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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

October 2021

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

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

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

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Editor's Note:
On September 15th 2021 the GE2P2 Global Foundation's Center for Informed Consent Integrity continued a series of webinars focused on integrity in informed consent. Dr. Eline M. Bunnik of Erasmus University shared perspectives from her May 2021 paper Mainstreaming informed consent for genomic sequencing: A call for action. During her presentation Dr. Bunnik also provided detail on the consortium and the help desk capability that was formed during this research. Her presentation was followed by an open discussion involving all call participants.

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

No new content identified for the following established categories:
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH

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

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COVID-19

Parental consent for the Covid-19 vaccine in children

Andrew Power
Practice Management, 17 September 2021; 31(8)
Abstract
Parents may not always agree on childhood immunisation and this may also apply to the Covid-19 vaccination. Dr Andrew Power, Medicolegal Consultant at Medical Protection, discusses how to resolve parental disagreement.

COVID-19 Vaccines and their Pitfalls in Informed Consent

Yousef Haik, Eleni Polymenopoulou
Hastings Science and Technology Law Journal, Summer 2021; 12(2)
Abstract
The World Health Organization declared the coronavirus (COVID-19) pandemic as a global health crisis. The search for a coronavirus vaccine escalated to a global competition. Drugs for other diseases as well as new formulations are proposed as potential candidates for the treatment or intervention of coronavirus. Almost all pharmaceutically able countries are pursuing potential vaccines. At the time of writing this article, two vaccines are already marketed and tested with promising interim results. Both vaccines use messenger RNA (mRNA) encapsulated in a lipid nanocarrier. Under ordinary circumstances, clinical trial authorizations oblige sponsors to disclose all risks to volunteers in order to formulate an informed knowledgeable decision. This however has been subject to exceptions during the pandemic. The mRNA-based vaccine has been rushed in unprecedented record speed to human clinical efficacy evaluation. This raises a number of questions related to the validity of volunteers' free and informed consent. The present article argues that informed consent of all risks as well as the protection of volunteers' personal data constitute concrete obligations under human rights law that cannot be derogated from in times of emergency – such as the COVID-19 pandemic. Furthermore, it suggests a risk governance framework through blockchain for international vaccine testing clinical trials.

Legal and Ethical Issues Around COVID-19 Vaccination Consent in Italian Children From 12 Years of Age

Roberto Scendoni, Nunzia Cannovo, Piergiorgio Fedeli, Mariano Cingolani

Journal of Legal, Ethical and Regulatory Issues, 2021; 24(Special Issue 1)

Open Access

Introduction

In Europe, there are currently two vaccines against COVID-19 recommended by the European Medicines Agency (EMA) for children aged 12 and older: Spikevax (Moderna) and Comirnaty (Pfizer-BioNTech). At the moment, about half of European countries have decided to age 12 as the minimum age for vaccination against COVID-19. In addition to Italy, France, Spain, Austria, Slovenia, Hungary, Czechia, Slovakia, Denmark, Switzerland, Romania, Bulgaria, Lithuania, Latvia and Estonia. Others (Germany, UK, Netherlands, Belgium, Sweden, Finland) recommend vaccination only for children in textual conditions facing COVID-19 or living with frail people. The Italian Medicines Agency (AIFA) has approved the extension of the therapeutic indications for Comirnaty on May 31 and for Spikevax on July 29, 2021.

The various scientific societies in Italy (SIPPS, SIP) agreed in favor of vaccinating children from 12 years old. However the problem of informed consent to COVID-19 vaccination in minors is absolutely emerging, in Italy as well as in other countries (Heuerman, 2021). According to national and international conventions, he should be informed, listened to and must participate in the co-decision process regarding medical treatment. Achieving a “triple” medical-parent-child therapeutic alliance is the main goal at this time of the pandemic, but this is not always possible (Morgan, 2021). The main key legal and ethical issues on the matter are represented below.

Editor’s Note: The Following articles all appear in Special Issue 2 of the BioLaw Journal, published by the Italian University of Trento.

Clinical trials in the time of a pandemic: Implications for informed consent

L. Palazzani

BioLaw Journal, 2021; Special Issue 2

Abstract

Focusing on clinical trials in the time of a pandemic, the contribution offers a comprehensive overview of the main challenges for investigators-physicians and patient-participants, discussing their ethical implications for the informed consent. Namely, adaptive and pragmatic trial designs can balance the rapidly changing standards of care with speed and agility, but these are designs which encompass specific implications for the informed consent process; the move towards the use of off-label drugs and compassionate pharmaceuticals in pandemics, which has been unavoidable due to the urgency of treating patients and the lack of knowledge on the virus, on the other hand raises many ethical questions that should be carefully addressed; the impact of the pandemic on ongoing clinical trials and on new trials, due to Covid-19 restrictions, needs proper consideration as well. Moreover, the contribution discusses the ethical conditions for deferred consent and key elements of re-consent alongside with ethical issues related to an electronic-digital consent in the case of tele-medicine and remote information-monitoring. Finally, the article encompasses a focus on patients’ vulnerabilities, including specific vulnerabilities (age, gender and ethnicity) that should be protected in conducting clinical research.

Informed consent and group vulnerability in the context of the pandemic

F. Macioce

BioLaw Journal, 2021; Special Issue 2

Abstract

Group vulnerability is a standard issue in bioethics. Research ethics guidelines highlight the need for protection of vulnerable participants, and clinical trials are ruled by ethical and legal principles that concern

possible health inequities experienced by vulnerable populations. In both the literature and the regulation, two conceptions of vulnerability are at work. On the one hand, the inherent vulnerability that is part of the human condition; on the other hand, the situational vulnerability that is associated with specific contextual factors, and that point out either a reduced autonomy or a greater risk of harms for individuals belonging to some groups. Both these two conceptions of vulnerability are exacerbated during a pandemic; on the one hand, specific populations are at heightened risk for medical complications from the virus (elderly, or immunodepressed);on the other hand, specific groups experience an increased vulnerability due to the social determinants of health, which influence individual resilience and exacerbate the impact of the virus. Among the many (income distribution, education and literacy, working condition, house and living conditions, disability, access to health services, etc.) the dramatic reduction of the space for free and informed consent, because of the mental and physical adverse effects coming from social isolation, age, culture, literacy, is relevant for both clinical research and practice. In this paper, I will discuss challenges for the informed consent in the context of the Covid-19 pandemic, with specific consideration of the condition of vulnerable groups.

