated pericardial drainage, compared with routine care among patients with large pericardial effusion. We used an abbreviated version of the UBACC to evaluate participant comprehension of key elements of the consent documentation and to guide discussions.
Method
Comprehension was assessed using a 10-item UBACC at baseline, 6 weeks, 3 months and 6 months follow-up to reiterate the information about the trial. Each response was scored from 0 to 3 and the sum at each visit was recorded to represent comprehension. A UBACC score ≥25 was considered adequate comprehension. Bivariate logistic regression was performed to evaluate comprehension over time. A multivariate analysis was conducted to identify predictors of UBACC score.
Results
The Informed Consent Comprehension (ICC) Study included 71 participants with a median age of 42 years; 45% were females and 49% had at least a secondary level of education. Level of comprehension improved with time; the odds of passing the evaluation at baseline compared with 6 months was higher (odds ratio (OR) 1.39, 95% confidence interval (CI) 1.17 - 1.65, $p<0.001$). Not using interpreters and having a secondary level of education were associated with higher comprehension. Despite knowing that they were participating in research, many participants still did not accept that the trial drug may have no effect.
Conclusion
It is feasible to use the UBACC questionnaire for informed consent comprehension evaluation in RCTs. Repeated learning during follow-up improves comprehension over time, while a low level of education and use of interpreters reduces comprehension.

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SOCIAL SCIENCE RESEARCH

"Ethics Ready"? Governing Research Through Informed Consent Procedures

Florence Caeymaex, Carole Wenger, Felicien de Heusch, Jean-Michel Lafleur
International Journal of Qualitative Methods, 11 April 2023
Open Access
Abstract

Social Scientists using ethnographic methods are increasingly confronted with ethical clearance procedures imposed by universities, national authorities, professional organizations and funders. In this article, we focus on informed consent procedures in particular and discuss how they govern fieldwork interactions. To do so, we first show how ethical clearance procedures in Europe have been influenced by biomedical science, creating a risk of "governing the social science research in the name of ethics" (Haggerty, 2004) through "anticipatory regulatory regimes" (Murphy and Dingwall, 2007). We subsequently discuss the implementation of ethical procedures negotiated with an ethical review panel in the framework of an EU-funded project in migration studies. In doing so, we show how Research Ethics Committees (RECs) can incentivize researchers to comply with ethical guidelines and procedures in order to be considered as "ethics ready" by the funder. Providing examples of different ethnographic situations, we argue that —while informed consent procedures might reinforce participants' vulnerabilities— they can also activate their desire to assert power. The article concludes with three recommendations that call for a redefinition of the relationships between institutions, researchers and participants through a co-construction of research ethics.

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HEALTH DATA/DATA

Privacy for IoT: Informed consent management in Smart Buildings

Chehara Pathmabandu, John Grundy, Mohan Baruwal Chhetri, Zubair Baig
Future Generation Computer Systems, August 2023; 145 pp 367-383
Abstract
Smart Buildings (SBs) employ the latest IoT technologies to automate building operations and services with the objective of increasing operational efficiency, maximising occupant comfort, and minimising environmental impact. However, these smart devices – mostly cloud-based – can capture and share a variety of sensitive and private data about the occupants, exposing them to various privacy threats. Given the non-intrusive nature of these devices, individuals typically have little or no awareness of the data being collected about them. Even if they do and claim to care about their privacy, they fail to take the necessary steps to safeguard it due to the convenience offered by the IoT devices. This discrepancy between user attitude and actual behaviour is known as the 'privacy paradox'. To address this tension between data privacy, consent and convenience, this paper proposes a novel solution for informed consent management in shared smart spaces. Our proposed Informed Consent Management Engine (ICME) (a) increases user awareness about the data being collected by the IoT devices in the SB environment, (b) provides fine-grained visibility into privacy conformance and compliance by these devices, and (c) enables informed and confident privacy decision-making, through digital nudging. This study provides a reference architecture for ICME that can be used to implement diverse end-user consent management solutions for smart buildings. A proof-of-concept prototype is also implemented to demonstrate how ICME works in a shared smart workplace. Our proposed solution is validated by conducting expert interviews with 15 highly experienced industry professionals and academic researchers to understand the strengths, limitations, and potential improvements of the proposed system.

