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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

February 2024 :: Issue 62

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
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT
YOUNG PERSONS

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.

SPOTLIGHT ARTICLES

This month we did not find a sufficient number of articles meeting our threshold for a spotlight section.

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BIOMEDICAL RESEARCH

Personalized and longitudinal electronic informed consent in clinical trials: How to move the needle?

Evelien De Sutter, Liese Barbier, Pascal Borry, David Geerts, John P.A. Ioannidis, Isabelle Huys
Digital Health, 23 January 2024
Abstract
Changes in the clinical trials landscape have been driven by advancements in digital technology. The use of electronic informed consent to inform research participants and to obtain their consent electronically has the potential to improve participant–researcher interactions over time, facilitate clinical trial participation, and increase efficiency in clinical trial conduct. A personalized electronic informed consent platform that enables long-term interactions with the research team could function as a tool to empower participant engagement in clinical trials. However, significant challenges persist impeding successful and widespread implementation. This Perspective provides insights into the opportunities and challenges for the implementation of electronic informed consent in clinical trials. It sets out key recommendations to promote the implementation of this innovative approach to the informed consent process, including the creation of uniform electronic informed consent platforms at regional and national level.

Participant comprehension and acceptability of enhanced versus text-only electronic informed consent: an innovative qualitative pilot study

Research

Amy Corneli, Summer Starling, Yujung Choi, Jurgis Vosylius, Leanne Madre, Andrew Mackinnon & Pamela Tenaerts

Pilot and Feasibility Studies, 17 January 2024

Open Access

Abstract

Background

The use of electronic informed consent (eIC) in decentralized trials offers a pragmatic approach to enrolling participants across multiple geographic areas.

Methods

Using a randomized, cross-over study design, we conducted a qualitative descriptive evaluation of two eIC approaches—text-only eIC and enhanced eIC—in a mock hypertension Phase III clinical trial. We assessed participant comprehension and acceptability (usability, satisfaction, and eIC preference).

Results

A total of 24 individuals with hypertension participated in the study: 12 reviewed the text-only eIC first, followed by the enhanced eIC, and 12 reviewed the enhanced eIC first, followed by the text-only eIC. The study population was diverse in gender, age, race, and geographic location. We found no descriptive differences in participant comprehension and satisfaction between the two eIC approaches. However, more participants preferred the enhanced eIC, and participants indicated that the digital elements were personable and made them feel more informed, engaged, comfortable, and prepared to participate in clinical research.

Conclusions

Our findings suggest that enhancing the eIC process with digital elements may have beneficial outcomes among potential participants beyond comprehension and satisfaction.

Stakeholders' perspectives on clinical trial acceptability and approach to consent within a limited timeframe: a mixed methods study

Original Research

Elizabeth Deja, Chloe Donohue, Malcolm G Semple, Kerry Woolfall

BMJ Open, 2 January 2023

Abstract

Objectives

The Bronchiolitis Endotracheal Surfactant Study (BESS) is a randomised controlled trial to determine the efficacy of endo-tracheal surfactant therapy for critically ill infants with bronchiolitis. To explore acceptability of BESS, including approach to consent within a limited time frame, we explored parent and staff experiences of trial involvement in the first two bronchiolitis seasons to inform subsequent trial conduct

Design

A mixed-method embedded study involving a site staff survey, questionnaires and interviews with parents approached about BESS.

Setting

Fourteen UK paediatric intensive care units.

Participants

Of the 179 parents of children approached to take part in BESS, 75 parents (of 69 children) took part in the embedded study. Of these, 55/69 (78%) completed a questionnaire, and 15/69 (21%) were interviewed. Thirty-eight staff completed a questionnaire.

Results

Parents and staff found the trial acceptable. All constructs of the Adapted Theoretical Framework of Acceptability were met. Parents viewed surfactant as being low risk and hoped their child's participation would help others in the future. Although parents supported research without prior consent in studies of time critical interventions, they believed there was sufficient time to consider this trial. Parents recommended that prospective informed consent should continue to be sought for BESS. Many felt that the time between the consent process and intervention being administered took too long and should be 'streamlined' to avoid delays in administration of trial interventions. Staff described how the training and trial processes worked well, yet patients were missed due to lack of staff to deliver the intervention, particularly at weekends.

Conclusion

Parents and staff supported BESS trial and highlighted aspects of the protocol, which should be refined, including a streamlined informed consent process. Findings will be useful to inform proportionate approaches to consent in future paediatric trials where there is a short timeframe for consent discussions.

Participants' understanding of informed consent in clinical trials: A systematic review and updated meta-analysis

Chengai Wu, Na Wang, Qianqian Wang, Chao Wang, Zhenjie Wei, Zhimin Wu, Shunan Yu, Xieyuan Jiang

PLOS One, 2 January 2024

Open Access

Abstract

Obtaining written informed consent from participants before enrolment in a study is essential. A previous study showed that only 50% of the participants in clinical trials understood the components of informed consent, and the methods of participants' understanding of informed consent were controversial. This updated meta-analysis aimed to estimate the proportion of participants in clinical trials who understand the different informed consent components. PubMed, EMBASE, the Cochrane Library, and Scopus were searched till April 2023. Therapeutic misconception, ability to name one risk, knowing that treatments were being compared, and understanding the nature of the study, the purpose of the study, the risks and side-effects, the direct benefits, placebo, randomization, voluntariness, freedom to withdraw, the availability of alternative treatment if withdrawn from the trial, confidentiality, compensation, or comprehension were evaluated. This meta-analysis included 117 studies (155 datasets; 22,118 participants). The understanding of the risks and side-effects was investigated in the largest number of studies (n = 100), whereas comprehension was investigated in the smallest number (n = 11). The highest proportions were 97.5%(95% confidence interval (CI): 97.1–97.9) for confidentiality, 95.9% (95% confidence interval (CI): 95.4–96.4) for compensation, 91.4% (95% CI: 90.7–92.1) for the nature of study, 68.1% (95% CI: 51.6–84.6) for knowing that treatments were being compared, and 67.3% (95% CI: 56.6–78) for voluntary nature of participants. The smallest proportions were the concept of placebo (4.8%, 95%CI: 4.4–5.2) and randomization(39.4%, 95%CI: 38.3–40.4). Our findings suggested that most participants understood the fundamental components of informed consent (study confidentiality, nature, compensation, voluntariness, and freedom to withdraw). The understanding of other components, such as placebo and randomization was less satisfactory.

