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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

May 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", "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 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:

Editor
Paige Fitzsimmons, MA
Associate Director, Center for Informed Consent Integrity
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

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:

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No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS

HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
TECHNOLOGY/OTHER MEDIATION

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

POLICY GUIDANCE/PROGRAM ACTION

Ethical Research in Fragile and Conflict Affected Contexts: Guidelines for Reviewers

Guidelines
UKRI Research and Innovation, 16 November 2021
Open Access
Rationale
Ethical considerations arise in all research. They are, however, amplified in fragile and conflict-affected contexts. The power imbalances between local and international researchers are increased and the risk of harm is augmented. The research takes place in a context where appropriate safeguards are often reduced and the probabilities of unethical research are magnified. Existing explorations of ethics and ethical review processes often focus primarily on the front end of the data cycle. Yet, we know that harm can occur at any stage in the research cycle. Ethical research in fragile and conflict-affected contexts therefore requires that researchers and funders reflect even more critically and systematically on every step of the research process – from defining the research agenda and selecting researchers through to data collection, analysis and dissemination and communication of findings. These UKRI and UNICEF reviewer guidelines provide a unique tool for reviewers to assure themselves, as reviewers and/or funders, that research projects funded will give systematic and on going consideration to the ethics of research in fragile and conflict-affected contexts. The tool provides seven criteria for consideration and a checklist for reviewers to use systematically to support their review process…

Editor's note: UK Research and Innovation provides research and innovation funding, funded through the science budget of the Department for Business, Energy and Industrial Strategy.

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COVID-19

A lesson from MMR: is choice of vaccine the missing link in promoting vaccine confidence through informed consent?

Research Article
J O'Neill
Ethics & Behaviour, 20 Apr 2022
Abstract
A recent study suggests that vaccine hesitancy amongst key demographics – including females, younger individuals, and certain ethnic groups – could undermine the pursuit of herd immunity against COVID-19 in the United Kingdom. At the same time, the UK Joint Committee on Vaccination and Immunization (JVCI) indicated that it will not facilitate the choice between available COVID-19 vaccines. This paper reflects upon lessons from the introduction of the UK's combined Measles, Mumps and Rubella (MMR) vaccine strategy of the 1980s when Member of Parliament Miss Julie Kirkbride argued that had parents been allowed to choose between vaccine variants, then the crisis of low herd immunity – and subsequent outbreaks – could have been avoided. This paper explores this argument, as applied to the COVID-19 vaccination strategy, by

considering how three key elements of informed consent – disclosure of risk, benefit, and reasonable alternatives – may be employed to tackle vaccine hesitancy and build vaccine confidence.

Organ transplantation during the COVID-19 pandemic – impact on deceased organ donor referrals and consent rates in the Western Cape, South Africa

H Bookholane, T Du Toit, E Muller, D Thomson

South African Journal of Surgery, 11 April 2022; 60

Abstract

Background

The impact of the COVID-19 pandemic on transplantation is multifactorial. This study reports on its influence on deceased donation for transplantation in the Western Cape.

Methods

The volume of referrals and those who were consented for organ donation in the province in the pre pandemic period of May 2017 to February 2020 were compared to those of the initial pandemic period (March through December 2020).

Results

Prior to the pandemic, there were 201 deceased donor referrals in the Western Cape province – 152 (75.6%) and 49 (24.4%) in public and private sectors, respectively. The mean referral rates ranged between 59 69 referrals per year, translating into a monthly rate of 4.8 (range 2.8–5.8). During the first 10 months of the pandemic, there were 18 referrals – 12 (66.7%) and six (33.3%) in the public and private sectors; a decrease of 63%, with a mean monthly referral rate of 1.8. The overall consent rate prior to the pandemic in the public and private sectors was 36.6% (38% and 27%, respectively) with an increase to 44.4% (37.5% and 62.5%) during the pandemic.

Conclusion

Despite a 10% increase in consent rate for deceased donation during the COVID-19 pandemic, there was a significant decrease in the number of potential donors referred. Strategies to improve organ donation and transplantation during and after the COVID-19 pandemic are required.

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BIOMEDICAL RESEARCH

Informed Consent for Potential Recipients of Pig Kidney Xenotransplantation in the United States

Luz A. Padilla. Daniel Hurst, Kathryn Maxwell, Kennan Gawlowicz Wayne Paris, David Cleveland, David K.C. Cooper

Transplantation, 27 April 2022

Abstract

Clinical trials of kidney xenotransplantation are being considered in the United States. Before this novel procedure can take place, investigators will have to obtain approval from the institutional review board. The consent form that will be used for such a trial and that will receive approval from the institutional review board will be complex. Informed consent—the process by which a research participant provides his/her permission to participate in a clinical trial—is a staple of the research process and most commonly is in the form of a physical document. In the case of a novel procedure with uncertain benefits and risks and a participant population in acute need of a transplant, the consent process is crucial. These complexities may raise several ethical considerations for the initial pig kidney xenotransplantation recipients in the United States that will require adaptations of the required elements of the informed consent process by the US Department of Human and Health Services. The ethical issues include (1) a subject's ability to withdraw from the trial, (2) restrictions on their reproductive rights, and (3) the possibility of the need for quarantine if there

is a perceived risk of xenozoonosis. This article aims to discuss ethical considerations that may challenge the general required elements of the informed consent form stipulated by the 45 Code of Federal Regulations 46 of the US Department of Health and Human Services and to suggest recommendations for deliberation.

Improving Consent and Response in Longitudinal Studies of Aging: Proceedings of a Workshop

Brian Harris-Kojetin

Improving Consent and Response in Longitudinal Studies of Aging: A Workshop, 25 March 2022

National Academies of Sciences, Engineering, and Medicine; Division of Behavioral and Social Sciences and Education; Committee on National Statistics

Excerpt

This Proceedings of a Workshop summarizes the presentations and discussions at the Workshop on Improving Consent and Response in Longitudinal Studies of Aging, which was held virtually and live-streamed on September 27-28, 2021. The workshop was convened by the Committee on National Statistics of the National Academies of Science, Engineering, and Medicine to assist the National Institute on Aging (NIA) with its methodological research agenda and inform the different longitudinal survey programs sponsored by NIA about practices and research to improve response and consent in other survey programs. The workshop was structured to bring together scientists and researchers from multiple disciplines and countries to share their research and insights on how to improve response and consent in large, representative longitudinal studies on aging.