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CAPACITY TO CONSENT

Assent and vulnerability in patients who lack capacity

Commentary
Christopher A Riddle
Journal of Medical Ethics, 17 April 2023

Excerpt

Smajdor's Reification and Assent in Research Involving Those Who lack Capacity claims, among other things, that 'adults who cannot give informed consent may nevertheless have the ability to assent and dissent, and that these capacities are morally important in the context of research'. More pointedly, she suggests we can rely upon Gillick competence, or that 'it is worth thinking about why the same trajectory [as children] has not been evident in the context of [adults with impairments of capacity to give informed consent (AWIC)]'. I argue that her likening assent in AWIC to assent in children is problematic for at least two related reasons. First, direct comparisons between AWIC and children run the risk of perpetuating or reinforcing infantilising stereotypes against people with disabilities. Second, I argue that people with disabilities are vulnerable in ways that most children are not, and thus, are dissimilar in a morally relevant manner…

Editor's note: The article which is referenced in this commentary was featured in the February edition of this digest and follows below.

Reification and assent in research involving those who lack capacity

Anna Smajdor

BMJ, 26 December 2022

Open Access

Abstract

In applied ethics, and in medical treatment and research, the question of how we should treat others is a central problem. In this paper, I address the ethical role of assent in research involving human beings who lack capacity. I start by thinking about why consent is ethically important, and consider what happens when consent is not possible. Drawing on the work of the German philosopher Honneth, I discuss the concept of reification—a phenomenon that manifests itself when we fail to observe or respond to our fellow humans' need for recognition. I suggest that assent is a way of responding to this moral need for recognition, which exists independently of cognitive capacity. I will look at the circumstances in which consent cannot be obtained from human beings, and ask whether some of the same ethically important considerations that underpin the need for consent might be achieved through seeking assent. I discuss the ways in which this might be beneficial for researchers, for prospective research participants and for society at large.

Autonomy of Individuals with Alcohol-Related Disorders: Informed Consent and Empowerment

João Paulo Barbosa Azevedo

Journal of Addiction & Addictive Disorders, 12 April 2023

Abstract

Informed consent is a central concern in the care practice of individuals with alcohol- related disorders, with research and clinical practice indicating that they often refuse or abandon treatment early. In the relational care encounter it is important not only to recognize the patient as the subject of will and decision-making power, but also to pay attention to the experiences of vulnerability and the importance of promoting autonomy. These issues are particularly relevant when individuals with alcohol-use disorders come to treatment suffering from coercion or disturbed by anxiety and/or depression. A study on informed consent ethical practice was conducted on a sample of 85 professionals from the Addictive Behaviours and Dependencies network of the Regional Health Administration of the North, Portugal. A questionnaire was used to survey ethical attitudes. The results suggest the importance of reinforcing the practice of informed consent of individuals with alcohol-related disorders suffering from coercion, anxiety or depression as a place of a psychological empowerment process.

Informed consent with people judged incapable of legally consenting

Amy Bittick, Ryan Holliman

Advances in Mental Health and Intellectual Disabilities, 6 April 2023

Abstract
Purpose
The purpose of this study is to consider informed consent with those who may be legally judged incapable of consent. Frequently individuals with traumatic brain injuries and intellectual disabilities may fall into this category. This paper seeks to consider aspects of guardianship, moral and legal implications and best practices for mental health professionals.
Design/methodology/approach
This practice piece reviews literature regarding informed consent, as well as pertinent issues in the professional literature regarding types of guardianship as well as the occurrence of "Lucid intervals." Furthermore, literature from moral philosophy and current legal research was examined to fully provide readers with a grasp of the legal and ethical landscape of this issue.
Findings
The paper finds that treating consent as a one-time binary event is lacking in both practicality and nuance. Moral philosophy and issues regarding paternalism are raised, as well as practice approaches to assessment of capability and how to engage in therapy in meaningful ways.
Originality/value
This paper provides insight into providing dignity-affirming therapy with a population that is often not considered in the literature of mental health ethics. When it is considered, the suggestions are so vague as to be of limited use. This manuscript provides nuance and practical applications to be a therapist that promotes dignity in those who might have varying levels of capacity to consent.

