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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

March 2022

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

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

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

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

No new content was identified for the following established categories:

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

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.

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COVID-19

Informed Consent and Protection of Personal Data in Genetic Research on COVID-19

Piergiorgio Fedeli, Roberto Scendoni, Mariano Cingolani, Marcelo Corrales Compagnucci, Roberto Cirocchi, Nunzia Cannovo

Healthcare, 11 February 2022; 10(349)

Open Access

Abstract

The particular characteristics of COVID-19 demand the careful biomedical study of samples from patients who have shown different symptomatology, in order to understand the genetic foundations of its phenotypic expression. Research on genetic material from COVID-19 patients is indispensable for understanding the biological bases for its varied clinical manifestations. The issue of "informed consent" constitutes the crux of the problem in regulating research biobanks, because it concerns the relationship between the person and the parts separated from the body. There are several consensus models that can be adopted, varying from quite restricted models of specific informed consent to forms that allow very broad authorization (open consent). Our current understanding of COVID-19 is incomplete. Thus, we cannot plan, with precision, the research to be conducted on biological samples that have been, or will be, collected from patients infected by the novel coronavirus. Therefore, we suggest utilizing the "participation pact" between researchers and donors, based on a new form of participation in research, which offers a choice based on the principles of solidarity and reciprocity, which represent the communication of "values". In the last part of this paper, the general data protection regulation concerning the matter is discussed. The treatment of personal data must be performed with explicit goals, and donors must be provided with a clear, transparent explanation of the methods, goals and time of storage. The data must not be provided to unauthorized subjects. In conclusion, open informed consent forms will be necessary for research on individual patients and on populations.

Ethical Aspects of the Informed Consent During COVID-19 Vaccination

Original Research

Zorin KV , Gurevich KG

Medical Ethics, 31 March 2021

Open Access

Abstract

The main tactics used for COVID-19 prevention should be both quarantine measures and the large scale vaccination of the population. This does raise many ethical issues related to obtaining informed consent in biomedical research and clinical practice. The full and adequate ethical review of vaccination against the novel coronavirus infection can be provided only subject to ethical aspects of voluntary informed consent. Without that, it would be impossible to control the quality, efficiency and safety of the vaccine, and, consequently, the patients' vaccination and its results.

Transparency informed consent related to patient dishonesty amid COVID-19 pandemic in Indonesia: In law perspective

Indonesian Research

Tiwuk Herawati, Fifik Wiryani, M. Nasser, Mokhammad Najih

Diponegoro Law Review, 2021; 6(2) pp 279-288

Abstract

To break the chain of transmission of COVID-19 outbreak, the public is expected to be honest in explaining chronological physical contact when treating to health facilities, especially if the patient experiences symptoms of COVID-19. Honesty of patients indicated by COVID-19 is very important so that the chain of transmission of COVID-19 does not expand and facilitate health workers in data collection. Denial, lies, even like the refusal of COVID-19 corpses if it continues to be left, does not mean the countermeasures of COVID-19 are increasingly stretched. This article tries to review the transparency of informed consent in relation to patient dishonesty, where transparent communication is expected by the patient to be honest and not to cover the perceived symptoms or various things related to COVID-19. This research is normative juridical research. In normative legal research, library material is the basic data that in research science is classified as secondary data.

Editor's note: Diponegoro Law Review is published by the Faculty of Law, Diponegoro University, Indonesia.

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BIOMEDICAL RESEARCH

Evaluation of a blockchain-based dynamic consent platform (METORY) in a decentralized and multicenter clinical trial using virtual drugs

Ki Young Huh, Seol Ju Moon, Sang-Un Jeong, Min-Ji Kim, Wooseok Yang, Myeonggyu Jeong, Min-Gul Kim, SeungHwan Lee

Clinical and Translational Science, 14 February 2022

Abstract

Blockchain is a novel data architecture characterized by a chronological sequence of blocks in a decentralized manner. We aimed to evaluate the real-world feasibility of a blockchain-based dynamic consent platform (METORY) in a decentralized and multicenter trial. The study consisted of three visits (i.e., screening and 2 follow-up visits) with a 2-week interval. Each subject was required to report the self-measured body temperatures and take a virtual investigational drug by entering the unique drug code on the application. To simulate real-world study settings, two major (i.e., changes in the schedule of body temperature measurement) and three minor protocol amendments (i.e., nonsignificant changes without any changes in the procedures) were set. Overall study completion rates, proportion of consent, and response time to each protocol amendment and adherence were evaluated. A total of 60 subjects (30 in each center) were enrolled in two study centers. All subjects completed the study, and the overall proportion of consent to each protocol amendment was 95.7 ± 13.7% (mean ± SD), with a median response time of 0.2 h. Overall, subjects took 90.8% ± 19.2% of the total drug, whereas compliance with the schedule was 69.1% ± 27.0%. Subjects reported 96.7% ± 4.2% of the total body temperature measurements whereas the adherence to the schedule was 59.0% ± 25.0%, which remarkably decreased after major protocol amendments. In conclusion, we evaluated a blockchain-based dynamic consent platform in real clinical trial settings. The results suggested that major changes should be avoided unless subjects' proper understanding is warranted.

