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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

November 2022 :: Issue 47

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

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

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

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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:

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

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

POLICY GUIDANCE/CODES/PROGRAM ACTION

Physician's Code of Medical Ethics updated

Press Release

World Medical Association, 8 October 2022

The revised Code, regarded as the foundation of ethical principles for physicians worldwide, defines the professional duties of physicians towards their patients, other physicians and health professionals, themselves, and society as a whole. It was adopted today in a unanimous vote at the WMA's annual General Assembly in Berlin by physician leaders from almost 60 national medical associations…

The Code says that physicians must respect not only the dignity and the rights of patients, but also explicitly mentions their autonomy…

Excerpt

…Duties to the patient

13. In providing medical care, the physician must respect the dignity, autonomy, and rights of the patient. The physician must respect the patient's right to freely accept or refuse care in keeping with the patient's values and preferences.

14. The physician must commit to the primacy of patient health and well-being and must offer care in the patient's best interests. In doing so, the physician must strive to prevent or minimise harm for the patient and seek a positive balance between the intended benefit to the patient and any potential harm.

15. The physician must respect the patient's right to be informed in every phase of the care process. The physician must obtain the patient's voluntary informed consent prior to any medical care provided, ensuring that the patient receives and understands the information needed to make an independent, informed decision about the proposed care. The physician must respect the patient's decision to withhold or withdraw consent at any time and for any reason…

Patient involvement in the development, regulation and safe use of medicines

Council for International Organizations of Medical Sciences (CIOMS)

Working Group XI on Patient involvement, 2022; 236 pages

Overview

…Informed consent and informed assent

Informed consent is a fundamental patient's right and an ethical imperative in medicine, whether for research, treatment, or sharing personal data. The patient needs to be given all relevant information and invited to ask questions about the procedure, treatment or data-sharing arrangement. To give informed consent, the patient should have the capacity to understand the implications of the consent. Also, the patient should be able to make the decision to give consent freely and without undue pressure.

When a child is too young to give informed consent, informed assent must be sought. The child should be meaningfully engaged in discussions about the research or medical procedure, according to the child's capacity. Consent should also be obtained from the child's parents or legal guardian. Moreover, the child's written agreement can be obtained if the child's literacy level allows this, taking into account emotional and psychological maturity as well as relevant individual circumstances. Informed assent is also appropriate for adults who do not have the legal capability to give consent…

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COVID-19

Community consultation for Exception from Informed Consent (EFIC) before and during the COVID-19 pandemic

Short paper

David J. Gagnon, Richard R. Riker, Frank Chessa, Christine Lord, Ashley Eldridge, Meghan Searight, Sarah Bockian, Barbara McCrum, Teresa L. May, Douglas Sawyer, David B. Seder

Resuscitation Plus, 20 October 2022

Abstract

Aim

Describe community consultation and surrogate consent rates for two Exception From Informed Consent (EFIC) trials for out-of-hospital cardiac arrest (OOHCA) - before and during the COVID-19 pandemic.

Methods

The PEARL study (2016-2018) randomized OOHCA patients without ST-elevation to early cardiac catheterization or not. Community consultation included flyers, radio announcements, newspaper advertisements, mailings, and in-person surveys at basketball games and ED waiting rooms. The PROTECT trial (2021-present) randomizes OOHCA survivors to prophylactic ceftriaxone or placebo; the community consultation plan during the pandemic included city council presentations, social media posts, outpatient flyers, but no in-person encounters. Demographics for PROTECT community consultation were compared to PEARL and INTCAR registry data, with p-value <0.05 considered significant.

Results

PEARL surveyed 1,362 adults, including 64% ≥60 years old, 96% high school graduates or beyond; research acceptance rate was 92% for the community and 76% for personal level. PROTECT initially obtained 221 surveys from electronic media – including fewer males (28% vs 72%,p<0.001) and those >60 years old (14% vs 53%;p<0.001) compared to INTCAR. These differences prompted a revised community consultation plan, targeting 79 adult in-patients with cardiac disease which better matched PEARL and INTCAR data: the majority were ≥60 years old (66%) and male (54%). Both PEARL and PROTECT enrolled more patients using surrogate consent vs EFIC (57%, 61%), including 71% as remote electronic consents during PROTECT.

Conclusions

Community consultation for EFIC studies changed with the COVID-19 pandemic, resulting in different demographic patterns. We describe effective adaptations to community consultation and surrogate consent during the pandemic.

AI Integrated Blockchain Technology for Secure Health Care—Consent-Based Secured Federated Transfer Learning for Predicting COVID-19 on Wearable Devices

Conference paper

T. Ravi Shanker Reddy, B. M. Beena

International Conference on Innovative Computing and Communications, 27 September 2022; Delhi India

Abstract

COVID-19 has been a major global challenge these days. The pandemic has changed human life, attitude, and behavior. This pandemic added a burden to people's life and health. With the new variants of SARS-CoV-2, a lot of people are even scared of going to the health centers to get the COVID-19 evaluation in fear of contamination and contagious, which caused the surge in the symptoms at later stages. Data collected across various sources can play an important role in predicting and identifying of COVID-19 virus based on the models and the classifications of this data using the most sophisticated machine learning models. The concern here is accessing or transferring an individual's data from their personal health devices which defers

users' privacy. In the recent past, there are a lot of research that has been done these days on how blockchain can help to securely track and transfer the data across trusted sources. Adding to this, federated learning also is helping on-device data usage without any critical data to be transferred to various external sources. The proposed study directs the stability of frequent health status with the help of wearable devices that capture health metrics like heart rate, blood oxygen levels, breathing rate, muscle activities, stress, emotions, movement patterns, sleep activity, precipitation, and mind/cognitive functions with the introduction of the data streams and models that can seamlessly transfer the data, with the assurance of data integrity, privacy, and control which is the scope of this paper. The usage of both the emerging technologies provides a value addition in terms of health data exchange with effective data distribution with decentralized privacy and computation. We have also introduced a consent-based personal health device registration mechanism on a blockchain consensus network with digital identity to allow and take back controls over who can access their data. We believe that this solution and the implementation would help everyone to predict the possible COVID-19 infections keeping data privacy at the most priority.

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BIOMEDICAL RESEARCH

Misconduct and Consent: The Importance of Informed Consent in Medical Research

Book Chapter

Marton Gergely, Fida K. Dankar, Saed Alrabaee

Integrity of Scientific Research, 14 October 2022; pp 81-91 [Springer]

Abstract

Human subject research in the medical arena offers an indisputable contribution to society. However, all medical research needs to be conducted through maintaining strict levels of research standards and by complying with applicable regulations and guidelines. Despite this, medical research misconduct has been around for centuries, with countless examples of gross ethical oversights and morally flawed decisions made by both medical practitioners and researchers. One area of such misconduct is within that of informed consent. Despite the continually evolving rules and regulations surrounding informed consent in medical research, countless breaches are present surrounding the topic. In this paper, we discuss the origins of informed consent, the regulations and guidelines surrounding it, the common types of informed consent necessary to be gathered, and the potential pitfalls therein. We conclude with an overview of a selection of breaches in informed consent in the area of medical research and their likely reasons.

