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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

April 2023 :: Issue 52

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

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

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

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

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
CULTURAL/COUNTRY CONTEXT
FREE PRIOR INFORMED CONSENT (FPIC)

HEALTH DATA
HUMANITARIAN CONTEXT

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

BIOMEDICAL RESEARCH

Design and validation of two instruments to analyze and evaluate the formal quality in the informed consent process of clinical trials with medicinal products

Original

Andrea G. Jaramillo Vélez, Margarita Aguas Compaired, Montserrat Granados Plaza, Eduardo L. Mariño, Pilar Modamio

Farmacia Hospitalaria, 16 March 2023

Abstract

Objective

The activity of sponsors and Ethics Committees for Research with medicines has increased in recent years. The objective was to design and validate 2 instruments to analyze and evaluate the formal quality of the patient information sheet and the informed consent form of clinical trials with drugs, in accordance with the legislation.

Methods

Design (Guideline for good clinical practice and European and Spanish regulations); validation (Delphi method and expert consensus: concordance ≥ 80%); reliability (inter-observer method, Kappa index). 40 patient information sheets/informed consent forms were evaluated.

Results

Very good concordance was obtained in both checklists (k ≥ 0.81, p b 0.001). The final versions consisted of checklist-patient information sheet: 5 sections, 16 items and 46 sub-items; and checklist-informed consent form: 11 items.

Conclusion

The instruments developed are valid, reliable and facilitate the analysis, evaluation, and decision-making on the patient information sheets/informed consent forms of clinical trials with drugs.

Editor's note: This is a Spanish language publication. Farmacia Hospitalaria is a publication of the Spanish Hospital Pharmacy Society.

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SOCIAL SCIENCE

Decisions to Enter Phase I Oncology Clinical Trials: Effectual and Ethical Informed Consent

Stephanie Solomon Cargill, Natalie Hardy

Patient Education and Counseling, April 2023

Abstract

When faced with advanced stage cancer, patients consider participating in Phase I oncology clinical research trials. The likelihood of patients benefiting from trial interventions is low (5%). Although scholarship has found that participants overestimate the benefit interventions, research has failed to assess the social context that may influence how potential participants evaluate their decision to participate. This

understanding is critical for ethical informed consent procedures. Thus, the aim of this pilot project was to examine oncology patients' decisions to enroll in Phase 1 trials. In-depth interviews were conducted with eight adults who were invited to participate in Phase 1 oncology clinical trials. Analysis was guided by Problematic Integration Theory (PI, e.g., Babrow, 2001), providing a framework for understanding tensions among desires and expectations, particularly when faced with uncertainty. Researchers took an iterative analytical approach shifting between respondents' viewpoints and PI theory. Analysis revealed that participants understood that when invited to the trial, their current treatments were ineffective. In facing the tension between the likelihood of benefitting from the trial intervention with the hope that the intervention would be successful (and incur few negative side effects), participants faced an ambivalent situation. Thus, participants entered conversations with research coordinators anticipating to enter the trial with few uncertainties. Participants expressed a desire for more information about the chances the trial would effectively treat their cancer, but trust that the medical team was acting in their best interest, providing hope.

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GENOMIC MEDICINE/GENE EDITING

Stakeholder perspectives on informed consent for the use of genomic data by commercial entities

Webinar Report

Baergen Schultz, Francis E Agamah, Cornelius Ewuoso, Ebony B Madden, Jennifer Troyer, Michelle Skelton, Erisa Mwaka

Journal of Medical Ethics, 20 March 2023

Abstract

In July 2020, the H3Africa Ethics and Community Engagement (E&CE) Working Group organised a webinar with ethics committee members and biomedical researchers from various African institutions throughout the Continent to discuss the issue of whether and how biological samples for scientific research may be accessed by commercial entities when broad consents obtained for the samples are silent. 128 people including Research Ethics Committee members (10), H3Africa researchers (46) including members of the E&CE working group, biomedical researchers not associated with H3Africa (27), representatives from the National Institutes of Health (16) and 10 other participants attended the webinar and shared their views. Several major themes emerged during the webinar, with the topics of broad versus explicit informed consent, defining commercial use, legacy samples and benefit sharing prevailing in the discussion. This report describes the consensus concerns and recommendations raised during the meeting and will be informative for future research on ethical considerations for genomic research in the African research context.

Ethical Considerations of Genome Sequencing for Pediatric Patients

Michelle M Sergi, Melissa C Keinath, Jonathan Fanaroff, Kathryn E Miller

Seminars in Pediatric Neurology, 1 March 2023

Abstract

Advancements in genetic testing in the healthcare setting, most recently genomic sequencing, has enhanced our ability to diagnose genetic conditions. These advances include increased accessibility and affordability of genomic technologies. With expanded use comes the potential for significant ethical challenges for clinicians, particularly considering the implications of testing a child for one condition and incidentally finding a different condition or health risk. In this focused review, we address various ethical considerations from informed consent to the rights of a child undergoing genetic testing.