How to obtain valid consent for research?

Manel Ben Fredj

International Journal of Research and Ethics, 1 February 2022; 5(1)

Abstract

There is a broad agreement on the need to protect humans participating in biomedical research. Research ethics encompasses three fundamental principles: autonomy, beneficence, and justice. In practice, valid consent from participants is considered as the main tool to protect the participants and to ensure their rights. Obtaining a valid consent for research requires the voluntariness and the capacity of participants with disclosing an adequate and clear information. Nevertheless, in some circumstances, the institutional review board (IRB) may make an exception and approve the waiver of consent. An approval by the IRB is always needed. This workshop introduces candidates to fundamental principles in ethics research and to the rules of consent writing in research. It addresses also the specific situations under which a waiver consent may be acceptable. The workshop proceeds in two sessions in which we: present the principles of research ethics with explaining the steps of obtaining a valid consent for research and organize work groups.

Recruitment, consent and retention of participants in randomised controlled trials : a review of trials published in the National Institute for Health Research (NIHR) Journals Library (1997–2020)

Original Research

Richard M Jacques, Rashida Ahmed, James Harper, Adya Ranjan, Isra Saeed, Rebecca M Simpson, Stephen J Walters

BMJ Open, 30 January 2022; 12(2)

Open Access

Abstract

Objectives

To review the consent, recruitment and retention rates for randomised controlled trials (RCTs) funded by the UK's National Institute for Health Research (NIHR) and published in the online NIHR Journals Library between January 1997 and December 2020.

Design

Comprehensive review.

Setting

RCTs funded by the NIHR and published in the NIHR Journals Library.

Data extraction

Information relating to the trial characteristics, sample size, recruitment and retention.

Primary and secondary outcome measures

The primary outcome was the recruitment rate (number of participants recruited per centre per month). Secondary outcomes were the target sample size and whether it was achieved; consent rates (percentage of eligible participants who consented and were randomised) and retention rates (percentage of randomised participants retained and assessed with valid primary outcome data).

Results

This review identified 388 individual RCTs from 379 reports in the NIHR Journals Library. The final recruitment target sample size was achieved in 63% (245/388) of the RCTs. The original recruitment target was revised in 30% (118/388) of trials (downwards in 67% (79/118)). The median recruitment rate (participants per centre per month) was found to be 0.95 (IQR: 0.42–2.60); the median consent rate was 72% (IQR: 50%–88%) and the median retention rate was estimated at 88% (IQR: 80%–97%).

Conclusions

There is considerable variation in the consent, recruitment and retention rates in publicly funded RCTs. Although the majority of (6 out of 10) trials in this review achieved their final target sample; 3 out of 10 trials revised their original target sample size (downwards in 7 out of 10 trials). Investigators should bear this in mind at the planning stage of their study and not be overly optimistic about their recruitment projections.

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SOCIAL SCIENCE RESEARCH

Patient-centred consent in women's health: does it really work in antenatal and intra-partum care?

Research
Jacqueline Nicholls, Anna L David, Joseph Iskaros, Anne Lanceley
BMC Pregnancy and Childbirth, 25 February 2022; 22(156)
Open Access
Abstract
Background
Legal and social changes mean that information sharing and consent in antenatal and intrapartum settings is contentious, poorly understood and uncertain for healthcare professionals. This study aimed to investigate healthcare professionals' views and experiences of the consent process in antenatal and intrapartum care.
Methods
Qualitative research performed in a large urban teaching hospital in London. Fifteen healthcare professionals (obstetricians and midwives) participated in semi-structured in-depth interviews. Data were collectively analysed to identify themes in the experiences of the consent process.
Results
Three themes were identified: (1) Shared decision-making and shared responsibility –engaging women in dialogue is often difficult and, even when achieved, women are not always able or do not wish to share responsibility for decisions (2) Second-guessing women – assessing what is important to a woman is inherently difficult so healthcare professionals sometimes feel forced to anticipate a woman's views (3) Challenging professional contexts – healthcare professionals are disquieted by consent practice in the Labour ward setting which is often at odds with legal and professional guidance.
Conclusions
Results suggest that there is a mismatch between what is required of healthcare professionals to effect an antenatal or intrapartum consent process concordant with current legal and professional guidance and what can be achieved in practice. If consent, as currently articulated, is to remain the barometer for current practice, healthcare professionals need more support in ways of enabling women to make decisions which healthcare professionals feel confident are autonomous whatever the circumstances of the consultation.

