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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

April 2024 :: Issue 64

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 a broad range of academic journals and utilize *Google Scholar* to search articles broadly capturing informed consent and assent. 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, including calls for public consultation and symposia/conferences which address consent/assent in whole or in part. 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 this digest using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. We lead each edition with a spotlight section highlighting articles which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
GENERAL/OTHER
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
PRE-PRINT SERVERS
SOCIAL SCIENCE RESEARCH

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 review the entire digest and to utilize the search function on our website where articles are cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the website. Beginning in 2024, we have undertaken an expansion of both these resources to better cover the evolving field.

SPOTLIGHT ARTICLES

We recognize a growing literature which argues [in whole or in part] that norms requiring the individual, prior, free, express and informed consent of persons to be involved in research must accommodate notions which integrate terms such as 'community-driven', 'decolonized', or 'culturally-appropriate' and which insist that consent processes "prioritize local/indigenous values and protocols." As an editorial policy, we have decided to group such literature together in this section of the digest.

More broadly, we recognize that this literature raises critically important issues around consent integrity. Our Center for Informed Consent Integrity is actively developing a position on this matter, mindful of core guidance in research involving human participants overall, and selected instruments such as the Universal Declaration on Bioethics and Human Rights [2005] which notes:

> *Article 12. Respect for cultural diversity and pluralism*
> The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

We will keep readers advised of our progress. If you have an interest in participating in our working group, please contact Paige Fitzsimmons [paige.fitzsimmons@ge2p2global.org].

Balancing Ethics and Culture: A Scoping Review of Ethico-Cultural and Implementation Challenges of the Individual-Based Consent Model in African Research

Richard Appiah, Giuseppe Raviola, Benedict Weobong
Journal Of Empirical Research On Human Research Ethics, 18 March 2024

Abstract
Objective
This review explores the ethico-cultural and implementation challenges associated with the individual-based informed consent (IC) model in the relatively collectivistic African context and examines suggested approaches to manage them.
Methods
We searched four databases for peer-reviewed studies published in English between 2000 to 2023 that examined the ethico-cultural and implementation challenges associated with the IC model in Africa.
Results
Findings suggest that the individual-based IC model largely misaligns with certain African social values and ethos and subverts the authority and functions of community gatekeepers. Three recommendations were proffered to manage these challenges, that researchers should: adopt a multi-step approach to IC, conduct a rapid ethical assessment, and generate an African-centered IC model.
Conclusions
A pluriversal, context-specific, multi-step IC model that critically harmonizes the cultural values of the local population and the general principles of IC can minimize ethics dumping, safeguard the integrity of the research process, and promote respectful engagement.

Culturally Competent Respect For The Autonomy Of Muslim Patients: Fostering Patient Agency By Respecting Justice

Kriszta Sajber, Sarah Khaleefah
Theoretical Medicine and Bioethics, 7 February 2024
Abstract
Although Western biomedical ethics emphasizes respect for autonomy, the medical decision-making of Muslim patients interacting with Western healthcare systems is more likely to be motivated by relational ethical and religious commitments that reflect the ideals of equity, reciprocity, and justice. Based on an in-depth cross-cultural comparison of Islamic and Western systems of biomedical ethics and an assessment of conceptual alignments and differences, we argue that, when working with Muslim patients, an ethics of respect extends to facilitating decision-making grounded in the patient's justice-related customs, beliefs, and obligations. We offer an overview of the philosophical contestations of autonomy-enhancing practices from the Islamic tradition of biomedical ethics, and examples that demonstrate a recommended shift of emphasis from an autonomy-centered to a justice-focused approach to culturally competent agency-promotion.

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BIOMEDICAL RESEARCH

Human Whole-Eye Donation for Research—Optimizing Clinical Trial Informed Consent

Special Communication
Katrina A. Bramstedt
JAMA Ophthalmology, 21 March 2024
Abstract
Importance
Posthumous whole-eye (globe) donations for research lack a mechanism that reinvolves the existing ophthalmic research team of the donor unless there is a preplanned donor directive. Disconnection between the deceased and their research team equates to lost opportunities for the research team to have a longitudinal view of the eyes that have been involved in their research.
Objectives

To use the clinical trial informed consent process to create a posthumous research donation opportunity that directs the donation to the currently affiliated research team of the donors (preserving the longitudinal research experience).

Evidence Reviewed

Current globe donation pathways were reviewed. Additionally, published advice from the fields of ophthalmology, brain banking, and implantable medical devices were used as reference points.

Findings

Globe donation represents a small but valuable type of ocular donation. Globe donation for research purposes is useful for investigators performing total human eye allotransplantation clinical trials, as well as for ophthalmic drug or device researchers. Results suggest that those performing invasive eye research should include the option of posthumous globe donation in their study protocols and informed consent forms to facilitate more opportunities for the generation of scientific knowledge.

Conclusions and Relevance

The longitudinal perspective can be valuable especially for eyes that have received long-term treatment with an investigational drug or device. This article poses a research-informed consent framework for posthumous globe donation.

Contraception Requirements in Clinical Research Consent Forms: Assessing and Supporting Gender Inclusive Practices

Research Article

Tara Coffin, Erin Brower, Sharad Adekar

Journal of Empirical Research on Human Research Ethics, 11 March 2024

Abstract

Gender-diverse individuals are underserved in clinical research settings. Reliance on gendered language throughout the consent process for clinical research contributes to the marginalization of these populations. The research objective was to assess use of gender-inclusive language used to describe the contraception requirement in consent forms. We categorized and analyzed contraception language in 289 clinical trial consent forms using a deductive and summative content analysis approach. We found that 79% (n = 227) of consent forms contained gender-inclusive language, 80% (n = 231) used terms that fell under the biological sex language, and 91% (n = 264) used gendered language. No consent forms used exclusively gender-inclusive language and the majority 63% (n = 182) featuring a combination of all three language types. There were many consent forms which would have been entirely gender-inclusive language if section headings with references to biological-sex-specific contraceptives were excluded, suggesting that gender-inclusive language may be attainable with minor revisions.

Public perception of participation in low-risk clinical trials in critical care using waived consent: a Canadian national survey

Dawn Opgenorth, D'Arcy J. Duquette, Linda Tyre, Robyn Auld, Kim Crowder, Peggy Gilchrist, Paul J. Young, Sean M. Bagshaw

Canadian Journal of Anesthesia, 8 March 2024

Abstract

Purpose

The acceptability of waiver of consent for participation in clinical research in intensive care unit (ICU) settings is uncertain. We sought to survey the Canadian public to assess levels of support, comfort, and acceptability for waived consent for low-risk clinical trials.