The Role of Different Aspects of Communication Behavior in the Assessment of Capacity to Consent

Luise Badenhoop, Stefanie Baisch, Susanne Penger, Julia Haberstroh
Journal of Gerontopsychology and Geriatric Psychiatry, 5 April 2023
Open Access
Abstract
Any medical treatment that interferes with physical integrity requires the informed consent of a patient capable of such consent. For people with dementia, the capacity to consent is questioned even in the early course of the disease. Particularly diagnostic instruments like the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) often deny people with dementia the capacity to consent because of high confounding of the results with patients' verbal abilities. To date, it remains unclear whether not only verbal but also nonverbal communication is associated with assessments of capacity to consent. The current study investigates associations between patients' verbal and nonverbal communication behaviors as assessed by the measure for Communication Behavior in People with Dementia in Ambulant Settings (CODEMamb) and capacity to consent as assessed by the MacCAT-T. We expected the strongest positive associations for verbal communication behaviors compared to nonverbal communication behaviors. Data of N = 43 patients with dementia (n = 8 capable of consent) were collected at two different German psychiatric clinics. The results show small to moderate correlations between the overall scores of CODEMamb and MacCAT-T. As expected, correlations were strongest for the verbal CODEMamb subscale. The results support current findings on the dependency of the MacCAT-T on verbal communication. Based on the findings, the discussion addresses how people with dementia can be enabled to make self-determined medical treatment decisions.

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YOUNG PERSONS

Informed Consent, Assent, and Confidentiality

Book Chapter

Eron Linver

Caring for the Hospitalized Child, May 2023 [American Academy of Pediatrics]

Excerpt

Informed consent is defined as the voluntary agreement of an individual or their authorized representative who has the legal authority to give such agreement. This consent must be exercised within the context of free choice, without any application of inducement or coercion. To give informed consent, an individual must have sufficient knowledge and understanding to be able to make a knowledgeable decision. Health care providers may have a different level of education and understanding than patients and their guardians. This knowledge gap can add complexity and potential misunderstandings to conversations surrounding informed consent…

Consent for the paediatric patient

Andrew Jones, James Hyde, Sharon Lee, Sondos Albadri, Laura Gartshore

Faculty Dental Journal, 1 April 2023; 14(2)

Abstract

Introduction

Obtaining valid consent is a fundamental process in dentistry. Written consent must be obtained where treatment involves conscious sedation or general anaesthesia. For children, consent may be provided by a person with parental responsibility (PR).

Methods

A retrospective evaluation was completed of 160 children over 2 UK hospital sites with paediatric services. Cases involving conscious sedation or general anaesthesia for dental treatment were selected. Data were obtained to establish whether it was documented that the correct person had provided consent for a child and whether all possible individuals with PR for the child were identified at the initial visit. UK national legislation and guidance was reviewed, from which a PR form (to determine PR status for a child) was created and implemented. A second evaluation was subsequently completed, again with 160 children.

Results

Combined data from both sites confirmed documentation of an appropriate person providing consent in 127 cases (79%) in the first evaluation. This improved to 155 cases (97%) following implementation of the PR form. All possible individuals who had PR for the child were identified at the initial visit in 35 cases (22%). This improved to 139 cases (87%) following the introduction of the PR form.

Conclusions

Use of a PR form improved documentation regarding valid consent for children.

Editor's note: This is a publication from the Royals College of Surgeons England.

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CULTURAL/COUNTRY CONTEXT

Informed Consent: How much information is enough? In a Obstetrics and Gynaecology Department in Tertiary Care Hospital – An Interventional Study

Indian Journal of Forensic Medicine & Toxicology, 17(2), April-June 2023

Open Access

Abstract

Permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits. A process in which patients are given important information, including possible risks and benefits, about a medical procedure or treatment,

genetic testing, or a clinical trial. This paper was an interventional study it was conducted in the Department of Forensic Medicine and Toxicology, Sri Manakula Vinayaga Medical College and Hospital, Madagadipet, Puducherry to audit and to improve it was conducted in the Department of Obstetrics and Gynaecology. The deficiencies were identified and it was analysed. The results of both pre-interventional and post-interventional were recorded, which showed the significant improvement in the consent form of the major and minor procedures. It is essential that this information be discussed in simple terminology that can be easily readily understood and help the patient to give proper consent for the procedures.

Traditional Health Care Practitioners' Perspectives on Applying Informed Consent During African Traditional Medical Practice in Akwa Ibom State, Nigeria: A Cross-Sectional Qualitative Study

Francis Akpa-Inyang, Sylvester C. Chima

Journal of Integrative and Complementary Medicine, 17 April 2023

Abstract

Introduction

This study explored the perspectives of traditional health care practitioners (THPs) practicing in the areas of herbalism, bone setting, and traditional birth attendance, from Akwa Ibom state, Nigeria, on the possibility and implications of applying informed consent (IC) during African traditional medicine (ATM) practice.