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SOCIAL SCIENCE RESEARCH

What do educational psychologists consider to be best practice when gaining consent across the 0 to 25 age range?

Althea Lyons, George Thomas

Educational Psychology In Practice, 8 November 2023

Abstract

Educational psychologists (EPs) have a legal and ethical obligation to gain informed consent prior to any psychological involvement. As EPs work across the 0 to 25 age range, the person giving consent may vary according to the needs of the individual service user and so it is necessary to be aware of relevant legislation and case law. This study explored what might be considered best practice for EPs in gaining consent across the 0 to 25 age range by conducting semi-structured interviews with six professionals as part of an expert reference group. The interviews were thematically analysed using a hybrid inductive-deductive approach. Six main themes were identified: ethical obligations; children's rights; legal obligations; partnership; informed consent; and, barriers to best practice. There was considerable overlap between some of the main themes, reflecting the complexity of the issue. The findings are discussed in relation to literature in other areas of psychological practice. Implications for practice for individual EPs and EP services are considered, such as the possibility of developing a guidance document for use across the profession, as well as directions for further research.

Agency and power in research: some thoughts about informed consent forms

Claudia Barcellos Rezendea

Saúde e Sociedade, 2023

Open Access

Abstract

This article discusses some premises that constitute informed consent forms, assuming they should not be taken for granted. I argue that the use of informed consent forms should be understood within a research relationship, which is always an intersubjective relation between two or more socially positioned individuals. I develop these reflection based on my recent experiences of anthropological research on pregnancy and birth, during which I used an informed consent form in two stages but not in an intermediary phase, which was dedicated to focus on kinship relations during pregnancy more than the bodily experience itself. Thus, by comparing these three situations, I examine their particularities in obtaining consent, discussing agency, power, and ethics in social research.

Editor's note: This is a Portuguese language publication. Saúde e Sociedade is a publication of the University of São Paulo.

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GENOMIC MEDICINE/GENE EDITING

The Need to Consider Context: A Systematic Review of Factors Involved in the Consent Process for Genetic Tests from the Perspective of Patients

Research Article

Frédéric Coulombe, Anne-Marie Laberge

AJOB Empirical Bioethics, 8 January 2024

Abstract

Background

Informed consent for genetic tests is a well-established practice. It should be based on good quality information and in keeping with the patient's values. Existing informed consent assessment tools assess knowledge and values. Nevertheless, there is no consensus on what specific elements need to be discussed or considered in the consent process for genetic tests.

Methods

We performed a systematic review to identify all factors involved in the decision-making and consent process about genetic testing, from the perspective of patients. Through public databases, we identified studies reporting factors that influence the decision to accept or decline genetic testing. Studies were included if they reported the perspective of patients or at-risk individuals. All articles were thematically coded.
Results
1989 articles were reviewed: 70 met inclusion criteria and 12 additional articles were identified through the references of included studies. Coding of the 82 articles led to the identification of 45 factors involved in decision-making and consent, which were initially divided into three domains: in favor of, against or with an undetermined influence on genetic testing. Each factor was also divided into three subdomains relating to the informed choice concept: knowledge, values or other. The factors in the "other" subdomain were all related to the context of testing (e.g. timing, cost, influence of family members, etc), and were present in all three domains.
Conclusions
We describe the network of factors contributing to decision-making and consent process and identify the context of genetic testing as a third component to influence this process. Future studies should consider the evaluation of contextual factors as an important and relevant component of the consent and decision-making process about genetic tests. Based on these results, we plan to develop and test a more comprehensive tool to assess informed consent for genetic testing.

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HEALTH DATA/DATA

Patient Perspectives on Data Sharing

Book Chapter
Louise C. Druedahl, Sofia Kälvemark Sporrong
The Law and Ethics of Data Sharing in Health Sciences, 20 December 2023 [Springer]
Open Access
Abstract
Data sharing is key for artificial intelligence and for future healthcare systems, but the perspectives of patients are seldom included in the larger debates of how, when, and what data to share. This chapter provides an overview of research on patient perspectives on data sharing and associated aspects, including patients' motivations, concerns, and views on privacy and conditions for sharing. Moreover, these perspectives are put into the evolving context of informed consent and today's European context of the General Data Protection Regulation (GDPR) and Data Governance Act (DGA). Overall, there seems to be a discrepancy between the patients' perspective on data sharing and the reality in which their data are to be shared. The current patient views are researched within relatively 'local' contexts, where the patient would consent to collecting data for primary use and on patients' preferences regarding consent and what they see as barriers and motivators for data sharing. However, the reality of data use is moving towards re-use of data for secondary purposes and a context of more altruistic consent such as the DGA. Questions remain regarding how patients perceive sharing and the role of their data in the larger governance of data; seemingly, patient views are lost in the wider debate of innovation and jurisdictional competitiveness. Ensuring that patients' voices are heard is essential for public acceptance of data sharing, and thus for inclusiveness and equity of results and innovations originating from patients' shared data.

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CAPACITY TO CONSENT

Informed Consent to Psychedelic-Assisted Psychotherapy: Ethical Considerations

Research Article

Andrew Lee, Daniel Rosenbaum, Daniel Z. Buchman

The Canadian Journal of Psychiatry, 17 January 2024

Excerpt

…Given that psychedelics can induce powerful nonordinary states of consciousness and increase suggestibility, challenges surrounding the informed consent process in [Psychedelic-Assisted Psychotherapy] PAP have begun to receive attention. For example, Smith and Sisti suggest that a process of "enhanced consent" be undertaken prior to PAP, characterized by special attention to the shifts in personality and values that can follow a psychedelic experience, the possible mental health side effects of psychedelics, and the possible use of therapeutic touch during treatment. However, Jacobs argues that owing to the particular effects of psychedelics—namely, mystical and ego-dissolution experiences which can occur acutely after administration and longer-term shifts in identity and values—the typical standards for informed consent may not be feasible.