Experimenting with modifications to consent forms in comparative effectiveness research: understanding the impact of language about financial implications and key information

Research

Nyiramugisha K. Niyibizi, Candace D. Speight, Gabriel Najarro, Andrea R. Mitchell, Ofer Sadan, Yi-An Ko, Neal W. Dickert

BMC Medical Ethics, 27 March 2022; 23(34)

Open Access

Abstract

Background

Informed consent forms are intended to facilitate research enrollment decisions. However, the technical language in institutional templates can be unfamiliar and confusing for decision-makers. Standardized language describing financial implications of participation, namely compensation for injury and costs of care associated with participating, can be complex and could be a deterrent for potential participants. This standardized language may also be misleading in the context of comparative effectiveness trials of standard care interventions, in which costs and risk of injury associated with participating may not differ from regular medical care. In addition, the revised U.S. Common Rule contains a new requirement to present key information upfront; the impact of how this requirement is operationalized on comprehension and likelihood of enrollment for a given study is unknown.

Methods

Two online surveys assessed the impact of (1) changes to compensation for injury language (standard vs. tailored language form) and (2) changes to the key information page (using the tailored compensation language form with standard key information vs. modified key information vs. modified key information plus financial information) on both likelihood of enrollment in and understanding of a hypothetical comparative effectiveness trial.

Results

Likelihood of enrolling was not observed to be different between the standard and tailored language forms in Study 1 (73 vs. 75%; $p = 0.6$); however, the tailored language group had a higher frequency of understanding the compensation for injury process specific to the trial (25 vs. 51%; $p < 0.0001$). Modifications to the key

information sheet in Study 2 did not affect likelihood of enrolling (88 vs. 85 vs. 85%; p = 0.6); however, understanding of randomization differed by form (44 vs. 59 vs. 46%; p = 0.002).
Conclusions
These findings suggest that refining consent forms to clarify key information and tailoring compensation for injury language to the nature of the study, especially in the context of comparative effectiveness trials, may help to improve study comprehension but may not impact enrollment.

Obtaining Informed Consent for Research Studies

Book Chapter
Lynne M. Bianchi
Research during Medical Residency, 2022 [Taylor & Francis]
Abstract
This chapter describes how to communicate the information included in our institutional review board-approved consent form in an effective and appropriate manner to optimize comprehension and minimize undue influence and coercion. Effective communication involves more than simply reading the form to someone. Informed consent requires that potential participants are given the required information and sufficient time to decide whether they wish to join a study. The informed consent document and conversations include discussion of the voluntary nature of participation, the study purpose, methods, duration, risks, benefits, confidentiality of records, contact information for questions or concerns. Whether investigator- or participant-initiated withdrawal, if there are treatments, protocols, or follow-up appointments required to protect the well-being of the participant upon study withdrawal, those are explained in the consent form and reviewed during informed consent conversations. A parent or legally authorized representative grants the consent for the individual to participate.

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SOCIAL SCIENCE RESEARCH

Use of pre-enrollment randomization and delayed consent to maximize participation in a clinical trial of opt-in versus opt-out tobacco treatment

Original Research
Babalola Faseru, Laura M. Mussulman, Niaman Nazir, Edward F. Ellerbeck, Elena Shergina, Taneisha S. Scheuermann, Byron J. Gajewski, Delwyn Catley, Kimber P. Richter
Substance Abuse, 18 April 2022; 43(1)
Abstract
Background
Enrollment in smoking cessation trials remain sub-optimal. The aim of this analysis was to determine the effectiveness of a modified Zelen's design in engaging hospitalized patients who smoke in a pragmatic OPT-IN versus OPT-OUT tobacco treatment trial.
Methods
At bedside, clinical staff screened smokers for eligibility, randomized eligible into study arms, and delivered the appropriate treatment approach. Study staff called randomized patients at one-month post-discharge, debriefed patients on the study design, and collected consent to participate. We used frequencies and percentages for categorical variables and means and standard deviations for quantitative variables to describe the characteristics of those who consented and were enrolled versus those who did not enroll. We also compared the characteristics of participants who consented and those who were reached and explicitly refused consent at one-month follow-up. We used the Cohen's d measure of effect size to evaluate differences.

Results
Of the 1,000 randomized, 741 (74.1%) consented to continue in the study at one-month follow-up. One hundred and twenty-seven (12.7%) refused consent and 132 (13.2%) were unreachable. Cohen's d effect size differences between those who consented/enrolled (n = 741) and those who were not enrolled (n = 259) were negligible (<0.2) for age, gender, race/ethnicity, and most forms of insurance. The effect size was small for Medicaid (0.36), and other public insurance (0.48). After excluding those unreached at 1 month (12.7%), there were medium Cohen's d effect size differences between those who consented to participate (n = 741) and those who explicitly refused (n = 127) with respect to age (0.55) and self-pay or no insurance (0.51). There were small to negligible effect size differences with respect to sex, race/ethnicity, and other forms of health insurance.
Conclusions
The modified Zelen's design resulted in successful enrollment of most participants who were initially randomized into the trial, including those not motivated to quit.

The ethical performance of access and consent in ethnographic research on social work encounters with migrant-background service users

Hanna Kara, Maija Jappinen, Camilla Nordberg, Anna-Leena Riitaoja
Qualitative Social Work, 2022; pp 1-16
Open Access
Abstract
In this article, we contribute to an emerging body of literature concerning the often overlooked topics of access and consent in research. We posit our understanding of access and consent as continuous ethical reflection and negotiation, conceptualised here as ethical performance, which is particularly valuable in research in institutional contexts defined by numerous power asymmetries. We draw empirically from research on street level institutional encounters between social work practitioners and migrant-background service users in the Helsinki capital region. Access in this research was a multi-stage process including various stage-related negotiations, and the previous stages always influenced the stages that followed. Nevertheless, access and consent were always erratic and subject to revision. We describe how the need for ethical reflexivity arises in various concrete, often unpredictable, situations, and argue for the importance of paying explicit analytical attention to negotiations regarding access and consent.