Methods

We performed a prospective cross-sectional survey of the Canadian public aged 18 yr or older. The survey was conducted by Ipsos between 19 and 23 November 2020. The survey content was derived from a

literature review and in consultation with a patient and family partnership committee. The survey focused on attitudes and beliefs on waived consent for participation in low-risk clinical trials in ICU settings. The survey contained 35 items focused on sociodemographics, general health status, participation in medical research, and levels of support and comfort with research and with waived consent. The survey used a case study of a low-risk clinical trial intervention in ICU patients. Analysis was descriptive.

Results

We included 2,000 participants, 38% of whom reported experience with ICU and 16% with medical research. Participation in medical research was more common among those with postsecondary education, those with chronic disease, and those who were employed in health care. Most (80%) would support a model of waived consent for low-risk clinical trials, citing medical benefits (36%) and low perceived risk (34%). Most (77%) were comfortable with personally participating in a low-risk clinical trial. Most (80%) believed waived consent approaches were acceptable. Half (52%) believed the waived consent process should provide information about the research and include the option of opting out. When asked whether participants should always give full informed consent, regardless of the practicality or level of risk, 74% and 72% agreed, respectively.

Conclusions

There is public support for models of waived consent for participation in low-risk pragmatic clinical trials in ICU settings in Canada; however, this is not universal. This information can inform and guide education, ethics, policy, and legal discussion on consent models.

Public support for and concerns regarding pediatric dose optimization for seizures in emergency medical services: An exception from informed consent (EFIC) trial

Ward CE, Adelgais KM, Holsti M, Jacobsen KK, Simon HK, Morris CR, Gonzalez VM, Lerner G, Ghaffari K, VanBuren JM, Lerner EB, Shah MI

Academic Emergency Medicine, 7 March 2024

Abstract

Background

Federal regulations allow exception from informed consent (EFIC) to study emergent conditions when obtaining prospective consent is not feasible. Little is known about public views on including children in EFIC studies. The Pediatric Dose Optimization for Seizures in EMS (PediDOSE) trial implements age-based, standardized midazolam dosing for pediatric seizures. The primary objective of this study was to determine public support for and concerns about the PediDOSE EFIC trial. The secondary objective was to assess how support for PediDOSE varied by demographics.

Methods

We conducted a mixed-methods study in 20 U.S. communities. Participants reviewed information about PediDOSE before completing an online survey. Descriptive data were generated. Univariable and multivariable logistic regression analysis identified factors associated with support for PediDOSE. Reviewers identified themes from free-text response data regarding participant concerns.

Results

Of 2450 respondents, 79% were parents/guardians, and 20% had a child with previous seizures. A total of 96% of respondents supported PediDOSE being conducted, and 70% approved of children being enrolled without prior consent. Non-Hispanic Black respondents were less likely than non-Hispanic White respondents to support PediDOSE with an adjusted odds ratio (aOR) of 0.57 (95% CI 0.42-0.75). Health care providers were more likely to support PediDOSE, with strongest support among prehospital emergency medicine clinicians (aOR 5.82, 95% CI 3.19-10.62). Age, gender, parental status, and level of education were not associated with support of PediDOSE. Common concerns about PediDOSE included adverse effects, legal and ethical concerns about enrolling without consent, and potential racial bias.

Conclusions

In communities where this study will occur, most respondents supported PediDOSE being conducted with EFIC and most approved of children being enrolled without prior consent. Support was lowest among non-

Hispanic Black respondents and highest among health care providers. Further research is needed to determine optimal ways to address the concerns of specific racial and ethnic groups when conducting EFIC trials.

Ethical Challenges with the Informed Consent Process in Pediatric Research Studies

Thabit S. Alotaibi

Medical Archives, 2024; 78(1) pp 65-67

Abstract

Background

Informed Consent (IC) is crucial in pediatric research, aligning with the National Research Act of 1974 and the Belmont Report's principles. Current regulations, particularly 45 CFR 46, provide additional safeguards for children in research.

Objective

This article explores ethical challenges in pediatric research IC, drawing from PubMed literature and regulatory guidelines to understand historical context, legislative milestones, and contemporary issues.

Methods

A literature review, primarily sourced from PubMed, informed the examination of pediatric research and IC, referencing guidelines from the American Academy of Pediatrics and regulations from the FDA and HHS.

Results

The study underscores the need for increased pediatric research due to the prevalence of drugs studied on adults. Despite legislative efforts like the FDAMA and Pediatric Research Equity Act, ethical challenges persist in obtaining IC in pediatric studies.

Conclusion

Pediatric research necessitates nuanced IC approaches, involving parents, guardians, and children. Ethical challenges such as coercion and compensation require attention, with recommendations emphasizing guideline adherence and increased public engagement for trust-building and pediatric health advancement.

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ARTIFICIAL INTELLIGENCE

Shaping the future of AI in healthcare through ethics and governance

Rabaï Bouderhem

Humanities and Social Sciences Communications, 15 March 2024

Open Access

Abstract

The purpose of this research is to identify and evaluate the technical, ethical and regulatory challenges related to the use of Artificial Intelligence (AI) in healthcare. The potential applications of AI in healthcare seem limitless and vary in their nature and scope, ranging from privacy, research, informed consent, patient autonomy, accountability, health equity, fairness, AI-based diagnostic algorithms to care management through automation for specific manual activities to reduce paperwork and human error. The main challenges faced by states in regulating the use of AI in healthcare were identified, especially the legal voids and complexities for adequate regulation and better transparency. A few recommendations were made to protect health data, mitigate risks and regulate more efficiently the use of AI in healthcare through international cooperation and the adoption of harmonized standards under the World Health Organization (WHO) in line with its constitutional mandate to regulate digital and public health. European Union (EU) law can serve as a model and guidance for the WHO for a reform of the International Health Regulations (IHR).

Consent and Identifiability for Patient Images in Research, Education, and Image-Based Artificial Intelligence

Research Letter

Trina Salvador, Lilly Gu, Jennifer L. Hay, Nicholas R. Kurtansky, Ruth Masterson-Creber, Allan C. Halpern, Veronica Rotemberg

JAMA Dermatology, 13 March 2024

Abstract

Increasing use of imaging for research, education, and development of image-based artificial intelligence (AI) is parallel to increasing concerns about confidentiality and autonomy. Regulatory requirements for collecting and processing personal information vary geographically, but even the most stringent legal guidelines do not require informed consent for sharing of deidentified data. Despite widespread use of imaging in dermatology and portability of digital image formats that enable both rapid intentional and inadvertent image sharing, information about attitudes and preferences on consent and identifiability are limited. Consequently, processes for obtaining informed consent are not standardized across clinical practices and research journals.4 To inform practices for protecting privacy, we performed a survey study to elucidate perspectives on image use, consent, and identifiability.