Issues of capacity and consent during the psychedelic experience have received less attention. Individuals using psychedelics often experience profound acute changes to their sensorium along with alterations in mood, detachment from the body, and distortions of their sense of self, time, and reality. Consequently, it may be difficult for patients to appreciate the risks and benefits of terminating the session during the psychedelic experience. It may also be difficult for observers to predict or interpret the internal process and distress of patients during sessions, as their observable behaviour may not be representative of their inner experience…

Informed consent for capacity assessment

Shaun T. O'Keeffe, Mary Donnelly

International Journal of Law and Psychiatry, January–February 2024

Abstract

In this paper we examine the role of informed consent to capacity assessment, focussing primarily on the two jurisdictions of England and Wales, and Ireland. We argue that in both jurisdictions, a capacity assessment should be regarded as a distinct intervention, separate from the 'original' intervention at issue, and that specific informed consent to the assessment should generally be sought in advance. As part of this, we consider what information should be provided so as to ensure informed consent. Having established a baseline requirement for informed consent, we also recognise that informed consent to assessment will not always be possible, either because the person is unable to understand the information about assessment or because the person refuses to be assessed and so, in the final part of the article, we explore how to proceed when informed consent is either not possible or not forthcoming, including an analysis of the implications of the statutory presumption of capacity.

Capacity to consent to treatment in severe eating disorders

Research Article

Giovanna Parmigiani, Lorenzo Tarsitani, Fabiano Grassi, Gabriele Mandarelli, Stefano Ferracuti

International Review of Psychiatry, 12 January 2024

Abstract

Eating disorders represent a disabling, deadly and costly condition, whose principal treatment is constituted by weigh restoration and psychotherapy. Partial or total refuse of treatment is very common, leading some authors to question their decision-making capacity (DMC) to consent to treatment. However, very few

studies have investigated treatment DMC, leading to contrasting results. Forty-five women were enrolled at the Psychiatric and Eating Disorders Unit of the University Hospital Policlinico Umberto I of Rome. Psychiatric symptoms severity (Brief Psychiatric Rating Scale Expanded, BPRS-E), treatment DMC (MacArthur Competence Assessment Tool for Treatment, MacCAT-T), depressive symptoms (Hamilton Depression Rating Scale, HAM-D), anxiety symptoms (Hamilton Anxiety Rating Scale, HAM-A), symptoms and psychological characteristics of eating disorders (Eating Disorder Inventory, EDI-3) and Metacognitive beliefs (Metacognitions Questionnaire 30, MCQ-30) were assessed. Sixty-seven percent of the total sample showed low treatment DMC; specifically, 70.4% of patients affected by Anorexia Nervosa, 72.7% of patients affected by Bulimia Nervosa, and 42.9% of patients affected by Binge Eating Disorder. Specific psychopathological symptoms enhance or hamper patients' decisional capacities. Clinicians should be aware of the risk of impaired DMC in this vulnerable group of patients and pay attention at those factors suggesting the need of an in-depth evaluation.

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TECHNOLOGY/OTHER MEDIATION

Comparing Anxiety Levels and Pain Scores for Video-assisted and Traditional Informed Consent in Extracorporeal Shockwave Lithotripsy: A Prospective, Randomised, Controlled Study

Nurul Zubaidah Shahul Hameed, Devindran Manoharan, Lee Say Bob, Susan Woo

Asian Journal of Research and Reports in Urology, 23 January 2024

Abstract

Aims

Traditionally, informed consent involves verbal and/or written material provided to the patient by a treating clinician. Multimedia interventions improve patients' knowledge and understanding during the informed consent process. This study aimed to compare pre-procedural anxiety levels and pain scores between educational video-assisted informed consent and traditional informed consent for extracorporeal shockwave lithotripsy (ESWL) at our centre.

Study Design

This was a prospective, randomised, controlled study conducted at two centres.

Place and Duration of Study

The study was conducted in two Urology centre Department of Urology, Penang General Hospital and Department of Urology, Hospital Kuala Lumpur between 15th May 2022 and 15th October 2022.

Methodology

The study group consisted of all adult patients undergoing ESWL in both centres. A video presentation explaining the ESWL procedure was developed in two languages, and group allocation was randomised using a computer-based random number generator. Anxiety levels were assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) questionnaire, visual analogue scale, and numerical rating scale used to collect data on pain scores.

Results

A total of 54 respondents, with a predominance of male patients (57.4%) and the majority of patients having completed secondary school education (53.7%). In comparing the two groups, the video-assisted respondents exhibited significantly lower anxiety scores regarding the procedure than those in the traditional group ($p< 0.05$). However, there were no statistically significant differences between the groups in terms of pain scores, both pre- and post-procedural.

Conclusion

Video-assisted informed consent can reduce procedure-related patient anxiety levels before ESWL; however, there was no difference in pain scores between the two consent methods. patients.

Practicing care-full scholarship: Exploring the use of 'visual informed consent' in a study of motherhood, health and agroecology in Coventry, UK

Research Article

Mai Abbas, Alex Franklin, Stefanie Lemke, Chiara Tornaghi

Qualitative Research, 10 January 2024

Open Access

Abstract

The demand for alternative methods of providing informed consent is increasing, especially in research with marginalised (or illiterate) research participants. This article discusses the co-creation of a visual informed consent (VIC), in collaboration with an artist. The VIC was inspired by the experience of obtaining informed consent from a group of migrant women with limited English proficiency, in empirical research undertaken on agroecology and health in Coventry, UK. Reflecting further on its creation and wider utility, this article explores the inner values that might guide researchers and lead to the co-creation of care-full tools that meet the needs of research participants. Specifically, this includes, reflecting on the iterative process of developing a VIC and using an ethics of care as a primary conceptual framework. Findings reveal that participants' understanding of ethical issues is facilitated using visual illustrations. It is argued that the creation of a VIC requires the researcher to be attentive to the embodied nature of research practice and guided by an ethics of care. A conceptual framework that integrates care and embodiment is presented, with the intention that it may further support the development of care-full research by others.