Consent Requirements for Testing Health Policies: An Intercontinental Comparison of Expert Opinions

Original Research Article
Astrid Berner-Rodoreda, Shannon McMahon, Nir Eyal, Puspita Hossain, Atonu Rabbani, Mrittika Barua, Malabika Sarker, Emmy Metta, Elia Mmbaga, Melkizedeck Leshabari, Daniel Wikler, Till Bärnighausen
Journal of Empirical Research on Human Research Ethics, 10 February 2022
Abstract
Individual informed consent is a central requirement for clinical research on human subjects, yet whether and how consent requirements should apply to health policy experiments (HPEs) remains unclear. HPEs test and evaluate public health policies prior to implementation. We interviewed 58 health experts in Tanzania, Bangladesh and Germany on informed consent requirements for HPEs. Health experts across all countries favored a strong evidence base, prior information to the affected populations, and individual consent for 'risky' HPEs. Differences pertained to individual risk perception, how and when consent by group

representatives should be obtained and whether HPEs could be treated as health policies. The study adds to representative consent options for HPEs, yet shows that more research is needed in this field – particularly in the present Covid-19 pandemic which has highlighted the need for HPEs nationally and globally.

Experiences and practices of key research team members in obtaining informed consent for pharmacogenetic research among people living with HIV: a qualitative study

Research Article

Nabukenya Sylvia, Ochieng Joseph, Kaawa-Mafigiri David, Munabi Ian, Nakigudde Janet, Nakwagala Frederick Nelson, Barugahare John, Kwagala Betty, Ibingira Charles, Twimwijukye Adelline, Sewankambo Nelson, Mwaka Erisa Sabakaki

Research Ethics, 7 February 2022

Abstract

This study aimed to explore experiences and practices of key research team members in obtaining informed consent for pharmacogenetics research and to identify the approaches used for enhancing understanding during the consenting process. Data collection involved 15 qualitative, in-depth interviews with key researchers who were involved in obtaining informed consent from HIV infected individuals in Uganda for participation in pharmacogenetic clinical trials. The study explored two prominent themes: approaches used to convey information and enhance research participants' understanding and challenges faced during the consenting process. Several barriers and facilitators for obtaining consent were identified. Innovative and potentially effective consenting strategies were identified in this study that should be studied and independently verified.

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GENOMIC MEDICINE/GENE EDITING

Informed consent, genomic research and mental health: A integrative review

Nina Kilkku, Arja Halkoaho

Nursing ethics, 4 February 2022

Open Access

Abstract

Background

Research on genomics has increased while the biobank activities are becoming more common in different countries. In the mental health field, the questions concerning the potential participants' vulnerability as well as capacity to give the informed consent can cause reluctancy in recruiting persons with mental health problems, although the knowledge and understanding of mental health problems has remarkably changed, and practice is guided with inclusive approaches, such as recovery approach.

Aim

The aim of this study was to describe the current knowledge of informed consent practices in the context of genomic research on mental health from the nurses' viewpoint.

Methods

An integrative review was conducted with search from seven international databases. Data consist 14 publications which were analyzed with thematic analysis.

Ethical considerations

Ethical requirements were respected in every phase of the research process.

Findings

Most of the papers were published in USA and between 2000-2010. Eight reports were categorized as discussion papers, four qualitative studies and one quantitative study. The thematic analysis provided

information on five themes: complexity with the capacity to consent, mixed emotions towards participation, factors influencing the decision to participate, nurses' informed consent process competence and variations between consent procedures.

Discussion

In the informed consent practices, there are various aspects which may affect both the willingness to participate in the study and the informed consent process itself. Implications for practice, education, research, and policies are discussed.

Conclusion

There is a need for more updated international research on the topic in the context of different international and national guidelines, legislation, and directives. This study provided a viewpoint to the more collaborative research activities with people with lived experiences also in this field of research following the ideas of recovery approach.

Informed consent practices for exome sequencing: An interview study with clinical geneticists in the Netherlands

Original Article

Wendy Bos, Eline M. Bunnik

Molecular Genetics & Genomic Medicine, 14 January 2022

Open Access

Abstract

Background

Genomic sequencing is being used more frequently in the clinic, not only by clinical geneticists, but also by other specialists ("mainstreaming"). The use of genomic sequencing gives rise to challenges regarding informed consent, as it can yield more, and more complex results.

Methods

This study maps the informed consent process for exome sequencing in the Netherlands by means of semistructured interviews with 14 clinical geneticists. Interviewees were asked about their strategies for informing patients about exome sequencing and supporting patients in their decision making, about what they think of as essential information elements, about the challenges they experience, and about their preferences for future policy and practice.

Results

Clinical geneticists typically discuss the following topics: the nature and aim of the test, the possible results (including unsolicited or incidental findings and Variants of Uncertain Significance) of the test and the consequences of those results for the patient and their family members. Some clinical geneticists use a layered approach to informed consent, meaning that they give short and concise information at first, and provide more detailed information depending on the situation or the needs of the patient.