Informed consent and artificial intelligence applied to RCT and Covid-19

A. E. Tozzi, G. Cinelli

BioLaw Journal, 2021; Special Issue 2

Abstract

Artificial intelligence (AI) tools allow to extract knowledge from big data and are increasingly used for research purposes applied to -omics, diagnostic images, complex patterns of diseases and system medicine, drug development, robotics, and other topics. The management of big data, largely made of individual clinical data, poses specific ethical challenges that must be addressed in research studies and that should be reflected in the informed consent process. Explaining the mechanisms used by AI algorithms in supporting clinical decision making may be particularly difficult because of the opacity of its process. Moreover, depending on the quality of data feeding their algorithms, AI applications may result in errors. As the General Data Protection Regulation (GDPR) includes the possibility that a patient withdraws his/her informed consent from a study, it may be challenging to update AI algorithms accordingly. On the other hand, AI tools may help support the recruitment and retention of participants in clinical trials matching eligibility criteria with individual data collected for clinical purposes in electronic health records, and improve data collection and analytics. The possibility to stream data from wearable devices offers the possibility to generate large data volumes relevant to Patient Reported Outcomes feeding AI predictive algorithms. The Covid-19 pandemic has promoted the application of digital tools and of AI in clinical trials in order to limit personal contacts. The pressure exerted by the pandemic will possibly speed up the adoption of AI solutions for clinical trials and will highlight their potential ethical implications.

Informed consent, clinical research, Covid-19 and contact tracing apps: Some neuroethical concerns

M. D. Garasic

BioLaw Journal, 2021; Special Issue 2

Abstract

The explosion of the Covid-19 pandemic has led us to introduce numerous states of exception in our everyday lives, sparking debates about their appropriateness at various levels. Among other changes we have adopted, there has been an increase of apps supporting our fight against Covid-19 all over the world. From apps helping us to join and coordinate clinical trials to contact tracing apps, various are the instances in which digital technology has -at least attempted to come to rescue to the scientific, public policy and political realms during the challenging times we are currently living in. Particularly in relation to contact tracing apps, ethical concerns have been raised over the level of transparency that they can guarantee, often stressing how the State needs to ensure a number of variables to be granted to citizens from privacy to fairness of

access and distribution through their compulsory status or not. In Western liberal democracies, the assumption has been that all risks associated with this digital technology would have to be dealt with by the State - hence making its misuse “only” public, albeit authoritarian in their most dystopian versions. Here, the intention is to stress some of the overlooked dimensions of the use of different types of Covid-19 related apps. More specifically, this paper takes issue with the secondary use of data that various private companies engaged in the fight against Covid-19 could make -with an unclear role for informed consent. Especially when in the hands of private, for profit, companies, attention should abound on what states of exceptions we are allowing to slip through our ethical supervision -and to what we are actually giving consent to when downloading these apps.

Informed consent for clinical research in the context of the Covid-19 pandemic between bioethics and biolaw: A general overview

L. Palazzani

BioLaw Journal, 2021; Special Issue 2

Abstract

The article examines the transformations of informed consent in the context of the Covid-19 pandemic, analyzing the bioethical discussion and in particular the national and international documents relevant to bioethical and biolegal issues, in both institutional bodies and bioethics committees. Informed consent is analyzed in the context of experimentation with treatments and vaccines, the use of biological samples and the processing of personal data.

Ethical and regulatory issues in vaccine research in the pandemic context and in the case of human challenge studies: Implications for informed consent

M. Daverio

BioLaw Journal, 2021; 2 pp 63-84

Abstract

In the pandemic context several specificities should be underlined for the case of vaccine trials, in addition to all ethical concerns raised for research related to pharmacological treatments which are also valid for vaccine research. Study population in vaccine trials is built up with healthy volunteers that should be carefully and fairly selected; as far as vaccine for emergency use are approved, the use of placebo in controlled studies raises ethical questions that should be discussed. Participants in vaccine trials should in any case be unduly influenced by any form of payment, and the gratuity of their act should be stressed in the communication and consent process. Moreover, in the context of experimentation with vaccines, sensitive ethical issues can arise also from the so-called “challenge studies”, since they concern intentionally infecting healthy people to investigate diseases and their treatments (human challenge trials involve exposing healthy volunteers to a pathogen to learn more about the disease it causes and to test vaccines quickly). The contribution finally includes a specific list of aspects to be included in well-designed information and consent process for participants’ in vaccine research in the Covid-19 pandemic.

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BIOMEDICAL RESEARCH

Strategies to enhance recruitment and consent to intensive care studies: a qualitative study with researchers and patient–public involvement contributors

Original Research

Katie Paddock, Kerry Woolfall, Frith, Megan Watkins, Carrol Gamble, Welters, Bridget Young

BMJ, 22 September 2021; 11(9)

Open Access

Abstract

Objective

Clinical trials and studies in intensive care units (ICUs) have complex consent processes and often encounter problems in recruiting patients. By interviewing research team members about the challenges in critical care research, we aimed to identify strategies to enhance recruitment and consent to ICU studies.

Methods

Semistructured interviews with UK-based researchers (N=17) and patient–public involvement (PPI) contributors (N=8) with experience of ICU studies. Analysis of transcripts of audio-recorded interviews drew on thematic approaches.

Results

Seven themes were identified. Participants emphasised the need for substitute decision-making processes in critical care studies, yet some researchers reported that research ethics committees (RECs) were reluctant to approve such processes. Researchers spoke about the potential benefits of research without prior consent (RWPC) for studies with narrow recruitment windows but believed RECs would not approve them. Participants indicated that the activity of PPI contributors was limited in critical care studies, though researchers who had involved PPI contributors more extensively were clear that their input when designing consent processes was important. Researchers and PPI contributors pointed to resource and staffing limitations as barriers to patient recruitment. Researchers varied in whether and how they used professional consultees as substitute decision-makers, in whether they approached families by telephone to discuss research and in whether they disclosed details of research participation to bereaved relatives.

Conclusion

Critical care research could benefit from RECs having expertise in consent processes that are suited to this setting, better staffing at research sites, more extensive PPI and an evidence base on stakeholder perspectives on critical care research processes. Guidance on professional consultee processes, telephoning relatives to discuss research, RWPC and disclosure of research participation to bereaved relatives could help to harmonise practice in these areas and enhance recruitment and consent to critical care studies.

Reshaping the review of consent so we might improve participant choice

Research Article

Hugh Davies

Research Ethics, 15 September 2021

Open Access

Abstract

Consent is one necessary foundation for ethical research and it's one of the research ethics committee's major roles to ensure that the consent process meets acceptable standards. Although on Oxford 'A' REC (an NHS Research Ethics Committee based in the UK) we've been impressed by the thought and work put into this aspect of research ethics, we've continued to have concerns about the suitability and effectiveness of consent processes in supporting decision making, particularly for clinical trials. There's poor understanding of what people want to help them decide; current processes don't provide the best grounding for informed consent and there's inadequate public involvement. We've also found a lack of proportionality with researchers failing to adapt consent procedures in proportion to the burdens and consequences of the study. As a result, people are often not best helped to make an informed choice when asked to join a research study. To address these concerns, we considered how we might improve this aspect of research ethics review. Recognising the central importance of the dialogue between the volunteer and researcher, we've drawn up a model or flowchart of what we deem good consent practice, proposing consent should be built around four simple steps:

> Step 1: Introducing the study and the choices: helping the potential participants get an overview of the proposal and introducing the key issues.

Step 2: Explaining all the details of the study using the detailed Participant Information Sheet.
Step 3: After a gap, if necessary, reviewing and checking understanding.
Step 4: Reaching agreement and recording consent.

These steps, we believe, could help all involved and this article lays out ways we might improve participant choice while complying with accepted principles and current regulations.