Informed consent in clinical trials

G P Kovane, V C Nikoderm, O Khondowe

South African Journal of Bioethics and Law, 12 October 2022; 15(2)

Abstract

Background

Informed consent (IC) is not only a regulatory but also an ethical requirement to participate in any clinical trial. It is essential to determine that research participants understand what they consent to. Studies that evaluate participants' understanding of IC conclude that recall and understanding of IC is often low, and researchers recommend that interactive multimedia interventions should be implemented to optimise understanding.

Objectives

To assess participants' understanding of IC of the research trial that they agreed to participate in.

Methods

A descriptive survey design, within a quantitative research approach, was used to conduct the study at two government hospitals in the Eastern Cape Province. A semi-structured, self-administered questionnaire was used to collect information from 170 participants in research studies. Descriptive statistics were used to analyse the results.

Results

Participants were recruited from among women who enrolled in any of the three studies that were ongoing at the two sites during the recruitment period. The study participants had a mean age of 25.9 years. Nearly one-third (30%) could not recall the purpose of the original trial that they consented to. The concept of randomisation was not understood by any of the participants.

Conclusion

Regardless of extensive efforts to ensure that participants understood their participation, this study unveiled poor recall of essential information on IC. It is proposed that IC should be short and only address essential components such as purpose, procedure, possible risks or benefits, alternative options if not participating and explaining the concept of voluntary participation.

Optimized Informed Consent for Psychotherapy: Protocol for a Randomized Controlled Trial

Leonie Gerke, Sönke Ladwig, Franz Pauls, Manuel Trachsel, Martin Härter, Yvonne Nestoriuc

JMIR Research Protocols, 30 September 2022; 11(9)

Abstract

Background

Informed consent is a legal and ethical prerequisite for psychotherapy. However, in clinical practice, consistent strategies to obtain informed consent are scarce. Inconsistencies exist regarding the overall validity of informed consent for psychotherapy as well as the disclosure of potential mechanisms and negative effects, the latter posing a moral dilemma between patient autonomy and nonmaleficence.

Objective

This protocol describes a randomized controlled web-based trial aiming to investigate the efficacy of a one-session optimized informed consent consultation.

Methods

The optimized informed consent consultation was developed to provide information on the setting, efficacy, mechanisms, and negative effects via expectation management and shared decision-making techniques. A total of 122 participants with an indication for psychotherapy will be recruited. Participants will take part in a baseline assessment, including a structured clinical interview for Diagnostic and Statistical Manual of Mental Disorders-fifth edition (DSM-5) disorders. Eligible participants will be randomly assigned either to a control group receiving an information brochure about psychotherapy as treatment as usual (n=61) or to an intervention group receiving treatment as usual and the optimized informed consent consultation (n=61). Potential treatment effects will be measured after the treatment via interview and patient self-report and at 2 weeks and 3 months follow-up via web-based questionnaires. Treatment expectation is the primary outcome. Secondary outcomes include the capacity to consent, decisional conflict, autonomous treatment motivation, adherence intention, and side-effect expectations.

Results

This trial received a positive ethics vote by the local ethics committee of the Center for Psychosocial Medicine, University-Medical Center Hamburg-Eppendorf, Hamburg, Germany on April 1, 2021, and was prospectively registered on June 17, 2021. The first participant was enrolled in the study on August 5, 2021. We expect to complete data collection in December 2022. After data analysis within the first quarter of 2023, the results will be submitted for publication in peer-reviewed journals in summer 2023.

Conclusions

If effective, the optimized informed consent consultation might not only constitute an innovative clinical tool to meet the ethical and legal obligations of informed consent but also strengthen the contributing factors of psychotherapy outcome, while minimizing nocebo effects and fostering shared decision-making.

Informed consent in clinical trials: Implementing methods to improve patient understanding in cancer research—A quality improvement initiative in a sarcoma trials unit

Meeting Abstract

Caitriona Goggin, Bader Al-Badri, Anna Stansfeld, Elizabeth Barquin, Benjamin Durand, Thuy-Giang Nguyen, Preethika Mahalingam, Eniola Ayeni, Andrea Napolitano, Shane Zaidi, Aisha Miah, Robin Lewis Jones, Charlotte Benson

American Society of Clinical Oncology Journal, Quality Care Symposium, 2022

Abstract

Background

Clinical trials are considered the cornerstone of improving outcomes for cancer patients. The understanding of an individual patient of the trial on which they are enrolled can vary significantly, with some studies demonstrating poor patient understanding of their involvement in trials. This exploratory study aimed to improve patient understanding of clinical trials and patient experience of the informed consent process by implementing measures to present complex trial information in alternative formats.

Methods

The project was undertaken in a sarcoma trials unit in a specialist cancer treatment centre. Baseline knowledge was assessed using an adapted version of the Quality of Informed Consent (QuIC) questionnaire. A decision-aid was created following focus group discussions with stakeholders, focusing on key trial questions for patients, such as consent, the research description, risks, benefits, and alternatives to the trial. A patient education video was produced by the research team, explaining general aspects of clinical trials in patient-friendly language. The decision-aids and videos were distributed during the informed consent process of trial recruitment over a 12-week period. The patient group was assessed with post-intervention questionnaires. Statistical analysis was descriptive due to the small numbers.

Results

Thirty sarcoma patients participated in the project, including baseline assessment of 15 patients previously enrolled on study, and 15 patients considering participation in a trial who underwent the intervention. 100% (n = 15) of the interventional group found the video and decision-aid useful. 60% (n = 18) of patients had a university level education, indicating a well-educated population. A pre- and post-intervention comparison demonstrated an improved understanding of 10 key elements of clinical trial information as shown in Table.

Conclusions

Our exploratory study has shown that patient education tools including decision-aids and patient videos can be successfully implemented to help improve patient understanding of clinical trial information and may be of benefit in other trials units. Further larger studies are required to confirm these findings.

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SOCIAL SCIENCE RESEARCH

Ethical Relativism and Circumstances of Social and Cultural Contingencies on Informed Consent in the Conduct of Research: Clinical Trials in Nigeria

Original Paper

Sola Aluko-Arowolo, Saheed Akinmayọwa Lawal, Isaac A. Adedeji, Stephen Nwaobilor

Asian Bioethics Review, 13 October 2022

Abstract

There have been debates across the globe for a social and culturally sensitive ethics to meditate a catalyst of template for informed consent (IC) in the conduct of social researches and clinical trial. The study adopted ethical relativism theory to explore social and cultural contingencies on IC with descriptive research design and snowball sampling techniques with a pool of 23 participants randomly and purposively selected amongst

the stakeholders including researchers. Seven lecturers and 5 medical practitioners from selected universities, 5 clergy members of different genders and denominations with 2 Imams, 1 chief and 2 traditional health practitioners completing the pool. The data were compiled separately with pseudonym to maintain the anonymity of the participants and content analysed thematically to probe awareness, understanding, patriarchy and religious dimensions on IC. The paper argued that ethics and law regulations must be strengthened to leverage on different individual values, norms and social indices. The paper concluded and suggested that researchers can avoid and resolve ethical dilemmas and maintain research regularity when ethical obligations are well understood and strictly adhered to, and to develop the Informed Consent Evaluation Feedback Tool (ICEFbT) with oversight function from Institution Review Board (IRB) in the universities and research institutes before the commencement of research and/or medical procedures.