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ARTIFICIAL INTELLIGENCE

Ethical and legal challenges of medical AI on informed consent: China as an example

Wang Y, Ma Z

Developing World Bioethics, 19 January 2024

Abstract

The escalating integration of Artificial Intelligence (AI) in clinical settings carries profound implications for the doctrine of informed consent, presenting challenges that necessitate immediate attention. China, in its advancement in the deployment of medical AI, is proactively engaging in the formulation of legal and ethical regulations. This paper takes China as an example to undertake a theoretical examination rooted in the principles of medical ethics and legal norms, analyzing informed consent and medical AI through relevant literature data. The study reveals that medical AI poses fundamental challenges to the accuracy, adequacy, and objectivity of information disclosed by doctors, alongside impacting patient competency and willingness to give consent. To enhance adherence to informed consent rules in the context of medical AI, this paper advocates for a shift towards a patient-centric information disclosure standard, the restructuring of medical liability rules, the augmentation of professional training, and the advancement of public understanding through educational initiatives.

Using ChatGPT to Facilitate Truly Informed Medical Consent

Fatima N. Mirza, Oliver Y. Tang, Ian D. Connolly, Hael A. Abdulrazeq, Rachel K. Lim, G. Dean Roye, Cedric Priebe, Cheryl Chandler, Tiffany J. Libby, Michael W. Groff, John H. Shin, Albert E. Telfeian, Curtis E. Doberstein, Wael F. Asaad, Ziya L. Gokaslan, James Zou, Rohaid Ali

New England Journal of Medicine AI, 10 January 2024

Abstract

Informed consent is integral to the practice of medicine. Most informed consent documents are written at a reading level that surpasses the reading comprehension level of the average American. Large language models, a type of artificial intelligence (AI) with the ability to summarize and revise content, present a novel opportunity to make the language used in consent forms more accessible to the average American and thus, improve the quality of informed consent. In this study, we present the experience of the largest health care system in the state of Rhode Island in implementing AI to improve the readability of informed consent documents, highlighting one tangible application for emerging AI in the clinical setting.

From Code to Care and Navigating Ethical Challenges in AI Healthcare

Book Chapter

Sourav Madhur Dey, Pushan Kumar Dutta

Human-Centered Approaches in Industry 5.0: Human-Machine Interaction, Virtual Reality Training, and Customer Sentiment Analysis, 2024 [IGI Global]

Abstract

Artificial intelligence (AI) has become a transformative force in the healthcare industry, offering unprecedented opportunities for improved diagnostics, patient treatment, and outcomes. However, its integration into healthcare systems has also brought to light a host of ethical concerns that require careful scrutiny. This chapter delves into the intricate nexus of ethics and AI in healthcare, shedding light on the multifaceted implications and challenges that arise. AI technologies such as machine learning (ML) and data analytics (DS) have immense potential to revolutionize healthcare. They can enhance diagnostic accuracy, enable the treatment of a larger number of patients, and improve patient outcomes. However, their implementation is not without ethical quandaries. These primarily revolve around data privacy, bias mitigation, transparency, responsibility, and patient independence. Transparency and interpretability are other essential aspects of the ethical discourse surrounding AI in healthcare.

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CULTURAL/COUNTRY CONTEXT

Study on the Reasons of Discharge with the Personal Consent of Patients Admitted to the Emergency Ward of Kowsar Hospital of Semnan, Iran

Mehdi Yarahmadi, Mehri Ayati, Mohammad Taghi Ghorbanian

Journal of Guilan University of Medical Sciences, 20 January 2024

Abstract

Background

Discharge against Medical Advice (DAMA) indicates the dissatisfaction of patients with the care services of the health system. Additionally, it threatens the patient's life and causes negative financial outcomes for hospitals.

Objective

This study aimed to identify the causes of self-discharge decisions in the emergency department at Kowsar Hospital, Semnan, Iran.

Methods

This was a descriptive-analytical study conducted between August 2021 to March 2022. The data were collected by a researcher-made questionnaire containing demographic characteristics and reasons for self-discharge, including three main concepts: personal, staff-related factors, and environmental factors with sub-concepts. Data were analyzed using SPSS.

Results

Of 140 patients with a mean age of 33.52 ± 16.17 years, 58.6% were men and 41.4% were women. Moreover, 63.6% of patients were married, 42.1% had a diploma education, and 11.4% had a history of taking neuropsychiatric drugs. Also, 42.9% of patients were covered by social security insurance. The highest rate of self-discharge was in the evening (42.1%) and night (37.9%) shifts. The most important reasons for self-discharge decision were problems related to insurance (30%), COVID-19 infection (26.4%), poor communication (17.1%), dissatisfaction with care (15.7 %), disrespectful behavior of staff (12.9%), and inappropriate emergency ward facilities (12.1%).

Conclusion

Make appropriate decisions to improve the quality of medical services and increase cooperation in health insurance, separating the departments of infectious diseases away from other departments, holding briefing sessions for physicians and medical staff, increasing awareness of patients about possible complications of self-discharge, and expanding the amenities of emergency ward can reduce the rate of self-discharge decision.

Editor's note: The Guilan University of Medical Sciences is located in Rasht, Iran.

Compliance with research ethics in epidemiological studies targeted to conflict-affected areas in Western Ethiopia: validity of informed consent (VIC) by information comprehension and voluntariness (ICV)

Research

Gemechu Tiruneh, Mekdes Yilma, Bizuneh Wakuma, Eba Abdisa, Lami Bayisa, Michelle Nichols, Anja Bedeker, Nicki Tiffin

BMC Medical Ethics, 18 January 2024

Open Access

Abstract

Background

The conduct of research is critical to advancing human health. However, there are issues of ethical concern specific to the design and conduct of research in conflict settings. Conflict-affected countries often lack strong platform to support technical guidance and monitoring of research ethics, which may lead to the use of divergent ethical standards some of which are poorly elaborated and loosely enforced. Despite the growing concern about ethical issues in research, there is a dearth of information about ethical compliance in conflict areas. Valid and ethically informed decision-making is a premier pact with research participants in settling possible ethical issues before commencing the research, which is ensured by gaining informed consent from prospective participants of the research.

Aims

This research aimed to explore compliance with research ethics and consent validity in community-based epidemiological research conducted previously.

Methods

Research participants were recruited in the western part of Ethiopia in three districts subjected to conflicts. A community-based cross-sectional study design was utilized, and 338 residents were enrolled as study participants. All participants had previously been enrolled as research participants in epidemiological studies. Data was collected using a questionnaire that was pilot-tested before the commencement of the main data collection. The questionnaire focused on participants' experiences of the informed consent process followed when they were recruited for an epidemiological study and covered themes such as essential information provided, level of comprehension, and voluntarism of consent.