Conclusion

During pre-test counseling for genomic sequencing, clinical geneticists use various strategies to enhance patient understanding and personalization of the informed consent process. Going forward, layering information may be part of a solution to ethical challenges of informed consent, also in mainstream settings.

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HEALTH DATA

Toward an architecture to improve privacy and informational self-determination through informed consent

Mohamad Gharib

Information and Computer Security, 23 February 2022

Abstract

Purpose

Most developed countries have enacted privacy laws to govern the collection and use of personal information (PI) as a response to the increased misuse of PI. Yet, these laws rely heavily on the concept of informational self-determination through the “notice” and “consent” models, which is deeply flawed. This study aims at tackling these flaws achieve the full potential of these privacy laws.

Design/methodology/approach

The author critically reviews the concept of informational self-determination through the “notice” and “consent” model identifying its main flaws and how they can be tackled.

Findings

Existing approaches present interesting ideas and useful techniques that focus on tackling some specific problems of informational self-determination but fall short in proposing a comprehensive solution that tackles the essence of the overall problem.

Originality/value

This study introduces a model for informed consent, a proposed architecture that aims at empowering individuals (data subjects) to take an active role in the protection of their PI by simplifying the informed consent transaction without reducing its effectiveness, and an ontology that can partially realize the proposed architecture.

Sovereign Digital Consent through Privacy Impact Quantification and Dynamic Consent

Article

Arno Appenzeller, Marina Hornung, Thomas Kadow, Erik Krempel, Jürgen Beyerer

Technologies, 21 February 2022; 10(35)

Open Access

Abstract

Digitization is becoming more and more important in the medical sector. Through electronic health records and the growing amount of digital data of patients available, big data research finds an increasing amount of use cases. The rising amount of data and the imposing privacy risks can be overwhelming for patients, so they can have the feeling of being out of control of their data. Several previous studies on digital consent have tried to solve this problem and empower the patient. However, there are no complete solution for the arising questions yet. This paper presents the concept of Sovereign Digital Consent by the combination of a consent privacy impact quantification and a technology for proactive sovereign consent. The privacy impact quantification supports the patient to comprehend the potential risk when sharing the data and considers the personal preferences regarding acceptance for a research project. The proactive dynamic consent implementation provides an implementation for fine granular digital consent, using medical data categorization terminology. This gives patients the ability to control their consent decisions dynamically and is research friendly through the automatic enforcement of the patients’ consent decision. Both technologies are evaluated and implemented in a prototypical application. With the combination of those technologies, a promising step towards patient empowerment through Sovereign Digital Consent can be made.

How Informed is Consent? A Field Experiment

Discussion Paper

Alexandra Avdeenko, Matthias Stelter

Centre for Economic Policy Research, 1 February 2022

Abstract

In an increasingly data-driven world, data protection and the requirement of obtaining informed consent rapidly gain relevance. The intention is to protect data holders. Yet, is consent provided by data holders truly informed? In the context of empirical research, the requirement for informed consent can affect external

validity and data quality of the evidence generated. Conducting a survey with 7,752 potential participants in rural Pakistan, we find that respondents are insufficiently informed about important aspects related to their consent. Experimentally changing the consent process, we find that showing an animated video has a negative impact on respondent's understanding, but additionally engaging them in an interactive dialogue about the informational text significantly improves understanding. Even though we find effects on levels of understanding, we do not find meaningful changes in consent rates and non-response behavior indicating no adverse effects on the quality of the survey.

Editor's note: The Centre for Economic Policy Research's network of Research Fellows and Affiliates includes economists conducting research on issues affecting the European economy.

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CAPACITY TO CONSENT

Factorial Structure of Nursing Practices Related to Support for Decision-Making Regarding Consent for Surgery in Elderly Patients with Dementia

Original Research
Sachiko Matsui, Miwa Yamamoto
Yonago Acta Medica, 22 February 2022; 65(1) pp 70–81
Open Access
Abstract
Background
When elderly patients with dementia require highly invasive treatment or surgery for lifethreatening conditions, decisions regarding consent for surgery are made based on informed consent provided by the family, which excludes the patient whose decision-making ability is deemed impaired due to the dementia. This study aimed to clarify the factorial structure of nursing practices related to support for decision-making regarding consent for surgery in elderly patients with dementia.
Methods
An anonymous self-administered questionnaire survey was completed by nurses with three or more years of experience working in orthopedic surgery wards at secondary emergency hospitals in the Kinki area. The survey collected data on participant attributes and nursing practices related to decision-making support. Data were analyzed by exploratory factor analysis (promax rotation) using nursing practice items related to decision-making support as variables. Internal consistency was examined.
Results
Participants were 112 nurses including 108 women (96.4%) and four men (3.6%), with a mean age of 38.3 (±SD 9.8) years. Exploratory factor analysis of the nursing practice items related to decision-making support demonstrated the validity of the observed 24 variables, with a Kaiser-Meyer-Olkin value of 0.858 and a significant Bartlett's test of sphericity ($P < 0.001$). Five components with eigenvalues of 1 or more were extracted, including "achieving advocacy for elderly patients with dementia through cooperation among medical professionals," "advice considering the lifestyles and values of patients and their families," "support with a deeper understanding of elderly patients with dementia," "support that helps elderly patients with dementia to express their intentions," and "nurses' attendance in IC sessions for elderly patients with dementia." The Cronbach's α coefficient for the 24 nursing practice items related to decision-making support was high, at 0.926.
Conclusion
The factorial structure of nursing practice related to support for decision-making regarding consent for surgery in elderly patients with dementia included five factors and 24 items. The reliability and construct validity of the factorial structure were also confirmed.