Analysing and optimising Informed Consent in cooperation with ethics committees and medical researchers

Igor Matic, Gianni De Nardi, Felix Steiner

AILA Review, 9 September 2021; 34(1) pp 37–56

Open Access

Abstract

Medical researchers are ethically and legally required to inform participants and get written permission before enrolling them into a human research project (Informed Consent). Accordingly, information and consent represent a complex procedure, and the participant concerned "must receive comprehensible oral and written information" (Swiss legislation: Human Research Act (HRA) Art. 16). A triangle of stakeholders is involved in the procedure: ethics committees that review and approve research projects and Informed Consent (IC) documents, medical researchers who produce the documents and discuss enrolment with patients, and patients who have to be informed comprehensibly. From a linguistic point of view, the question arises as to which perceptions of comprehensibility form the basis of the IC process and how shared language can be established considering the complex relationship between these stakeholders. This contribution presents findings from two perspectives (ethics committees and researchers) while considering the needs of all three stakeholders. Firstly, the conceptualisation of comprehensibility among three ethic committees is presented, and steps toward harmonisation are outlined. Secondly, limitations of how researchers conduct oral IC information are analysed, and the measures that were implemented to improve patient information are discussed. A transdisciplinary approach is key in establishing these solutions because they do not stem from linguistic analysis alone but have been developed in close collaboration with members of ethics committees and medical researchers. Thus, the project shows how the expertise of applied linguistics in cooperation with practitioners can deliver an important impact in both academic analysis and optimisation of professional procedures.

Quantifying Withdrawal of Consent, Loss to Follow-Up, Early Drug Discontinuation, and Censoring in Oncology Trials

Brooke E. Wilson, Michelle B. Nadler, Alexandra Desnoyers, Eitan Amir

Journal of the National Comprehensive Cancer Network, 3 September 2021

Open Access

Abstract

Background

Censoring due to early drug discontinuation (EDD) or withdrawal of consent or loss to follow-up (WCLFU) can result in postrandomization bias. In oncology, censoring rules vary with no defined standards. In this study, we sought to describe the planned handling and transparency of censoring data in oncology trials supporting FDA approval and to compare EDD and WCLFU in experimental and control arms.

Methods

We searched FDA archives to identify solid tumor drug approvals and their associated trials between 2015 and 2019, and extracted the planned handling and reporting of censored data. We compared the proportion of WCLFU and EDD between the experimental and control arms by using generalized estimating equations, and performed logistic regression to identify trial characteristics associated with WCLFU occurring more frequently in the control group.

Results
Censoring rules were defined adequately in 48 (59%) of 81 included studies. Only 14 (17%) reported proportions of censored participants clearly. The proportion of WCLFU was higher in the control group than in the experimental group (mean, 3.9% vs 2.5%; β-coefficient, −2.2; 95% CI, −3.1 to −1.3; P<.001). EDD was numerically higher in the experimental arm in 61% of studies, but there was no statistically significant difference in the proportion of EDD between the experimental and control groups (mean, 21.6% vs 19.9%, respectively; β-coefficient, 0.27; 95% CI, −0.32 to 0.87; P=.37). The proportion of EDD due to adverse effects (AEs) was higher in the experimental group (mean, 13.2% vs 8.5%; β-coefficient, 1.5; 95% CI, 0.57–2.45; P=.002). WCLFU was higher in the control group in studies with an active control group (odds ratio [OR], 10.1; P<.001) and in open label studies (OR, 3.00; P=.08).
Conclusions
There are significant differences in WCLFU and EDD for AEs between the experimental and control arms in oncology trials. This may introduce postrandomization bias. Trials should improve the reporting and handling of censored data so that clinicians and patients are fully informed regarding the expected benefits of a treatment.

Exemption from informed consent: When it is possible in investigational product and drug trials?

Review Article
Swati Verma
Saudi Journal of Anesthesia, 2 September 2021; 15(4) pp 428-430
Abstract
One of the most important ethical step in conducting investigational product trials or drug trials is obtaining informed consent from the participants. Although consent from the participants regarding participation is of prime importance but is not always practical or feasible. There may be several instances where it is practically impossible to obtain informed consent, whereas in some cases, obtaining informed consent from the trial participants adversely affects the quality and validity of the study data. Obtaining informed consent is a highly complex and technical process if the participants are not literate or suffering from a terminal illness, Also in some instances obtaining informed consent regarding the washout of prior prescribed medicine which may affect the trial outcomes. Although many guidelines exist for obtaining proper informed consent while very scarce literature exists on the instances where it can be waived off. Therefore, this brief narrative review aims to provide insight into currently available knowledge about when to obtain informed consent during testing of investigational product trials and drug trials and other possible scenarios where it can be waived off considering the effects of the washout period.

Telephone consent: optimizing the recruitment of research participants

Research
Lívia Loamí Ruyz Jorge de Paula, Mateus Frederico de Paula, Levon Badiglian-Filho
Revista Bioética, April-June 2021; 29(2)
Abstract
Informed consent aims to protect the autonomy of potential research participants, providing the information necessary to make the right decision. This study reports the experience of collecting the informed consent via telephone from individuals. Telephone contact was successfully achieved for more than 90% of the participants; 1.16% understood the survey, but did not accept to participate; and 0.70% refused to provide telephone consent and required a consent form by mail. Women from all regions of Brazil participated and most had some procedure in the hospital at least 62 days after the date of the call. The results show that telephone consent can be an alternative method of recruiting patients given the high rate of acceptance of the participants and time gains in data collection.

The Challenges of Multiculturalism on Informed Consent in Clinical Research

Joseph Tham

Studia Universitatis Babes-Bolyai Bioethica, 2021; 65 pp 174-175

Abstract

The UNESCO Chair in Bioethics and Human Rights held its 6th international workshop to discuss the issues of Informed Consent and Clinical Research. Being part of the i-Consent consortium, a project funded by the European Union's Horizon 2020 research and innovation program, the workshop focused on the multicultural and interdisciplinary dimension of ethical requirements of informed consent applied to translational/clinical research. Bioethical experts from Buddhism, Confucianism, Christianity, Hinduism, Islam and Judaism discussed the key challenges and the requirements of informed consent in clinical research. Some of the ethical gaps, barriers and challenges present in obtaining informed consent from patients/subjects in different, challenging cultural contexts were identified, as they represent minority groups and vulnerable populations. One of the findings is that many religious traditions do not accept the Western idealization of the autonomous self and prefer a more relational or communitarian understanding of doctorpatient/researcher-subject relationship. Western medicine and its current gold standard of informed consent that is practiced globally may not adequately address the theoretical skepticism towards the underlying principle of autonomy by different religions and cultures. This tension is becoming more pronounced with migrant and minority groups when they are asked to participate in clinical research as well as doing research in different parts of the world. A shift from individual to relational autonomy may offer a more nuanced improvement of the readability, design and obtaining process of consent forms. This shift will take into consideration the conscious and unconscious cultural biases of the investigators; multicultural and religious variables of the subjects' understanding; cross-cultural vision of vulnerability, knowledge, communication and empathy; the need for individualized approaches to promote health protective behaviors; and framing questions for a multi-layered informed consent which includes East/West - North/South perspectives.