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CAPACITY TO CONSENT

Right To Consent In Informed Consent For Medical Treatment For People With Mental Health Disorders

Santi Novia Ayu Kurniawati, Erna Dyah Kusumawati

International Journal of Business, Economics and Law, April 2023; 28(3)

Open Access

Abstract

Based on the philosophy of legal protection, this article seeks to determine the interpretation of the meaning of mental disorders according to the Civil Code and the application of informed consent to medical treatment for people with mental disorders governed by the Civil Code. Based on the principle of legal protection, this article also seeks to determine the implementation of informed consent to medical treatment for people with mental problems. In this study, the normative law method is being employed. The study's findings reveal that one interpretation of the idea of mental disorder, based on Article 433 of the Civil Code which reads, "Any adult who is constantly dumb, sick of the brain, or dark-eyed should be put under guardianship, even when he is occasionally proficient with his mind." maintains that mental disorder is a sort of inability to act or incompetence to conduct a legal act. Following the requirements of the Civil Code, even if those under guardianship are adults, they are considered legally incapable. Due to their inability to act for themselves, individuals with mental problems must give informed consent to medical treatment through family members or legal guardians. The application of informed consent to medical treatment for people with mental problems is governed by the Civil Code, which requires physicians to acquire permission from the patient's family (supporters, according to the Civil Code). Due to their inability to make decisions for themselves, people with mental disorders cannot give informed permission for medical treatment. However, under Law No. 18 of 2014 concerning Mental Health, social services will assume the role of guardian if the patient has no family or relatives.

Editor's note: The Civil Code referenced in this abstract is present in Indonesia.

Cardiac Interventions In The Absence Of Assent: An Ethical Dilemma

Complex Clinical Cases

Cooper B. Kersey, Beteal Ashinne, Jeffrey Keenan, James N. Kirkpatrick

Journal of the American College of Cardiology, March 2023

Open Access

Abstract

Background

Cardiovascular practitioners increasingly encounter complex treatment decisions, further complicated when patient decisional-capacity is impaired. We present an ethical conundrum of a patient without decision-making capacity who declined a life-saving surgery.

Case

A 63-year-old woman with schizophrenia and a prior history of mitral and aortic valve endocarditis was found to have recurrent endocarditis of her bioprosthetic mitral valve. Surgical management was recommended, but the patient declined. During a formal capacity assessment, the patient was deemed unable to comprehend her medical condition or the consequences of refusing surgery. The patient then developed transient complete heart block. Goals of care discussions revealed that the patient valued life prolongation and amelioration of her symptoms.

Decision-making

The patient's durable power of attorney gave consent to proceed with the surgery. Surrogate decision-making rests on substituted judgement (based on knowledge of what the patient would have wanted) or best interest standards (based on beneficence or non-maleficence). The hospital ethics team supported the decision to proceed with surgery over the objections of the patient, in light of the prognosis without surgery,

the likelihood of surgical benefit, and the values and goals the patient espoused. The ethics consult team also recommended seeking assent for the surgery from the patient. Assent is not required in addition to consent from a surrogate, but it oftentimes facilitates interventions without chemical or physical restraints. Ultimately, the patient provided passive assent and underwent successful re-do mitral and aortic valve replacements and was discharged in stable condition.

Conclusion

We highlight a case in which cardiovascular clinicians encountered a patient without decision-making capacity refusing a life-saving intervention. Cardiovascular clinicians should be familiar with important ethical elements involved in complex decision-making, including autonomy and its limits, substituted judgement and best interests standards, and standards and laws pertaining to surrogate decision-makers.

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YOUNG PERSONS

Parents' and child welfare workers' understandings of consent to emergency placements

Research Article

A.S. Storhaug, M.K. Fylkesnes, E. Langsrud, Ø. Christiansen

Nordic Social Work Research, 22 March 2023

Abstract

Emergency placements of children are often made in haste and experienced as dramatic. This article is based on interviews with 9 parents who have consented to emergency placements and their caseworkers. We explore parents' reasons for giving their consent to placement and the child welfare workers' understanding of these consents. This leads to a discussion of what constitutes valid consent from parents in emergency cases. Relational autonomy is applied as a perspective to understand the context and influencing factors of parental consent. The results, derived by thematic analysis, show three main themes regarding parents' reasons for their consent: (1) The child wanted to move out, (2) the parents couldn't manage the situation, and (3) parents felt the child welfare service (CWS) gave them no choice. Parents experience a high degree of pressure in the context of giving their consent, either from their child or the CWS. Asymmetrical power dynamics between the CWS and parents were highly present and relevant in parents' reasons for consent, especially when the CWS communicated that the alternative to consent is coercive placement. Furthermore, it is often unclear to the parents what consent entails. This is especially evident through CWS's regulation of child-parent contact. In the discussion, we emphasize a high degree of awareness on the part of CW workers with regards to understanding how contextual and relational factors influence parent's choice to consent; when consent is valid; how far consent extends, and the potential weakening of parents' legal security when a voluntary placement is conducted.