Editor's note: Yonago Acta Medica (YAM) is a peer-reviewed journal, specializing in medical sciences, published by Tottori University Medical Press, Japan.

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YOUNG PERSONS

Consent and parental responsibility - the past, the present and the future

Asma Keshtgar, Mohamed Hania, Mohammad O. Sharif
British Dental Journal, 28 January 2022; 232 pp 115 – 119
Open Access
Abstract
Introduction
Informed consent is the 'permission or agreement' given by the patient for a proposed action. This paper explores the clinician's role in obtaining informed consent, provides an overview of consent and parental responsibility in the UK, and presents practical adjuncts to aid dental professionals in ascertaining who has parental responsibility to delineate persons capable of providing assent on behalf of an underage patient.
Consent and parental responsibility
While the principles of consent have largely stayed constant with time, subtleties in parental responsibility legislation exist in different regions of the UK. An audit exploring consent and parental responsibility knowledge among clinicians within the orthodontic department at the UCLH Eastman Dental Hospital demonstrated that none of the respondents met the gold standard (100%). The results ranged from 59-89% with a mean score of 74%. The majority of questions answered incorrectly related to knowledge of parental responsibility.
Conclusion
It is the responsibility of clinicians providing any care within the UK to stay up to date with legislation and regulations regarding consent and parental responsibility. Knowledge-based questionnaires can highlight areas of knowledge deficit which can be addressed through continuous professional development. This paper provides a flowchart summarising parental responsibility and a prefilled parental responsibility questionnaire as adjuncts to simplify the process of dental professionals ascertaining parental responsibility.

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RIGHTS/LEGAL/LEGISLATIVE

Health care providers' ethical perspectives on waiver of final consent for Medical Assistance in Dying (MAiD): a qualitative study

Research
Caroline Variath, Elizabeth Peter, Lisa Cranley, Dianne Godkin
BMC Medical Ethics, 30 January 2022; 23(8)
Open Access
Abstract
Background
With the enactment of Bill C-7 in Canada in March 2021, people who are eligible for medical assistance in dying (MAiD), whose death is reasonably foreseeable and are at risk of losing decision-making capacity, may enter into a written agreement with their healthcare provider to waive the final consent requirement at the time of provision. This study explored healthcare providers' perspectives on honouring eligible patients' request for MAiD in the absence of a contemporaneous consent following their loss of decision-making capacity.
Method

A critical qualitative methodology, using a feminist ethics theoretical lens with its focus on power and relationality, was used to examine how socio-political and environmental contexts influenced healthcare providers' moral agency and perspectives. Semi-structured interviews were conducted with 30 healthcare providers (13 physicians, six nurse practitioners, nine nurses and two social workers) from across Canada who provide MAiD-related care.

Results

Themes identified include; (1) balancing personal values and professional responsibilities, (2) anticipating strengths and limitations of the proposed waiver of final consent amendment, (3) experiencing ethical influences on decisions to enter into written agreements with eligible patients, (4) recognizing barriers to the enactment of MAiD in the absence of a contemporaneous consent and (5) navigating the potential for increased risks and burden.

Discussion

To our knowledge, this is the first study in Canada to explore healthcare providers' perspectives on waiving the final consent for MAiD using a written agreement. Most participants supported expanding eligible people's access to MAiD following loss of capacity, as they believed it would improve the patients' comfort and minimize suffering. However, the lack of patients' input at the time of provision and related ethical and legal challenges may impact healthcare providers' moral agency and reduce some patients' access to MAiD. Providers indicated they would enter into written agreements to waive final consent for MAiD on a case-by-case basis. This study highlights the importance of organizational, legal and professional support, adequate resources, clear policies and guidelines for the safety and wellbeing of healthcare providers and to ensure equitable access to MAiD.