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BIOBANKING

Harmonising the human biobanking consent process: an Irish experience

Open Letter

Lydia O'Sullivan, Tomás Carroll, Niamh Clarke, Sarah Cooper, Ann Cullen, Laura Gorman, Billy McCann, Blánaid Mee, Nicola Miller, Verena Murphy, Máiréad Murray, Jackie O'Leary, Sharon O'Toole, Emma Snapes, Suzanne Bracken

HRB Open Research, 17 September 2021; 4(96)

Open Access

Abstract

Biobanks are repositories of human biological samples and data. They are an important component of clinical research in many disease areas and often represent the first step toward innovative treatments. For biobanks to operate, researchers need human participants to give their samples and associated health data. In Ireland, research participants must provide their freely given informed consent for their samples and data to be taken and used for research purposes. Biobank staff are responsible for communicating the relevant information to participants prior to obtaining their consent, and this communication process is supported by documentation in the form of Participant Information Leaflets and Informed Consent Forms (PILs/ICFs). PILs/ICFs should be concise, intelligible, and contain relevant information. While not a substitute for layperson and research staff discussions, PILs and ICFs ensure that a layperson has enough information to make an informed choice to participate or not. However, PILs/ICFs are often lengthy, contain technical language and can be complicated and onerous for a layperson to read. The introduction of the General Data Protection Regulation (GDPR) and

the related Irish Health Research Regulation (HRR) presented additional challenges to the Irish biobank community. In May 2019, the National Biobanking Working Group (NBWG) was established in Ireland. It consists of members from diverse research backgrounds located in universities, hospitals and research centres across Ireland and a public/patient partner. The NBWG aimed to develop a suite of resources for health research biobanks via robust and meaningful patient engagement, which are accessible, GDPR/HRR-compliant and could be used nationally, including a PIL/ICF template. This open letter describes the process whereby this national biobank PIL/ICF template was produced. The development of this template included review by the Patient Voice in Cancer Research, led by Professor Amanda McCann at University College Dublin and the Health Research Data Protection Network.

Collecting Biospecimens and Obtaining Biobank Consent From Patients in an Academic Health Care Setting

T.J. Kasperbauer, Amy Waltz, Brenda Hudson, Bridget Hawryluk, Courtney Moore, Karen Schmidt, Peter H. Schwartz

Academic Medicine, 14 September 2021

Abstract

Academic health centers and health systems increasingly ask patients to enroll in research biobanks as part of standard care, raising important practical and ethical questions for integrating biobank consent processes into health care settings. This article aims to assist academic health centers and health systems considering implementing these integrated consent processes by outlining the 5 main issues—and the key practical and ethical considerations for each issue—that Indiana University Health and the Indiana Biobank faced when integrating biobank consent into their health system, as well as the key obstacles encountered. The 5 main issues to consider include the specimen to collect (leftover, new collection, or add-ons to clinical tests), whether to use opt-in or opt-out consent, where to approach patients, how to effectively use digital tools for consent, and how to appropriately simplify consent information.

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HEALTH DATA

AI, big data, and the future of consent

Open Forum

Adam J. Andreotta, Nin Kirkham, Marco Rizzi

AI & Society, 30 August 2021

Open Access

Abstract

In this paper, we discuss several problems with current Big data practices which, we claim, seriously erode the role of informed consent as it pertains to the use of personal information. To illustrate these problems, we consider how the notion of informed consent has been understood and operationalised in the ethical regulation of biomedical research (and medical practices, more broadly) and compare this with current Big data practices. We do so by first discussing three types of problems that can impede informed consent with respect to Big data use. First, we discuss the transparency (or explanation) problem. Second, we discuss the re-repurposed data problem. Third, we discuss the meaningful alternatives problem. In the final section of the paper, we suggest some solutions to these problems. In particular, we propose that the use of personal data for commercial and administrative objectives could be subject to a 'soft governance' ethical regulation, akin to the way that all projects involving human participants (e.g., social science projects, human medical data and tissue use) are regulated in Australia through the Human Research Ethics Committees (HRECs). We also consider alternatives to the standard consent forms, and privacy policies, that could make use of some of the latest research focussed on the usability of pictorial legal contracts.

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CAPACITY TO CONSENT

Reconsidering research exclusion for serious mental illness: Ethical principles, current status, and recommendations

J. Irene Harris, Devin Hanson, Jennie Leskela, John Billig, Viviana Padilla-Martinez, Jennifer Boyd, Tasha Nienow

Journal of Psychiatric Research, November 2021; 143 pp 138-143

Abstract

Background

Historically, individuals managing serious mental illness (SMI) have often been excluded from research, typically because of concern that these individuals may not be able to understand and provide truly informed consent. As treatment has improved, the assumption that individuals managing SMI may not be capable of consent needs to be re-examined. Systematic exclusion from research may limit empirically tested treatments available for people managing SMI, and may contribute to the health care disparities seen in this population.

Objectives

This article examines this issue by documenting current rates of research exclusion for high disease burden conditions, based on empirical review of studies in ClinicalTrials.gov.

Research design

Current rates of exclusion from studies for psychiatric conditions were assessed through systematic review of relevant clinical trials on ClinicalTrials.gov.

Subjects

Subjects in this inquiry are either articles accessed in the literature reviews, or descriptions of studies in public data on ClinicalTrials.gov.

Measures

The primary measure was a previously published coding system to document the extent and types of research exclusion related to psychiatric status.

Results

Among studies of interventions for substance use disorders and chronic pain, individuals managing SMI were more likely to be excluded than those with other psychiatric disorders at statistically significant levels. This was not the case among studies of interventions for ischemic heart disease. In studies of substance use disorders, 9% explicitly excluded SMI and 83% could exclude people with SMI based on broader exclusion criteria. In studies of chronic pain these two categories of exclusion were 16% and 55%, and in studies of ischemic heart disease, these two categories of exclusion were 1% and 20%.

Conclusions

Evidence indicates that it is ethically and scientifically more appropriate to exclude based on capacity to consent than membership in the group of individuals managing SMI. The discussion outlines techniques researchers can use for more equitable and generalizable sampling.

'Surrogate decision-making' in India for women competent to consent and choose during childbirth

Kaveri Mayra, Zoë Matthews, Jane Sandall

Agenda: Empowering women for gender equity, 1 September 2021

Open Access

Abstract

In a postcolonial, deeply patriarchal culture, decisions are often made for Indian women about every aspect of their life – beginning with whether they will be allowed to be born. This is followed by every life decision, including education and marriage. A 'surrogate decision-maker' is a guardian who decides for an adult incapable of making their own decisions due to a mental health condition, or as a substitute based on a patient's stated or predicted wishes. However, the majority of Indian women are 'controlled' and 'allowed' or otherwise regarding everything. No choice in women's life is women's own, including decisions about deeply personal experiences such as giving birth.