Perceptions of pediatric deceased donor consent: A survey of organ procurement organizations

Gretchen B Chapman, Alison Butler, Mandy Lanyon, Justin Godown, Daniel J Lebovitz

Pediatric Transplant, 21 March 2023

Abstract

Background

Children awaiting transplantation face a high risk of waitlist mortality due to a shortage of pediatric organ donors. Pediatric donation consent rates vary across Organ Procurement Organizations (OPOs), suggesting that some OPOs might utilize more effective pediatric-focused donor recruitment techniques than others. An online survey of 193 donation requestor staff sheds light on the strategies that OPO staff utilize when approaching potential pediatric deceased organ donors.

Methods

In collaboration with the Association of Organ Procurement Organizations, the research team contacted the executive directors and medical directors of all 57 of the OPOs in the US. Of these, 51 OPOs agreed to participate, and 47 provided contact information for donation requestor staff. Of the 379 staff invited to participate in the survey, 193 provided complete responses.
Results
Respondents indicated more comfort approaching adult donors than pediatric donors, and they endorsed approach techniques that were interpersonal and emotional rather than professional and informative. Respondents were accurate in their perceptions about which donor characteristics are associated with consent. However, respondents from OPOs with high consent rates (according to data from the Scientific Registry of Transplant Recipients), and those from OPOs with low consent rates were very similar in terms of demographics, training, experience, and reported techniques.
Conclusions
Additional research is needed to better determine why some OPOs have higher consent rates than others and whether the factors that lead to high consent rates in high-performing OPOs can be successful when implemented by lower-performing OPOs.

Children's ages of consent to non-urgent heart surgery: The views of two paediatric cardiology teams

Original Article
Priscilla Alderson, Hannah Bellsham-Revell, Liz King, Trisha Vigneswaran, Jo Wray
Children & Society, 4 March 2023
Open Access
Abstract
Paediatric cardiology practitioners and related experts report unusually young ages when they begin to inform children about their non-urgent heart surgery and begin to respect children's consent or refusal. Research methods included observations in two paediatric cardiology units, audio-recorded interviews with 45 experts, and qualitative data analysis. Significantly younger ages were cited than are usually recommended in the clinical and legal literature. Interviewed practitioners took seriously children's consent to or refusal of a heart transplant from around 6 years, and a child's firm refusal of induction of anaesthesia from around 4 years, when surgery might be postponed.

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TECHNOLOGY/OTHER MEDIATION

Effective Informed Consent Communication Skills for Senior Medical Students (Sub-Interns)

Katharine A. Robb, Hanna D. Zembrzuska, Marcy Rosenbaum
Patient Education and Counseling, April 2023
Abstract
Background
Obtaining informed consent from patients for procedural tests/treatments is an important communication task for health care providers, involving more than just getting a consent form signed. To ensure that patients have understanding to make informed decisions, effective communication skills are needed in conducting informed consent conversations. Several studies have demonstrated that new postgraduate learners (interns) lack skills to conduct these conversations effectively. Sub-internship rotations aimed at preparing senior medical students for their upcoming role as postgraduate trainees may be an appropriate place to introduce learners to informed consent skills.
Methods

We developed an educational intervention on effective informed consent communication skills for sub-interns in Internal Medicine. Educational components included: 1) A pre-workshop self-study module on blood transfusion and joint aspiration; 2) A two-hour experiential workshop on Zoom (or in person) where students learn about and practice effective informed consent conversation communication skills on the two procedures. Each student engages in a consent conversation (7-10 minutes) with a simulated patient while the other students watch, followed by debriefing and learner feedback. Two versions of each case are enacted ("easy" versus "apprehensive" patient) demonstrating how to apply the skills to patients with different reactions and concerns.

Assessment/evaluation

Pre-intervention assessments indicating the need for this session included data from entering intern OSCEs (N=33 over 3 years) in which interns scored lowest on the informed consent station and a needs assessment survey revealing sub-interns (N=24) desired formal training in informed consent skills. A post-intervention evaluation survey revealed all participating sub-interns found being able to practice, receive feedback and observe others practice was helpful in enhancing their informed consent skills. A pre-post retrospective survey will collect evaluation data from subsequent sessions.

Discussion

Time efficient experiential informed consent sessions are feasible to help better prepare senior learners for these important conversations and shared decision making.

Personalized surgical informed consent with stereoscopic visualization in neurosurgery—real benefit for the patient or unnecessary gimmick?

Original Article - Neurosurgery general

Nicolas Hertzsprung, Kiril Krantchev, Thomas Picht, Anna L. Roethe, Kerstin Rubarth, Josch Fuellhase, Peter Vajkoczy, Güliz Acker

Acta Neurochirurgica, 28 February 2023

Open Access

Abstract

Background

Informed consent of the patient prior to surgical procedures is obligatory. A good and informative communication improves patients' understanding and confidence, thus may strengthen the patient-doctor relationship. The aim of our study was to investigate the usefulness of additional stereoscopic visualization of patient-specific imaging during informed consent conversation.