Methods

Semistructured interviews were conducted with 11 THPs, consisting of 5 herbalists, 3 traditional bone setters (TBS), and 3 traditional birth attendants (TBAs), who represented the diverse groups that the study intended to cover. In-depth interviews were conducted using a semistructured guide and were recorded, transcribed, and analyzed using thematic analysis with the assistance of NVivo® qualitative analysis software.

Results

Participants were seven males (64%) and four females (36%), 35–67 years of age, with 5–25 years of experience as THPs. Forty-six percent of participants were herbalists (27%), TBS, and TBAs (27%). Most participants (82%) were Annang, and (18%) were Ibibio first-language speakers. Three major themes emerged from the data analysis: (i) Existing ethical framework related to IC, (ii) knowledge of consent, and (iii) application of IC during traditional medical practice. These themes and relevant subthemes were explored. All (100%) THPs agreed that it was essential to communicate risks and benefits while allowing patients to ask questions before treatment. All participants (100%) stated that risk communication is essential in ATM, whereas 36% said they communicated all therapy benefits to their patients. Respondents believed patients could make an informed choice if they had complete information disclosure. However, THPs in this study had limited knowledge of formal IC rules and regulations.

Conclusions

This study revealed that THPs in this setting disclose a diagnosis, risks, some benefits, and treatment options to patients. Consent/agreement was obtained verbally and voluntarily during ATM practice, consistent with IC doctrine. THPs had limited knowledge of the critical elements of IC. However, they suggested that a form of IC that does not conflict with traditional African norms could be applicable in ATM. IC could facilitate documentation and help reduce risks in ATM practice.

Determination of the Readability Level of Consent Forms Used in the Gynecology and Obstetrics Clinic at Suleyman Demirel University

Cem Dağdelen, Evrim Erdemoğlu

Cureus, 5 April 2023; 15(4)

Open Access

Abstract

Background

This study aimed to evaluate the readability level of consent forms used for interventional procedures in the obstetrics and gynecology clinic and to determine the readability of the texts according to the education level of the patient.

Methodology

This study determined the readability of patient consent forms used before interventional procedures in the gynecology and obstetrics clinic at the Suleyman Demirel University Hospital, Isparta. The consent forms were divided into two main groups according to their use in obstetrics and gynecology procedures. The readability level of consent forms was assessed using two readability formulas developed by Ateşman and Bezirci-Yılmaz, which determine the readability level of Turkish texts in the literature.

Results

When the consent forms were analyzed according to Atesman's readability formula, they were found to be readable with more than 15 years of education at the undergraduate level, while according to Bezirci-Yılmaz's readability formula, they were found to be readable with 17 years of education at the postgraduate level.

Conclusions

Easy-to-read consent forms will ensure that patients are more informed about interventional procedures and participate more effectively in the treatment process. There is a need to develop readable consent forms suitable for the general education level.

Editor's note: Suleyman Demirel University is located in the Karasay region of Kazakhstan.

Cardiac Transplant in Southeast Asia: Challenges and Opportunities

R. Sulague, N. Cruz, R. Ricardo, P. Alfonso, D. Vervoort

The Journal of Heart and Lung Transplantation, April 2023; 42(4)

Abstract

Purpose

Among the 18.6 million cardiovascular deaths worldwide, 33.5% occurred in Southeast Asia, where cardiovascular diseases constitute 40.2% of all causes of mortality and injury. There is higher prevalence of symptomatic heart failure in Southeast Asian countries compared with the rest of the world. While advances improved cardiac transplantation, challenges remain to make it widely available. The study aims to discuss its challenges and opportunities in Southeast Asia.

Methods

A review of related literature was conducted on PubMed using combinations of variations of key terms such as cardiac transplant, heart transplant, Southeast Asia, and countries within the region. Ministries of health websites in the region were reviewed for cardiac transplant-related policies. The global burden of disease of heart failure-associated conditions from 2000 to 2019 in disability-adjusted life-years were assessed in the Southeast Asian region and other select geographical region using the Institute for Health Metrics and Evaluation Global Burden of Disease Results Tool.

Results

Southeast Asia's burden of disease is comparable to Western Europe but does not have the same high volume of cardiac centers, health workforce, and robust network of organ donors. Substantial financial risk protection remains limited for most of the countries. Main barriers to organ donation include knowledge gaps, sociocultural and religious restrictions, and lack of infrastructure. At present, all countries follow an opting-in system based on informed consent, except Singapore which follows an opting-out system based on presumed consent. Association of Southeast Asian Nations may be optimized to promote cooperation, physician mobility, improved training, and policymaking.