Our article is embedded in feminist epistemology and uses voice-centred relational analysis of interviews with four women from impoverished backgrounds in Bihar, India, to explore decision making around childbirth and throughout their lives. The surrogate decision-makers in the birth environment are: 1) healthcare and non-healthcare providers, and/or 2) family members (who play the dominant role in every other decision about women's lives). They communicate amongst themselves about a woman's active bodily experience. Through I-poems we present women's varied levels of resistance and non-resistance to obstetric violence, which can be looked at as an extension of their response to violence in their routine lives. We find similarities in women's conditioning to endure, and argue that women should be the key stakeholders of their decisions about themselves and their bodies, which includes decisions about birth.

Dental informed consent challenges and considerations for cognitively impaired patients

Review Article

Ahmed Alsaleh, Anjuli Kapila, Iftee Shahriar, Yvonne L. Kapila,

Periodontology, 31 August 2021

Open Access

Abstract

Because the US population is living to an older age, the number of individuals with cognitive impairment and periodontitis is increasing, as both conditions/diseases increase with age. Dental informed consent best practices for dental/periodontal treatment of individuals with cognitive impairment have not been explored, yet warrant consideration, because complex dental treatments to address periodontal needs/edentulism raise challenges for informed consent in the elderly with cognitive impairment. The purpose of this review is to help practitioners better understand this topic and develop best practices in dentistry for informed consent of patients with cognitive impairment that need extensive dental treatment, including surgical and implant therapy.

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TECHNOLOGY/OTHER MEDIATION

Personalized Video Consent: A New Tool in the Preoperative Consent-Giving Process

Viewpoints

Debraj Shome, Komal Doshi, Sapna Vadera, Vaibhav Kumar, Rinky Kapoor

Plastic and Reconstructive Surgery, October 2021; 148(4) pp 677e-679e

Open Access

Excerpt

Medicolegal jurisprudence is ever increasing, and it is the right of each patient to have in-depth knowledge about their surgical procedure. Consent means voluntary and mutual agreement or permission. Preoperative informed consent should not only delineate the procedure, but also highlight the concerned risks.

However, written consent has certain drawbacks, including language, medical terms, understanding complications, expectations, and queries regarding surgery. An innovative approach to make informed consent simpler and more patient-friendly, such as video informed consent, may help in overcoming these barriers.

In medicolegal cases, video consent can change the scenario, as it can be recorded in a language that the patient understands, and has the ability to visually record the patient's responses. Also, the patient-clinician conversation can be recorded and preserved for future reference…

Video-augmentation of the Informed Consent Process in Mental Health Research: an Exploratory Study from India

Abhijit Nadkarn, Sheena Wood, Ankur Garg, Danielle Fernandes, Ethel D'Souza, Urvita Bhatia

Asian Journal of Psychiatry, 23 September 2021

Abstract

Only around 50-75% of individuals fully understand the various aspects of informed consent in research. The aim of our study was to examine whether supplementing the conventional paper-based informed consent process with an audiovisual aid improves participants' understanding of the informed consent process and the information conveyed to them. Participants from two mental health/substance use intervention development studies were recruited for this study through consecutive sampling. They were then administered the traditional paper information and consenting process by itself or in combination with a video depicting the procedures of the study. Subsequently a bespoke questionnaire was administered to assess the participants' understanding of the information conveyed to them about the parent study. The various domains of the questionnaire were compared between those who were administered the two different consenting processes using the chi square test. 27 (58.7%) participants were administered the traditional consenting process and 19 were administered the video-supplemented consenting process. The video-supplemented consenting process was not superior to the traditional paper-based informed consent process on any of the domains examined. In settings with participants having a limited education, and in research involving people with mental health or substance use problems, further research is necessary to identify of contextually relevant best practices for the informed consent process.

Evaluating the potential utility of three-dimensional printed models in preoperative planning and patient consent in gastrointestinal cancer surgery

M Povey, S Powell, N Howes, D Vimalachandran, P Sutton

Annals: Royal College of Surgeons of England, September 2021; 103(8) pp 615-620

Abstract

Introduction

The Future of Surgery report from the Royal College of Surgeons of England acknowledges the important role that three-dimensional imaging will play in support of personalised surgical interventions. One component of this is preoperative planning. We investigated surgeons' and patients' perceptions of this evolving technology.

Materials and methods

Ethical approval was obtained. From a normal computed tomography scan, three-dimensional models of the stomach, pancreas and rectum were rendered and printed on an Ultimaker™ three-dimensional printer. Semi-structured interviews were performed with surgeons and patients to explore perceived model effectiveness and utility. Likert scales were used to grade responses (1 = strongly disagree; 10 = strongly agree) and qualitative responses recorded.

Results

A total of 26 surgeons (9 rectal, 9 oesophagogastric, 8 pancreatic) and 30 patients (median age 62 years, interquartile range, IQR, 68–72 years; 57% male) were recruited. Median surgeon scores were effectiveness for preoperative planning, 6 (IQR 3–7), authenticity, 5 (IQR 3–6), likability, 6 (IQR 4–7), promoting learning, 7 (IQR 5–8), utility, 6 (IQR 5–7) and helping patients, 7 (IQR 5–8). Median patient scores were usefulness to the surgeon, 8 (IQR 7–9), authenticity, 8 (IQR 6–8), likability, 8 (IQR 7–8), helping understanding of condition, 8 (IQR 8–9), helping understanding of surgery, 8 (IQR 7–9) and feeling uncomfortable, 1 (IQR 1–4). Median

overall decisional conflict score (0 = no; 100 = high) was 22 (IQR 19–28) and decision effectiveness was 25 (IQR 19–30).

Discussion

Overall, patients and surgeons considered that three-dimensional printed models were effective and had potential utility in education and, to a lesser extent, preoperative planning. Patient decisional conflict and effectiveness scores were weighted towards certainty in decision making but had room for improvement, which three-dimensional models may help to facilitate.

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YOUNG PERSONS

The Narrative Approach to Informed Consent: Empowering Young Children's Rights and Meaningful Participation [BOOK]

Fiona Mayne, Christine Howitt

Routledge, 16 November 2021

Abstract

The Narrative Approach to Informed Consent: Empowering Young Children's Rights and Meaningful Participation is a practical guide for researchers who want to engage young children in rights-based, participatory research. This book presents the Narrative Approach, an original and innovative method to help children understand their participation in research. This approach moves away from traditional paper-based consent to tailor the informed consent process to the specific needs of young children. Through the Informing Story, which employs a combination of interaction, information and narrative, this method enables children to comprehend concepts through storytelling. Researchers are stepped through the development of an Informing Story so that they can deliver accurate information to young children about what their participation in research is likely to involve. To further inform practice, the book documents the implementation of the Narrative Approach in four case studies demonstrating the variety of settings in which the method can be applied.

The Narrative Approach to Informed Consent addresses the rights of young children to be properly researched, expands opportunities for their active and engaged research participation, and creates a unique conceptual ethical space within which meaningful informed consent can occur. This book will be an invaluable tool for novice and experienced researchers and is applicable to a wide range of education and non-education contexts.