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HEALTH DATA

Computable Consent – From Regulatory, Legislative, and Organizational Policies to Security Policies

Conference paper
Zoran Milosevic, Frank Pyefinch
International Conference on Enterprise Design, Operations, and Computing, 28 September 2022; Italy
Abstract
Consumer-facing health applications are increasingly requiring flexible approaches for expressing consumer consent preferences for the use of their health data across multiple providers, and across cloud and on-premises systems. This and the recognition of the need for clear governance and legislative rules that specify enforceable policies over how consumer data is used by the nominated and other providers, including AI vendors, increasingly require machine readable, i.e. computable consent expressions. These expressions can be regarded as additional constraints over security policies, applicable to all stakeholders, while accommodating rules from regulatory and legislative policies. Support for both kind of policies contribute to improving consumer trust in the use of their data. This is applicable to both care delivery processes but also research projects, such as clinical trials. This paper proposes a computable consent framework and positions it in the context of the new developments within Health Level Seven (HL7®) Fast Health Interoperability Resources (FHIR®) standard. The proposal is based on the use of precise policy concepts from the ISO/ITU-T RM-ODP (Reference Model for Open Distributed Processing) standard. The aim is to provide general standards-based policy semantics guidance to interoperability/solution architects and implementers involved in digital health applications. The framework is driven by consent requirements, while leveraging broader policy input from medico-legal community.

Consent form, the highest ethical standard in creating DNA databases for criminal investigation

Renata Jankova, Pavlinka Donevska-Stefanov, Natasha Bitoljanu, Goran Pavlovski, Robert Janevski, Aleksandar Stankov
Forensic Science International: Genetics Supplement Series, 25 October 2022
Abstract
Preparation of DNA databases for the purpose of criminal investigation opens discussions about ethical-legal issues concerning violation of human rights. The practice shows that one of the human rights that can be misused while creating such a database is the right to freedom, the freedom to make a decision. When preparing DNA databases, the right to freedom refers to free decision of the person to be sampled for carrying out the test. The right to freedom and respect to self-determination of the person implies the necessity of prior consent of the subject when preparing a database on general population level. This is not a

case when databases are created from persons under investigation for committing a crime, who are compulsory subjected for obtaining samples for DNA analysis. Legal regulations approve the duty of the police and its authorization in collecting samples for personal or criminalistic identification, analyzing, keeping and eliminating collected personal information when criminal prosecution is concerned. In these cases, consent form from the subject is not necessary. However, we should be aware that the process of taking and collecting of personal information by the national institutions can have direct impact of privacy of the subject, no matter if this information is going to be used or not. In purpose of fair balance between public and private interest, consent form can be redefined and the person from whom the biological material is provided will be unequivocally made aware of the purposes for which his genetic data will be used, how long his DNA will undergo further automated processing, and about the procedure and under what conditions his DNA profile can be removed from the national DNA databases.

Safeguarding Personal Data: Meta Consent as a Remedy to Section 28(2)(c) of Kenya's Data Protection Act

Wanditi Gathumbi

Strathmore Law Review, 2022; 7(1) pp 127-159

Abstract

Biometric identity systems have been adopted in the Global South, following the Global North's lead. The greatest discrepancy, however, is the existence of legal frameworks that govern the use, storage and processing of the data collected. The Kenyan government's roll-out of the Huduma Namba registration exercise in April 2019 with no existing data protection law in Kenya exemplifies this. Thereafter, Parliament passed the Data Protection Act. Unfortunately, parts of this law are not keen enough to protect personal data. Deviating from the requirement for personal data to be directly collected from the data subject, section 28(2)(c) of the referenced Act permits indirect collection of personal data from a source other than the data subject themselves. Relying on desk-based research and using the Huduma Namba exercise as a case study, this paper examines this permission and the imminent danger it poses to privacy of the personal data of Kenyans. Finding that section 28(2)(c) exposes personal data to the privacy violations of secondary use and exclusion threatens the right to privacy, this research suggests that the meta consent model as embraced by the healthcare sector emerges as a feasible solution. This model allows data subjects to determine their consent preferences i.e., how and when they wish their consent to be sought for further collection and use, at the point of primary collection of personal data. Additionally, this paper recommends that the model should be embraced by the judiciary in its adjudication of matters and finally, that an amendment incorporating the solution should be made.

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BIOBANKING

Improving the Practice of Obtaining Informed Consent for Biobanking in Clinical Settings

Laura Arregui Egido, María Villalobos-Quesada

Biopreservation and Biobanking, 29 September 2022

Abstract

Background

Biobanks form key research support infrastructures that ensure the highest sample quality for scientific research. Their activity must align closely and proportionally to the interests of researchers, donors, and society. Informed consent (IC) is a central tool to guarantee the protection of donors' rights and interests.

Aim

This study aimed to analyze the challenges of obtaining IC for biobanking in clinical settings and ways to improve this process.
Methods
Biobank Bellvitge University Hospital HUB-ICO-IDIBELL in Barcelona received 8671 IC forms between 2017 and 2020. The mistakes that caused IC forms to be rejected by the Biobank were analyzed. In addition, interventions aimed at physicians to improve the IC process were evaluated through a calculation of the relative risk (RR). Finally, physicians who submitted samples to the Biobank, most of whom are involved in research activities, were surveyed about the barriers to collecting IC and how to improve this process.
Results
During 2017–2020, 19.6% of IC forms were rejected. The most relevant cause of rejection was the use of outdated IC forms, followed by missing patient information or mistakes having been made by the physician. Evaluation of the rejection rates before and after interventions to improve the IC process suggests significant improvement (27.7% before interventions (January 2017–May 2018) compared to 9.6% after interventions (February–December 2020), RR 0.4 95% CI 0.34–0.47; $p < 0.0001$). According to the physicians, the most important barrier to collecting IC is the time constraint, and they consider digitalization as a viable solution.
Conclusions
Our research offers a view of the less well-understood practical challenges that physicians and biobanks face when collecting IC in clinical settings. It suggests that, despite multiple challenges, continuous monitoring, training, and information programs for physicians are key to optimizing the IC process in clinical settings.

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YOUNG PERSONS

Parental Preferences Surrounding Timing and Content of Consent Conversations for Clinical Germline Genetic Testing Following a Child's New Cancer Diagnosis

Original Reports
Belinda N. Mandrell, Liza Marie Johnson, Mary Caples, Jami Gattuso, Jamie L. Maciaszek, Roya Mostafavi, Katianne M. Howard Sharp, Kim E. Nichols
JCO Precision Oncology, 20 October 2022
Abstract
Purpose
Clinical genomic testing is increasingly being used to direct pediatric cancer care. Many centers are interested in offering testing of tumors and paired germline tissues at or near the time of cancer diagnosis. We conducted this study to better understand parent preferences surrounding timing and content of consent conversations for clinical germline genetic testing of their children with cancer as a part of real-time cancer care.
Patients and Methods
A seven-question survey developed by the Division of Cancer Predisposition and collaborators at St Jude Children's Research Hospital (St Jude) was distributed to members of the St Jude Patient Family Advisory Council, which included parents of childhood cancer survivors and bereaved parents whose children with cancer had died. Parents were asked to provide free text comments after each question. Qualitative methods were used to derive codes from parent comments, and survey results were depicted using descriptive statistics.
Results
The survey was completed by 172 parents. Ninety-three (54%) endorsed an approach for consent conversations ≥ 1 month after cancer diagnosis, whereas 58 (34%) endorsed an approach at 1-2 weeks and 21 (12%) at 1-2 days. Needing time to adjust to a new or relapsed cancer diagnosis and feeling overwhelmed were frequent themes; however, parents acknowledged the urgency and importance of testing. Parents desired testing of as many cancer-related genes as possible, with clinical utility the most important factor for

proceeding with testing. Most parents (75%) desired germline results to be disclosed in person, preferably by a genetic counselor.