An In-Depth Qualitative Interview: The Impact of Artificial Intelligence (AI) on Consent and Transparency

Book Chapter

Sharon L. Burton, Darrell N. Burrell, Calvin Nobles, Yoshino W. White, Maurice E. Dawson, Kim L. Brown-Jackson, S Rachid Muller, Dustin I. Bessette

Multisector Insights in Healthcare, Social Sciences, Society, and Technology, 2024 [IGI Global]

Abstract

AI is impacting consent and transparency adversely. Although AI can potentially augment transparency in decision-making via advanced technology, it is creating new concerns. This chapter focuses on the impact of AI systems on individuals' ability to provide informed consent for using their data, and the relationship between transparency in AI decision-making processes and issues related to accountability and trust. Discussed are GDPR (European Union General Data Protection Regulation), and CCPA (California Consumer Privacy Act) due to their consent and transparency within their broader privacy protection frameworks. Applied is a qualitative methodology and in-depth interview design using a communication and collaboration platform to explain the connection between AI consent and transparency. Research results offer avenues to understanding the challenges of informed consent and legal and ethical considerations regarding consent and transparency. Beneficiaries of this research are practitioners, academics, and learners in AI, cybersecurity, and criminology/criminal justice.

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HEALTH DATA/DATA

Attitude towards consent-free research use of personal medical data in the general German population

Research Article

Gesine Richter, Nourane Trigui, Amke Caliebe, Michael Krawczak

Heliyon, 30 March 2024; 10(6)

Open Access
Abstract
Background
The design of appropriate consent procedures for the secondary use of personal health data is a key concern of current medical research. In Germany, the concept of 'data donation' has recently come into focus, defined as a legal entitlement to the research use of personal medical data without prior consent, combined with an easy-to-exercise right of the data subjects to opt-out.
Methods
Standardized online interviews of 3,013 individuals, representative of the German online population, were conducted in August 2022 to determine their attitude towards data donation for medical research.
Results
A majority of participants supported a consent-free data donation regulation, both for publicly funded (85.1%) and for private medical research (66.4%). Major predictors of a positive attitude towards data donation included (i) sufficient appreciation of the respective kind of research (i.e. public or private), (ii) a reciprocity attitude that patients who benefit from research have a duty to support research, and (iii) sufficient trust in data protection and data control.
Conclusion
People's attitude towards data donation to medical research is generally positive in Germany and depends upon factors that can be curbed by legislation and internal rules of procedure. Worthy of note, designing data donation in the form of an opt-out regulation does not necessarily mean that the paradigm of informedness has to be abandoned. Rather the process of information provision must be shifted towards the creation of basic knowledge in the general population about the risks and benefits of data-intensive medical research ('health data literacy').

Beware: Processing of Personal Data—Informed Consent Through Risk Communication

Lukas Seiling, Rita Gsenger, Filmona Mulugeta, Marte Henningsen, Lena Mischau, Marie Schirmbeck
IEEE, 14 March 2024
Open Access
Abstract
Background
The General Data Protection Regulation (GDPR) has been applicable since May 2018 and aims to further harmonize data protection law in the European Union. Processing personal data based on individuals' consent is lawful under the GDPR only if such consent meets certain requirements and is "informed," in particular. However, complex privacy notice design and individual cognitive limitations challenge data subjects' ability to make elaborate consent decisions. Risk-based communication may address these issues.
Literature review
Most research focuses on isolated aspects of risk in processing personal data, such as the actors involved, specific events leading to risk formation, or distinctive (context-dependent) consequences. We propose a model combining these approaches as the basis for context-independent risk communication.
Research questions
1. What are relevant information categories for risk communication in the processing of personal data online? 2. Which potentially adverse consequences can arise from specific events in the processing of personal data online? 3. How can consequences in the processing of personal data be avoided or mitigated?
Research methodology
The GDPR was examined through a systematic qualitative content analysis. The results inform the analysis of 32 interviews with privacy, data protection, and information security experts from academia, Non-Governmental Organizations, the public, and the private sector.
Results

Risk-relevant information categories, specific consequences, and relations between them are identified, along with strategies for risk mitigation. The study concludes with a specified framework for perceived risk in processing personal data.

Conclusion

The results provide controllers, regulatory bodies, data subjects, and experts in the field of professional communication with information on risk formation in personal data processing. Based on our analysis, we propose information categories for risk communication, which expand the current regulatory information requirements.

Consent as a compositional act – a framework that provides clarity for the retention and use of data

Research

Minerva C. Rivas Velarde, Christian Lovis, Marcello Ienca, Caroline. Samer, Samia Hurst

Philosophy, Ethics, and Humanities in Medicine, 6 March 2024

Open Access

Abstract

Background

Informed consent is one of the key principles of conducting research involving humans. When research participants give consent, they perform an act in which they utter, write or otherwise provide an authorisation to somebody to do something. This paper proposes a new understanding of the informed consent as a compositional act. This conceptualisation departs from a modular conceptualisation of informed consent procedures.

Methods

This paper is a conceptual analysis that explores what consent is and what it does or does not do. It presents a framework that explores the basic elements of consent and breaks it down into its component parts. It analyses the consent act by first identifying its basic elements, namely: a) data subjects or legal representative that provides the authorisation of consent; b) a specific thing that is being consented to; and c) specific agent(s) to whom the consent is given.

Results

This paper presents a framework that explores the basic elements of consent and breaks it down into its component parts. It goes beyond only providing choices to potential research participants; it explains the rationale of those choices or consenting acts that are taking place when speaking or writing an authorisation to do something to somebody.

Conclusions

We argue that by clearly differentiating the goals, the procedures of implementation, and what is being done or undone when one consent, one can better face the challenges of contemporary data-intensive biomedical research, particularly regarding the retention and use of data. Conceptualising consent as a compositional act enhances more efficient communication and accountability and, therefore, could enable more trustworthy acts of consent in biomedical science.