Methods

Patients scheduled for a brain tumor surgery were screened for this study prospectively. The primary exclusion criteria were cognitive or visual impairments. The participants were randomized into two groups. The first group underwent a conventional surgical informed consent performed by a neurosurgeon including a demonstration of the individual MRI on a 2D computer screen. The second group received an additional stereoscopic visualization of the same imaging to explain the pathology more in-depth. The patients were then asked to fill in a questionnaire after each part. This questionnaire was designed to assess the potential information gained from the patients with details on the anatomical location of the tumor as well as the surgical procedure and possible complications. Patients' subjective impression about the informed consent was assessed using a 5-point Likert scale.

Results

A total of 27 patients were included in this study. After additional stereoscopic visualization, no significant increase in patient understanding was found for either objective criteria or subjective assessment. Participants' anxiety was not increased by stereoscopic visualization. Overall, patients perceived stereoscopic imaging as helpful from a subjective perspective. Confidence in the department was high in both groups.

Conclusion

Stereoscopic visualization of MRI images within informed consent conversation did not improve the objective understanding of the patients in our series. Although no objective anatomical knowledge gain was noted in

this series, patients felt that the addition of stereoscopic visualization improved their overall understanding. It therefore potentially increases patient confidence in treatment decisions.

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RIGHTS/LEGAL/LEGISLATIVE

Legally Effective but Ethically Inadequate: Institutional Review Board Policies for Consent from Legally Authorized Representatives

Robert R. Harrison

Ethics & Human Research, 27 March 2023

Abstract

The prevailing approach to enrolling decisionally impaired adults in clinical research is to rely on permission from a default surrogate, one identified by law rather than by the prospective research participant. Reliance on a surrogate transfers the focus of ethical protection from a researcher-participant relationship to a researcher-surrogate relationship; the selection and role of the surrogate are therefore important. The Common Rule defers to state law governing default surrogate consent to research, but most states have no such law; for those states, the Common Rule defers to institutional policy. I reviewed twenty-five of the study sites with the highest National Institutes of Health funding levels to elaborate the content of institutional review board (IRB) policies and compare those to a suggested paradigm for ethically defensible policies. My findings suggest that IRB policies provide inadequate protection because they recognize surrogates who lack knowledge of the subject's current values and preferences without imposing adequate additional safeguards.

Minor Consent Laws for Sexually Transmitted Infection and Human Immunodeficiency Virus Services in the United States: A Comprehensive, Longitudinal Survey of US State Laws

Kimberly M. Nelson, Alexandra Skinner, Claire D. Stout, Will Raderman, Emily Unger, Julia Raifman, Madina Agénor, Michele L. Ybarra, Shira I. Dunsiger, S. Bryn Austin, Kristen Underhill

American Journal of Public Health, 8 March 2023

Abstract

Objectives

To assess changes in minor consent laws for sexually transmitted infection (STI) and HIV testing, treatment, and prevention services in all 50 US states and the District of Columbia from 1900 to 2021.

Methods

We coded laws into minor consent for (1) health care generally; (2) STI testing, treatment, and prevention; (3) HIV testing, treatment, and prevention; and (4) pre- or postexposure prophylaxis for HIV prevention. We also coded confidentiality protections and required conditions (e.g., threshold clinician judgments).

Results

The largest increase in states allowing minors to consent to STI services occurred during the 1960s and 1970s. By 2021, minors could consent independently to STI and HIV testing and treatment in all 50 states plus DC, STI prevention services in 32 jurisdictions, and HIV prevention services in 33 jurisdictions. Confidentiality protections for minors are rare. Prerequisites are common.

Conclusions

Although the number of states allowing minors to consent independently to STI and HIV services has increased considerably, these laws have substantial limitations, including high complexity, prerequisites requiring clinician judgments, and neglect of confidentiality concerns.

Waivers of informed consent in research with competent participants and the Declaration of Helsinki

Perspective
Rafael Dal-Ré
European Journal of Clinical Pharmacology, 8 March 2023
Open Access
Excerpt
The World Medical Association started revisions to the Declaration of Helsinki in 2022 and it will have to address numerous issues that have arisen in research ethics since the last 2013 revision [1]. In the face of critical issues that have surfaced during the COVID-19 pandemic, less salient but nevertheless critically important issues may go unnoticed. One of these concerns is the conditions under which it is ethically permissible to modify or waive written informed consent in research with competent participants…

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POLICY/GUIDANCE/CODES/PROGRAM ACTION

Guidance Paper 2: Obtaining Consent in Research involving Children – Understanding the Legal and Ethical Framework