Conclusion

Parents described urgency and benefits associated with germline testing, but desired flexibility in timing to allow for initial adjustment after their child's cancer diagnosis.

Editor's note: JCO is an American Society of Clinical Oncology Journal.

Children's understanding and consent to heart surgery: Multidisciplinary teamwork and moral experiences

Priscilla Alderson, Hannah Bellsham-Revell, Nathalie Dedieu, Liz King, Rosa Mendizabal, Katy Sutcliffe

Journal of Child Health Care, 27 September 2022

Abstract

Mainstream law and ethics literature on consent to children's surgery contrasts with moral experiences of children and adults observed in two heart surgery centres. Research interviews were conducted with 45 practitioners and related experts, and with 16 families of children aged 6 to 15, admitted for non-urgent surgery, as well as an online survey. Thematic data analysis was informed by critical realism and childhood studies.Impersonal adult-centric mainstream literature assumes young children cannot consent. It is based on dichotomies: adult/child, competent/incompetent, respect or protect children, inform or distract them, use time swiftly or flexibly, verbal/non-verbal communication, respect or control children and reason/emotion.Through their moral experiences, adults and children resolve these seeming dichotomies. Through understanding young children's reasoning and emotions about complex distressing decisions related to heart surgery, adults share knowledge, control, trust and respect with them. They see children's consent or refusal before non-urgent surgery as a shared personal moral experience within the child's life course, beyond mere legal compliance. Adults help children to understand and 'want' the surgery that offers things they value: better health or to 'be more like their friends'. If children are not convinced, sometimes surgery is postponed or occasionally cancelled.

Readability and comprehension of paediatric informed consent and assent forms from a single institution in South Africa

Mwanaidi Kafuye, Mariana Kruger

Tanzania Journal of Health Research, 2022; 23 pp 39-39

Abstract

Background

Informed consent and assent forms are fundamental prerequisites in the conduct of ethical paediatric health research. For paediatric research, parents or the legal caretaker of a child should provide informed consent along with the child or adolescent. Readability and comprehension of consent and assent forms in both therapeutic and non-therapeutic studies play a critical role during the informed decision-making process of study participants.

Objectives

To assess the readability scores and to determine the school grade level of informed consent forms (ICFs), and informed assent forms (IAFs) also to assess accuracy and completeness of elements of ICFs and IAFs.

Methods

We used web-based readability score calculator to determine scores of Flesch Kincaid Reading Ease (FRE), Flesch-Kincaid Grade Level (FKGL) and length (word count) of the assent and consent forms, respectively. We also assessed inclusion of essential elements in the ICFs and IAFs using consent form guidance available in the South African Department of Health: Ethics in Health Research Guidelines (2015) as standard.

Results

The mean Flesch Kincaid readability ease score for 28 ICFs was 57 while that of the23 IAFs was 68. Furthermore, the higher the Flesch Kincaid Reading Ease scores the lower was the Flesch-Kincaid Grade Level score (p < 0.001). The therapeutic ICF and IAF forms were substantially longer than the non-therapeutic ICF and assent forms (p < 0.001). Most ICFs and IAFs provided accurate and complete elements of ICF with regards to research information with adherence to the Ethics guideline of the South African Department of Health.

Conclusion and recommendations

There were higher word counts in both ICFs and IAFs for therapeutic studies versus non-therapeutic studies. The study concludes that both ICFs and IAFs were difficult to comprehend with significantly higher Flesch Kincaid reading grade levels than the NIH/AMA/USDHHS recommended reading grade level 6.

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TECHNOLOGY/OTHER MEDIATION

A cost–consequence analysis of eLearning videos designed to supplement the consent process in lower limb arthroplasty

J Brock, A Sale, U Jayaraju, A Chandetreya, P Lee

Royal College of Surgeons of England Annals, 19 October 2022

Abstract

Introduction

Since the Montgomery ruling in 2015 surgeons have been tasked with identifying material risk when taking informed consent. Despite this, there has been limited uptake of technological aids to supplement the consent process although such aids are shown to improve patient knowledge and satisfaction. ConsentPLUS is a free-to-access website with bite-sized educational videos designed to clearly explain lower limb arthroplasty procedures to patients and aid their consent.

Methods

We performed a prospective cost–consequence analysis, outlining any costs associated with the intervention and any quantitative or qualitative impacts the intervention may have on patients.

Results

A total of 3,143 consecutive patients were identified who were undergoing total knee or hip replacement in 25 elective NHS orthopaedic units. The total cost of development and projected 10-year running fees for ConsentPLUS total £75,000. Health Foundation support means the service is free-to-access for centres throughout the UK. Mean exposure time per patient was 10min 29s, equivalent to £185,437 of additional contact time according to the National Tariff. Mean clinic time was reduced by 17min owing to the earlier identification of material risk. Patient knowledge on pre- and post-video quizzes increased from 7.01 to 9.08 following eLearning (paired t-test = 0.998). The process had an overall satisfaction rate of 97%.

Conclusion

Educational eLearning videos are an accessible and digestible way to supplement the consent process. This enables earlier identification of material risk in clinics owing to improved patient knowledge, leading to increased patient satisfaction with arthroplasty consenting.

Digitized and structured informed patient consent before contrast-enhanced computed tomography: feasibility and benefits in clinical routine

Original Article

Markus Kopp, Jan Peter Roth, Frederik Geisler, Sascha Daniel, Theresa Ruettinger, Christoph Treutlein, Eva L. Balbach, Rafael Heiss, Matthias Wetzl, Nouhayla El Amrani, Alexander Cavallaro, Michael Uder, Matthias S. May

Insights into Imaging, 11 October 2022; 13(164)

Open Access

Abstract

Background

To evaluate the feasibility and benefits of digitized informed patient consent (D-IPC) for contrast-enhanced CT and compare digitized documentation with paper-based, conventional patient records (C-PR).

Methods

We offered D-IPC to 2016 patients scheduled for a CT. We assessed patient history (e.g., CT examinations, malignant or cardiovascular diseases) and contraindications (red flags) for a CT (e.g., thyroid hyperfunction, allergies) using a tablet device. We evaluated the success rate of D-IPC and compared patient age between the subgroups of patients who were able or unable to complete D-IPC. We analyzed the prevalence of marked questions and red flags (RF). RF were compared with the documentation from C-PR. We estimated greenhouse gas (GHG) emissions for paperless workflow and provide a cost–benefit analysis.

Results

Overall, 84.4% of patients completed D-IPC. They were younger (median 61 years) than unsuccessful patients (65 years; $p < 0.001$). Patients who marked questions (21.7%) were older than patients without inquiries (median 63.9 vs 59.5 years; $p < 0.001$). The most prevalent RF was thyroid disease (23.8%). RF were considered critical for contrast-agent injection in 13.7%, requiring personalized preparation. The detection rate for RF documented with D-IPC was higher than for C-PR (n = 385 vs. 43). GHG emissions for tablet production are 80–90 times higher than for paper production. The estimated costs were slightly higher for D-IPC (+ 8.7%).