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GENOMIC MEDICINE/GENE EDITING

Moving from 'fully' to 'appropriately' informed consent in genomics: The PROMICE framework

Julian J Koplin, Christopher Gyngell, Julian Savulescu, Danya F Vears
Bioethics, 7 April 2022
Abstract
Genomic sequencing technologies (GS) pose novel challenges not seen in older genetic technologies, making traditional standards for fully informed consent difficult or impossible to meet. This is due to factors including the complexity of the test and the broad range of results it may identify. Meaningful informed consent is even more challenging to secure in contexts involving significant time constraints and emotional distress, such as when rapid genomic testing (RGS) is performed in neonatal intensive care units. In this article, we propose that informed consent matters not for its own sake, but because obtaining it furthers a range of morally important goals, such as promoting autonomy, well-being, and trust in medicine. These goals form the basis of a new framework [PROmoting Morally Important Consent Ends (PROMICE)] for assessing the ethical appropriateness of various informed consent models. We illustrate this framework with two

examples: (a) a tiered and layered consent model for obtaining consent for GS, and (b) consent for RGS in critically ill newborns. We conclude that appropriately-rather than fully-informed consent provides the correct standard for genomic medicine and research.

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HEALTH DATA

Machine learning applications in healthcare and the role of informed consent: Ethical and practical considerations

Research Article

Giorgia Lorenzini, David Martin Shaw, Laura Arbelaez Ossa, Bernice Simone Elger

Clinical Ethics, 24 April 2022

Abstract

Informed consent is at the core of the clinical relationship. With the introduction of machine learning (ML) in healthcare, the role of informed consent is challenged. This paper addresses the issue of whether patients must be informed about medical ML applications and asked for consent. It aims to expose the discrepancy between ethical and practical considerations, while arguing that this polarization is a false dichotomy: in reality, ethics is applied to specific contexts and situations. Bridging this gap and considering the whole picture is essential for advancing the debate. In the light of the possible future developments of the situation and the technologies, as well as the benefits that informed consent for ML can bring to shared decision-making, the present analysis concludes that it is necessary to prepare the ground for a possible future requirement of informed consent for medical ML.

Public opinion on sharing data from health services for clinical and research purposes without explicit consent: an anonymous online survey in the UK

BMJ Open, 7 April 2022

Abstract

Objectives

UK National Health Service (NHS/HSC) data is variably shared between healthcare organizations for direct care, and increasingly de-identified for research. Few large-scale studies have examined public opinion on sharing, including of mental health (MH) versus physical health (PH) data. We measured data sharing preferences.

Design/Setting/Interventions/Outcomes

Pre-registered anonymous online survey, measuring expressed preferences, recruiting Feb–Sep 2020. Participants were randomized to one of three framing statements regarding MH versus PH data.

Participants

Open to all UK residents. Participants numbered 29275; 40% had experienced a MH condition.

Results

Most (76%) supported identifiable data sharing for direct clinical care without explicit consent, but 20% opposed this. Preference for clinical/identifiable sharing decreased with geographical distance and was slightly less for MH than PH data, with small framing effects. Preference for research/de-identified data sharing without explicit consent showed the same small PH/MH and framing effects, plus greater preference for sharing structured data than de-identified free text. There was net support for research sharing to the NHS, academic institutions, and national research charities, net ambivalence about sharing to profit-making companies researching treatments, and net opposition to sharing to other companies (similar to sharing publicly). De-identified linkage to non-health data was generally supported, except to data held by private

companies. We report demographic influences on preference. A majority (89%) supported a single NHS mechanism to choose uses of their data. Support for data sharing increased during COVID-19.
Conclusions
Support for healthcare data sharing for direct care without explicit consent is broad but not universal. There is net support for the sharing of de-identified data for research to the NHS, academia, and the charitable sector, but not the commercial sector. A single national NHS-hosted system for patients to control the use of their NHS data for clinical purposes and for research would have broad support.

Foundations for Meaningful Consent in Canada's Digital Health Ecosystem: Retrospective Study

Nelson Shen, Iman Kassam, Haoyu Zhao, Sheng Chen, Wei Wang, Sarah Wickham, Gillian Strudwick, Abigail Carter-Langford

JMIR Medical Informatics, 31 March 2022; 10(3)

Abstract
Background
Canadians are increasingly gaining web-based access to digital health services, and they expect to access their data from these services through a central patient access channel. Implementing data sharing between these services will require patient trust that is fostered through meaningful consent and consent management. Understanding user consent requirements and information needs is necessary for developing a trustworthy and transparent consent management system.
Objective
The objective of this study is to explore consent management preferences and information needs to support meaningful consent.
Methods
A secondary analysis of a national survey was conducted using a retrospective descriptive study design. The 2019 cross-sectional survey used a series of vignettes and consent scenarios to explore Canadians' privacy perspectives and preferences regarding consent management. Nonparametric tests and logistic regression analyses were conducted to identify the differences and associations between various factors.
Results
Of the 1017 total responses, 716 (70.4%) participants self-identified as potential users. Of the potential users, almost all (672/716, 93.8%) felt that the ability to control their data was important, whereas some (385/716, 53.8%) believed that an all or none control at the data source level was adequate. Most potential users preferred new data sources to be accessible by health care providers (546/716, 76.3%) and delegated parties (389/716, 54.3%) by default. Prior digital health use was associated with greater odds of granting default access when compared with no prior use, with the greatest odds of granting default access to digital health service providers (odds ratio 2.17, 95% CI 1.36-3.46). From a list of 9 information elements found in consent forms, potential users selected an average of 5.64 (SD 2.68) and 5.54 (SD 2.85) items to feel informed in consenting to data access by care partners and commercial digital health service providers, respectively. There was no significant difference in the number of items selected between the 2 scenarios (P>.05); however, there were significant differences (P<.05) in information types that were selected between the scenarios.
Conclusions
A majority of survey participants reported that they would register and use a patient access channel and believed that the ability to control data access was important, especially as it pertains to access by those outside their care. These findings suggest that a broad all or none approach based on data source may be accepted; however, approximately one-fifth of potential users were unable to decide. Although vignettes were used to introduce the questions, this study showed that more context is required for potential users to make informed consent decisions. Understanding their information needs will be critical, as these needs vary with the use case, highlighting the importance of prioritizing and tailoring information to enable meaningful consent.

A Big Data Framework for Consent

Book Chapter

Wei Yap, Muhammad Rizwan Asghar

Trust, Security and Privacy for Big Data, 2022 [Taylor&Francis]

Abstract

Privacy is a vast and vital area of law with possibly diverse interpretations, legislation and standards worldwide with the aim to protect data. Consent plays a vital role in preserving privacy as it ensures that all involved parties understand the reason for the use and collection of data. Many organisations still have lengthy guidelines that cause legibility and usability issues. This makes it difficult for a data subject to understand what they are consenting to and creates a restrictive environment for consent. Unfortunately, existing works do not provide any solution for implementing a dynamic privacy consent framework. In this book chapter, we aim at presenting a dynamic consent framework for big data to ensure that each privacy consent policy is legible, understandable, usable, and customisable. We propose a new method to communicate, analyse, and request consent from a data subject in a way that is simple and understandable. We also aim to ensure that this framework does not increase the burden on data subjects to provide consent while implementing an ability to simplify and audit the consent process.