National Centre for Research Methods, 2023
Open Access
Excerpt
This guidance paper describes the importance of obtaining consent from and on behalf of child participants involved in research. It is Guidance Paper 2 in the series The Ethics of Research Involving Children: Common Questions, Potential Strategies and Useful Guidance. Ethical research considers the international and domestic law, as well as ethical and professional, obligations towards ensuring that participants provide valid consent. Issues around consent are paramount in research ethics applications. The law and ethics of consent are not just about ensuring that the child is fully aware of the implications of his or her involvement in the research and is kept safe (which might necessitate obtaining consent also from adults with parental responsibility); it is equally about ensuring that overly paternalistic approaches to consent are avoided, as such approaches may unintentionally undermine children's autonomy and prevent children from making decisions and expressing themselves on their own terms. As the ESRC notes in its ethical guidance: "Researchers should consider the ethics implications of silencing and excluding children from research." Beazley et al. (2009: 370) refer to this as children's right to be 'properly researched' which 'translates into: children being participants in research; using methods that make it easy for them to express their opinions, views and experiences; and being protected from harm'…

> *Editor's note: The national Centre for Research Methods delivers a programme of research methods training across the UK. The ESRC referenced stands for the Economic and Social Research Council in the UK.*

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MEDICAL/SURGICAL

A Multi-Institutional Informed Consent Proposal as a Prevention Tool for Combined Oral Contraceptive Intake and Thrombotic Risk

Marina Vinciguerra, Eliano Cascardi, Bruno Lamanna, Maricla Marrone, Fortunato Pititto, Enrica Macorano, Romualdo Sciorio, Giorgio Maria Baldini, Antonio Malvasi, Andrea Ballini, Gerardo Cazzato, Antonella Vimercati, Senthil Kumaran, Ettore Cicinelli, Salvatore Scacco, Miriam Dellino

Journal of Personalised Medicine, 27 March 2023

Open Access

Abstract

Combined oral contraceptives (COC), are among the most widely used contraceptive methods in the world today. Despite the different changes in terms of estrogen/progestogen combinations and dosages, the thromboembolic risk for a woman who takes combined oral contraceptives persists to date.

Methods

The review of relevant literature and international guidelines on prescription of combined oral contraceptives made it possible to create a proposal for informed consent to be used for prescribing.

Results

The several sections of our consent proposal were designed according to a rationale in order to cover all the aspects presented by worldwide guidelines: how to take, adverse effects, advertisements, extra-contraceptive benefits and effects, a checklist for condition at risk of thromboembolism, the signature of the woman.

Conclusions

An informed consent to standardize combined oral contraceptives prescription can improve women's eligibility, mitigate thromboembolic risk, and assure legal protection to healthcare providers. In this systematic review in particular, we refer to the Italian medical–legal scenario, to which our group of researchers belongs. However, the model proposed was designed in the respect of main healthcare organization guidelines, and it could be easily used by any center in the world.

Measuring Impact of Simulation-Based Informed Consent Training on Surgical Intern's Long-Term Confidence

Original Reports

Gwyneth A. Sullivan, Kelly Harmon, Genevieve F. Gill-Wiehl, Seungjun Kim, Jose M. Velasco, Edie Y. Chan, Scott W. Schimpke

Journal of Surgical Education, 24 March 2023

Objective

Our objective was to evaluate the outcome of a training program on long-term confidence of interns and attending physicians.

Design

In this prospective cohort study, general surgery interns underwent a training program on informed consent that involved didactics, standardized patient encounters, and supplemental procedure specific guides at the start of the academic year. At the end of the academic year, we surveyed interns from the classes of 2020 (trained) and 2019 (untrained) about their experience and confidence in obtaining an informed consent. Further, we queried attending physicians on their experience and confidence in the interns at the end of each academic year.

Setting

Single academic general surgery residency program based at 2 urban tertiary hospitals.

Participants

General surgery interns including unmatched preliminary residents and categorical interns from general surgery, interventional radiology, and urology.

Results

Twenty-four incoming interns participated in the training program. Intern confidence discussing operation benefits improved from a median score of 4 to 5 ($p = 0.03$), and total confidence improved from a median

score of 15 to 17.5 (p = 0.08). There was no difference in median total confidence scores (15 vs. 17.5; p = 0.21) between classes. Attending physicians had similar median total confidence scores following intervention (10 vs. 11; p = 0.87). Intern satisfaction was 80% with the didactic session, and 90% with standardized patient encounters. Twenty percent of learners used the supplemental procedure specific guides.

Conclusions

Implementation of an intern targeted program on informed consent that incorporated didactics and standardized patient encounters was viewed as useful and may contribute to long-term improvements in confidence.

Editor's note: The publication refers to research conducted by members of Rush University Medical Center in Chicago, Illinois.