Results

Over half of the study participants, 176 (52%), were not provided with essential information before consenting. And 135 (40%) of them did not comprehend the information provided to them. One hundred and ninety (56%) participants freely and voluntarily agreed to partake in one of these epidemiological studies,

with over a quarter (97; 28.7%) of them reporting they were subjected to undue influence. Written consent was obtained from only 32 (9.4%) of the participants.

The Role of Male Consent in Assisted Reproductive Technology Procedures: an Examination of Japanese Court Cases

Original Paper

Yuko Muraoka, Minori Kokado, Kazuto Kato

Asian Bioethics Review, 18 January 2024

Open Access

Abstract

With the development of assisted reproductive technologies, medical, ethical, legal, and social issues have arisen that did not exist when natural conception was the only means of childbirth. In Japan, men tend to believe that assisted reproductive technologies are not directly related to them, with the literature showing that men are often reluctant to be involved in fertility treatment processes. To better understand this situation, this study analyzes the role of male consent during assisted reproductive technology procedures in Japan. First, we examined Japanese court cases that dealt with issues related to male consent during assisted reproductive technology procedures and identified three situations in which problems related to male consent during such procedures may arise. Next, we analyzed the background of such issues and the implications of the lack of consent regarding men's reproductive rights. Finally, we explored the need for legislation on assisted reproductive technologies. The study concludes that discussions on the scope of male partner rights in assisted reproductive technology procedures are key for minimizing unnecessary conflict between partners, thus ensuring both the rights of women who wish to have children and the welfare of their children.

Culturally appropriate consent processes for community-driven indigenous child health research: a scoping review

Research

Cindy Peltier, Sarah Dickson, Viviane Grandpierre, Irina Oltean, Lorrilee McGregor, Emilie Hageltorn, Nancy L. Young

BMC Medical Ethics, 3 January 2024; 25(3)

Open Access

Abstract

Background

Current requirements for ethical research in Canada, specifically the standard of active or signed parental consent, can leave Indigenous children and youth with inequitable access to research opportunities or health screening. Our objective was to examine the literature to identify culturally safe research consent processes that respect the rights of Indigenous children, the rights and responsibilities of parents or caregivers, and community protocols.

Methods

We followed PRISMA guidelines and Arksey and O'Malley's approach for charting and synthesizing evidence. We searched MEDLINE, PsycINFO, ERIC, CINAHL, Google Scholar, Web of Science, Informit Indigenous Collection, Bibliography of Native North Americans, and Sociological Abstracts. We included peer-reviewed primary and theoretical research articles written in English from January 1, 2000, to March 31, 2022, examining Indigenous approaches for obtaining informed consent from parents, families, children, or youth. Eligible records were uploaded to Covidence for title and abstract screening. We appraised the findings using a Two-Eyed Seeing approach. These findings were inductively coded using NVivo 12 and analyzed thematically.

Results
We identified 2,984 records and 11 eligible studies were included after screening. Three key recommendations emerged: addressing tensions in the ethics of consent, embracing wise practices, and using relational approaches to consent. Tensions in consent concerned Research Ethics Board consent requirements that fall short of protecting Indigenous children and communities when culturally incongruent. Wise practices included allowing parents and children to consent together, land-based consenting, and involving communities in decision-making. Using relational approaches to consent embodied community engagement and relationship building while acknowledging consent for Indigenous children cannot be obtained in isolation from family and community.
Conclusions
Very few studies discussed obtaining child consent in Indigenous communities. While Indigenous communities are not a monolith, the literature identified a need for community-driven, decolonized consent processes prioritizing Indigenous values and protocols. Further research is needed to examine nuances of Indigenized consent processes and determine how to operationalize them, enabling culturally appropriate, equitable access to research and services for all Indigenous children.

Family roles in informed consent from the perspective of young Chinese doctors: a questionnaire study

Research
Hanhui Xu, Mengci Yuan
BMC Medical Ethics, 3 January 2024; 25(2)
Open Access
Abstract
Background
Based on the principle of informed consent, doctors are required to fully inform patients and respect their medical decisions. In China, however, family members usually play a special role in the patient's informed consent, which creates a unique "doctor-family-patient" model of the physician-patient relationship. Our study targets young doctors to investigate the ethical dilemmas they may encounter in such a model, as well as their attitudes to the family roles in informed consent.
Methods
A questionnaire was developed including general demographic characteristics, the fulfillment of the obligation to fully inform, who will be informed, and the ethical dilemmas in decision-making. We recruited a total of 421 doctors to complete this questionnaire, of which 368 met the age requirements for this study. Cross tabulation and Pearson's chi-squared test were used to analyze the differences between types of patients for categorical variables, and a p-value < 0.05 was considered statistically significant.
Results
Our data shows that only 20 doctors (5.40%) stated "informing the patient alone is sufficient" when it comes to informing patients of their serious conditions. The rest of the participants would ensure that the family was informed. When facing elderly patients with decision-making capacity, the data was statistically different (3.8%; $P < 0.001$) The primary reason for ensuring that family members be informed differs among the participants. In addition, when family members asked doctors to conceal the patient's medical condition for the best interests of patients, 270 doctors (73.4%) would agree and cooperate with the family. A similar proportion (79.6%) would do so when it comes to elderly patients.
Conclusions
(1) Chinese doctors pay extra attention to informing the patient's family, which may not be in the patient's best interests. (2) Chinese doctors treat adult (but not elderly) patients and elderly patients differently when it comes to informing family members. (3) When family members request that doctors withhold information from patients "in the best interest of the patient," the majority choose to comply with the request, although this may cause them distress.

Surgical informed consent practices and influencing factors in sub-Saharan Africa: a scoping review of the literature

Systematic Review

Chiara Pittalis, Cherie Sackey, Paul Okeny, Bip Nandi, Jakub Gajewski

BMJ Quality & Safety, 30 December 2023

Open Access

Abstract

Introduction

Current international standards in consent to surgery practices are usually derived from health systems in Western countries, while little attention has been given to other contexts such as sub-Saharan Africa (SSA), despite this region facing the highest burdens of disease amenable to surgery globally. The aim of this study was to examine how the concept of informed consent for surgery is interpreted and applied in the context of SSA, and factors affecting current practices.