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CAPACITY TO CONSENT

Research Ethics and Intellectual Disability

Book Chapter

Kevin Mintz, David Wasserman

The Disability Bioethics Reader, 2022 [Routledge]

Abstract

This chapter focuses on the exclusion of people with cognitive disabilities from research that is not related to their disabilities. Wasserman and Mintz argue that despite real limitations with regard to consent (most people with cognitive disabilities will only be able to assent), denying people with cognitive disabilities the ability to participate in research is largely unjustifiable. Moreover, it has effects that ought to be avoided namely, moral harm of persons with cognitive disabilities and increased vulnerability to abuses and violations when they do participate in research. Wasserman and Mintz argue that there is no good reason to exclude people with cognitive disabilities on the basis of their limitations, especially because people of similar cognitive ages are able to participate in research.

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YOUNG PERSONS

Living bioethics, theories and children's consent to heart surgery

Research Article

Priscilla Alderson, Deborah Bowman, Joe Brierley, Nathalie Dedieu, Martin J Elliott, Jonathan Montgomery, Hugo Wellesley

Clinical Ethics, 7 April 2022

Abstract

Background

This analysis is about practical living bioethics and how law, ethics and sociology understand and respect children's consent to, or refusal of, elective heart surgery. Analysis of underlying theories and influences will contrast legalistic bioethics with living bioethics. In-depth philosophical analysis compares social science traditions of positivism, interpretivism, critical theory and functionalism and applies them to bioethics and childhood, to examine how living bioethics may be encouraged or discouraged. Illustrative examples are drawn from research interviews and observations in two London paediatric cardiac units. This paper is one of a series on how the multidisciplinary cardiac team members all contribute to the complex mosaic of care when preparing and supporting families' informed consent to surgery.

Results

The living bioethics of justice, care and respect for children and their consent depends on theories and practices, contexts and relationships. These can all be undermined by unseen influences: the history of adult-centric ethics; developmental psychology theories; legal and financial pressures that require consent to be defined as an adult contract; management systems and daily routines in healthcare that can intimidate families and staff; social inequalities. Mainstream theories in the clinical ethics literature markedly differ from the living bioethics in clinical practices.

Conclusion

We aim to contribute to raising standards of respectful paediatric bioethics and to showing the relevance of virtue and feminist ethics, childhood studies and children's rights.

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RIGHTS/LEGAL/LEGISLATIVE

Who Decides?: Informed Consent Doctrine Applied to Denial of Reproductive Health Care Information at Crisis Pregnancy Centers

Kassandra DiPietro

Iowa Law Review, March 2022; 107(3) pp 1253-1281

Abstract

Crisis pregnancy centers are largely religiously affiliated organizations that advertise pregnancy support but often do not provide full and accurate information about abortion or contraception. Often attacked for false advertising and operating without medical licenses, crisis pregnancy centers recently have begun converting to medical centers with medical staff on site. Since medical providers owe additional duties to their patients, crisis pregnancy centers operated by medical staff must follow additional procedures, such as providing informed consent. Informed consent doctrine is based on the idea of autonomous decision-making and requires medical providers to accurately inform patients of their viable medical options. Even though crisis pregnancy centers often fail to inform people about critical reproductive health care, people who visit crisis pregnancy centers still would have difficulty bringing a claim of informed consent against these centers. Applying informed consent doctrine to crisis pregnancy centers highlights the discrepancy between the philosophical purpose of informed consent and the doctrine in practice today. Courts should loosen the causation and injury requirements for informed consent doctrine, at least in reproductive health care cases. Making this change would be the first step in holding crisis pregnancy centers accountable and could help courts more accurately apply reproductive-specific tort claims generally.

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FREE PRIOR INFORMED CONSENT (FPIC)

Free prior and informed consent and Indigenous rights: a bulwark against discrimination and platform for self-determination

Book Chapter

Cathal Doyle

Research Handbook on the International Law of Indigenous Rights, 12 April 2022; pp 96-128 [Edward Elgar]

Abstract

This chapter examines the development of free prior and informed consent (FPIC) norms in the international law of Indigenous rights. The first section traces the international law lineage of FPIC from initial colonial encounters through to contemporary Indigenous rights instruments. The second part probes more deeply into the cotemporary concept of FPIC based on extensive jurisprudence and recommendations, linking FPIC to self-determination and non-discrimination. The third part provides some perspective on state measures undertaken to implement FPIC and closes with attention to roles taken up by Indigenous peoples themselves in doing so.

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CULTURAL/COUNTRY CONTEXT

Tips for Managing Ethical Challenges in Advance Care Planning: A Qualitative Analysis of Japanese Practical Textbooks for Clinicians

Article

Environmental Research and Public Health, 9 April 2022

Yoshihisa Hirakawa, Kaoruko Aita, Mitsunori Nishikawa, Hidenori Arai, Hisayuki Miura

Abstract

Background

While advance care planning (ACP) provides healthcare professionals with valuable tools to meet patients' needs in a person-centered manner, several potential ethical challenges are inherent to the process. However, recent studies have largely focused on ACP practicalities such as implementation, execution, and completion rather than on the ethical challenges that clinicians routinely encounter in ACP practices.

Research question/aim/objectives

This study aimed to identify tips for clinicians managing ethical challenges in ACP practices.

Methods

It performed a brief search for all Japanese published books pertaining to ACP practice available as of January 2021 using the keywords "advance care planning (ACP)" and "autonomy" and analyze the content of nine practical ACP textbooks for clinicians.

Results

Two major themes capturing the essential recommendations for managing ethical challenges in ACP were ultimately identified, namely interprofessional ethics and informed consent.

Conclusion

The findings suggested tips for managing ethical challenges in ACP: refer to ethical frameworks for interprofessional collaboration and ethical decision making, assess decision-making capacity of family substitute decision makers and one's eligibility for the role, understand the standard process of informed consent and how to handle situations when the patient are not well informed about the diagnosis and prognosis of non-cancer illness.