Conclusion

D-IPC is feasible, but patient age is a relevant factor. Marked questions and RF help personalize IPC. The availability of patient history by D-IPC was superior compared to C-PR.

Informed consent for third molar extraction; a comparison of conventional verbal consent versus video-assisted consent

Ciara Mulvihill

Trinity College Dublin, Dental Science Thesis, 2022

Abstract

Background

The goal of the informed consent process is to provide patients with the necessary educational information, defend their autonomy, and allow active involvement in treatment planning and decision-making. The informed consent process must not only describe the operation in full, but also provide information on the procedure's rationale, alternative therapies, associated benefits, risks, and complications. However, the process of acquiring informed consent is fraught with issues.

Objective

This research aims to assess if presenting information about third molar extraction via an informative, narrated, animated video changes a patient s perception of the consent process for third molar extraction when compared to conventional verbal/written consent. The outcomes that are evaluated include patient understanding, patient satisfaction and patient anxiety.

Methods

In this post test-only control clinical trial patients scheduled for surgical removal of an impacted mandibular third molar that fulfilled the predetermined criteria were invited to participate in the study. The criterion variable was the presentation of an animated information consent video. Participants were randomly assigned into 2 equal groups receiving either verbal consent or video-assisted consent. After signing the consent form patients then filled out an electronic questionnaire rating their experience of the consent process. At the postoperative review, 7-14 days after the procedure, patients were asked to fill out a questionnaire rating their experience of the consent retrospectively. The outcome variables were patients self-reported level of understanding, patient anxiety measured on the Dental Anxiety Scale and patient

satisfaction. The data were analysed with Pearson s chi-squared tests, Fisher s Exact test, and linear regression analysis.
Results
Ninety patients fulfilled the inclusion criteria and were included in the study. The video-assisted group reported higher levels of understanding of the proposed procedure (P<0.001) and the associated risks/complications (P<0.004). Patients were more satisfied with information delivered to them via video. 98% of patients in the video consent group felt that the video-assisted consent was beneficial. There was no statistically significant change in the reported level of anxiety when video-assisted consent was used.
Conclusion
The present study suggests that video-assisted consent may improve patients level of understanding of the potential postoperative risks and complications involved in surgical removal of an impacted mandibular third molar. This improved understanding did not increase patients dental anxiety compared with conventional verbal/written consent but improved patients level of satisfaction with the amount of information that they received.

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RIGHTS/LEGAL/LEGISLATIVE

A Qualitative Content Analysis of Comments on Press Articles on Deemed Consent for Organ Donation in Canada

Danielle E. Fox, Maoliosa Donald, Christy Chong, Robert R. Quinn, Paul E. Ronksley, Meghan J. Elliott, Ngan N. Lam
Clinical Journal of the American Society of Nephrology, October 2022
Abstract
Background and objectives
In 2019, two Canadian provinces became the first jurisdictions in North America to pass deemed consent legislation to increase deceased organ donation and transplantation rates. We sought to explore the perspectives of the deemed consent legislation for organ donation in Canada from the viewpoint of individuals commenting on press articles.
Design, setting, participants, & measurements
In this qualitative descriptive study, we extracted public comments regarding deemed consent from online articles published by four major Canadian news outlets between January 2019 and July 2020. A total of 4357 comments were extracted from 35 eligible news articles. Comments were independently analyzed by two research team members using a conventional content analysis approach.
Results
Commenters' perceptions of the deemed consent legislation for organ donation in Canada predominantly fit within three organizational groups: perceived positive implications of the bills, perceived negative implications of the bills, and key considerations. Three themes emerged within each group that summarized perspectives of the proposed legislation. Themes regarding the perceived positive implications of the bills included majority rules, societal effect, and prioritizing donation. Themes regarding the perceived negative implications of the bills were a right to choose, the potential for abuse and errors, and a possible slippery slope. Improving government transparency and communication, clarifying questions and addressing concerns, and providing evidence for the bills were identified as key considerations.
Conclusions
If deemed consent legislation is meant to increase organ donation and transplantation, addressing public concerns will be important to ensure successful implementation.

An ex-ante cost-utility analysis of the deemed consent legislation compared to expressed consent for kidney transplantations in Nova Scotia

Research

Prosper Koto, Karthik Tennankore, Amanda Vinson, Kristina Krmpotic, Matthew J. Weiss, Chris Theriault, Stephen Beed

Cost Effectiveness and Resource Allocation, 6 October 2022; 20(55)

Open Access

Abstract

Background

This study was an ex-ante cost-utility analysis of deemed consent legislation for deceased organ donation in Nova Scotia, a province in Canada. The legislation became effective in January 2021. The study's objective was to assess the conditions necessary for the legislation change's cost-effectiveness compared to expressed consent, focusing on kidney transplantation (KT).

Method

We performed a cost-utility analysis using a Markov model with a lifetime horizon. The study was from a Canadian payer perspective. The target population was patients with end-stage kidney disease (ESKD) in Atlantic Canada waitlisted for KT. The intervention was the deemed consent and accompanying health system transformations. Expressed consent (before the change) was the comparator. We simulated the minimum required increase in deceased donor KT per year for the cost-effectiveness of the deemed consent. We also evaluated how changes in dialysis and maintenance immunosuppressant drug costs and living donor KT per year impacted cost-effectiveness in sensitivity analyses.

Results

The expected lifetime cost of an ESKD patient ranged from $177,663 to $553,897. In the deemed consent environment, the expected lifetime cost per patient depended on the percentage increases in the proportion of ESKD patients on the waitlist getting a KT in a year. The incremental cost-utility ratio (ICUR) increased with deceased donor KT per year. Cost-effectiveness of deemed consent compared to expressed consent required a minimum of a 1% increase in deceased donor KT per year. A 1% increase was associated with an ICUR of $32,629 per QALY (95% CI: − $64,279, $232,488) with a 81% probability of being cost-effective if the willingness-to-pay (WTP) was $61,466. Increases in dialysis and post-KT maintenance immunosuppressant drug costs above a threshold impacted value for money. The threshold for immunosuppressant drug costs also depended on the percent increases in deceased donor KT probability and the WTP threshold.

Conclusions

The deemed consent legislation in NS for deceased organ donation and the accompanying health system transformations are cost-effective to the extent that they are anticipated to contribute to more deceased donor KTs than before, and even a small increase in the proportion of waitlist patients receiving a deceased donor KT than before the change represents value for money.

The Current Practice and Medico Legal Aspects of Informed Consent in Obstetrics and Gynaecology in a Teritary Care Hospital, Can We Improve?: An Interventional Study

Shreen R., Kagne R.N., Jayasree M

Indian Journal of Forensic Medicine and Toxicology, October-December 2022; 16(4)

Open Access

Abstract

The Informed Consent plays major role in both Patients and the Doctors to carry out various aspects in the surgical procedures. This paper was an interventional study it was conducted in the Department of Forensic Medicine and Toxicology, Sri Manakula Vinayaga Medical College and Hospital, Madagadipet, Puducherry to audit and to improve it was conducted in the Department of Obstetrics and Gynaecology. The deficiencies were identified and it was analysed. The results of both pre-interventional and post-interventional were recorded, which showed the significant improvement in the consent form of the major and minor

procedures. This study results will give importance on documenting the Informed Consent day to day life practice.