Ethical considerations in healthcare IT: A review of data privacy and patient consent issues

Review Article

Adekunle Oyeyemi Adeniyi, Jeremiah Olawumi Arowoogun, Chioma Anthonia Okolo, Rawlings Chidi, Oloruntoba Babawarun

World Journal of Advanced Research and Reviews, 22 February 2024; 21(02) pp 1660–1668

Abstract

This paper delves into the ethical considerations in healthcare Information Technology (IT), focusing on data privacy and patient consent issues. It explores the intersection of technological advancements in healthcare

IT and the ethical imperatives guiding their application, specifically examining challenges in ensuring data privacy and obtaining informed consent amidst the complexities introduced by digital health technologies. Through a review of existing ethical theories, regulatory frameworks, and the implications of artificial intelligence (AI) and big data, the paper highlights technological solutions and policy recommendations to address these ethical challenges. It emphasizes the importance of balancing innovation with ethical considerations to protect patient rights and maintain trust in the healthcare system. The paper advocates for ongoing research and stakeholder engagement to evolve ethical standards aligned with technological advancements in healthcare IT.

Data Privacy and E-Consent in the Public Sector

Book Chapter

Abhay Bhatia, Anil Kumar, Pankhuri Bhatia

The Ethical Frontier of AI and Data Analysis, 2024 [IGI Global]

Abstract

In the era of the internet, all face administrative and legal responsibilities obtaining informed consent and safeguarding personal information, with the public growing mistrust to data collection. Moral consent management takes place in account of person's views, subjective norms, and sense of control. When obtaining consent, this chapter aims to combat this cynicism. It accomplishes this by creating a novel conceptual model of online informed consent that combines the TPB with the autonomous authorisation model of informed consent. It is argued logically and is bolstered. As a result, it develops a model for online informed consent that is based on the ethic of autonomy and makes use of theory based on behaviour to enable a method of eliciting agreement that can put interest of users first and then promotes moral the information management and the marketing techniques. This approach also presents an innovative idea, the informed attitude for the validity of informed consent. It also indicates that informed permission may be given against.

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TECHNOLOGY/OTHER MEDIATION

Optimizing the consent process for emergent laparoscopic cholecystectomy using an interactive digital education platform: a randomized control trial

Anood Alqaydi, Erin Williams, Sulaiman Nanji, Boris Zevin

Surgical Endoscopy, 18 March 2024

Abstract

Background

Informed consent is essential for any surgery. The use of digital education platforms (DEPs) can enhance patient understanding of the consent discussion and is a method to standardize the consent process in elective, ambulatory settings. The use of DEP as an adjunct to standard verbal consent (SVC) has not been studied in an acute care setting.

Methods

We conducted a prospective randomized control trial with patients presenting to the emergency department of a tertiary care hospital with acute biliary pathology requiring a laparoscopic cholecystectomy (LC) between August 2021 and April 2023. Participants were randomized 1:1 to receive either a DEP module with SVC or SVC alone. Baseline procedure-specific knowledge and self-reported understanding of risks and benefits of LC were collected using a questionnaire. Primary outcome was immediate post-intervention knowledge assessed using a 21-question multiple choice questionnaire. Secondary outcomes were delayed procedure-specific knowledge and participants' satisfaction with the consent discussion.

Results
We recruited 79 participants and randomized them 1:1 into the intervention group (DEP + SVC, n = 40) and the control group (SVC, n = 39). Baseline demographics and baseline procedure-specific knowledge were similar between groups. The immediate post-intervention knowledge was significantly higher for participants in the intervention versus the control group with a Cohen's d effect size of 0.68 (85.2(10.6)% vs. 78.2(9.9)%; p = 0.004). Similarly, self-reported understanding of risks and benefits of LC was significantly greater for participants in the intervention versus the control group with a Cohen's effect size of 0.76 (68.5(16.4)% vs. 55.1(18.8)%; p = 0.001). For participants who completed the delayed post-intervention assessment (n = 29), there continued to be significantly higher retention of acquired knowledge in the intervention group with a Cohen's effect size of 0.61 (86.5(8.5)% vs. 79.8 (13.1)%; p = 0.024). There was no difference in participants' self-reported satisfaction with the consent discussion between groups (69.5(6.7)% vs. 67.2(7.7)%; p = 0.149).
Conclusion
The addition of digital education platform to standard verbal consent significantly improves patient's early and delayed understanding of risks and benefits of LC in an acute care setting.

Assessing the impact of mixed reality-assisted informed consent: A study protocol

Gianluca Scalia, Stefano Maria Priola, Sruthi Ranganathan, Tejas Venkataram, Valeria Orestano, Salvatore Marrone, Bipin Chaurasia, Rosario Maugeri, Domenico Gerardo Iacopino, Lidia Strigari, Maurizio Salvati, Giuseppe Emmanuele Umana

Surgical Neurology International, March 2024

Abstract
Background Informed consent is a crucial aspect of modern medicine, but it can be challenging due to the complexity of the information involved. Mixed reality (MR) has emerged as a promising technology to improve communication. However, there is a lack of comprehensive research on the impact of MR on medical informed consent. The proposed research protocol provides a solid foundation for conducting future investigations and developing MR-based protocols that can enhance patients' understanding and engagement in the decision-making process.
Methods
This study will employ a randomized controlled trial design. Two arms will be defined: MR-assisted informed consent (MRaIC) as the experimental arm and conventional informed consent (CIC) as the control arm consent, with 52 patients in each group. The protocol includes the use of questionnaires to analyze the anxiety levels and the awareness of the procedure that the patient is going to perform to study the impact of MRaIC versus CIC before medical procedures.
Results
The study will evaluate the impact of MR on patients' information comprehension, engagement during the process of obtaining informed consent, emotional reactions, and consent decisions. Ethical concerns will be addressed.
Conclusion
This study protocol provides a comprehensive approach to investigate the impact of MR on medical informed consent. The findings may contribute to a better understanding of the effects of MR on information comprehension, engagement during the process of obtaining informed consent, psychological experience, consent decisions, and ethical considerations. The integration of MR technology has the potential to enhance surgical communication practices and improve the informed consent process.

Trust-Building: Why Virtual Formats Threaten the Moral Ends of Surgical Informed Consent

John H. Lee, Katherine E. Neff, Christian J. Vercler

Annals of Surgery, Surgical Perspectives, 26 February 2024

Abstract
The COVID-19 pandemic forced a wide range of medical practices to virtual formats, including the preoperative informed consent practice. However, virtual informed consent persists despite the pandemic largely considered resolved. The continued use of virtual formats relies on a problematic "information-transfer" model of informed consent. We suggest that a "trust-building" model of consent as a better conceptualization of what is occurring during the consent process. Highlighting how virtual formats might fail to fulfill this fuller understanding of consent on both interpersonal and systemic levels, we offer up an ethical structure for physicians to navigate this novel virtual space.