Study about Informed Consent for Surgical Care in East Africa

Richard Wismayer

New Horizons in Medicine and Medical Research, 6 April 2022; 3 pp 210-215

Abstract

In the developed world, informed surgical consent is one of the pillars of ethical conduct in surgical practise. Only a few researchers in low-income developing countries have investigated the practise of pre-operative surgical consent. During the informed consent process, the patient has the right to make an autonomous and independent decision about his or her surgical treatment after the surgeon caring for the patient has provided the necessary information. The World Medical Association (WMA) Declaration of Lisbon encourages patient autonomy and independent decision-making. Informed consent in surgical practise may be influenced by factors such as family and cultural background, education, religion, and socioeconomic status. Few studies have reviewed consent practises among surgeons in East Africa to document best surgical practises and identify areas for improvement in the East African setting. The purpose of this review was to report on the authors' personal experiences with surgical consent among Ugandan surgeons, as well as to discuss the specific challenges faced in East Africa. In Uganda, informed consent administration and documentation remain deficient. In medical schools, better medical ethics education and communication skills training are required. For fully trained surgeons, refresher courses in medical ethics and communication skills may also be required.

Examining Informed Consent Processes for Indigenous families in Research: A Scoping Review Protocol

Cindy Peltier, Lorrilee McGregor, Mia Bourque, Irina Oltean, Nancy Young

Open Science Forum, 4 April 2022

Abstract

Introduction

Though numerous research pursuits in Indigenous communities have been undertaken, very few have consistently addressed community priorities, or collaborated with Indigenous peoples throughout the research process. This scoping review protocol proposes to explore the existing wise consent processes that respect the rights of Indigenous families (parents, children), and Indigenous community protocols.

Methods and analysis

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for conducting scoping reviews will be followed closely. All primary and theoretical studies of any design written in English from January 1st 2000 to March 31st 2022 examining Indigenous approaches to obtaining informed consent among parents or families and/or children and youth, will be included. Two reviewers will independently review the literature in order to apply the inclusion and exclusion criteria. Data from studies will be extracted and charted in NVivo, following the Arksey and O'Malley's (2005) framework. The Critical Appraisal Skills Programme (CASP) checklists, depending on the study design of each included study, and the original and modified Aboriginal and Torres Strait Islander Quality Appraisal Tool (ATSI) versions, will be used to assess study quality. A narrative synthesis of the informed consent literature will be reported.

Dissemination

This scoping review will evaluate the existing informed consent processes, barriers to consent, and alternative consent processes in the literature. Results will be shared via conferences, reports and social media with our Indigenous communities, and disseminated through a peer-reviewed publication. This scoping review may prove useful to others who are investigating informed consent processes among Indigenous families in research.

Comparative analysis of informed consent for spine surgery in patients in Ethiopia and Poland and the importance of verbal contact with patients based on the medical mission "Polish Medical Team Helping Hand"

Zygmunt Siedlecki, Abat Sahlu, Adu Sileshy, Surafel Mekonnen Mendere, Amanuel Firew Dilnesaw, Yemisirach Bizuneh, Sebastian Grzyb, Bizuayehu Mengesha Tegene, Abenezer Tirsit, Maciej Śniegocki

Journal of Education, Health and Sport, 3 April 2022; 12(2)

Abstract

The authors present a comparative analysis of the issue of legal consents for surgical procedures between Ethiopia and Poland. The analysis is based on the procedures performed as part of the Polish medical mission "Polish Medical Team Helping Hand". As part of this project, the authors performed ten surgical procedures for percutaneous spine stabilization in soldiers injured during the war with gunshots of the spine and after falling from a height. All soldiers signed informed written consent to the procedure. However, the authors noticed a significant role of additional oral/ verbal (not written) information in discussing the details of the procedure, which in Polish hospitals must be in writing for formal and legal reasons. The authors conclude that while the written consent for surgical treatment is key and necessary both in Poland and in Ethiopia, in the case of medical procedures performed in Ethiopia, oral communication between the doctor and patients and oral explanations are more binding even regardless of the language barrier.

Informed consent in dentistry and medicine in Spain: Practical considerations and legality

M Otero, N Oishi, F Martínez, M-T Ballester, J Basterra

Medicina oral, patología oral y cirugía buccal, 3 April 2022

Abstract

Background

The healthcare practice of dentistry, as well as medicine, is framed within a legal environment. Patients have the right to know all the information related to any action performed on them and dental or medical doctors are obliged to obtain their patient's prior written informed consent (IC) before undertaking any healthcare procedures.

Material and methods

Here we reviewed the legality and jurisprudence in Spain regarding IC. We also used INFLESZ text readability analysis software to analyse a sample of official Spanish informed consent documents (ICDs) from different surgical and interventional procedures related to dentistry and oral cavity interventions.

Results

It is a mistake to confound IC with ICDs. This error prevents physicians from considering the former as a care process in which the patient's authorisation signature is the last link in a chain formed, almost in its entirety, by the informative process and deliberation alongside the patient. Multiple factors can influence communication between practitioners and their patients. Importantly, treatment adherence is greater when patients feel involved and autonomous in shared decision-making and when the circumstances of their lives are adequately considered. We concluded that although the ICDs we analysed conformed to the requirements set out in international law, they were somewhat difficult to read according to the reading habits of the general Spanish population.

Conclusions

Knowledge about the legality of IC helps professionals to understand the problems that may arise from their non-compliance. This is because the omission or defective fulfilment of IC obligations is the origin of legal responsibility for medical practitioners. In this sense, to date, there have been more convictions for defective ICs than for malpractice. The information provided in ICs should include the risks, benefits, and treatment alternatives and must be tailored to the needs and capabilities of the patient to enable autonomous decision-making.

Factors affecting willingness to participate in vaccine clinical trials in an underdeveloped country: perspective from Nepal

Research Paper

Ram Hari Chapagain, Santosh Adhikari, Bishnu Rath Giri, Pankaj Ray, Nisha Jyoti Shrestha, Bina Prajapati, Prakash Joshi, Sunita Pokharel, Suresh Man Tamang, Birendra Prasad Gupta, T. Anh Wartel, Sushant Sahastrabuddhe, Ganesh Kumar Rai, Tarun Saluja

Human Vaccines & Immunotherapeutics, 6 March 2022

Open Access

Abstract

Due to the inherent complex nature of clinical trials, individual's willingness to participate and hence, enrollment in a clinical trial maybe challenging. When it comes to vaccine clinical trial in children, informed consent needs to be secured from the parents or legally acceptable representatives (LARs). Some of the factors which contribute to hesitancy in taking part in clinical trials are based on the level of education, living standards, part of the world they live, associated burden of disease, fear of different procedures in clinical trial, side effects, limited understanding, limited time, and mistrust with Investigational product. This study included 201 parents/LARs, who approached Kanti Children Hospital site in Kathmandu with the interest to get their children enrolled in a vaccine clinical trial with objectives of describing the reasons for agreeing or disagreeing to participate in the vaccine clinical trial, factors affecting decision making, and finding the major concerns of parents/LARs. The acceptance for the study vaccine was 136 (67.7%) whereas denial was 65 (32.3%). This study showed that age, education level, family structure, advice from family and friends, and medical guidance play important roles in willingness of parents to get their child enrolled in the trial. If a proper counseling is done, fear of blood sampling is not a big factor which is contrary to the belief among clinical researchers. Safety of vaccine, frequency of injections, and cost of vaccine were the main concerns of the parents, which need to be addressed extensively while planning for any clinical trial in children.