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CULTURAL/COUNTRY CONTEXT

Knowledge and Attitudes of Research Participants in China Toward Electronic Informed Consent in Clinical Trials: A Cross Sectional Study

Research Article

Zhanqing Hu, Chenxi Ouyang, Jessica Hahne, Kaveh Khoshnood, Jinqiang Zhang, Xiyu Liu, Ying Wu, Xiaomin Wang

Journal of Empirical Research on Human Research Ethics, 28 January 2022

Abstract

This study aims to investigate the knowledge and attitudes of participants and potential participants in clinical trials toward electronic informed consent. We conducted a survey-based cross-sectional study in Hunan Province, China in March 2021. A total of 547 respondents were included in this study. All questions in an 8-item survey section assessing participants' knowledge of electronic informed consent received correct answers from at least 70% of participants. In terms of attitude scores, most participants (86.3%) believed that electronic informed consent is more convenient than the paper-based version, and more than half (51.2%) believed that electronic informed consent could completely replace the paper-based version. Responses indicated that common concerns about electronic informed consent were its security and confidentiality, legal benefits, and implications for rights protection.

The Analysis Causes of Informed Consent in Supporting the Quality of Medical Record In Graha Hospital Medika Banyuwangi

Rizqi Aji Aprilia, Erma Sulistyaningsih, Leersia Yusi Rat

International Journal of Innovative Science and Research Technology, December 2021; 6(12)

Abstract

Backgrounds

Informed consent is an agreement given by the patient or family after receiving a clear explanation of the patient's medical or dental action to be carried out. The standard of completeness of the Informed Consent is based on the Hospital Minimum Service Standard No. 290 of 2008 and the hospital quality standard is 100%. The number of incomplete informed consent at Graha Medika Hospital in the third quarter of 2020 was 11.14%, 26.90%, and 41%, which means that the standard for completeness of informed consent has not been achieved. The purpose of the study was to analyze the factors causing incomplete informed consent.

Methods

The research design used a quantitative approach with a cross-sectional research design. The population and sample were 258 informed consent forms. The unit of analysis was 30 medical doctors who filled out the informed consent. Data analysis used univariate, bivariate with Spearman Rank, and multivariate with Partial Least Square.

Results

The bivariate analysis results showed that the resource indicator had a relationship with the completeness of Informed Consent with a value of 0.005. A multivariate analysis that organizational factors had a relationship with the completeness of Informed Consent with a value of 0.001.

Conclusion

Strengthening the resource sector with a solid organizational commitment will increase the completeness of informed consent, which is inseparable from the quality of the organization's management function. A good management function will run in harmony with the level of compliance of good service personnel.

Editor's note: The International Journal of Innovative Science and Research Technology is an open access peer-reviewed international forum for scientists and engineers published in India.

Informed Consent among Hansen's Disease Patients – A Nigerian Perspective

I.A. Meka, A.O. Meka, O.O. Kanu, N. Ekeke, K.O. Adagba, A.O. Iseoluwa - Adelokiki, I. Alobu, J. Offor

African Journal of Health Sciences, November-December 2021; 34(6)

Open Access

Summary

Background

Informed consent entails providing potential participants with adequate information needed to decide whether or not to participate in research. In Nigeria, Hansen's disease has remained a disease of public health importance. The associated stigmatization often renders patients vulnerable and prone to exploitation. The act of obtaining informed consent from these patients remain an issue of ethical importance. The study aimed to determine the willingness of Hansen's disease patients to give consent to use their data in the form of pictures, videos and/or oral interviews by a third party.

Materials and Methods

This descriptive cross-sectional study was carried out in three states in Nigeria; Ebonyi, Ogun and Cross River States. Data was collected from consenting participants using researcher-administered semi-structured questionnaires.

Results

The study included 93 respondents with a mean (SD) age of 44.9 (20.1) years. The majority 57 (61.29%) of the respondents were farmers while the majority 67 (72.04%) attained primary education. A total of 26 (27.96%) respondents had suffered discrimination in the course of their disease. In their responses, 83 (89.2%) would allow the use of their pictures, 80 (86.0%) their videos and 86 (92.5%) their recorded oral interviews. Among those who would not give consent, the commonest reasons adduced were an intrusion into privacy and lack of trust.

Conclusion

Though a majority of the patients would give consent for use of their data intrusion into privacy and lack of trust were major constraints for those not willing to give consent. Caregivers and stakeholders should put more effort into trying to win patients' trust before seeking informed consent.