Conclusion

Southeast Asian countries may benefit from considering opting-out scheme for donation, implementing a national system for organ donation, forming a centralized body directing all transplant activities, and improving public health education on transplantation.

Understanding of informed consent by patients at the Faculty of Dentistry of the University of Costa Rica

José Manuel Fernández Chaves

Medicina Legal de Costa Rica, March 2023

Abstract

Introduction

Informed consent is the result of the evolution of the relationship between health professionals and their patients or users where the principle of autonomy is above anything else. There are many articles on informed consent but none of the studies found assessed whether patients really understand it. The objective of this research was to determine the level of understanding of informed consent by the patients of the Clinic of Oral Surgery of the Faculty of Dentistry of the University of Costa Rica, in the period August to September 2022, by means of a questionnaire that would allow correlating the understanding with the level of schooling.

Materials and methods

A questionnaire was administered to 100 people divided into two parts, one on sociodemographic data and the other to establish the understanding of informed consent and to determine whether the level of schooling was related to the understanding of the same.

Results

The group between 20 and 30 years of age was the largest, of these 51% had university studies, and although the majority (98%) referred to knowing the concept of informed consent, only 33% obtained the correct answers to the clinical questions asked.

Conclusions

Even though patients refer to knowing what informed consent is the results suggest an unclear understanding of important concepts such as complications or immediate or late adverse reactions produced by the effect of dental treatments or surgical procedures.

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RIGHTS/LEGAL/LEGISLATIVE

Adoption without parental consent

Book Chapter

Julie Doughty

Adoption Law, 25 April 2023 [Elgar]

Abstract

This chapter places controversy about adoption without birth parents' consent in England and Wales in a wider historical and social context. Although it may appear that legal challenges have become more common in adoption proceedings, it is argued that these rarely succeed and that the relatively few reported cases give only a partial picture of birth parents' experiences. Three aspects of consent are considered: whether the consent given is valid; withholding consent; and actively contesting court proceedings. Research suggests that, historically, birth parents in the UK, Australia and the USA have been coerced into surrendering their babies, some in circumstances that raise doubts about mothers' mental capacity to consent. Current debates focus on less direct coercion through a lack of support services for families facing poverty and adverse circumstances. The background to relevant provisions in the Adoption and Children Act 2002 is examined, and case law relating to different stages of the court process is analysed. Although courts give serious consideration to human rights principles and due process, the discussion indicates limited opportunities for birth parents to effectively resist adoption by refusing their formal consent or making court applications. Legal mechanisms designed to allow non-consenting parents to challenge the adoption process, where this

was justified, do not appear to offer a realistic prospect of overturning an adoption plan, once this has been approved in care proceedings.

Incapacitous patients, assisted reproductive technology, and the importance of informed consent

Lisa Cherkassky

Legal Studies, 20 April 2023

Abstract

The principle of self-determination has gained significant judicial support over the last three decades, and the choice to procreate using assisted reproductive technology is a clear example of our right to choose a treatment that enhances our personal lives. The Human Fertilisation and Embryology Act 1990 (as amended in 2008) stipulates that each party must give written, informed consent to ensure that our reproductive materials are used within strict parameters. However, the growing number of posthumous conception cases in several jurisdictions has raised concerns, particularly in situations where gametes are extracted from incapacitous patients without their consent, leading to posthumous parenthood. The landmark case of Y v A Healthcare NHS Trust [2018] EWCOP 18 caused significant concern when it authorised the retrieval, storage and use of sperm from a suspected brain stem dead man for procreative purposes under the Mental Capacity Act 2005. It has never been known to be in the 'best interests' of a patient who lacks capacity to procreate in English law, and the consequences of this decision could be highly significant, raising questions about the exploitation of incapacitous patients and the misuse of genetic material. The decision has since been confirmed as the correct approach by the Court of Protection in Re X (Catastrophic Injury: Collection and Storage of Sperm) [2022] EWCOP 48, and a public consultation has now been opened by the Human Fertilisation and Embryology Authority. This paper examines the rigorous consent regime of the 1990 Act and the ethical complexities of retrieving gametes from incapacitous patients for procreative purposes. It will be determined that the 1990 Act's preference for a rigorous consent regime for public policy reasons is appropriate, and any alternative forms of consent could open a slippery slope to the unethical use of vulnerable individuals for their reproductive materials.