Informed consent forms for gynecologic cancer surgery: recommendations from the Korean Society of Gynecologic Oncology

장하균, 심승혁, 이마리아, Won Moo Lee 오경진, 유헌종, 김미경, 김민규, 이광범, 소경아, 김영태, 이대우, Doo-Yoon Hyun 이종민

Obstetrics & Gynecology Science, March 2022; 65(2) pp 105 - 112

Abstract

The sociomedical environment is changing. In the traditional physician-patient relationship, the physician was authoritative and the patient was obedient. The contractual relationship featured patient consent to the physician's decision. Today, the physician must explain fully the planned medical treatment, and any alternative, to the patient, who has the right to choose her treatment after considering the benefits and side-effects. The Korean Society of Gynecologic Oncology thus decided to standardize the surgical consent forms to meet the legal requirements of modern medicine, improve patient understanding of the surgical details, and protect medical staff from legal disputes. To determine the format and content, subcommittees for each cancer type collected and reviewed all relevant articles and the current consent forms of domestic medical institutions. After several meetings, 16 basic items to be included for each type of gynecologic cancer were selected. Also, to help patients understand the surgical details, figures were included. The revised forms were legally reviewed in terms of the appropriateness of the format and content. We also developed English versions to provide adequate information for foreign patients. We hope that these efforts will promote trust between patients and physicians, and contribute to effective treatment by laying a foundation of mutual respect.

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MEDICAL/SURGICAL

Consent for trainee participation in abortion care: A clinical survey

Meeting Report

Lara Crystal-Ornelas, Jessica Ma, Kelsey Holt, Christine Dehlendorf

The Annals of Family Medicine, 20 April 2022

Abstract

Context

Abortion care is an essential form of primary healthcare and is included in primary care medical training. Obtaining informed consent for trainee involvement in abortion care requires careful attention to avoid harm for patients while ensuring adequate training for the future provision of healthcare. Policies and practices related to obtaining this consent have not previously been documented; doing so has the potential to inform the development of future guidelines.

Objective

To identify current clinical practices, policies, and perspectives related to informed consent for trainee participation in abortion care.

Study Design

Cross-sectional study using a REDCap survey.

Setting

Abortion clinics training medical students and Family Medicine (FM) and/or Obstetrics and Gynecology (OBGYN) residents.

Population Studied

Surveys were disseminated via email to directors of resident abortion training programs, with 46 responses (one per site) were collected in total. Of these sites, 67% were located in large cities, 44% were ambulatory care clinics within hospitals, and 20% were resident primary care clinics. The most common trainees at these sites were OBGYN residents (83%), medical students (70%), and FM residents (30%).

Results

Just under half - 48% - reported their site has an informed consent form that mentions trainee involvement in abortion care, while 52% reported no mention of trainee involvement in their forms. With respect to policy, 65% reported their site has a general policy for trainee involvement in healthcare while 15% reported having no such policy. Notably, 20% reported not knowing whether such a policy exists. While 46% expressed the belief that asking patients specifically about trainee involvement in abortion care is very or extremely important, 80% of respondents reported that their clinical site does not provide training on obtaining this consent. Answers varied widely as to who conducts consent for trainee involvement and when consent occurs.

Conclusions

Survey responses illustrated a wide variability in clinical practices and perspectives around consent for trainee involvement in abortion care. Given the sensitive and stigmatized nature of abortion care, guidelines for the consent process can ensure that patient needs are met and their autonomy respected. Research is needed to assess patient perspectives to inform the development of these guidelines.

Informed Consent in Endoscopy: Read, Understood or Merely Signed

A.C. Carvalho, R. Cardoso, F. Pires, S. Ventura, C. Rodrigues, Â. Domingues, J. Pinho, D. Martins, P. Sousa, R. Araújo, E. Cancela, A. Castanheira, P. Ministro, M. Vieira, A. Silva

Endoscopy, 14 April 2022; 54(S01)

Abstract

Aims

While informed consent is a requirement for all invasive procedures such as those in gastrointestinal endoscopy, its standardization is a challenge. Recently, our national digestive endoscopy society developed

proposals for informed consent forms and information leaflets for esophagogastroduodenoscopy and colonoscopy. The main objective was to evaluate if patients read and understood these documents.
Methods
Adult patients proposed for elective esophagogastroduodenoscopy and colonoscopy and who were able to give their informed consent were included. Informed consent forms and information leaflets were sent to patients, with a small text instruction added to the body of the informed consent form. Prior to endoscopy it was assessed whether patients adequately read the informed consent form, based on 3 criteria: patient signature, table questionnaire completion and performance of the text instruction.
Results
In total, 184 patients were included: 80 women and 104 men with a mean age of 63.6±12.4 years. Most had only basic education (77.2%) and had previously undergone an endoscopy (91.8%). 157 patients stated they had read the form (85.3%), while 27 (14.7%) did not. While most signed the form (141, 76.6%), only 46 patients (25.0%) met all 3 criteria for adequate reading and comprehension. No statistically significant association between informed consent form adequate reading and any of the assessed variables was found.
Conclusions
Most patients do not adequately read informed consent forms. Infographic strategies can direct patients' attention and may improve these results, but they are no substitute of an effective doctor-patient relationship in obtaining informed consent.