Methods

A systematic search of Medline, Embase and African Journal OnLine databases as well as grey sources was executed in May 2023 to retrieve relevant literature published since 2010 in English language against a set of given criteria. The socioecological framework for health was used for organising and summarising the identified evidence.

Results

A total of 27 papers were included in the review. Findings revealed that consent to surgery practices is generally substandard across SSA and the process is not adequate. Patients' understanding of informed consent is limited, likewise awareness of their rights to decision-making. A range of factors at the individual, interpersonal, institutional and system/societal levels affect the informed consent process.

Conclusion

There is a need to find more culturally acceptable and ethical ways to include the participation of patients in the decision-making process for surgical treatment in the SSA and define standards more closely aligned with the local context.

The challenges and potential solutions of achieving meaningful consent amongst research participants in northern Thailand: a qualitative study

Research

Rachel C Greer, Nipaphan Kanthawang, Jennifer Roest, Carlo Perrone, Tri Wangrangsimakul, Michael Parker, Maureen Kelley, Phaik Yeong Cheah

BMC Medical Ethics, 19 December 2023

Open Access

Abstract

Background

Achieving meaningful consent can be challenging, particularly in contexts of diminished literacy, yet is a vital part of participant protection in global health research.

Method

We explored the challenges and potential solutions of achieving meaningful consent through a qualitative study in a predominantly hill tribe ethnic minority population in northern Thailand, a culturally distinctive population with low literacy. Semi-structured interviews were conducted with 37 respondents who had participated in scrub typhus clinical research, their family members, researchers and other key informants. A thematic analysis was conducted.

Results

Our analysis identified four interrelated themes surrounding participants' ability to give consent: varying degrees of research understanding, limitations of using informal translators, issues impacting decisions to join research, and voluntariness of consent. Suggestions for achieving more meaningful consent included the use of formal translators and community engagement with research populations.
Conclusions
Participant's agency in decision making to join research should be supported, but research information needs to be communicated to potential participants in a way that they can understand. We found that improved understanding about the study and its potential benefits and harms goes beyond literacy or translation and requires attention to social and cultural factors.

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RIGHTS/LEGAL/LEGISLATIVE

Clinical Informed Consent and ABA

Abraham Graber, Allison Maguire
Behavior Analysis in Practice, 8 January 2024
Open Access
Abstract
The practice of clinical informed consent in America is governed by over 100 years of case law. Although predominant ethics resources for behavior analysts offer some guidance regarding the provision of clinical informed consent, such guidance remains limited. The goal of this article is thus to expand the contemporary literature on clinical informed consent in behavior analysis by providing a historical and contemporary guide to relevant case law. The article will highlight seminal moments in the history of case law regarding clinical informed consent, discuss their applicability to the process of clinical informed consent in behavior analysis, and provide an enhanced understanding of the ethical and legal obligations related to informed consent in the therapeutic context.

Editor's note: ABA stands for applied behavior analysis.

Towards the implementation of law n. 219/2017 on informed consent and advance directives for patients with psychiatric disorders and dementia. Physicians' knowledge, attitudes and practices in four northern Italian health care facilities

Research
Corinna Porteri, Giulia Ienco, Mariassunta Piccinni, Patrizio Pasqualetti
BMC Medical Ethics, 6 January 2024
Open Access
Abstract
Background
On December 2017 the Italian Parliament approved law n. 219/2017 "Provisions for informed consent and advance directives" regarding challenging legal and bioethical issues related to healthcare decisions and end-of life choices. The law promotes the person's autonomy as a right and provides for the centrality of the individual in every scenario of health care by mean of three tools: informed consent, shared care planning and advance directives. Few years after the approval of the law, we conducted a survey among physicians working in four health care facilities specific for the care of people suffering from psychiatric disorders, cognitive disorders and dementia located in the North of Italy aiming to investigate their perceived knowledge and training need, attitudes regarding law n. 219/2017 provisions, and practices of implementation of the law.

Methods
A semi-structured questionnaire was developed on an online platform. The invitation to participate in the survey was sent by email to the potential participants. Information was collected by means of the online platform (Google Forms) which allows to export data in a spreadsheet (Windows Excel) to perform basic statistical analysis (frequency distributions, bar chart representation).
Results
Twenty-five out of sixty physicians participated in the survey. None of the respondents value their knowledge of the law as very good, 10 good, 13 neither poor nor good, 1 poor and 1 very poor. All the respondents want to learn more about the law (21 yes and 4 absolutely yes). The majority of respondents agrees with the content of the law as a whole (3 absolutely agree, 13 agree), and on each provision. The question on the clarity of the concept of capacity in the law received mixed answers and this impacted on the physicians' opinion regarding the legitimacy in principle for our groups of patients to realize shared care planning and write advance directives. Thirteen physicians neither introduced the theme of shared care planning nor arranged for shared care planning and the main reason for this was that no patient was in a clinical situation to require it. When shared care planning is realized, a variability in terms of type and number of meetings, mode of tracking and communication is registered.
Conclusions
Our survey results indicate a need for more clarity regarding the interpretation and implementation of the law in the patient groups under study. There are in particular two related areas that deserve further discussion: (1) the question of whether these patient groups are in principle legitimized by the law to realize shared care planning or write advance directives; (2) the notion of capacity required by the law and how this notion can be declined in real-life situations.

Informed consent – Ethical doctrine and a legal mandate

Review Article
Anjali Gera, Jayashree Sood
Current Medicine Research and Practice, November - December 2023; 13(6) pp 286-291
Open Access
Abstract
Informed consent is not only an ethical doctrine but also a legal mandate in medical practice and clinical research. The concept of consent has changed over the last few decades from doctor-focused to patient-focused. This provides adequate knowledge to the patient about disease and treatment options so that the patient and doctor can make shared decisions. Respecting the patient's autonomy, disclosure of material risks and solicitation of the patient's preferences are very important in the process of informed consent. The relationship between doctor and patient should be one of trust and communication. An honest and ethically obtained consent can prevent litigations and medicolegal repercussions.