The Relevance of Consent in the Digital Age: A Consideration of Its Origins and Its Fit for Digital Application

Book Chapter

Marietjie Botes

Security and Trust Management, 4 April 2023 [Springer]

Abstract

Consent originated in the 1800s to protect incarcerated prisoners against unwanted medical treatment and was later formalized in the Nuremberg Code in response to harmful medical experiments that was conducted on prisoners of war during World War II. These co-called ethical principles was later reinforced and extended to protect the control and decisional power that individuals need over their bodies in The Belmont Report. Today these ethical consent principles are codified in laws such as the GDPR. Considering that these ethical consent principles were developed around biomedical treatments and experiments, it begs the question whether these same principles are still relevant and can be successfully applied in a digital environment. This paper critically considers the application of the original ethical consent principles in the digital age and highlights certain critical challenges. The aim of the paper is to draw attention to the fact that the concept of consent and whether it can still be applied ethically in a digital environment must be considered first before digital consent models or consent automation tools are developed, because such a consideration will have a critical impact on how these tools must be developed to remain, not only legal, but also ethical and subsequently sustainable.

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POLICY/GUIDANCE/CODES/PROGRAM ACTION

Bridging the "consent gap". Mechanisms of legitimization in a cross-border megaproject

Silvia Lucciarini, Rossana Galdini

Policy & Society, 2023

Abstract

In the recent debate on megaprojects, greater attention is devoted to the functioning of the inter-organisational and multi-actor networks that are one of the most innovative features of recent years. The complexity of these structures brings out governability issues for a megaproject's management. Mutual recognition and consent become elements capable of inaugurating more collaborative processes and practices to reduce organisational and management criticalities in megaprojects. This paper focuses on a neglected relational dimension, namely legitimacy. We argue that legitimacy is instead the central dimension that attributes effectiveness and capacity for action to the organisations involved. Legitimacy regulates the relationship between various organisations – and especially – between organisations and the public sphere. Institutionalist theory assigns a central role to legitimacy in the construction of social processes, defining it as a generalised form of social acceptance towards an actor, an idea or a project. In this paper, we hypothesise that the legitimacy attributed and "held" by the stakeholders is a crucial element in countering three critical aspects of megaprojects, namely the uncertainty, complexity and conflict acting on the construction of public consensus and the quality of relations between the participating stakeholders. We verify our hypothesis by analysing a cross-border megaproject, the Fehmarnbelt Fixed Link between Germany and Denmark. The paper concentrates on the mechanisms with which stakeholders can acquire legitimacy using the Eriksen discursive legitimation scheme. These mechanisms are different (evidence-based, public participation, and legislators' command) and produce different outcomes in terms of increasing or containing these three criticalities.

Editor's note: This is an Italian language publication.

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MEDICAL/SURGICAL

An Evaluation of Sex-Based Differences in Surrogate Consent for Older Adults Undergoing Surgical Intervention

Nupur Nagarkatti, Samuel M. Miller, Vanita Ahuja, Eric B. Schneider, Sanjay Mohanty, Lisa M. Kodadek

Journal of Surgical Research, August 2023; 288 pp 246-251

Abstract

Introduction

Differences between female and male patients have been identified in many facets of medicine. We sought to understand whether differences in frequency of surrogate consent for operation exist between older female and male patients.

Materials and methods

A descriptive study was designed using data from the hospitals participating in the American College of Surgeons National Surgical Quality Improvement Program. Patients age 65 y and older who underwent operation between 2014 and 2018 were included.

Results

Of 51,618 patients identified, 3405 (6.6%) had surrogate consent for surgery. Overall, 7.7% of females had surrogate consent compared to 5.3% of males ($P < 0.001$). Stratified analysis based on age categories showed no difference in surrogate consent between female and male patients aged 65-74 yy (2.3% versus 2.6%, $P = 0.16$), but higher rates of surrogate consent in females than males among patients aged 75-84 y old (7.3% versus 5.6%, $P < 0.001$) and age ≥85 y (29.7% versus 20.8%, $P < 0.001$). A similar relationship was seen

between sex and preoperative cognitive status. There was no difference in preoperative cognitive impairment in female and male patients age 65-74 y (4.4% versus 4.6%, P = 0.58), but higher rates of preoperative cognitive impairment were seen in females than males for those age 75-84 (9.5% versus 7.4%, P < 0.001) and aged ≥85 y (29.4% versus 21.3%, P < 0.001). Matching for age and cognitive impairment, there was no significant difference between rate of surrogate consent in males and females.
Conclusions
Female patients are more likely than males to undergo surgery with surrogate consent. This difference is not based on patient sex alone – females undergoing operation are older than their male counterparts and more likely to be cognitively impaired.