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RIGHTS/LEGAL/LEGISLATIVE

Must Consent Be Informed? Patient rights, state authority, and the moral basis of the physician's duties of disclosure

D. Robert MacDougall

Kennedy Institute of Ethics Journal, September 2021; 31(3) pp 247-270

Abstract

Legal standards of disclosure in a variety of jurisdictions require physicians to inform patients about the likely consequences of treatment, as a condition for obtaining the patient's consent. Such a duty to inform is special insofar as extensive disclosure of risks and potential benefits is not usually a condition for obtaining consent in non-medical transactions.

What could morally justify the physician's special legal duty to inform? I argue that existing justifications have tried but failed to ground such special duties directly in basic and general rights, such as autonomy rights. As an alternative to such direct justifications, I develop an indirect justification of physicians' special duties from an argument in Kant's political philosophy. Kant argues that pre-legal rights to freedom are the source of a duty to form a state. The state has the authority to conclusively determine what counts as "consent" in various kinds of transactions. The Kantian account can subsequently indirectly justify at least one legal standard imposing a duty to inform, the reasonable person standard, but rules out one interpretation of a competitor, the subjective standard.

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CULTURAL/COUNTRY CONTEXT

Challenges of the informed consent in some countries of the MENA region: A Literature Review

Review

T.Habiba, K.Richaa, F.Abou-Mrad

Ethics, Medicine and Public Health, December 2021; 19

Summary

Background

The world of medicine has seen a shift from a paternalistic to a patient-centred approach along with a surge in medical research in the MENA region. This medical revolution is accompanied by ethical challenges, most importantly concerning the informed consent. Countries in the MENA region have become aware of this, as several studies aim to study these challenges, their cause, and their solution. This article summarizes all the major findings of these studies.

Methods

A total of 36 articles were reviewed in order to form a proper idea about the importance of informed consent and its applicability in some countries of the MENA region. Literature review included the following countries: Algeria, Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Syria, Tunisia, UAE, and Yemen. Excluding criteria were studies conducted in a country not considered to be part of the MENA region and articles not relevant to our objectives.

Results

Challenges of the informed consent in the MENA region are the result of several interrelated factors unique to this region including cultural, religious, and legislative factors.

Conclusion

Efforts have been made to improve the ethical behaviour of physicians in the MENA region, however we are still far behind as several undeniable factors play a significant role, thus forcing an adapted informed consent form and procedure to every country and every population.

OP23 Parental consent for time-critical neonatal trials in low and middle-income countries: is it truly informed?

Stuti Pant, Maya Annie Elias, Kerry Woolfall, Sudhin Thayyil

Journal of Epidemiology & Community Health, 15 September 2021; SSM Annual Scientific Meeting Oral presentations, Obesity Diabetes & Global Health

Abstract

Background

Parental consent rates for neonatal interventional trials are significantly higher in Low and middle-income countries (LMIC) than in high-income countries, raising concerns about the credibility of the consent processes (Patterson et al PLOS One 2021). We conducted a mixed-methods study to understand the

informed consent process in a neonatal cooling trial [Hypothermia for encephalopathy in low and middle-income countries (HELIX) trial] conducted in India, Sri Lanka and Bangladesh.

Methods

Term infants with neonatal encephalopathy, aged less than six hours were randomly allocated to cooling therapy or usual care, following informed parental consent. The consenting process was audio-video (A-V) recorded in all cases. We analysed the A-V records of the consent process using a 5-point Likert scale on three parameters – Empathy, Information, Autonomy. Additionally, we used exploratory observation method to capture relevant aspects of consent process and discussions between parents and professionals. Finally, we conducted in-depth interviews with a subgroup of 20 parents and 15 health care professionals. A thematic analysis was performed on the observations of A-V records and on the interview transcripts.

Results

In HELIX trial, a total of 475 parents were approached, of which 408 (86%) consented. Of these, 294 *A-V records were analysed. Median (Interquartile range) score for empathy, information, autonomy* was 5 (0), 5 (1) and 5 (1) respectively. However, thematic analysis suggested that the parental decision to participate was based on a unreserved trust in the treating doctors, therapeutic misconception, and access to an expensive treatment free of cost. Most parents did not understand the concept of a clinical trial, nor the nature of the intervention. Lower levels of parental education and misinformation further convoluted the voluntary informed consent process. Parents were visibly incapacitated, and many told the doctor to do whatever is best for the baby. Clinicians lacked equipoise and were biased towards cooling therapy as it was already a standard of care in high-income countries, and this influenced parental decision making. However, the HELIX trial results subsequently showed cooling was harmful and increased mortality in these settings.

Conclusion

Despite rigorous research governance and consent process, parental decisions were heavily influenced by situational incapacity and a trust in doctors to make the right decision on their behalf. Further research is required to identify culturally and context appropriate strategies to ensure truly informed trial participation.

Recruiting pupils for a school-based eye study in Nigeria: Trust and informed consent concerns

Research Article

Ferdinand Chinedum Maduka-Okafor, Onochie Ike Okoye, Ngozi Oguego, Nnenma Udeh, Ada Aghaji, Obiekwe Okoye, Ifeoma R Ezegwui, Emmanuel Amaechi Nwobi, Euzebus Ezugwu, Ernest Onwasigwe, Rich E Umeh, Chiamaka Aneji

Research Ethics, 8 September 2021

Open Access

Abstract

School-based research presents ethical challenges, especially with respect to informed consent. The manner in which pupils and their parents respond to an invitation to participate in research is likely to depend on several factors, including the level of trust between them and the researchers. This paper describes our recruitment and consent process for a school-based eye study in Nigeria. In the course of our study, a particular governmental incident helped to fuel public mistrust in governmental programs and posed a potential threat to our recruitment efforts. The recruitment and consent process included series of advocacy visits to stakeholders in the education sector, highly interactive briefing and health talk sessions in schools, use of telephone services as a medium for information dissemination, age-appropriate study information, parental consent, and pupil assent. Of the 6598 pupils provided with study information, 5723 returned parental consent forms. There were 69 cases of pupils who dissented despite having parental consent. The two leading concerns for the parents/guardians were the rumors regarding a military/governmental-sponsored health campaign and the side-effects of the dilating eye-drops. Nevertheless, our high level of recruitment suggests our recruitment and consent process was successful in assuaging fears for the vast majority of pupils and their parents.

Informed Consent in Russia: Misuse and Abuse

Irina S. Mylnikova

Medical Ethics, 31 March 2021

Open Access

Abstract

Even T. Beauchamp and J. Childress, the founders of ethical principlism, noted that in practice the principles of bioethics, which they might have formulated, may conflict, and adherence to one principle may violate the other. To date, the conflict between the principle of autonomy and the doctrine of informed consent, and the principle of vulnerability formulated ten years later (one of the principles introduced by P. Kemp) and the necessity to take care of the patient is one of the major irreconcilable conflicts. This conflict is especially severe in Russia, where the informed consent was immediately enshrined as a statutory provision without prior discussion with the medical and non-medical communities, which gave rise to numerous opportunities for misuse and abuse, and stepped up the bureaucratic pressure both on patients, who became more vulnerable, and the physicians, who started using the informed consent to their advantage, sometimes being openly market oriented. The growth of mutual mistrust, sometimes reaching the level of aggression, forces one to find a remedy for this situation. In the author's view, this requires revision of the patient's autonomy concept and the concept of informed consent considering the acceptance of the patient's intense vulnerability and the patient's need for the healthcare specialists' (physicians and nurses) personal involvement and care. It may be helpful to consult the writings of the ethics of care, feminist ethics and other ethical trends representation, as well as the results of field research aimed to combine principles of freedom and patient care in a given situation.