Informed Consent in Reproductive Therapy

Book Chapter

Ofra G. Golan

Hot Topics in Human Reproduction, 17 March 2023 [Springer]

Abstract

This chapter examines the unique aspects of informed consent to reproductive therapy. It discusses the significance of the informed consent process for this patients' population, as the core of patient-centered care. Professionals' and patients' perception of the process are reviewed, as well as relevant case law. Further, the issues that are most important for patients are revealed, and some guidance is given accordingly as to the information on which emphasis should be put and to the decision points toward which it should be explained and discussed with the patients.

Evaluating the Efficacy of Surgical Consent

Carlos A. Delgado, Michelle R. McCullers, Scott W. Bloom

The American Surgeon, 15 March 2023

Abstract

Background

Patient autonomy is the most important of the core values of medical ethics, yet the process of obtaining surgical consent remains a lesser scrutinized area of modern surgical practice. Informed consent implies a patient's understanding of nature of the operation, indications, risks, benefits, and alternatives. Surgical consent has traditionally been obtained through verbal communication and formalized by signing a legal document. This process oftentimes leaves patients unequipped with adequate knowledge about the procedure they just consented to. In most cases, it is simply impossible for the non-medically trained layperson to fully understand the nuances of surgery in a conversation. Some may argue a degree of paternalism may be inevitable; we believe there is room for improvement.

Methods

We chose to examine English-speaking adult patients undergoing common procedures (laparoscopic cholecystectomy, open inguinal hernia repair, and skin mass/soft tissue excision). We asked 71 patients to complete a free response survey on the risks, benefits, and alternatives to the operation they had just consented to. The patients were administered the survey either in the outpatient clinic or in the preoperative area.

Results

Our analysis showed that most of our patients understand the inherent risks, benefits, and alternatives when being consented but that less than 50% of those consented were considered to have adequate understanding of the procedures they were consented for.

Discussion

This study highlights key deficits and potential areas of improvement in the informed consent process. Based on the results, we have significant room for improvement and the responsibility to do so.

Comparison of the Structured Consent Process Using Modified Delphi Technique with the Standard Process in Obtaining Informed Consent for Procedures in ENT by PHASE III MBBS Students

Original Article

Sapna Sreedharan Nambiar

Indian Journal of Otolaryngology and Head & Neck Surgery, 15 March 2023

Open Access

Abstract

Communication skill is a core competency and the training must begin in the undergraduate period itself. The Phase III MBBS students during their ENT posting are required to obtain informed consent for procedures and surgeries in ENT which forms the basis for efficient communication skills in house-surgency (internship) and residency. Informed consent taking is an important aspect and in the clinical postings, the teaching of communication skills along with history taking and physical examination can go a long way in making a strong foundation to good doctor patient relationships. This study aimed to compare the structured consent process using modified Delphi technique with the standard process in obtaining informed consent for procedures in ENT by PHASE III MBBS students. The need to sensitise the MBBS students on appropriate consent taking procedures with familiarisation of the essential elements of the Kalamazoo consensus statement were raised, accepted and final OSCE assessment attributes decided by the modified Delphi technique. The Modified Delphi technique is a unique means to obtain opinions of experts across the field in various spheres so as to identify lacunae if any in the existing teaching with means to reach a valid and reliable consensus. Our study included Phase III MBBS students posted to the Department of ENT, Govt Medical College Kozhikode during Jan–Feb 2022 wherein one batch of 30 students were taught with 2 classes on informed consent taking by the structured process obtained after Modified Delphi technique and included as; “MD” group and another batch of 30 students from the entire batch taught by the standard process was included as; “T” group respectively. After completion of the clinical postings an assessment was carried out with OSCE stations in Mar 2022; wherein 10 students were evaluated for each of the 6 common ENT procedures, 5 students from “T” group and 5 students from “MD” group respectively. Median total score of MD group was 6.5 (3.25–8) and median score of T group was 4.5 (2.25–6.75). The difference in mean ranks of these scores was statistically significant, $p < 0.0001$. The feedback assessment using the questionnaire with Likert scale had all 30(100%) students recommend this method of structured consent taking for enhancement of communications skills. However 20% of the students were not satisfied with the teaching learning method expressing the need for more time allocation and demonstrations. Informed consent taking requires the appropriate training in the undergraduate period itself as seen by the improved OSCE scores on assessment after teaching by the structured consent taking process as well as from the feedback of the students.

ACR–ARS Practice Parameter on Informed Consent Radiation Oncology

Original Article

Hurwitz, Mark D., Chundury, Anupama, Goodman, Chelain R., Jones, Joshua, Lo, Simon S., Saeed, Hina, Small, William Jr, Schechter, Naomi R.

American Journal of Clinical Oncology, 8 March 2023

Abstract

Objectives

Consent is a communication process between the patient and a health care provider, in which both parties have the opportunity to ask questions and exchange information relevant to the patient’s diagnosis and treatment. The process of informed consent is designed to protect a patient’s autonomy in their medical decision-making in the context of an asymmetric relationship with the health care system. A proper consent

process assures a patient's individual autonomy, reduces the opportunity for abusive conduct or conflicts of interest, and raises trust levels among participants. This document was developed as an educational tool to facilitate these goals.