Informed Decision-Making and Capabilities in Population-based Cancer Screening

Ineke L L E Bolt, Maartje H N Schermer, Hanna Bomhof-Roordink, Danielle R M Timmermans

Public Health Ethics, 3 October 2022

Abstract

Informed decision-making (IDM) is considered an important ethical and legal requirement for population-based screening. Governments offering such screening have a duty to enable invitees to make informed decisions regarding participation. Various views exist on how to define and measure IDM in different screening programmes. In this paper we first address the question which components should be part of IDM in the context of cancer screening. Departing from two diverging interpretations of the value of autonomy—as a right and as an ideal—we describe how this value is operationalized in the practice of informed consent in medicine and translate this to IDM in population-based cancer screening. Next, we specify components of IDM, which is voluntariness and the requirements of disclosure and understanding. We argue that whereas disclosure should contain all information considered relevant in order to enable authentic IDM, understanding of basic information is sufficient for a valid IDM. In the second part of the paper we apply the capability approach in order to argue for the responsibility of the government to warrant equal and real opportunities for invitees for IDM. We argue that additional conditions beyond mere provision of information are needed in order to do so.

Towards a technologically assisted consent in the upcoming new EU data laws?

Andrés Chomczyk Penedo

Privacy in Germany, 2 September 2022

Abstract

The European Commission (Commission) put forward an ambitious proposal package of new legislation for the digital economy, including the Digital Markets Act, the Digital Services Act, or the Data Governance Act. Despite their different scopes, they all share a recurring topic: the relevance of (personal) data in enabling a data-intensive economic model around data sharing and the role of data subjects in granting permission to do so. As such, the purpose of this article is to explore how the Commission and other EU institutions intended to strengthen consent in these novel data regulations through technological tools but also novel assistance duties, but also the potential shortcoming around this approach.

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CULTURAL/COUNTRY CONTEXT

Cross Sectional Study on Knowledge and Awareness on Informed Consent Among Nurses in Tertiary Care Hospital Hyderabad

K Srinivasulu, Sannidhi Ramyasri, Thamba Pranavi, KB Ronitha Vasuki Devi, Fathima Ashraf

Indian Journal of Forensic Medicine and Toxicology, October-December 2022; 16(4)

Open Access

Abstract

Nurses have a legal duty to ensure and obtain informed consent from their patients before undertaking any examination or procedure. Informed consent allows patients to make their decisions with their healthcare providers, this collaborative decision making process is mandatory in medical practice. A cross sectional study on knowledge and awareness on informed consent among nurses working in a tertiary care teaching hospital was conducted at Hyderabad, Telangana, 200 nurses working in various departments of the hospital were

participated in this study, a questionnaire was prepared in regard to informed consent and assessed their knowledge levels by grading. The data was taken into Excel sheet and statistic evaluation was done by using MS Excel software. We found 67.7% are having awareness on informed consent whereas 32.3% are unaware. Similar results were observed in studies conducted in India and abroad, periodical workshops and continuous medical education programs can achieve better results.

Factor Analysis of Incomplete Informed Consent in Medical Record Installation Bangil Hospital in 2021

Mahbubah, Arma Roosalina, Holipah Holipah

Jurnal Kedokteran Brawijaya, 24 October 2022

Open Access

Abstract

Medical action is an action taken on a patient in the form of diagnostic or therapeutic. All medical procedures to be performed on the patient must in consent. To conduct an informed consent filling, is when the patient agrees to be used as a medical action after being given an explanation by the officer. The one whose in charges to take a medical action must be a medical personnel. According to the hospitals' standard minimum services, the completeness informed consent filling must be 100%. Bangil Hospital achieved 37% of completeness informed consent filling. This study aims to analyze the causative factors of informed consent incompleteness at Bangil Hospital. This study using a descriptive data analysis. Data collection techniques in this study are using a document studies, interviews and FGD. Document studies were conducted on 100 informed consent documents, interviews and FGDs were conducted to related officers to determine the causative factors of informed consent incompleteness documents which were analyzed using fishbone diagrams. From the results of the analysis, were determined that the priority of the root of the problem to be solved first are the man factor and the method. Thus, The CARL method used to find out an alternative solutions to cope the priority of the root of the problem. From the results of the scoring conducted, the main factor of informed consent incompleteness at Bangil Hospital was due to the absence of a flow in filling out the informed consent. Keywords: Informed consent, medical action, incompleteness.

Editor's note: Jurnal Kedokteran Brawijaya is published by the Faculty of Medicine at Universitas Brawijaya, Indonesia.

Evaluation of consent forms for clinical practice in Spanish Public Hospitals

Original Article

E. Morales-Valdivia, R. Camacho-Bejarano, A.M. Brady, M.I. Mariscal-Crespo

Journal of Healthcare Quality Research, 27 September 2022

Abstract

Objective

To evaluate the access, development, and quality of consents forms for clinical practice within the Spanish Public Hospitals.

Method

A cross-sectional study was conducted in a two-stage process (January 2018–September 2021). In stage 1, A nationwide survey was undertaken across all public general hospitals (n = 223) in the Spanish Healthcare System. In stage 2, Data was taken from the regional health services websites and Spanish regulations. Health Regional Departments were contacted to verify the accuracy of the findings. Data was analyzed using a descriptive and inferential statistics (frequencies, percentages, Chi-square & Fisher's exact tests).

Results

The response rate was 123 (55.16%) of Spanish Public Hospitals. The results revealed a range of hospital departments involved in the development of consent documents and the absence of a standardized approach to consent forms nationally. Consent audits are undertaken in 43.09% hospitals and translation of written consents into other languages is limited to a minority of hospitals (35.77%). The validation process of

consent documentation is not in evidence in 13% of Spanish Hospitals. Regional Informed Consent Committees are not place in the majority (70.7%) of hospitals. Citizens can freely access to consent documents through the regional websites of Andalusia and Valencia only.
Conclusion
Variability is found on access, development and quality of written consent across the Spanish Public Hospitals. This points to the need for a national informed consent strategy to establish policy, standards and an effective quality control system. National audits at regular intervals are necessary to improve the consistency and compliance of consent practice.

Development and validation of informed consent for blood transfusion questionnaire

Original Article
Mohd Hilmi Senin, Mastura Mohd Sopian, Bakiah Shaharuddin, Muhammad Jaffri Mohd Nasir
Asian Journal of Transfusion Science, 2022
Abstract
Introduction
Blood transfusion warrants written informed consent from the patient. However, patients have poor knowledge regarding blood transfusions as evidenced by nonstandardized information retained by patients from the informed consent discussion. The problem stems from suboptimal patient knowledge on the elements of informed consent. This study describes the development and validation of a new questionnaire to assess the knowledge on informed consent for blood transfusion from the patients' perspective.
Subjects and Methods
The development phase consisted of literature review, small group discussion, expert review meeting, content, and face validity. We evaluated the psychometric properties of Informed Consent for Blood Transfusion Questionnaire (ICBTQ) using reliability test and item response theory among a sample of 95 patients in Hospital Universiti Sains Malaysia.
Results
ICBTQ was formulated to include sociodemographic and knowledge sections. ICBTQ possessed excellent content validity. The face validity index (FVI) of clarity and comprehension were both 0.97. Thus, the universal FVI was 0.96. One item was added following the advice given by one of the content experts. ICBTQ had excellent face validity. For the validation phase, ICBTQ demonstrated an acceptable Cronbach's Alpha value. One item was omitted in view of low corrected item-total correlation. In the item response theory (IRT) analysis, ICBTQ exhibited good difficulty and discriminatory indexes. Assessments of item-fit indicated that all items of the model were well-fitted.
Conclusions
Based on the IRT and reliability analysis, the knowledge section of the ICBTQ was psychometrically valid to be used among patients.