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MEDICAL/SURGICAL

Informed consent challenges and strategies: A qualitative study of the orthodontists' perspective

N Conduru Fernandes Moreira, L Keenan, G Cummings, C Flores-Mir

Orthodontics & Craniofacial Research, 18 September 2021

Abstract

Objective

To identify the barriers and strategies perceived by orthodontists when obtaining consent from their adult patients concerning patients' comprehension or recollection of treatment information.

Settings and sample population

The sample comprised 12 orthodontists working in 8 different cities in Alberta, Canada.

Methods

An exploratory investigation using qualitative inquiry was conducted. Participants were recruited through a combination of purposive, maximum variation and snowball sampling. Data were collected through audio-recorded, semi-structured interviews until saturation was reached. Then, data were analysed using thematic analysis. Quality and credibility were achieved by employing member checks, memo writing and analyst triangulation strategies.

Results

Two major themes were identified, with subthemes: (1) Challenges that may interfere with patients' comprehension and recollection of treatment information (i. patients' internal barriers, ii. patients' external barriers and iii. financial barriers); and (2) strategies to optimize information delivery and communication (i. tailoring the content to be delivered, ii. communication fashion, iii. communication timing and iv. being accommodative).

Conclusion

The participants reported barriers that may be overlooked in the daily routine of orthodontic practices. Information is provided that may guide orthodontists to overcome or minimize these challenges, increase patient comprehension and improve the quality of informed consent processes.

Do hospital consent forms for cardiology procedures meet health literacy standards? Evaluation of understandability and readability

Ruwani Peiris, Samuel Cornell, Kim Greaves, Carissa Bonner

Patient Education and Counseling, 14 September 2021

Abstract

Objectives

Consent forms that are difficult to understand may jeopardize informed consent. The aim of this study was to determine whether consent documents for cardiology-related procedures could be easily read and understood by patients with low health literacy.

Methods

All 37 cardiology-related consent forms with patient information material were retrieved from a publicly available suite of documents from one state in Australia. Two raters independently assessed documents and resolved discrepancies through discussion. Understandability was assessed using the Patient Education Materials Assessment Tool for Printed materials (PEMAT-P). Readability was assessed using the Gunning Fog Index, SMOG and Flesch Reading Ease formulas. Images were assessed using the 5C Image checklist. Results were analyzed descriptively.

Results

Only 1 of 37 forms met the general PEMAT-P threshold (70%) for being 'understandable'. The average readability score was high, requiring a grade 10–12 level of education to understand. Most images lacked useful captions, had low visual clarity, and were not purpose-designed for the material.

Conclusions

The current format for cardiology consent forms does not meet recommended standards for understandability and readability.

Practice implications

Development of consent forms would benefit from taking health literacy principles into account with patient input, and purpose-designed images should be included in all forms to reinforce text.

The ethics of informed consent and shared decision-making in pediatric surgery

Deborah S. Loeff, Baddr A. Shakhsheer

Seminars in Pediatric Surgery, 5 September 2021

Abstract

Informed consent is a required feature in the practice of pediatric surgery. Surgeons cannot practice the trade without it and most of us learned to do it as part of our "apprenticeship" in surgical training. We were bystanders when the senior resident or attending spoke to the patient and family and we were silent witnesses to the signing of the document called a "consent." Intentional instruction about informed consent is rudimentary in most residencies. By the time we become surgical fellows, it is assumed that we have the requisite skill set to perform this "task" so we can get on with what we like to do best; operating. For many, it is viewed as a perfunctory step which, if done properly, will comply with hospital policies, might someday be exhibited during medical litigation, and ultimately it will occupy a tiny bit of memory in the hospital EMR system. However, this "thing" called the informed consent is much more than an item on a pre-op check list. The re-branding of the term "informed consent" into "shared decision-making" underscores the "re-evolution" that has occurred in thought and practice from the act of obtaining an individual's permission for treatment toward the process leading up to that act.1 It reflects some of our most important ethical values in healthcare and is still the source of scholarly inquiry and controversy. In this paper, the terms "informed

consent" and "shared decision-making" will be used interchangeably but the intention is focused on the process of how physicians and their patients make choices together. If you have not thought about this topic recently, I encourage you to take a moment and explore some of the interesting and challenging questions which are still unanswered. Although the ethical principles underlying informed consent are shared by adult and pediatric medicine, there are many aspects which are unique to the medical care of children. This article highlights some of those challenges and controversies illustrated by two case studies and viewed through the lens of bioethics.

A Survey to Assess the Informed Consent Practices of Physicians Caring for oocyte Donors

Christina Shields, Winifred Mak

Fertility and Sterility, 1 September 2021; 116(3)

Abstract

Objective

With increasing demand for donor oocytes, appropriate informed consent of oocyte donors (OD) is a priority as these women assume risk for a procedure that does not directly benefit them. Our study sought to investigate how physicians counsel on risks as part of informed consent of OD.

Materials and Methods

Physicians involved in the care of OD were invited to complete an anonymous 17-question online survey which included demographic variables and assessment of counseling practices such as whether short- and long-term complications are discussed with OD. The University of Texas Institutional Review Board approved the study.

Results

96 physicians responded (estimated response rate 17%). Respondents work in academic institutions (48%), private fertility clinics (46%), practices affiliated with commercial egg banks (6%), practices affiliated with academic institutions (11%), and are located across the Northeast (30%), Southeast (23%), Midwest (27%), Southwest (8%), and West (12%). Respondents in our study most often obtain consent either in person only or in person with other educational material. 98% responded that they always counsel on short-term potential side effects, versus 70% who always counsel on long-term potential side effects. A majority reported counseling on the incidence of ovarian hyperstimulation syndrome (OHSS) as 1-5% and acute serious complication (ASC) as <0.5% in accordance with the American Society for Reproductive Medicine (ASRM) bulletin on oocyte donation. The most discussed side effects are moderate pain / discomfort (100%), OHSS (96%), bloating (93%), intraperitoneal bleeding (79%), infection (78%), and ovarian torsion (78%). Interestingly, 21% also discussed general risk of cancer and 26% discussed risk of ovarian cancer. Regarding the maximum number of oocyte donation cycles, 65% of physicians recommend no more than 6 cycles and 32% recommend 3-5 cycles. Only 56% of respondents are aware of literature investigating long-term health outcomes of OD. Finally, 78% agree or strongly agree there should be a modality to track long-term health outcomes of OD.

Conclusions

Reassuringly, the majority of the physicians in our study counsel OD appropriately according to the ASRM guidelines and therefore from a physician's perspective, appropriate informed consent is being obtained. There is a knowledge gap on long-term health outcomes of OD, likely due to lack of research in this area. Most physicians caring for OD agree that long-term health outcomes should be tracked.