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MEDICAL/SURGICAL

Nursing Roles in the Quality of Information in Informed Consent Forms of a Spanish County Hospital

José Manuel García-Álvarez, Alfonso García-Sánchez
Nursing Reports, 4 January 2024; 14(1) pp 89-98
Abstract
Background

Because of their direct and continuous contact with the patient, nurses play a relevant role in ensuring that informed consent forms are complete and easy to read and comprehend. The objective of this study was to analyze the legibility and formal quality of informed consent forms for non-surgical procedures in a county hospital.

Methods

The readability of these forms was analyzed using the INFLESZ scale and the information they provided according to the formal quality criteria established for these forms.

Results

Readability was difficult in 78.08% of the forms analyzed. No form fulfilled all the criteria, the most non-compliant being the non-appearance of the verification of delivery of a copy to the patient (100%), the contraindications (94.59%), and the alternatives (83.78%) of the procedure. Statistically significant differences were observed between disciplines with respect to the INFLESZ readability score and the formal quality score, but no statistically significant correlation was found between the two scores.

Conclusions

The informed consent forms for non-surgical procedures analyzed presented mostly difficult readability and poor formal quality, making it difficult for patients to have understandable and complete information. Nursing professionals should be actively involved in their improvement to facilitate patient decision making.

A Pilot Study On The Global Practice On Informed Consent In Paediatric Dentistry

Original Research

Nicoline Potgieter, Gemma Bridge, Marlies Elfrink, Morenike O. Folayan, Sherry Shiqian Gao, Sonia Groisman, Ashwin Jawdekar, Arthur M. Kemoli, David Lim, Phuong Ly, Shani Mani, Ray M. Masumo, Joana Monteiro, Majorie K. Muasya, Ambrina Qureshi, Norman Tinanoff

Frontiers in Oral Health, 2024

Abstract

Background

Conducting oral treatment early in the disease course is encouraged for better health outcomes. Obtaining informed consent is an essential part of medical practice, protecting the legal rights of patients and guiding the ethical practice of medicine. In practice, consent means different things in different contexts. Silver Diamine Fluoride (SDF) and Silver Fluoride (SF) are becoming popular and cost-effective methods to manage carious lesions, however, cause black discolouration of lesions treated. Obtaining informed consent and assent is crucial for any dental treatment and has specific relevance with SDF/ SF treatments.

Methods

The aim of this paper is to describe informed consent regulations for dental care in a selection of countries, focusing on children and patients with special healthcare needs. An online survey was shared with a convenience sample of dental professionals from 13 countries. The information was explored and the processes of consent were compared.

Results

Findings suggest that there are variations in terms of informed consent for medical practice. In Tanzania, South Africa, India, Kenya, Malaysia and Brazil age is the determining factor for competence and the ability to give self-consent. In other countries, other factors are considered alongside age. For example, in Singapore, the United Kingdom, and the United States the principle of Gillick Competence is applied. Many countries' laws and regulations do not specify when a dentist may overrule general consent to act in the "best interest" of the patient.

Conclusion

It is recommended that it is clarified globally when a dentist may act in the "best interest" of the patient, and that guidance is produced to indicate what constitutes a dental emergency. The insights gathered provide insights on international practice of obtaining informed consent and to identify areas for change, to more

efficient and ethical treatment for children and patients with special needs. A larger follow up study is recommended to include more or all countries.

Implementing co-production to enhance patient safety: the introduction of the Patient Safety Consent tool, an example of a simple local solution to a common challenge

Abdulelah Alhawsawi, David Greenfield

International Journal for Quality in Health Care, 28 December 2023

Abstract

Zero harm is one of the priorities that all healthcare systems are aspiring for. However, more than two decades after 'To Err is Human' report, many systems are struggling to identify or implement strategies to achieve this important goal. One of the very powerful, yet underutilized strategies towards transforming patient safety and achieving Zero Harm is 'co–production'. Co-production of health is defined as 'the interdependent work of users and professionals who are creating, designing, producing, delivering, assessing, and evaluating the relationships and actions that contribute to the health of individuals and populations'. Simply put, co-production means that patients contribute alongside professionals to the provision of health services. While we know the importance and potential value of co-production, many health systems are underutilizing the approach. Actions to effectively implement and sustain changes to service provision to use co-production are elusive. To realize improvements, a key requirement for health professionals is addressing the question: how can we implement and sustain co-production in efficient, effective ways? To address this challenge, and thereby improve patient safety and work towards zero harm, we introduce the 'Patient Safety Consent' (PSC) tool, a simple co-production tool to empower patients and families to become more active members in their own healthcare. Implementing the co-production of care, requires a shift in the traditional attitudes and power dynamics between healthcare professionals and patients. Professionals explicitly share service information, diagnosis assessments, treatment options, decision-making and involve patients and their families in determining the direction and actions for their care; conversely, patients and families take on an active role in engaging in discussions, potential care pathways, and ongoing decisions about their treatment and care. Hence, the PSC tool is a direct, engaging, comprehensive and, where used effectively, a powerful strategy for changing the dynamics and outcomes of care…

Probability and informed consent

Book Chapter

Nir Ben-Moshe, Benjamin A. Levinstein, Jonathan Livengood

Theoretical Medicine and Bioethics, 8 August 2023 [Springer]

Abstract

In this paper, we illustrate some serious difficulties involved in conveying information about uncertain risks and securing informed consent for risky interventions in a clinical setting. We argue that in order to secure informed consent for a medical intervention, physicians often need to do more than report a bare, numerical probability value. When probabilities are given, securing informed consent generally requires communicating how probability expressions are to be interpreted and communicating something about the quality and quantity of the evidence for the probabilities reported. Patients may also require guidance on how probability claims may or may not be relevant to their decisions, and physicians should be ready to help patients understand these issues.

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GENERAL/OTHER

Blockchain-Based Dynamic Consent for Healthcare and Research

Book Chapter
Wendy M. Charles
Blockchain in Healthcare, 30 December 2023 [Springer]
Abstract
As individuals gain greater access control over their health information, dynamic consent solutions are increasingly offered to allow individuals to make informed choices about their permissions over time. Blockchain-based tools and technologies are emerging to enhance the capabilities of dynamic consent solutions to offer individuals more engagement. While blockchain-based systems cannot replace all human interactions, blockchain features can increase granularity, transparency, and trust. This chapter describes the benefits and drawbacks of dynamic, informed consent and proposes several design and feature considerations to optimize blockchain-based features.