Methods

This practice parameter was produced according to the process described under the heading "The Process for Developing ACR Practice Parameters and Technical Standards" on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters—Radiation Oncology of the ACR Commission on Radiation Oncology in collaboration with the ARS. Committee members were charged with reviewing the prior version of the informed consent practice parameter published in 2017 and recommending additions, modifications, or deletions. The committee met through remote access and subsequently through an online exchange to facilitate the development of the revised document. Focus was given on identifying new considerations and challenges with informed consent given the evolution of the practice of radiation oncology in part driven by the COVID-19 pandemic and other external factors.

Results

A review of the practice parameter published in 2017 confirmed the ongoing relevance of recommendations made at that time. In addition, the evolution of the practice of radiation oncology since the publication of the prior document resulted in the need for new topics to be addressed. These topics include remote consent either through telehealth or telephone and with the patient or their health care proxy.

Conclusions

Informed consent is an essential process in the care of radiation oncology patients. This practice parameter serves as an educational tool designed to assist practitioners in optimizing this process for the benefit of all involved parties.

Evidence-based informed consent form for total knee arthroplasty

Methodology

Satvik N. Pai, Madhan Jeyaraman, Nicola Maffuli, Naveen Jeyaraman, Filippo Migliorini, Ashim Gupta

Journal of Orthopaedic Surgery and Research, 2 March 2023

Open Access

Abstract

Introduction

Informed consent documentation is often the first area of interest for lawyers and insurers when a medico-legal malpractice suit is concerned. However, there is a lack of uniformity and standard procedure about obtaining informed consent for total knee arthroplasty (TKA). We developed a solution for this need for a pre-designed, evidence-based informed consent form for patients undergoing TKA.

Materials and methods

We extensively reviewed the literature on the medico-legal aspects of TKA, medico-legal aspects of informed consent, and medico-legal aspects of informed consent in TKA. We then conducted semi-structured interviews with orthopaedic surgeons and patients who had undergone TKA in the previous year. Based on all of the above, we developed an evidence-based informed consent form. The form was then reviewed by a legal expert, and the final version was used for 1 year in actual TKA patients operated at our institution.

Results

Legally sound, evidence-based Informed Consent Form for Total Knee Arthroplasty.

Conclusion

The use of legally sound, evidence-based informed consent for total knee arthroplasty would be beneficial to orthopaedic surgeons and patients alike. It would uphold the rights of the patient, promote open discussion and transparency. In the event of a lawsuit, it would be a vital document in the defence of the surgeon and withstand the scrutiny of lawyers and the judiciary.

Patient Information and Consent for Care in the Intensive Care Unit

Review

Jean-Philippe Rigaud, Fiona Ecarnot, Jean-Pierre Quenot

Healthcare, 27 February 2023; 11(5)

Abstract

In this paper, we review the ethical issues involved in providing information to, and obtaining consent (for treatment and/or research) from patients in the intensive care unit. We first review the ethical obligations of the physician in treating patients, who are by definition, vulnerable, and often unable to assert their autonomy during situations of critical illness. Providing clear and transparent information to the patient about treatment options or research opportunities is an ethical and, in some cases, legal obligation for the physicians, but may be rendered difficult, not to say impossible in the intensive care unit by the patient's health state. In this context, we review the specificities of intensive care with respect to information and consent. We discuss who the right contact person is in the ICU setting, with possible choices including a surrogate decision maker, or a member of the family, in the absence of an officially designated surrogate. We further review the specific considerations relating to the family of critically ill patients, and the amount and type of information that may be given to them without breaching the tenets of medical confidentiality. Finally, we discuss the specific cases of consent to research, and patients who refuse care.

Informed consent in episiotomy: Co-analysis with midwives and distillation of best practice

Jennifer MacLellan, Sara S. Webb, Carmen Byrne, Emily Brace, Elizabeth Glyn-Jones, Elizabeth Edwards, Tracey Hunter, Jacqueline Longton, Jane Cleary, Katie Christie, Lorna Dow, Jo Gould

Birth, 16 February 2023

Open Access

Abstract

Background

Performing an episiotomy where clinically indicated is a key intervention in the Obstetric Anal Sphincter Injury Care Bundle (OASI-CB) implemented across England and Wales to reduce the risk and increase the detection of severe perineal trauma after birth. Standards of consent provided to people in maternity care generally and for episiotomy specifically have been reported as suboptimal. Compromising birthing people's personal autonomy or sense of control has been linked to a dissatisfying birth experience, negative psychological sequelae, and litigation.

Methods

This study explored experienced midwives' practice of informed consent for episiotomy during a midwife-led birth. We sampled 43 midwives across eight NHS Trusts in England and Wales using online focus groups and telephone interviews about their experience of consent in episiotomy. Using qualitative content analysis and art-based co-analysis methods with eight midwives from across the research sites, we co-analyzed and co-constructed three themes and four practice recommendations from the data.