Asking informed consent may lead to significant participation bias and suboptimal cardiovascular risk management in learning healthcare systems

Research
Anna G. M. Zondag, T. Katrien J. Groenhof, Rieke van der Graaf, Wouter W. van Solinge, Michiel L. Bots, Saskia Haitjema
BMC Medical Research Methodology, 22 April 2023; 23(98)
Open Access
Abstract
Background
The Utrecht Cardiovascular Cohort – CardioVascular Risk Management (UCC-CVRM) was set up as a learning healthcare system (LHS), aiming at guideline based cardiovascular risk factor measurement in all patients in routine clinical care. However, not all patients provided informed consent, which may lead to participation bias. We aimed to study participation bias in a LHS by assessing differences in and completeness of cardiovascular risk management (CVRM) indicators in electronic health records (EHRs) of consenting, non-consenting, and non-responding patients, using the UCC-CVRM as an example.
Methods
All patients visiting the University Medical Center Utrecht for first time evaluation of a(n) (a)symptomatic vascular disease or condition were invited to participate. Routine care data was collected in the EHR and an informed consent was asked. Differences in patient characteristics were compared between consent groups. We performed multivariable logistic regression to identify determinants of non-consent. We used multinomial regression for an exploratory analysis for the determinants of non-response. Presence of CVRM indicators were compared between consent groups. A waiver (19/641) was obtained from our ethics committee.
Results
Out of 5730 patients invited, 2378 were consenting, 1907 non-consenting, and 1445 non-responding. Non-consent was related to young and old age, lower education level, lower BMI, physical activity and haemoglobin levels, higher heartrate, cardiovascular disease history and absence of proteinuria. Non-response increased with young and old age, higher education level, physical activity, HbA1c and decreased with lower levels of haemoglobin, BMI, and systolic blood pressure. Presence of CVRM indicators was 5–30% lower in non-consenting patients and even lower in non-responding patients, compared to consenting patients. Non-consent and non-response varied across specialisms.
Conclusions
A traditional informed consent procedure in a LHS may lead to participation bias and potentially to suboptimal CVRM, which is detrimental for feedback on findings in a LHS. This underlines the importance of reassessing the informed consent procedure in a LHS.

Expanding the boundaries of previously obtained informed consent in research: Views from participants in the Personalised Risk-based Mammascreening study

Lutomski JE, Rainey L, de Jong M, Manders P, Broeders MJM

Health Expectations: an International Journal of Public Participation in Health Care and Health Policy, 4 April 2023

Abstract

Introduction

Understanding participants' concerns and information needs regarding broadened consent is crucial to ensure transparency and participant autonomy. Our study qualitatively examined these issues in women participating in the Personalized RISk-based MAmmascreening study (PRISMA). The original PRISMA informed consent was project-specific (i.e., breast cancer research), limiting the scope of secondary research. We explored participants' needs for broadened consent to preserve informed decision-making while maximising the potential re-use of data.

Methods

Focus groups (FGs) were performed following a semistructured discussion guide. Two independent researchers analysed the data thematically using an inductive approach.

Findings

Twenty-three asymptomatic women and 13 women diagnosed with breast cancer were randomly divided into six FGs. Four superordinate themes were identified: (1) Normalization, (2) Attitude towards the pharmaceutical industry, (3) Privacy and (4) Knowledge. Our participants viewed data sharing as an important conduit for advancing medical science. Perceived integrity was more often attributed to noncommercial than commercial parties, with a marked mistrust towards the pharmaceutical industry. Most requested information needs related to data protection. Participants' ideal consent process would confer a range of options; for example, they would be able to choose with whom data can be shared, whether data will be de-identified or anonymous, the expiration date of their consent and how, if requested, general and personal study results would be disclosed.

Conclusion

Our participants expressed clear information needs and a strong desire to be actively engaged in future data sharing decisions. Given that many researchers collaborate with commercial parties, building public confidence in these institutions would be beneficial. Illustrative examples addressing privacy concerns and clarifying difficult terms would aid consent decision-making. Although our participants displayed great altruism in sharing their data and accepted that broad consent would ultimately facilitate future research, broad consent did not reflect their ideal situation. Dynamic consent may be an option but warrants further feasibility research.

Patient and public contribution

Women were recruited from the general breast cancer screening population. Their perceptions and information needs, as reported in this study, will not only inform broadened consent for PRISMA but ideally guide other consent templates and decisions regarding consent processes.