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MEDICAL/SURGICAL

Informed Consent for Endoscopic Biliary Drainage: Time for a New Paradigm

Marco Spadaccini, Cecilia Binda, Alessandro Fugazza, Alessandro Repici, Ilaria Tarantino, Carlo Fabbri, Luigi Cugia, Andrea Anderloni

Medicina, 22 February 2022; 58(3) pp 331

Open Access

Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is considered as the first option in the management of malignant biliary obstruction. In case of ERCP failure, percutaneous transhepatic biliary drainage (PTBD) has been conventionally considered as the preferred rescue strategy. However, the use of endoscopic ultrasound (EUS) for biliary drainage (EUS-BD) has proved similarly high rates of technical success, when compared to PTBD. As a matter of fact, biliary drainage is maybe the most evident paradigm of the increasing interconnection between ERCP and EUS, and obtaining an adequate informed consent (IC) is an emerging issue. The aim of this commentary is to discuss the reciprocal roles of ERCP and EUS for malignant biliary obstruction, in order to provide a guide to help in developing an appropriate informed consent reflecting the new biliopancreatic paradigm.

Informed Consent from a Historical, Societal, Ethical, Legal, and Practical Perspective

Original Article

Lee M. Jameson, Sandra K. Al-Tarawneh

Journal of Prosthodontics, 20 February 2022

Abstract

Informed consent is often perceived as a regulatory obligation without recognizing its educational potential in the dynamic provider/patient relationship. This article discusses the complex interaction of ethics, society, and law through a historical and practical perspective. The purpose is to provide the general dentists and specialists with a comprehensive understanding of the complexity and practical dimensions of informed consent.

Consent for Delivery Room Studies: What Can Be Learned from Perceptions of Parents

Original Paper

Maria C. den Boer, Mirjam Houtlosser, Ruben S. G. M. Witlox, Henriëtte A. van Zanten, Martine C. de Vries, Arjan B. te Pas

Neonatology, 18 February 2022

Open Access

Abstract

Background

Obtaining ethically valid consent to participate in delivery room (DR) studies from parents facing an imminent premature birth can be challenging. This study aims to provide insight into parental experiences with and perceptions of consent for DR studies.

Methods

Semistructured interviews were conducted with parents of very and extreme preterm infants. Interviews were audio-recorded, transcribed, and analyzed using the qualitative data analysis software Atlas. ti V.8.4.

Results

Twenty-five parents were interviewed. Despite being in an emotional and stressful situation, most parents considered being approached for DR studies as valuable. According to parents, this was mostly due to appropriate timing and communication, compassion, and investigators not being obtrusive. Interviewed parents generally decided to accept or decline study participation based on perceived risk. Parents differed widely in how risk of specific study interventions was perceived, but agreed on the fact that parental consent is needed for DR studies that involve risk. There was no consensus among parents on deferred consent for DR studies running at our NICU. However, parents considered deferred consent appropriate for observational studies. Furthermore, it became clear that parental misunderstanding of various aspects of DR studies, including aims, the concept of randomization, and risk associated with specific interventions, was common.
Conclusions
Insight into parental perceptions of consent for DR studies allowed us to determine areas where the validity of parental consent can be improved. Further research on parental perspectives for consent for DR studies will allow us to establish consent procedures that are considered both valid and valuable.

Informed consent: perceptions and practice of orthopaedic trainees

Jodie Atkin, Ian W Incoll, John Owen, Chris Conyard
Australian and New Zealand journal of surgery, 4 February 2022
Abstract
Background
The purpose of informed consent is to provide patients with adequate information about a proposed plan or intervention, including the benefits and risks, so that they can make an informed decision about their medical treatment. The literature suggests that trainees are often delegated the task of obtaining consent with inadequate knowledge, skill or experience. The aim of this study is to determine the extent orthopaedic surgical trainees have been exposed to education about the informed consent, their perceived ability to obtain consent effectively and the frequency with which they routinely address elements of the process when consenting patients.
Methods
An eight-item questionnaire assessing trainees' experience with informed consent was distributed to trainees undertaking Australian orthopaedic surgery training in 2019.
Results
Of the 239 trainees, 102 completed the questionnaire. Although 99% of trainees were confident that they can obtain valid consent from patients, when asked about aspects of the process, many trainees do not address them. Only 29% of trainees always ask patients about goals of care and 21% always advise the patient of who will be performing the procedure. Trainees who indicated that they had received education on informed consent during surgical training are significantly more likely to address key elements.
Conclusion
Trainees' perceptions of their knowledge and skill in relation to informed consent does not align with their reported practice. Although the majority of trainees had received some education on informed consent, greater emphasis on explicit teaching and formal assessment should be undertaken during surgical training, prior to trainees completing this activity independently.

Patient attitudes towards side effect information: An important foundation for the ethical discussion of the nocebo effect of informed consent

Research Article
Mette Sieg, Lene Vase
Clinical Ethics, 1 February 2022
Abstract

A growing body of evidence suggests that the informed consent process, in which patients are warned about potential side effects of a treatment, can trigger a nocebo effect where expectations about side effects increase side effect occurrence. This has sparked an ethical debate about how much information patients ought to receive before a treatment while trying to balance the moral principles of patient autonomy and nonmaleficence. In keeping with the principle of patient autonomy, the opinion of patients themselves in relation to how much information they want about side effects is of utmost relevance in this debate. The literature was searched to identify surveys assessing patient attitudes towards side effect information. Across a broad variety of patient populations, treatment types, and countries, the majority of patients wished to be fully informed of potential side effects, particularly in relation to frequent and severe side effects, while only a small minority wanted minimal or no information at all. Results from this review suggest that nocebo research should focus on methods of avoiding nocebo effects of informed consent while ensuring that patients are well-informed about potential side effects.