Results

Three themes were constructed from the data: Assent rather than consent, Change in culture to support best practice, and Standardized information. These themes informed the shaping of four recommendations for best practice in episiotomy informed consent.

Conclusion

This study has shown how variations in midwifery practice and culture may impact birthing people's experience of informed consent in episiotomy. Midwives may not have the knowledge or skills to conduct a detailed consent conversation, leading to variation in practice and messages for birthing people. The use of antenatal discussion aids can offer women the opportunity to become informed and fully participate in the decision-making process.

A Well-understood Surgical Informed Consent: A Scoping Review

Rieke Cahya, Adik Wibowo

Unnes Journal of Public Health, January 2023

Open Access

Abstract

The implementation of surgical consent has shifted from simply getting a signature to a focus on doctor-patient communication. Providing adequate information is very important for patients in making decisions so that patients voluntary agree to medical action. Understanding of the medical information that has been provided is the basis for patients to give consent, but in reality many patients find it difficult to understand and doctor fail to administer proper information.The purpose of this scoping review are to evaluate patient's understanding of the standard surgical informed consent prosess or those given by other methods and to identify factors that influence this patient's understanding. Three electronic database (ProQuest, ScienceDirect, and Scopus) were used to search literature from 2017 until 2022. A total of 391 articles were identified and 25 articles were selected according to the PRISMA guidelines and the PCC framework. 9 of 11 articles stated that patient understanding level was low. Factors that influence it include education background, age and language limitations. 12 studies (85%) showed that patient understanding improved with the use of additional information media. Overall, the patient's understanding of surgical informed consent is still low. Communication between doctor and patient plays a big role in it. Various interventions to improve the communication process can be used to improve patient understanding.

Editor's note: Unnes Journal of Public Health is published by Universitas Negeri Semarang (UNNES) in cooperation with the Association of Indonesian Public Health Experts.

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GENERAL/OTHER

Trustworthiness as information: Satisfying the understanding condition of valid consent

Martin RK

Bioethics, 21 March 2023

Abstract

Within medical ethics, there is widespread agreement that morally valid consent includes an understanding condition. Disagreement centers on what is meant by that understanding condition. Tom Dougherty proposed that this understanding condition should be divided into the two mutually exclusive categories of descriptive information and contextual information. Further, Dougherty argues that each type of information is necessary to satisfy the understanding condition. In contrast, I argue that when the deontic aspect of valid consent is in view, each type of information can be sufficient to satisfy the understanding condition on its own. Moreover, by analyzing delegation, which is conceptually related to consent since both are morally transformative actions, I show that delegation often depends not on descriptive or contextual information but on trust. So, I argue that trustworthiness can also be a type of information that does the same work as descriptive and contextual information in satisfying the understanding condition for valid consent.

Editor's note: The referenced article by Tom Do can be found here.

Consent and Trust in the Doctor Patient Relationship

Book Chapter

Philipp Bonhoeffer, Federico Festa, Lamia Ait Ali, Pierluigi Festa

The Patient as a Person, 21 March 2023 [Springer]

Abstract

Trust, defined as an assured reliance on the character, ability, strength, or truth of someone or something is an immensely precious subject matter in medicine. However, the historical doctor/patient relationship based

on trust alone has shown important shortcomings. Consequently, the medical consent developed for the interest and legal protection of patients. This in turn led to a vulnerability of doctors who then needed to defend themselves whenever litigation occurred. As a result, the formal medical consent has rapidly shifted in its application as a protection to health professionals, far removed from its original purpose. Vigilance and trust need to be carefully balanced. After educating patients for years to be vigilant about wrong doings of doctors, patients have lost the clear benefit and comfort that trust brings in a good patient–doctor relationship. It is known that trust plays a major role in the healing process. Trust, therefore is a good thing and there is no reason why the positive effect of trust should be neglected in classical medicine.

Misconceptions about the Doctrine of Informed Consent in the Medical Profession

Kelvin Christie, Maurice A. Dean, Isiah Lyman

Research Developments in Medicine and Medical Science, 4 March 2023; pp 136-157

Abstract

This article focuses on common misunderstandings in healthcare regarding how physicians and medical researchers apply the doctrine of informed consent. The specific myth addressed has to do with the level of care expected of medical professionals when treating patients. This paper also explains how the legal history of informed consent has led to misconceptions about informed consent as applied to both medical researchers and medical physicians. There has long been a public misconception that medical researchers are subject to a lower standard of care than medical doctors in cases involving informed consent. We argue that this misconception is largely attributed to the fact that statutes, ethical regulations, guidelines, and legal precedents within the medical and research profession are governed by two separate bodies of laws and regulatory guidelines. Furthermore, informed consent in the medical setting has traditionally been enacted primarily from case law, while informed consent in the research setting has primarily been enacted from statutory law and regulations.

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