Are Patients Willing to Be Informed on the Risks and Complications Associated with the Proposed Therapy? A Survey on Informed Consent

Aigli Dafni, Panagoula Oikonomou, Konstantinos Anagnostopoulos, Christos Tsalikidis, Nigyar Dzhafer, Alexandra K. Tsaroucha, Mickael S. Pitiakoudis

Folia Medica, 31 August 2021; 63(4) pp 569-575

Abstract

Introduction
Informed consent is essential to the patient-physician relationship. The paternalistic old-time approach used by physicians to achieve the optimal management is changing today; detailed medical information must be disclosed to the patients regarding their health problem.
Aim
The aim of this study was to highlight the value of informed consent in the context of medical practice as well as to emphasize its importance through the prism of human rights.
Materials and methods
A patient survey was conducted in two public and one private hospitals in Greece. Eighty-three inpatients from the Surgical Departments of Democritus University Hospital of Alexandroupolis (DUHA), Laikon University Hospital of Athens (LUHA) and a private hospital were included in the study. A questionnaire regarding patients' attitude towards informed consent was distributed to patients prior to surgery.
Results
The majority of the patients (63.86% in DUHA, 59.38% in LUHA, and 78.95% in the private hospital) opted for full disclosure regarding the course and development of their condition.
Conclusion
Patients want to be informed about their treatment options and possible complications so that they can make decisions about their treatment after a comprehensive and understandable discussion.

Informed consent and birth preparedness/complication readiness: A qualitative study at two tertiary maternity units

Original Article
Sally Ely, Susanne Langer, Hans Peter Dietz
The Australian and New Zealand Journal of Obstetrics and Gynaecology, 29 August 2021
Abstract
Background
Informed consent in obstetrics should involve full disclosure of risks, benefits and alternative interventions. However, we have found no evidence of a formal informed consent process before an attempt at vaginal delivery in published policy or practice. The idea of informed consent in vaginal birth has attracted controversy and has been the subject of some debate.
Aim
To explore the perspectives and experiences of informed consent and birth preparedness/complication readiness for birthing women in a high resource setting.
Materials and methods
Qualitative study using semi-structured interviews to examine experiences and perspectives of women following birth.
Results
Forty telephone interviews were concluded. Eight statement categories were identified: (i) no issues of consent, (ii) absent/inadequate informed consent, (iii) adequate birth preparedness/complication readiness, (iv) inadequate birth preparedness/complication readiness, (v) desire to forfeit decision making to a trusted and accountable health professional, (vi) belief that informed consent is not realistic in birth under some circumstances, (vii) negative feelings related to birth and (viii) poor postnatal follow-up.
Conclusions
When complications arose during birth, 20% of participants felt that informed consent was absent/inadequate, 25% of participants suggested policy change in favour of a formal informed consent process and 55% of participants suggested policy change in favour of increased birth preparedness/complication readiness. Our study suggests that informed consent for vaginal birth and formal birth preparedness/complication readiness should form part of routine antenatal care. Women's preferences for decision-making and informed consent should be established before birth.

Ethical evaluation of informed consent forms used in cardiology clinics and the importance of institutional standardized approach

Original Article

Aksüyek Savaş Çelebi, Perihan Elif Ekmekçi, Müberra Devrim Güner

Turkish Society of Cardiology, 9 February 2021; 49(6) pp 477-487

Open Access

Abstract

Objective

This study aimed to evaluate the content of informed consent forms (ICFs) used during cardiology interventions by the university, research and training (R&T), and private hospitals with regard to ethical standards and compare them with the Turkish Society of Cardiology (TSC) templates and among various institutions.

Methods

A total of 185 forms from the university, R&T, and private hospitals and 19 TSC templates were selected and analyzed for 26 criteria. Compliance with TSC templates was also evaluated. Data were presented as the percentage of ICFs satisfying the criteria and compared using the Fisher exact test, and 95% confidence intervals were calculated.

Results

TSC templates were more compatible and included more information to comply with ethical standards than ICFs of all 3 types of healthcare institutions. The areas of improvement for these templates were prospects of treatment and alternative treatments, quality of life, explanation
for third-party consent, duration of hospitalization, and time to return to normal life. Among the 3 types of hospitals, R&T-ICFs were more compatible with templates. Private hospital ICFs had the poorest compliance with TSC templates. Separate anesthesia ICFs and detailed information about exposure to radioactivity were lacking.

Conclusion

The current ICFs for cardiology interventions have major ethical deficiencies and need urgent improvement. Professional societies such as TSC are essential institutions to develop and provide guidance and templates for ICFs to meet the ethical standards during the informed consent process and standardization of the process among various institutions.

Informed Consent in Dentistry – When, Why and How

Jelena Roganović

Studia Universitatis Babes-Bolyai Bioethica, 2021; 65 pp 147

Abstract

For dentists, as well as for other health care practitioners, it is mandatory to obtain informed consent from their patients, implying that a dialog has taken place and that patients understand the risks, benefits and alternatives to rendered treatments. Having in mind that majority of dental procedures are surgical in nature, leading to irreversible change to orofacial tissues and with the risk of unwanted side effects, well-documented informed consent process needs to be a basic norm in the dental practice. Clinical experience suggests that verbal discussion along with providing informed consent forms may not be enough and that patients response and understanding may improve by adding adjunctive materials like brochures or videos related to planned procedures. Many companies for implants and dental materials supply dental offices with the brochures and pamphlets, mostly for marketing purposes. Therefore, the use of these materials must be used with caution while objectively discussing other reasonable options. With the increasingly growing phenomenon of dental tourism, an important dentist-patient relationship ethical issues arise. Namely, issues regarding patient autonomy over practitioner choice, patient safety, and optimal care are under constant reconsideration while informed consent has to specify circumstances underlying treatment plan and posttreatment care. Currently, there is a paucity of information regarding informed consent in dentistry, and

vital ethical issues associated with recent developments in dental practice need to be addressed in the near future.

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GENERAL/OTHER

Raising Awareness of Data Sharing Consent Through Knowledge Graph Visualisation

Research Article

Christof Bless, Lukas Dötlinger, Michael Kaltschmid, Markus Reiter, Anelia Kurteva, Antonio J. Roa-Valverde, Anna Fensel

IOS Press, 2021; 53 pp 44 – 57

Open Access

Abstract

Knowledge graphs facilitate systematic large-scale data analysis by providing both human and machine-readable structures, which can be shared across different domains and platforms. Nowadays, knowledge graphs can be used to standardise the collection and sharing of user information in many different sectors such as transport, insurance, smart cities and internet of things. Regulations such as the GDPR make sure that users are not taken advantage of when they share data. From a legal standpoint it is necessary to have the user's consent to collect information. This consent is only valid if the user is aware about the information collected at all times. To increase this awareness, we present a knowledge graph visualisation approach, which informs users about the activities linked to their data sharing agreements, especially after they have already given their consent. To visualise the graph, we introduce a user-centred application which showcases sensor data collection and distribution to different data processors. Finally, we present the results of a user study conducted to find out whether this visualisation leads to more legal awareness and trust. We show that with our visualisation tool data sharing consent rates increase from 48% to 81.5%.

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