From informed to empowered consent

Original Article
Chelsea O. P. Hagopian
Nursing Philosophy, 29 December 2023
Abstract
Informed consent is ethically incomplete and should be redefined as empowered consent. This essay challenges theoretical assumptions of the value of informed consent in light of substantial evidence of its failure in clinical practice and questions the continued emphasis on autonomy as the primary ethical justification for the practice of consent in health care. Human dignity—rather than autonomy—is advanced from a nursing ethics perspective as a preferred justification for consent practices in health care. The adequacy of an ethic of obligation (namely, principlism) as the dominant theoretical lens for recognising and responding to persistent problems in consent practices is also reconsidered. A feminist empowerment framework is adopted as an alternative ethical theory to principlism and is advanced as a more practical and complete lens for examining the concept and context of consent in health care. To accomplish this, the three leading conceptions of informed consent are overviewed, followed by a feminist critique to reveal practical problems with each of them. The need for a language change from informed to empowered consent is strongly considered. Implications for consent activities in clinical practice are reviewed with focused discussion on the need for greater role clarity for all involved in consent—beyond and inclusive of the patient-physician dyad, as the practice and improvement of consent is necessarily a transdisciplinary endeavour. Specific concrete and practical recommendations for leveraging nursing expertise in this space are presented. Perhaps what is most needed in the discourse and practice of consent in health care is nursing.

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PRE-PRINT SERVERS

Ethics of Informed Consent in Medical settings: A qualitative study of clinicians managing patients presenting with self-harm in Pakistan

Rakhshi Memon, Muqaddas Asif, Bushra Ali Shah, Tayyeba Kiran, Ameer B Khoso, Sehrish Toque, Jahanara Miah, Ayesha Ahmad, Imran B Chaudhry, Nasim Chaudhry , Nusrat Husain, Sarah JL Edwards
BMC Medical Ethics [under review], 24 January 2024
Abstract
Background

informed consent is considered to be the standard method for respecting the autonomy of individual participants in research and is thought to be based on several conditions: 1) providing information on the purpose of the research or a specific treatment, what it will entail, 2) the participants being mentally competent to understand the information and weigh it in the balance, and 3) the participants to be free from coercion. While there are studies of informed consent in other countries, especially Low and Middle Income Countries (LMICs), this study explored the role of cultural norms in the process of obtaining informed consent by clinicians in healthcare settings in general and mental health in particular, specifically focusing on the tension between contexts of Western autonomy and collectivist values in cultures such as Pakistan.
Methods
Qualitative interviews with 20 clinicians in Pakistan to explore consent processes in participant recruitment in Randomised Controlled Trials (RCTs), using a topic guide to gain an understanding of the consent process in Pakistan when recruiting participants in RCTs and decision-making regarding treatments and the influence of cultural norms' impact on attitudes and beliefs in the collectivist culture.
Results
The interviews revealed that shared decision making was more morally important than individual autonomy, the role of the family played a dominant part in the consent-taking procedure, the decision of the elder and/or family patriarch took prominence, and that clinicians and researchers encountered significant challenges in consent process in Pakistan. Four distinct themes emerged which were 1) Family deciding for patients, 2) Benefits of involving family in consent process, 3) Gender disparity in consent process, 4) Challenges experienced by clinicians during consent process in Pakistan.
Conclusions
The concept of consent is generally considered important in many cultures, however, there are two strands of understanding. There seems to be consensus that participant agreement is necessary to protect the participant but with regards to autonomy there are significant cultural differences whether it is the right for autonomy of the individual (western) or family, community, or expert authority in other cultures, in Pakistan clinician-researchers sometimes preferred one approach and sometimes the other as they appreciated the interests of the patient to be.

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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].

Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Availability

Food and Drug Administration, HHS.
Scheduled Pub. Date: 12/22/2023 FR Document: 2023-28210 PDF: https://downloads.regulations.gov/FDA-2023-D-5259-0002/attachment_1.pdf 8 Pages (109 KB)
Submit either electronic or written comments on the draft guidance by **February 20, 2024**
Summary
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Master Protocols for Drug and Biological Product Development." The draft guidance addresses the design and analysis of trials conducted under a master protocol as well as the submission of documentation to support regulatory review. The primary focus is on randomized umbrella and platform

trials that are intended to contribute to a demonstration of safety and substantial evidence of effectiveness. The considerations in this guidance apply to a range of therapeutic areas. The draft guidance is intended to clarify the Agency's thinking on the use of master protocols in drug and biological product development, which was previously addressed in FDA's guidance entitled "COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention." FDA is also announcing the withdrawal of the guidance entitled "COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention.

Excerpt

C. Informed Consent

The informed consent process should cover all treatment arms in the trial to which the subject could be randomized.[13,14] In a platform trial allowing drugs to enter and leave the trial over time, the consent form should be modified over time to reflect the drugs currently under evaluation… The informed consent process should occur prior to a subject's randomization and avoid substudy-specific consent. Consent that occurs after subjects have been randomized to one of the substudies may result in subjects with different prognostic characteristics across substudies, raising concern about the comparability of each drug group with the shared control group (comprised of control subjects from different substudies). To illustrate the concern, consider a master protocol with two drugs (drug A and drug B) in which the subject consents to screening and randomization to a substudy as part of the master protocol, with a substudy-specific informed consent process to occur after randomization to that substudy; after the substudy-specific consent, the subject is then randomized to the drug or its matched control. With this process, comparing drug A against the shared control arm (including subjects who received either control for drug A or control for drug B) may result in noncomparable groups if subjects who would consent to participating in the drug A substudy differ from subjects who would consent to participating in the drug B substudy.

> 13 Some consent processes allow a subject to be randomized in the trial even if the subject only consents to a subset of the drugs under evaluation; under such a process, subjects should not have the potential to be randomized to drugs for which they do not consent.
> 14 See the guidance for IRBs, Clinical Investigators, and Sponsors Informed Consent (August 2023).

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NEW 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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