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YOUNG PERSONS

Gillick competence: an inadequate guide to the ethics of involving adolescents in decision-making

Clinical ethics
Avraham Bart, Georgina Antonia Hall, Lynn Gillam
Journal of Medical Ethics, 20 February 2024
Abstract
Developmentally, adolescence sits in transition between childhood and adulthood. Involving adolescents in their medical decision-making prompts important and complex ethical questions. Originating in the UK, the concept of Gillick competence is a dominant framework for navigating adolescent medical decision-making from legal, ethical and clinical perspectives and is commonly treated as comprehensive. In this paper, we argue that its utility is far more limited, and hence over-reliance on Gillick risks undermining rather than promoting ethically appropriate adolescent involvement. We demonstrate that Gillick only provides guidance in the limited range of cases where legal decisional authority needs to be clarified. The range of cases where use of Gillick actually promotes adolescent involvement is narrower still, because several features must be present for Gillick to be enacted. Each of these features can, and do, act as barriers to adolescent involvement. Within these limited situations, we argue that Gillick is not specific or strong enough and is reliant on ethically contestable principles. Moreover, in most situations in adolescent healthcare, Gillick is silent on the ethical questions around involving adolescents. This is because it focuses on decisional authority—having the final say in decision-making—which is one small subset of the many ways adolescents could be involved in decision-making. The implication of our analysis is that use of Gillick competence tends to limit or undermine adolescent involvement opportunities. We propose that those working with adolescents should be judicious in seeking Gillick's guidance, instead drawing on and developing alternative frameworks that provide a comprehensive model for adolescent involvement.

Evaluating the Decisional Capacity for Informed Consent of Transition age Children to Adolescents in Human Subject Research

Research Article
Kamran Salayev, Ulviyya Aslanova, Kerim Munir
Journal of Empirical Research on Human Research Ethics, 10 December 2023
Abstract
This study aimed to evaluate children's capacity for informed consent. We translated into Azerbaijani language and adapted the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC). We enrolled four healthy groups: children aged 11, 12, and 13 years and adults. We provided the participants with information about the simulated research proposal and a related informed consent form. Subsequently, they were administered the UBACC. The mean total UBACC scores were 11.9 (11-year-olds),

12.7 (12-year-olds), 14.0 (13-year-olds), and 16.0 (adults). The gradual increase in the mean UBACC scores with age suggests the continuous maturation of the capacity to comprehend the informed consent process. There was no specific cutoff age to decide whether the children were competent enough to provide informed consent.

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CAPACITY TO CONSENT

Lack of assent to dental examination in children with intellectual disabilities: Dentists' practices in Europe and ethical issues

Original Article

Ariane Camoin, Isabelle Blanchet, Lionel Dany, Pierr Le Coz, Bérengère Saliba-Serre, Corinne Tardieu

Special Care in Dentistry, 19 March 2024

Abstract

Aim

(1) To determine the repartition of criteria which can be considered as marks of lack of assent by the child with intellectual disabilities from the dentist's point of view and whether that influences the decision to examine the patient or not. (2) To explain the decision of practitioners and determine the ethical implications of these practices.

Methods

An anonymous and structured questionnaire was distributed online using the scenario of a 9-year-old child with moderate cognitive impairment with eight different oppositional behaviours. The practitioners were asked about their perception of the patient's lack of assent and about their decision to perform the dental examination or not.

Results

The proportion of them who performed a dental examination despite the patient's refusal represented between 13% and 28.8% of the population of respondents.

Conclusion

There was an ambivalence among the practitioners who carried out a dental consultation when children were uncooperative. They adopted a teleological point of view. It calls for us to reflect on the ethical principles of autonomy and beneficence.

Reliability of clinical judgment for evaluation of informed consent in mental health settings and the validation of the Evaluation of Informed Consent to Treatment (EICT) scale

Original Research

Nicola Di Fazio, Donato Morena, Federica Piras, Fabrizio Piras, Nerisa Banaj, Giuseppe Delogu, Felice Damato, Paola Frati, Vittorio Fineschi, Stefano Ferracuti, Gabriele Sani, Claudia Dacquino

Frontiers of Psychology - Quantitative Psychology and Measurement, 26 February 2024

Excerpt

The competence assessment to give informed consent in the legal and healthcare settings is often performed merely through clinical judgment. In the present pilot study, we evaluated the reliability of clinical judgment in the mental health field, with a focus on assessing the general competence of outpatients with schizophrenia. Moreover, we tested a new scale ("Evaluation of Informed Consent to Treatment" -"EICT" Scale) suitable as a standardized assessment tool. The scale assesses four dimensions of competence, Understanding, Evaluating. Reasoning and Expressing a choice. Thirty-four outpatients with schizophrenia were evaluated for their competence to consent by five referring clinicians with different backgrounds

(psychiatrist, forensic psychiatrist, geriatrician, anesthetist, and medico-legal doctor). Correlation analyses were conducted between the scores obtained by the clinicians on a modified version of the Global Assessment of Functioning scale (GAF) designed specifically to subjectively assess functioning in each of the four competence dimensions. Moreover, two validated competence scales (Mac-CAT-T, SICIATRI-R), and a neuropsychological battery were administered along with scales for evaluating neuropsychiatric symptoms severity and side effects of medication…

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Comprehension of informed consent and voluntary participation in registration cohorts for phase IIb HIV vaccine trial in Dar Es Salaam, Tanzania: a qualitative descriptive study

Research
Masunga K. Iseselo, Edith A. M. Tarimo
BMC Medical Ethics, 13 March 2024; 25(29)
Open Access
Abstract
Background
Informed consent as stipulated in regulatory human research guidelines requires volunteers to be well-informed about what will happen to them in a trial. However, researchers may be faced with the challenge of how to ensure that a volunteer agreeing to take part in a clinical trial is truly informed. This study aimed to find out volunteers' comprehension of informed consent and voluntary participation in Human Immunodeficiency Virus (HIV) clinical trials during the registration cohort.
Methods
We conducted a qualitative study among volunteers who were enrolled in the registration cohort of HIV clinical trials in Dar es Salaam, Tanzania. A purposive sampling strategy was used to obtain twenty study participants. The data were collected between June and September 2020 using a semi-structured interview guide. In-depth interviews were used to collect the data to obtain deep insights of the individual study participants on the comprehension of informed consent and participation in the clinical trial. A thematic analysis approach was used to analyze the data. Themes and subthemes were supported by the quotes from the participants.
Results
Volunteers described comprehension of informed consent from different perspectives. They reported that various components of the informed consent such as study procedure, confidentiality, risk and benefits were grasped during engagement meetings. Furthermore, the volunteers' decision to participate in the registration cohort was voluntary. However, trial aspects such as health insurance, free condoms, and medical checkups could have indirectly influenced their reluctance to withdraw from the study.
Conclusion
Engagement meetings may increase the comprehension of informed consent among potential participants for HIV clinical trials. However, trial incentives may influence participation, and thus future research should focus on the challenges of giving incentives in the study. This will ensure comprehension and voluntary participation in the context of HIV clinical trials.