Consent: A Pocket Guide for Nursing and Health Care

Book

Marc Cornock

April 2023 [Scion Publishing Ltd]

Excerpt

Consent is a concept that can be complex and difficult to understand, but it does not have to be. This book is a handy pocket-sized guide to the consent process that treats consent as an essential part of your everyday practice. From assent to self-determination, via legally valid consent, it’s full of practical detail about: what consent is, who can give consent, the ways in which consent can be given…

To Consent or Not to Consent to Screening, That Is the Question

Bjørn Hofmann

Healthcare, 30 March 2023

Abstract
The objective of this article is to address the controversial question of whether consent is relevant for persons invited to participate in screening programs. To do so, it starts by presenting a case where the provided information historically has not been sufficient for obtaining valid informed consent for screening. Then, the article investigates some of the most relevant biases that cast doubt on the potential for satisfying standard criteria for informed consent. This may indicate that both in theory and in practice, it can be difficult to obtain valid consent for screening programs. Such an inference is profoundly worrisome, as invitees to screening programs are healthy individuals most suited to make autonomous decisions. Thus, if consent is not relevant for screening, it may not be relevant for a wide range of other health services. As such, the lack of valid consent in screening raises the question of the relevance of one of the basic ethical principles in healthcare (respect for autonomy), one of the most prominent legal norms in health legislation (informed consent), and one of the most basic tenets of liberal democracies (individual autonomy). Thus, there are good reasons to provide open, transparent, and balanced information and minimize biases in order to ascertain informed consent in screening.

Editor's note: This article belongs to the Special Issue The Rationalities of Medical Screening.

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GENERAL/OTHER

Consent in Surrogacy - Free or Manufactured?

Ms. Soumya Verma

Indian Journal of Ethics, Logic and Philosophy, 21 April 2023

Abstract
Consent has an important role to play in the ethical domain, and the method by which consent is obtained should also be taken into consideration. It should not be taken by coercion, violence, or force. Surrogacy, a highly debatable topic in the domain of applied ethics whose legitimacy is significantly affected by consent, given by the surrogate mothers, which can change the different moral considerations and ethical claims. The contemporary debate on the issue of surrogacy seems to be between traditionalists and liberals, but this paper will take the debate further. In this paper, we shall try to problematize the liberal conception, which looks at the consent given by women in surrogacy limited to its face value, i.e., they limit consent to their saying "yes" because they have reproductive rights over their own bodies. This paper will further argue that consent in surrogacy should not be limited to its face value as taken by liberals, as it is not an ideal society, situations are different for different women, and there could be different social realities that constitute the factors behind that consent. Financial constraint, an important social reality, will be the focus of this paper, which leads a woman to give consent for surrogacy arrangements.

Consent as an act of commitment

Robert E. Goodin

European Journal of Philosophy, 16 April 2023

Abstract
Some say that consent is essentially just a state of mind. Others say it is essentially just a communication. Many say it is both. I say it is neither. Instead it is an act, or rather a pair of acts—an internal mental act in the first instance, an external performative act in the second. Each of those acts is an act of commitment, intrapersonally in the first case and interpersonally in the second. The content of the commitment is, familiarly enough, to give permission to someone else to do something that it would be wrong for them to do without your permission. The novelty lies in seeing consent as an act of commitment in those two dimensions and in seeing those as commitments that persist until and unless undone by an act of a similar sort.

Posthumous autonomy: Agency and consent in body donation

Tom Farsides, Claire F. Smith

Philosophical Psychology, 6 April 2023

Abstract

Six people were interviewed about the possibility of becoming posthumous body donors. Interview transcripts were analyzed using interpretative phenomenological analysis. Individual-level analysis suggested a common interest in Personhood Concerns and a common commitment to Enlightenment Values. Investigations of these possible themes across participants resulted in identification of two sample-level themes, each with two subthemes: Autonomy, with subthemes of agency and consent, and Rationality, with subthemes of knowledge/epistemology and materialism/ontology. This paper concentrates on the former. Consent for posthumous body donation was felt to sometimes fall short of adequately identifying donors' preferences about what happened after consent was given, even with respect to actions for which consent established permission. In turn, paucity of information about donors' preferences limited others' ability to act as proxy agents to facilitate donors' posthumous autonomy. Thus, while consent may curtail violations of people's autonomy by authorizing actions for which permission has been established, it may fall short of facilitating their autonomy in ways that might be possible with greater knowledge of those people's desires. Alternative methods of establishing consent are explored that might better-determine people's desires and thereby improve others' ability to act as proxy agents for them to facilitate their subsequent (even posthumous) autonomy.

# # # #

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