Use and Perceptions of Shared Decision-Making by General Surgery Faculty and Trainees

Maham Javaid, Melanie Fritz, Mollie O'Brien, Sunday Clark, Suzanne Mitchell, Sabrina E. Sanchez
Journal of Surgical Research, 10 March 2022; 276 pp 323-330
Abstract
Introduction
The purpose of this study was to assess the practice and perceptions of shared decision-making (SDM) by both faculty and residents at Boston Medical Center and explore barriers and facilitators to implementing SDM at our institution.
Methods
We created and distributed an online survey assessing provider demographic and training characteristics, experiences with the informed consent process, practices in SDM, and perceptions about SDM. We used descriptive statistics to summarize provider characteristics and survey responses and univariate analysis to determine associations between them.
Results
Fifteen surgeons and 19 surgical residents completed the survey (49% response rate). Most respondents were aware of and had a positive attitude toward SDM (91% and 76%, respectively); 35% reported having SDM training. Providers had varying levels of engagement with different SDM practices, and there were inconsistent associations between provider characteristics and the use of SDM. Often providers thought the patient's health literacy, foreign primary language, clinical condition, and socioeconomic factors were barriers to the SDM process.
Conclusions
Although most general surgery faculty and residents at our institution had a positive view of SDM, they engaged in SDM behaviors inconsistently, with no clear association between clinician characteristics and specific behaviors. We identified several barriers to SDM consistent with those identified by providers in other specialties. This highlights the need for further research to study live general surgery provider-patient interactions, as well as structured SDM education to train general surgery providers to reliably engage their patients in effective SDM.

Procedure and Informed Consent of Patients for Capsule Endoscopy

Book Chapter

Byung Ik Jang

Small Intestine Disease, 5 April 2022; pp 79-82 [Springer]

Abstract

Capsule endoscopy allows the intestinal mucosa of patient to be examined without discomfort after a patient swallows the capsule for small intestinal examination. When conducting capsule endoscopy for diagnosing small intestinal disease, medical staffs must be fully aware of the entire procedures to ensure quality of capsule endoscopy and improvement of diagnosis. When conducting capsule endoscopy, patients must be fully informed of the preparation process before examination, the endoscopy itself and provisions after the examination. After being informed of all needed information, patients can then sign the consent for capsule endoscopy.

Awareness on consent and counselling among patients attending tertiary care hospitals : a cross-sectional study

M. S. Rao, P. Sagar, B. V. S. R. Kumari

Sri Lanka Journal of Surgery, 31 March 2022

Abstract

Introduction

Surgical consent and counselling are an integral part of medical practice and medical education. This study was done to know how many of the residents provide complete and accurate information to the patient during their training period.

Methods

Sixty residents from various surgical departments and 40 patients who were undergoing surgery were selected. The data was collected through interviews using two different questionnaires. The resident's questionnaire provided the information they provide to patients. The patient's questionnaire provided information on the level of their understanding from the interaction. Data were analysed using coGuide.

Results

Out of 60 residents, 56(92 %) reported that the side effects and consequences were explained fully. 25% of residents mentioned the name of the surgery and nearly 100% did not mention the operating surgeon's or unit in charge name. About 79% of residents felt that the patient was convinced with their way of communication, nearly 93 % of patients were convinced their disease process was explained well and 50% felt that the doctor informed the consequences of surgery well. 75% responded that doctor did not inform about the side-effects 98% were not aware of the alternative forms of treatment and, 87% of patients were not informed about the chances of recurrence of disease where ever applicable.

Conclusion

The majority of residents were convinced that their conveying skills are adequate for surgical counselling but they felt the need to improve. The majority of patients denied discussing complications when occurred.

Toolkit for the management of breast implants and the importance of Informed educated consent

Editorial

Anand K Deva, Mark Ashton

Australasian Journal of Plastic Surgery, 31 March 2022; 5(1)

Open Access

Abstract

Breast implants have had a long and chequered history of periodic regulatory activity and class actions and are associated with significant medium and long term health risks, including the development breast implant associated anaplastic large cell lymphoma (BIA-ALCL). NSW Health through the Agency of Clinical Innovation

has just released a toolkit for the management of breast implants. These are the result of collaborative clinical consensus across leaders in plastic and reconstructive surgery, breast surgery and radiology with support from the Surgical Services Taskforce and evidence directorate of the agency. Input was also sought from health consumers to ensure that the language and structure of the information was both comprehensive and accessible to women who were either considering either cosmetic augmentation or reconstruction and/or have breast implants in place.

Patient Satisfaction with Informed Consent for Cesarean and Operative Vaginal Delivery

Karen S. Levy, Martha K. Smith, Meagan Lacroix, Mark H. Yudin

Journal of Obstetrics and Gynaecology Canada, 29 March 2022

Abstract

Objective

To evaluate patient satisfaction with the informed consent process for elective cesarean delivery (CD), emergency CD, and operative vaginal delivery (OVD).

Methods

A cross-sectional, survey-based study was conducted among patients on the postpartum floor of our institution. Patients were approached after delivery to complete a previously pilot-tested questionnaire, based on validated literature. One hundred eighty-four surveys were included in the analysis. Levels of patient satisfaction were compared across modes of delivery using $\chi 2$ tests of independence. Secondary objectives included evaluating the relationship between satisfaction scores and the patient's recall of the consent process and emotional state during the consent process.

Results

A significant association was found between patient satisfaction with the consent process and mode of delivery ($P < 0.001$). Those in the elective and emergency CD groups were significantly more likely to express high rates of satisfaction compared with those in the OVD group (odds ratio [OR] 9.03; 95% CI 2.80–29.10 and OR 3.97; 95% CI 1.34–11.76, respectively). High levels of satisfaction were significantly more common among those who had greater recall of the consent process (OR 25.2; 95% CI 7.34–87.04) and those who reported low levels of distress during the process (OR 15.1; 95% CI 4.70–48.66).

Conclusion

Informed consent during OVD is associated with lower rates of patient satisfaction compared with CD. Efforts are needed to improve the consent process for OVD to increase patient satisfaction and promote patient-centred care.

The Consent Process for Elective Hip and Knee Arthroplasty: Does Information on Handwritten Forms Meet Prescribed Standards?

Anirudh Sharma, Osasumwen Adelowo, Santosh Bindumadhavan, Naufal Ahmed, Amir-Reza Jenabzadeh

Cureus, 28 March 2022; 14(3)

Abstract

Introduction

The process of informed consent is vital, not only to good clinical practice and patient care, but also to avoid negligence and malpractice claims. Elective hip and knee arthroplasty numbers are increasing globally, and the British Orthopaedic Association (BOA) has endorsed standards for obtaining written consent for these procedures. Many centres in the United Kingdom and globally, use handwritten consent forms to document informed consent, leaving open the potential for missing out important procedure and risk-related information. Our study aimed to assess whether information on handwritten consent forms was compliant with BOA standards for elective arthroplasty of the hip and knee.