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MEDICAL/SURGICAL

Assessing Adult Patients' Understandings of Secondary Malignancy Risk Terms in Radiation Therapy Consent

N.Vartanian, M.Wilson, R.P.Ermoian
International Journal of Radiation Oncology*Biology*Physics, 1 November 2022; 114(3) pp e500-e501
Abstract
Purpose/Objective(s)
Informed consent is an essential component of cancer care. The terms "second tumors" or "secondary tumors" are sometimes used in radiation therapy consent. Their incidences are sometimes described as

"rare," although vary greatly from nearly negligible in patients treated with palliative intent, to 20% in young patients undergoing myeloablative total body irradiation. We evaluated whether patients without prior knowledge of radiation therapy interpret the terms in a way consistent with physician intent.

Materials/Methods

We screened 164 adult subjects who did not require medical interpreters at a university-affiliated family medicine clinic, excluding cancer patients and those with any prior knowledge of or experience with radiation treatment. One hundred subjects were eligible for and completed a 12-question multiple choice questionnaire, which assessed their understanding of the term "secondary tumor" or "second tumor", and how they would interpret the terms "small chance" or "rare" in the context of a "bad side effect."

Results

Twenty-nine percent of subjects correctly identified that "secondary tumors" referred to new and different tumors caused by treatment. Forty-nine percent thought the term referred to their original tumor recurring, and 22% thought the term referred to new and different tumors not caused by radiation therapy. Subjects with college degrees were not more likely to choose the correct answer than subjects without college degrees p=0.63. College degree status was not available for 5 subjects. Given choices between 1:10, 1:100, 1:1000, and 1:100,000, subjects associated "rare" with 1:1000 or 1:100,000 82% of the time. The term "small chance" was associated with 1:1000 or 1:100,000 59% of the time.

Conclusion

Adult non-cancer patients have a demonstrably different understanding than radiation oncologists of the terms "second tumor" or "secondary tumor." Additionally, patient understanding of the terms "rare" or "small chance" varies from secondary malignancy incidences in many clinical scenarios. Radiation oncologists should use clearer terms for secondary malignancies and their incidence.

Survey of Informed Consent Procedures in Urology

Juliana Kim, Arnav Srivastava, Alexandra Tabakin, Eric A Singer

Journal of the American College of Surgeons, November 2022; 235(5)

Abstract

Introduction

The American Urological Association and American College of Surgeons codes of professionalism require surgeons to disclose the specific roles and responsibilities of trainees to patients during the informed consent process. This study analyzes how these requirements are met by urology training programs.

Method

An anonymous electronic survey was distributed to the program directors (PDs) of the 143 ACGME urology residency programs in the US in 2021. Responses were procured during 3 months. Information was collected regarding program demographics, aspects of the program's consent process, and the disclosure of the role and participation of residents to patients.

Result

Of 143 distributed surveys, 30.0% (n = 43) received a response. Of responding PDs, 67.4% reported that attending physicians lead the consent process. The topics covered during consent discussion include possible complications (25.1%), expected recovery time (22.8%), length of the surgery (22.2%), the people involved (18.0%), and their specific roles (7.2%). Of PDs, 48.8% and 87.8% of do not explicitly discuss trainee involvement or when a resident performs the majority of the case, respectively (Figure). Of PDs, 78.8% do not communicate medical student involvement. Of PDs, 73.2% reported having a patient decline participation of a trainee after describing their role.

Conclusion

Despite the American Urological Association and American College of Surgeons codes of professionalism, many urologists involved in the training of residents may not disclose resident participation in surgery to patients. Further discussions are needed to explore how to better balance resident education while strengthening the informed consent process.

How I Learned is How I Teach – Perspectives on How Faculty Surgeons Approach Informed Consent Education

Erin M. White, Andrew C. Esposito, Vadim Kurbatov, Xujun Wang, Michael G. Caty, Maxwell Laurans, Peter S. Yoo

Journal of Surgical Education, 15 October 2022

Abstract

Objective

To understand the variability of surgical attending experience and perspectives regarding informed consent and how it impacts resident education

Design

A novel survey was distributed electronically to explore faculty surgeon's personal learning experience, knowledge, clinical practice, teaching preferences and beliefs regarding informed consent. Chi-square and Kruskal-Wallis testing was performed to look for associations and a cluster analysis was performed to elucidate additional patterns among.

Setting

Single, tertiary, university-affiliated health care system (Yale New Haven Health in Connecticut), including 6 teaching hospitals.

Participants

Clinical faculty within the Department of Surgery.

Results

A total of 85 surgeons responded (49% response rate), representing 17 specialties, both private practice and university and/or hospital-employed, with a range of years in practice. Across all ages, specialties, the most common method for both learning (86%) and teaching (82%) informed consent was observation of the attending. Respondents who stated they learned by observing attendings were more likely to report that they teach by having trainees observe them (OR 8.5, 95% CI 1.3-56.5) and participants who recalled learning by having attendings observe them were more likely to observe their trainees (OR 4.1, 95% CI 1.5-11.2).Cluster analysis revealed 5 different attending phenotypes with significant heterogeneity between groups. A cluster of younger attendings reported the least diverse learning experience and high levels of concern for legal liability and resident competency. They engaged in few strategies for teaching residents. By comparison, the cluster that reported the most diverse learning experience also reported the richest diversity of teaching strategies to residents but rarely allowed residents to perform consent with their patients. Meanwhile, 2 other cluster provided a more balanced experience with some opportunities for practice with patients and some diversity of teaching– these clusters, respectively, consist of older, experienced general surgeons and surgeons in trauma and/or critical care.

Conclusions

Surgeon's demographics, personal experiences, and specialty appear to significantly influence their teaching styles and the educational experience residents receive regarding informed consent.

Informed consent for psychotherapy: Ethical illusion or clinical reality? A survey about psychotherapists' attitudes and practices in Germany

Leonie Gerke, Ann-Katrin Meyrose, Yvonne Nestoriuc

Clinical Psychology and Psychotherapy, 10 October 2022

Abstract

Objective

This study aimed to assess clinicians' attitudes and their current clinical practices regarding informed consent for psychotherapy.

Method

A convenience sample of N = 530 clinicians in Germany (n = 418 licensed psychotherapists and n = 112 postgraduate psychotherapy trainees) took part in an online survey.