Adults with capacity - a practical guide to gaining consent

Katie Crawley

Nature; BDJ Student, 31 January 2022; 29 pp 10

Introduction

Consent is an essential component of dentistry. Dental students often have very good theoretical knowledge of the consent process, but they may struggle to apply this knowledge practically within dental school. This article therefore presents a practical guide to obtaining valid consent from adults with capacity.

Living Kidney Donor Knowledge of Provided Information and Informed Consent: The PRINCE Study

Article

Emerentia Q. W. Spoon, Kirsten Kortram, Sohal Y. Ismail, Daan Nieboer, Frank C. H. d'Ancona, Maarten H. L. Christiaans, Ruth E. Dam, Hendrik Sijbrand Hofker, Arjan W. J. Hoksbergen, Karlijn Ami van der Pant, Raechel J. Toorop, Jacqueline van de Wetering, Jan N. M. Ijzermans, Frank J. M. F. Dor

Journal of Clinical Medicine, 28 January 2022; 11(698)

Open Access

Abstract

Background

Informed consent for living kidney donation is paramount, as donors are healthy individuals undergoing surgery for the benefit of others. The informed consent process for living kidney donors is heterogenous, and the question concerns how well they are actually informed. Knowledge assessments, before and after donor education, can form the basis for a standardized informed consent procedure for live kidney donation.

Methods

In this prospective, a multicenter national cohort study conducted in all eight kidney transplant centers in The Netherlands, we assessed the current status of the informed consent practice for live donor nephrectomy. All of the potential living kidney donors in the participating centers were invited to participate. They completed a pop quiz during their first outpatient appointment (Cohort A). Living kidney donors completed the same pop quiz upon admission for donor nephrectomy (Cohort B).

Results

In total, 656 pop quizzes were completed (417 in Cohort A, and 239 in Cohort B). The average donor knowledge score was 7.0/25.0 (±3.9, range 0–18) in Cohort A, and 10.5/25.0 (±2.8, range 0–17.5) in Cohort B. Cohort B scored significantly higher on overall knowledge, preparedness, and the individual item scores ($p < 0.0001$), except for the long-term complications ($p = 0.91$).

Conclusions

Donor knowledge generally improves during the live donor workup, but it is still quite disappointing. Long-term complications, especially, deserve more attention during living kidney donor education.

Respecting Patient Autonomy: Voluntary Informed Consent in Modern Medicine

Original Research

Grebenshchikova EG, Chuchalin AG

Medical Ethics, January 2021

Open Access

Abstract

The article reveals the most influential in modern bioethics approach to understanding voluntary informed consent as a way to implement the principle of respect for patient autonomy, which is determined by both legal regulation and socio-cultural factors. The authors discuss the main elements of informed consent, its specificity in clinical trials, and criteria for autonomous choice.

Types of Off-Label Drug Use and Informed Consent Doctrine When Prescribing Them

S. M. Drogovoz, V. M. Khomenko, V. V. Krynychko, M. Barus, A. Kovpak, M. O. Ostapets, T. O. Artiukh

Pharmacology Online, 2021; 3

Open Access

Abstract

Today, medicine does not have a sufficient arsenal of drugs for the personalized treatment of cancer, neurological, psychiatric, pediatric patients, HIV-infected patients. An important aspect of informed consent when prescribing drugs off label is informing patients about potentially unknown risks, as well as about the existence of a rationale for such prescription of the drug. Thus, the doctrine of informed consent means, on the one hand, the doctor provides the patient with complete information about the use of an off label drug, an alternative method of treatment, the risks and potential benefits of such an alternative, and on the other hand, the patient decides whether he is ready to be treated with a drug that will be used off label, and confirms this with informed consent. In modern good medical practice, the patient's rights take precedence over the opinion of the medical practitioner. Informed consent is an integral component of the modern relationship between doctors and their patients and a means of ensuring that the doctor's beliefs do not override the patient's right to self-determination and personal integrity.

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GENERAL/OTHER

Consent [BOOK CHAPTER]

Kate McCombe

Quick Hits in Obstetric Anesthesia, 1 January 2022; pp 93-96 [Springer]

Abstract

Adult patients with capacity have absolute autonomy over their bodies and so we must seek valid consent before any medical intervention. Failing to gain consent risks criminal prosecution for battery (harmful or offensive contact with another person), a civil claim in medical negligence for financial compensation, and disciplinary action from the professional regulators e.g. the General Medical Council (GMC) in the UK.

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