The informed consent process: An evaluation of the challenges and adherence of Ghanaian researchers

Paa-Kwesi Blankson, Florence Akumiah, Amos Laar, Lisa Kearns, Samuel Asiedu Owusu

Developing World Bioethics, 13 March 2024

Abstract

This study assessed challenges faced by researchers with the informed consent process (ICP). In-depth interviews were used to explore challenges encountered by Investigators, Research assistants, Institutional Review Board members and other stakeholders. An electronic questionnaire was also distributed, consisting of Likert-scale responses to questions on adherence to the ICP, which were derived from the Helsinki Declaration and an informed consent checklist of the US Department of Health and Human Research (HSS). Responses were weighted numerically and scores calculated for each participant. The median score of the level of adherence to the informed consent process was 93%. Most of the respondents (60%) cited the lack of time for the ICP to be a challenge, with 65% indicating a lengthy consent document to be the main challenge with the informed consent document. Challenges with language and communication were the dominant theme among informants. Despite the high adherence of Ghanaian researchers and research assistants to the ICP, challenges are still prevalent, requiring diligent and continuous efforts in research implementation.

Voluntariness of consent in paediatric HIV clinical trials: a mixed-methods, cross-sectional study of participants in the CHAPAS-4 and ODYSSEY trials in Uganda

Original Research

Shafic Makumbi, Francis Bajunirwe, Deborah Ford, Anna Turkova, Annabelle South, Abbas Lugemwa, Victor Musiime, Diana Gibb, Imelda K Tamwesigire

BMJ Open, 1 March 2024

Open Access

Abstract

Objectives

To examine the voluntariness of consent in paediatric HIV clinical trials and the associated factors.

Design

Mixed-methods, cross-sectional study combining a quantitative survey conducted concurrently with in-depth interviews.

Setting and participants

From January 2021 to April 2021, we interviewed parents of children on first-line or second-line Anti-retroviral therapy (ART) in two ongoing paediatric HIV clinical trials [CHAPAS-4 (ISRCTN22964075) and ODYSSEY (ISRCTN91737921)] at the Joint Clinical Research Centre Mbarara, Uganda.

Outcome measures

The outcome measures were the proportion of parents with voluntary consent, factors affecting voluntariness and the sources of external influence. Parents rated the voluntariness of their consent on a voluntariness ladder. Indepth interviews described participants' lived experiences and were aimed at adding context.

Results

All 151 parents randomly sampled for the survey participated (84% female, median age 40 years). Most (67%) gave a fully voluntary decision, with a score of 10 on the voluntariness ladder, whereas 8% scored 9, 9% scored 8, 6% scored 7, 8% scored 6 and 2.7% scored 4. Trust in medical researchers (adjusted OR 9.90, 95% CI 1.01 to 97.20, p=0.049) and male sex of the parent (adjusted OR 3.66, 95% CI 1.00 to 13.38, p=0.05) were positively associated with voluntariness of consent. Prior research experience (adjusted OR 0.31, 95% CI 0.12 to 0.78, p=0.014) and consulting (adjusted OR 0.25. 95% CI 0.10 to 0.60, p=0.002) were negatively associated with voluntariness. Consultation and advice came from referring health workers (36%), spouses (29%), other family members (27%), friends (15%) and researchers (7%). The indepth interviews (n=14) identified the health condition of the child, advice from referring health workers and the opportunity to access better care as factors affecting the voluntariness of consent.

Conclusions

This study demonstrated a high voluntariness of consent, which was enhanced among male parents and by parents' trust in medical researchers. Prior research experience of the child and advice from health workers and spouses were negatively associated with the voluntariness of parents' consent. Female parents and parents of children with prior research experience may benefit from additional interventions to support voluntary participation.

Biomedical research on autism in low- and middle-income countries: Considerations from the South African context

Siobhan de Lange, Dee Muller, Chloe Dafkin

Developing World Bioethics, 26 February 2024

Abstract

Autism Spectrum Disorder (ASD) is a neurodevelopmental condition characterized by social/communicative difficulties and perseverative behaviours. While research on autism has flourished recently, few studies have been conducted on the disorder in non-Western contexts. In low- and middle-income countries (LMICs), biomedical research on autism is required to better understand the needs of the population and to develop contextually appropriate interventions. However, autistic individuals are a vulnerable study population and LMICs present with various considerations. While the presentation of autism is heterogeneous, stigma is a common social consequence affecting research. Drawing specifically on the South African context, the ethical intersections of these issues are discussed, along with the limitations of the current informed consent process. Community engagement is recommended as an adjunct to informed consent to ensure that biomedical research is conducted in a more inclusive way. Practical pointers are provided for implementing systematic support for conducting community engagement alongside biomedical research.

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RIGHTS/LEGAL/LEGISLATIVE

Comparative study on informed consent regulation in health care among Italy, France, United Kingdom, Nordic Countries, Germany, and Spain

Research Paper

Vittorio Bolcato, Chiara Franzetti, Giovanni Fassina, Giuseppe Basile, Rosa Maria Martinez, Livio Pietro Tronconi

Journal of Forensic and Legal Medicine, 14 March 2024

Open Access

Abstract

The information and subsequent expression of will, so-called informed consent, have become the essential element of health right, understood as the right to autonomous choice in health, based on the fiduciary relationship between physician and patient. This gradually leads European Countries to adopt special legislations and to issue frequent judgments on the subject. However, new challenges in daily clinical practice call for further study of legal solutions. The authors analyse and compare the regulations on informed consent in health care of Italy, France, the United Kingdom, the Nordic Countries, Germany, and Spain. The health and legal contexts, existence of special regulations on informed consent and their characteristics are discussed. Informed consent resulted a mandatory requirement. Clear communication about treatment, therapeutic alternatives, and major risks, discussed in conversation, but preferably documented in writing, are agreed upon. The possibility of dissent and withdrawal of consent are also included. There is a growing interest in involving and regulating the entire health team in information and consent. Lowering the age of consent for minors or analysing the maturity of minors are attempts to increase their participation in health

decisions. On another side, the protection of adult incapables persons requires greater involvement of family and fiduciaries to better adapt to changing health needs. Health policy must take responsibility for training health professionals and citizens about the value of health information and communication as a shared choice in care planning, to strengthen the bond of trust with the healthcare system and users.