Methods

We retrospectively reviewed 70 handwritten consent forms, across theatre lists of 12 arthroplasty consultants at our elective arthroplasty centre. These included 35 forms each for hip and knee arthroplasty

respectively. We compared the information on these forms to the standards prescribed by the BOA. We assessed compliance of the forms with common, less common and rare risks of hip and knee replacement, as described by the BOA. We also noted the designation of the person filling out the form (consultant, registrar or nurse practitioner) and whether this affected information on the form. We assessed the forms for legibility issues, and whether the setting (clinic/pre-operative ward) affected information on the form.

Results

None of the 70 forms reviewed achieved full compliance with BOA standards. When assessed for common risks of hip and knee arthroplasty, the number of compliant forms was 25.7% and 42.8%, respectively. None of the forms mentioned all rare risks of either hip or knee arthroplasty. We identified legibility issues in 12 of 70 (17.1%) forms. There was no significant difference in information written on forms filled out by consultants, registrars or nurse practitioners, or between forms filled out in the clinic versus those on the pre-operative ward.

Conclusion

Handwritten forms lack compliance with prescribed standards for written informed consent in elective hip and knee arthroplasty. Ideally, a pre-written consent form should be used, but with the option of adding information individually tailored to the patients' background. This ensures that good clinical practice is optimally followed, and reduces the potential risk of any litigation.

Informed Consent is Poorly Documented when Obtaining Toxicology Testing at Delivery in a Massachusetts Cohort

Kathleen J.Koenigs, Joseph H. Chou, Samuel Cohen, Moira Nolan, Gina Liu, Mishka Terplan, Brian M. Cummings, Timothy Nielsen, Nicole A. Smith, Joseph Distefano, Sarah N. Bernstein, Davida M. Schiff

American Journal of Obstetrics & Gynecology MFM, 27 March 2022

Abstract

Background

Positive toxicology testing at delivery can have enormous consequences for birthing persons and their families, including charges of child abuse/neglect and potential loss of custody for the birthing parent. State and national guidelines therefore stipulate clinicians should obtain consent prior to toxicology testing at delivery.

Objective

We examined: (1) clinician documentation of patient consent for peripartum toxicology testing and (2) the extent to which patient and hospital characteristics were associated with documented consent.

Study Design

Retrospective cohort of individuals who underwent toxicology testing within 96 hours of delivery between April 2016 and April 2020 at five affiliated hospitals across Massachusetts. Medical records were reviewed for documentation of: clinician intent to obtain maternal toxicology, testing indication, verbal consent to testing, and child protective services involvement. Hierarchical multivariable logistic regression was used to examine the association between patient and hospital characteristics and documentation of verbal consent.

Results

Among 60,718 deliveries, 1562 maternal toxicology tests were obtained. Verbal consent for testing was documented in 29.8% of cases (n=466). Documented consent was lacking across most demographic groups. Consent was no more likely to be documented when a report was filed with child protective services, and less likely in cases where the birthing parent lost custody prior to discharge (p=.003). In our multivariable model, consent was least likely to be documented when a maternal complication (abruption, hypertension, preterm labor, preterm premature rupture of membranes, intrauterine fetal demise) was the indication for testing (aOR, 0.46; CI, 0.28 to 0.76). Verbal consent was twice as likely to be documented in delivery hospitals with established consent policies (aOR, 2.10; CI, 1.01 to 4.37).

Conclusion

Consent for toxicology testing at delivery appears to be infrequently obtained based on clinician documentation. Provider education and hospital policies for obtaining informed consent are needed to protect the rights of birthing individuals.

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GENERAL/OTHER

Will obtaining digital consent from patients in advance of undergoing procedures improve the quality of the consent process?

Opinion
Tessa Richards
BMJ, 26 April 2022; 377
Open Access
Excerpt
…During my patient journey I have always (as here) been "consented" for procedures on the day. While I have read up about—and mentally committed to—the interventions in advance, pre-operative anxiety has meant I have been quite unable to take in information, let alone pose questions, as my doctors have sped through the standard spiel on potential risks and harms…

Surgeons, Hernia Surgery and Informed Consent in the Seventeenth Century Ottoman Istanbul

Surgical History
Mahmut Said Degerli
World Journal of Surgery, 10 April 2022
Abstract
Background
In the seventeenth century Ottoman Istanbul, especially Greek surgeons specialized in hernia surgery. Both Muslim and non-Muslim patients had signed contracts with surgeons in sharia courts before undergoing a surgery. In this study, we analyze these documents, which serve as informed consent in the Ottoman period, in detail.
Methods
We used Istanbul Sharia Court Registers (Istanbul Sicils) as the primary information source. We scanned a total of twenty nine registers dating back to the seventeenth century. In six of these registers, we determined a total of twenty one informed consents (known as rıza senedi in Turkish literature) regarding hernia surgery and surgeons. Based on these data, we examined the surgeons and hernia surgeries, the fees received by surgeons, and the informed consent documents of the seventeenth-century Istanbul.
Results
In the scanned informed consents, we identified five male surgeons and twenty one patients. While four of the surgeons were Greek, one of them was Muslim. The contracts show that the patients were informed about possible complications before operations, and their permissions were obtained accordingly. The contracts also clearly state that a blood-money from the surgeons would not be requested if a patient dies during or after an operation. The cost of operations ranged between 500 and 2100 akče.
Conclusions
The patient-physician relationship in Ottomans was seen as a business relationship. Medical processes were recorded in courts before treatment fees were paid. These court records had been a practice that protected the patients and the physicians in terms of criminal liability.

Consent, Interaction, and the Value of Shared Understanding

Research Article

Richard Healey

Legal Theory, 28 March 2022; 28(1) pp 35 - 58

Abstract

Recent years have seen a proliferation of philosophical work on consent. Within this body of work, philosophers often appeal to an account of the interests, values, or functions that underpin the power of consent. By far the most commonly cited value realized by the power of consent is the promotion and protection of the power-holder's autonomy. This focus on autonomy yields what I call the Gate Opener Model of consent, according to which the central valuable function of consent is to give the power-holder control over whether other people can act in certain ways. In this article, I argue that the Gate Opener Model of consent is inadequate. I then defend an alternative Relational Model of consent, according to which a central valuable function of consent is to enable a non-instrumentally valuable form of interaction between people.

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