Results
Most clinicians (84%) reported obtaining informed consent for psychotherapy in their daily routine. However, many psychotherapists felt unsure about satisfactorily fulfilling the legal (63%) and ethical obligations (52%). The two most frequently reported components of information disclosure related to explaining the terms and conditions of psychotherapy (96%) and the psychotherapeutic approach (91%). Providing information about mechanisms of psychotherapy (33%) and the role of expectations (30%) were least practiced. One in five psychotherapists reported not informing clients about potential risks and side effects. A considerable proportion reported concern about inducing anxiety in patients by disclosing information about risks and side effects (52%).
Conclusions
Although obtaining informed consent for psychotherapy seems to be the rule rather than the exception in clinical practice, the quality of its implementation in terms of legal, ethical and clinical demands remains questionable. Training psychotherapists in providing comprehensive informed consent enables informed decision-making and might have a positive influence on treatment expectations and outcomes.

Subtotal Cholecystectomy Results in High Peri-operative Morbidity and Its Risk-Profile Should be Emphasised During Consent

Original Scientific Report
James Lucocq, David Hamilton, John Scollay, Pradeep Patil
World Journal of Surgery, 8 October 2022
Open Access
Abstract
Background
Subtotal cholecystectomy aims to reduce the likelihood of bile duct injury but risks a multitude of less severe, yet significant complications. The primary aim of the present study was to report peri-operative outcomes of subtotal laparoscopic cholecystectomy (SLC) relative to total laparoscopic cholecystectomy (TLC) to inform the consent process.
Method
All laparoscopic cholecystectomies between 2015 and 2020 in one health board were included. The peri-operative outcomes of SLC (n = 87) and TLC (n = 2650) were reported. Pre-operative variables were compared between the two groups to identify risk factors for SLC. The outcomes between the SLC and TLC were compared using univariate, multivariate and propensity analysis.
Results
Risk factors for SLC included higher age, male gender, cholecystitis, increased biliary admissions, ERCP, cholecystostomy and emergency cholecystectomy. Following SLC, rates of post-operative complication (45.9%), imaging (37.9%) intervention (28.7%) and readmission (29.9%) were significant. The risk profile was vastly heightened compared to that of TLC: intra-operative complications (RR 9.0; $p < 0.001$), post-operative complications [bile leak (RR 58.9; $p < 0.001$), collection (RR 12.2; $p < 0.001$), retained stones (RR 7.2; $p < 0.001$) and pneumonia (RR 5.4; $p < 0.001$)], post-operative imaging (RR 4.4; $p < 0.001$), post-operative intervention (RR 12.3; $p < 0.001$), prolonged PLOS (RR 11.3; $p < 0.001$) and readmission (RR 4.5; $p < 0.001$). The findings were consistent using multivariate logistic regression and propensity analysis.
Conclusion
The relative morbidity associated with SLC is significant and high-risk patients should be counselled for the peri-operative morbidity of subtotal cholecystectomy.

Understanding consent for surgery and for treatment in orthopaedics

Editorial
Vane Antolič, Marius M. Scarlat

International Orthopaedics, 30 September 2022; 46 pp 2459–2460
Open Access
Excerpt
Consenting to treatment implies that a person gives permission before receiving any type of medical care, test or examination. The Consent protects the doctor from the accusation of an “unwanted touch”. Surgery is a complex medical act involving treatments, acts, and manoeuvres that could be harmful, although they are expected to be beneficial and amend positively the patient's health. Prior to obtaining consent for the proposed succession of acts, the surgeon must provide the patient with information about the nature of the treatment, the expected benefits, material risks and adverse effects, alternate treatments, and the consequences of not having the surgery. Consent for surgery has become a critical component of surgical practice and is of increasing importance and must be updated with patient and legal expectations. For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. The principle of consent is an important part of medical ethics and international human rights law.

How do patients benefit from consent?

Robert Wheeler
The Bulletin, 30 September 2022; 104(7) pp 364-365
Abstract
Our legal contributor discusses how gaining consent for treatment, and the importance of discussing all alternatives available to a patient, is vital to maintaining good practice.
Editor’s note: The Bulletin is published by the Royal College of Surgeons of England.

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GENERAL/OTHER

The process of gaining consent, retrospectively, when the institution has closed down

Research Article
Lida Anagnostaki
Journal of Child Psychotherapy, 17 October 2022
Abstract
The paper has a twofold aim. First, it describes the complex process of gaining consent retrospectively for the publication of clinical material after the institution, where therapy was taking place, had closed down. The clinical material was derived from the psychotherapeutic work with an autistic young boy and his family. Details of the complicated process of gaining consent to publish this material are provided. The second aim of this paper is to discuss the important role of ‘trust’ when asking or granting consent for publication of clinical material. It is argued that trust at different levels (and amongst various people) plays a pivotal role in gaining consent for publication.

Is the Current Informed Consent Model Flawed?

Book Chapter
Bert Heinrichs, Serap Ergin Aslan
Integrity of Scientific Research, 14 October; pp 549–557 [Springer]
Abstract
Informed consent is a widely acknowledged ethical principle that plays a crucial role, both in research ethics and medical ethics. However, empirical findings as well as theoretical considerations suggest that the current model of informed consent might be flawed. In particular, the understanding of information disclosed to

patients and research participants during the consent process proves to be limited. This, in turn, casts serious doubt on the validity of the consent. In this paper, we will review the current state of research on informed consent and discuss the charge of inadequacy. Subsequently, we will examine some suggestions that have been presented in the literature to improve the current model of informed consent. At the end, we will summarize the current state of the discussion and give a brief outlook on future developments.

The Ethics of Advocacy and Consent

Book Chapter

Jill Pluquailec

Dis/orientating Autism, Childhood, and Dis/ability, 13 October 2022; pp 103–121 [Springer]

Abstract

This chapter, though short, is presented discretely between the end of the methodology chapter and before the analytical chapters because it is both methodological and analytical. It explores ethical issues, particularly in relation to advocacy and consent, which were necessary in developing, delivering and writing an ethical project. At the heart of the project is a queering of normative conceptualisations of autistic childhood which, as has already been discussed, requires a queering of traditional, theoretical and methodological orientations.

Editor's note: Chapter bibliography available at title link above.

Autonomy and Liberty: An Ethical Focus on Human Consent

Jenia Kakchingtabam

International Journal of Arts Humanities & Social Sciences, 8 October 2022

Abstract

This paper aims to examine the problematic relation between autonomy and liberty from the ethical aspect of human consent. The term consent is derived from the Latin conjunction where "con" mean 'together' with "sentire" meaning to 'feel', 'think' or 'judge'. We feel safe and secure when we participate in the collective life consensually. This idea of protection is provided by the liberal tradition thereby bringing a new complex form of human relation on the basis of consent and informed life. In fact, this new complex relation claims to provide us the benefit of protection from harms and constraints. Autonomy, on the other, indicates self-ruling capacities of a person to make certain plans or goals wherein the significance of consent protects from external wrongful coercion. And, here the question is, how can we discover the significance of autonomous consent of an individual within the sphere of liberty? This paper discusses the ethical issue of consent that seems to be interwoven in the concept of liberty and autonomy in three different sections. The first section examines the question that how and why consent occupies an important place in the social and the political relations of human beings? Further, the second section argues that the meaning of consent is not implied only in the sphere of social and political relation. Consent expresses a person's sensitivity and experiences by allowing others to perceive the importance of human autonomy across the different areas of life. And, the third section addresses the crucial ethical crux of consent from the aspect of care and concern.

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