The Application of the Doctrine of Informed Consent in South African Medical Law: Reflections on Significant Developments in the Case Law

Marno Swart, Pieter Carstens

South African Law Journal, 1 March 2023

Abstract

The doctrine of informed consent is the foundation of the physician–patient relationship. This doctrine remains controversial despite its importance, and issues involving consent are frequently litigated. This article examines the application of the doctrine of informed consent in South African medical law as it has developed in South African case law. This examination first sets a normative background for consent as a ground of justification against a wrongful act in either contract or delict (or both) that is significantly influenced by the Constitution of the Republic of South Africa, 1996. Against this normative background, a selected anthology of nine significant judgments by South African courts is analysed, with specific attention paid to the critical shift prompted by the promulgation of the Constitution. Finally, the analyses of the nine judgments are consolidated and collated to draw conclusions about the triumphs and failings of the South African courts, based on the normative background. This analysis reveals which aspects of the doctrine of informed consent have crystallised in South African medical law and which remain unclear.

The new legal requirements of consent in Kuwait

Journal Article

Noura Hezam Almutairi

International Data Privacy Law, 28 February 2024

Extract

Introduction

Private and public sector controllers collect and process Internet user data. Consent is a legitimate basis for processing their information. Consent is the legal tool that enables Internet users to control their data to safeguard their right to privacy. Nonetheless, laws governing consent in Kuwait have failed to achieve their objective for three reasons.

First, many Internet users are unwilling to read and understand the content of the privacy notice (of social media sites, smart mobile apps, Internet of Things [IoT] devices such as Fitbit) or cookies (of e-commerce companies such as Amazon and search engines such as Google). The notice may be written in complex and vague language, such as legal jargon, or be overly long. Therefore, Internet users consent to cookies and privacy notices without knowing how their collected data will be used or to whom it will be disclosed.

Secondly, while a user may understand the privacy notice, they only sometimes have an option or right to refuse. This instance is similar to a contract of adhesion, as the individual's consent is not freely given. Finally, vulnerable Internet users, such as children, may consent to privacy notices without understanding the implications of agreeing to them…

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FREE PRIOR INFORMED CONSENT (FPIC)

Free, Prior, and Informed Consent, A Norm in Development or a Corporate Obligation?

Laurence Klein, María Jesús Muñoz-Torres, María Ángeles Fernández-Izquierdo

International Journal on Minority and Group Rights, 27 Feb 2024

Abstract

Free, Prior, and Informed Consent (fpic) is crucial for the exercise of indigenous peoples' right to self-determination, a binding human rights norm, as it provides them with the opportunity to determine how their lands and resources are developed. While numerous companies have committed to respecting fpic in their corporate policies, there continues to be a huge disconnect between public rhetoric and actions on the ground, and indigenous peoples generally struggle to have a meaningful voice in decision-making processes that concern them. Even if the United Nations Guiding Principles on Business and Human Rights (ungp, 2011) have compelled companies to gain ground with regards to their responsibility to respect human rights, the 'do-no-harm' principle does not require them to take positive actions towards fulfilling human rights. This approach is inconsistent with the moral foundation of human rights, which implies duties, and does not account for the substantial economic and political power that increases companies' potential as guarantors of human rights. Based on the normative and moral legitimacy sustaining the narrative on corporate human rights obligations and the political, moral and legal imperative behind fpic, this article asserts that companies have a normative obligation to observe fpic, which they ought to operationalise in the context of heightened requirements regarding their human rights due diligence.

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MEDICAL/SURGICAL

Consent in pregnancy: A qualitative study of the experiences of ethnic minority women

Zahra Khan, Anne Lanceley, Katherine Maslowski, Lily Hutton, Jacqueline Nicholls

Patient Education and Counseling, June 2024

Open Access

Abstract

Objective

Consent in ante-natal and birthing contexts is often challenging, controversial and poorly understood. Increasing evidence indicates that ethnic minority women's overall experiences of ante-natal care are unsatisfactory, but little is known about their involvement in the consent process. This study aims to explore the views and experiences of ethnic minority women when making decisions requiring their consent.

Design

Qualitative interview study

Setting

A national study conducted in the UK

Sample

Seventeen self-selecting ethnic minority women who had given birth in a UK hospital in the previous 12 months.

Methods

In-depth telephone interviews with seventeen women. A thematic analysis was conducted with a focus on women's experiences of the consent process.

Results

Three themes were identified. 1. Compromised choice: women experienced limited choice; some women were not asked for their consent at all, or consent was presumed. 2. Pressured consent and silencing: women reported feeling undermined and 'othered' based on their ethnicity. 3. Impersonal consent: discussions were impersonal and not tailored to women as individuals; some women suggested that healthcare professionals ignored cultural concerns which were important to them.

Practice Implications
There is an urgent need for healthcare professionals to be supported in actively facilitating consent consultations which enable women from ethnic minority backgrounds to freely voice their concerns and priorities without censure.
Conclusions
This exploratory study is a first step towards understanding how consent is experienced by ethnic minority women. Many women's experiences reflected failure of healthcare professionals to support genuine choice-making which was perceived to be further undermined by negativity related to women's ethnicity and cultural identity. There is a need for further research focusing on the consent experiences of specific ethnic minority groups.

Are we gaining valid consent for dental extractions? A retrospective audit on restorability assessment at one dental institution

Research
Melody Shirazi, Jasleen Batra, Maria Devine
British Dental Journal, 15 March 2024
Abstract
Introduction
This paper explores the widely relevant topic of obtaining valid consent in dental practice, focusing on assessing restorability of teeth planned for extraction. The General Dental Council stresses discussing treatment options, benefits and risks for informed decision-making. The study evaluates if pertinent factors, including tooth structure, endodontic status, periodontal health and patient considerations, are considered before consent.
Aim
To ensure restorability has been assessed and all options communicated with patients for completeness of the consent process before tooth extraction.
Objective
To assist clinicians in their systematic assessment of a tooth's restorability and provide a framework for contemporaneous documentation.
Materials and methods
A two-week retrospective audit of oral surgery outpatients at a dental hospital in London was conducted, analysing the frequency of restorability discussions and patient involvement in decision-making. A simplified restorability guide and educational interventions were introduced to target the set standard of 100% of consenting clinicians to discuss restorability with patients.
Results
Results from two audit cycles show a significant increase in documented restorability discussions and consideration of patient factors.
Discussion
The study recognised restorability assessment subjectivity, thus creating a simplified tool for clinicians. Patients may lack awareness of restorability options, consequences of edentulism, future costs and tooth replacement considerations, emphasising the importance of documented discussions.
Conclusion
Educational interventions and a simplified restorability guide proved beneficial and showed significant improvement in communication with patients regarding restorability and gaining valid consent. Further consideration should be given to barriers patients face when opting for tooth extraction of their restorable teeth, including discussions regarding long-term consequences.

Genetic counselors' and community clinicians' implementation and perceived barriers to informed consent during pre-test counseling for hereditary cancer risk

Alexandra Capasso, Bita Nehoray, Nicholas Gorman, Emily A Quinn, Daiana Bucio, Kathleen R Blazer

Journal of Genetic Counselling, 13 March 2024

Abstract

As demand for genetic cancer risk assessment (GCRA) continues to increase, so does the sense of urgency to scale up efforts to triage patients, facilitate informed consent, and order genetic testing for cancer risk. The National Society of Genetic Counselors outlines the elements of informed consent that should be addressed in a GCRA session. While this practice resource aims to improve health equity, research on how well the elements of informed consent are implemented in practice is lacking. This retrospective and prospective mixed-methods study assessed how adequately the elements of informed consent are addressed during pre-test GCRA among 307 community clinicians (CC) and 129 cancer genetic counselors (GC), and barriers they face to addressing these elements. Results revealed that more than 90% of both cohorts consistently addressed components of at least 5 of the 10 elements of informed consent during a pre-test consultation. Technical aspects and accuracy of the test and utilization of test results were the most similarly addressed elements. Notably, GCs more often review the purpose of the test and who to test, general information about the gene(s), and economic considerations whereas CCs more often review alternatives to testing. Both cohorts reported psychosocial aspects of the informed consent process as the least adequately addressed element. Time constraints and patient-related concerns were most often cited by both cohorts as barriers to optimal facilitation of informed consent. Additional barriers reported by CCs included provider lack of awareness, experience, or education, and availability of resources and institutional support. Findings from this study may contribute to the development of alternative delivery models that incorporate supplementary educational tools to enhance patient understanding about the utility of genetic testing, while helping to mitigate the barrier of time constraints. Equally important is the use of this information to develop continuing education tools for providers.

Current Status of Informed Consent Form for Acupotomy in Korean Medicine Hospitals and Development of a Standard Informed Consent Form Using Delphi Method

Original Article

Jihun Kim, Bonhyuk Goo, Hyongjun Kim, Kyoungsuk Seo, Myungjin Oh, Myungseok Ryu, Sang-Hoon Yoon, Kwang Ho Lee, Hyun-Jong Lee, Jungtae Leem, Hyungsun Jun, Jeong Ihn Sook, Sung Woon Choi, Tae Wook Lee, Yeonhak Kim, Yoona Oh, Kunhyung Kim, Gi Young Yang, Eunseok Kim

The Journal of Korean Medicine, 1 March 2024; 45(1) pp 180-199

Abstract

Objectives

This study was conducted to develop a standard acupotomy consent form that takes into account the unique characteristics of Korean Medicine. The study was motivated by the increasing importance of patient autonomy and the growing number of legal disputes related to medical malpractice in the clinical field of Korean Medicine.

Methods

The analysis phase of the study involved a survey of the current status of acupotomy consent forms in Korean Medicine hospitals nationwide. The items of each form were analyzed based on the contents of the Medical law and the standard contract for medical procedures of the Fair Trade Commission (FTC). In the development and evaluation phase, the items and contents of the acupotomy consent form were evaluated using a 5-point Likert scale and content validity was assessed through two rounds of Delphi surveys. In the improvement phase, the contents of the consent form were revised based on the results of a survey of inpatient and outpatient patients in the Department of Acupuncture and Moxibustion at Pusan National University Korean Medicine Hospital, and real-time online meeting. The final version of the standard

acupotomy consent form was completed after undergoing proofreading and corrections by a linguistics expert.

Results

Only 30% of Korean Medicine hospitals have implemented acupotomy consent forms. The items of the consent forms did not fully include the items presented in the Medical act and the standard contract for medical procedures of the FTC. To address this issue, two rounds of Delphi surveys and a real-time discussion were conducted with a panel of 12 experts on 27 preliminary items of consent forms. The items and contents that met the criteria for content validity ratio, convergence, and consensus were derived. Based on the derived items and content, a standard acupotomy consent form was developed.

Conclusions

The standard consent form for acupotomy is anticipated to ensure patient autonomy and enhance transparency and liability in acupotomy. Furthermore, it is expected to serve as evidence in case of medical disputes related to acupotomy and contribute as a reference document for the development of standard consents forms for various procedures of Korean Medicine. However, the limitations of the study include that the survey of consent forms was limited to only training hospitals of Korean Medicine, and the standard consent form is only applicable to adults in Korea. Future studies are needed to address these limitations.

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UPCOMING CALLS FOR PUBLIC CONSULTATION

We will selectively include calls for public consultation from multilateral agencies, governments, INGOs and other sources where there is a clear intersection with consent/assent. This might be obvious from the title of the draft guidance, regulations, etc., but more often, it will be a thematic area or topic – if properly addressed at all. If you would like to explore participation with our working group developing submissions for these calls, please contact us [david.r.curry@ge2p2global.org].

Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards

21 CFR Part 50 [Docket No. FDA-2022-D-2997] **Comments due: May 1, 2024**

SUMMARY:

The Office for Human Research Protections, Office of the Assistant Secretary for Health (OHRP), and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled "Key Information and Facilitating Understanding in Informed Consent."

This draft guidance provides recommendations related to two provisions of the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule) by the U.S. Department of Health and Human Services (HHS) and identical provisions in FDA's proposed rule "Protection of Human Subjects and Institutional Review Boards." FDA's proposed rule, if finalized, would harmonize certain sections of FDA's regulations on human subject protections and institutional review boards (IRBs), to the extent practicable and consistent with other statutory provisions, with the revised Common Rule, in accordance with the 21st Century Cures Act (Cures Act). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA's proposed rule.

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NEW NORMATIVE/ REGULATORY GUIDANCE REFERENCING CONSENT

No new regulatory guidance identified.

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SYMPOSIA/CONFERENCES

We will selectively include information on major symposia and conferences which address issues, evidence, analysis or debates involving consent/assent. This listing will include [1] meetings already concluded but which are posting presentations/recordings, etc.; [2] future meetings which have posted registration/logistics information, and [3] meetings which have announced calls for abstracts/panels, etc.

No new symposia/conferences identified.

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Acknowledgements: *Foundation Senior Fellows Barbara Redman, PhD, and David Curry, MS, review the manuscripts for each edition.*

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