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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

May 2024 :: Issue 65

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 referencing informed consent or 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:

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No new content was identified for the following established categories:

COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
FREE PRIOR INFORMED CONSENT (FPIC)
GENERAL/OTHER
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT

Please note that while we strive to identify the primary subject area for the categorization of content, 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 Spotlight the article by Landi et al. in *Frontiers in Medicine,* **The creation of an adaptable informed consent form for research purposes to overcome national and institutional bottlenecks in ethics review: experience from rare disease registries**. This ambitious article addresses variability and inconsistency in the consent process in the EU context and suggests a method for overcoming these challenges. The authors developed a template that allowed participants options to consent to participation independently of consenting to the reuse of their data, an area which is the target of much current thinking. We note discussion of the creation of an adaptable assent template, the pediatric material is being finalized to collect minors' assent, and that "ICF machine-readability is also progressing to enhance data discovery and facilitate its access and reuse conditions."

The creation of an adaptable informed consent form for research purposes to overcome national and institutional bottlenecks in ethics review: experience from rare disease registries

Original Research

Annalisa Landi, Yanis Mimouni, Viviana Giannuzzi, Franz Schaefer, Annagrazia Altavilla, Spencer Gibson, Daria Julkowska

Frontiers in Medicine, 27 March 2024

Abstract

Background

The lack of harmonization of evaluation criteria by Ethics Committees in the European Union (EU) has led to inconsistent ethics reviews received by research sites participating in multicenter non-interventional studies. The European General Data Protection Regulation (GDPR) appears to be implemented at national level with a substantial degree of variance in interpretation. The European Reference Networks (ERNs) were struggling in

setting an Informed Consent Form (ICF) for registries, allowing reuse of data for research purposes. The aim of this work is to develop an adaptable ICF for research purposes to be used in ERN registries.
Methods
To work on this challenge, a team was established within the European Joint Programme on Rare Diseases (EJP RD) to develop a patients' registry ICF template allowing easy adaptation to ERNs, country, and site-level specificities. ERN and patients' representatives validated the choice of developing a GDPR-compliant template for research purposes. The feedback received from 34 Ethics Committees on the Clinical Patient Management System ICF, including the submission of patients' data to the ERN registries and the EU consent regulatory framework were analysed along with existing ontologies for data access and reuse. An adaptable ICF was developed following iterative cycles of consultation and review by clinicians, research experts, ethics and regulatory advisors, and patients' representatives. The development of pediatric material for minor participants was also undertaken.
Results & Conclusions
Research oriented ICF templates for adults and for parents/legal representatives of patients were released in 26 national languages. This adaptable ICF aims to foster, according to patients' preferences, the reuse of registries data for research purposes in compliance with the applicable laws and standards. Pediatric material is being finalized to collect minors' assent. ICF machine-readability is also progressing to enhance data discovery and facilitate its access and reuse conditions.

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BIOMEDICAL RESEARCH

Advancing Randomized Clinical Trials in Surgery: Role of Exception From Informed Consent, Central Institutional Review Board, and Bayesian Approaches

Review
Amelia W. Maiga, Rebecca A. Snyder, Lillian S. Kao, Mehul V. Raval, Mayur B. Patel, Martin L. Blakely
Journal of Surgical Research, 25 April 2024
Introduction
…In order to address the unique challenges of designing and conducting randomized clinical trials in surgery, surgeon investigators from the Society of University Surgeons and the Association for Academic Surgery hosted a didactic session at the 2023 Academic Surgical Congress. In this paper, we summarize the key discussion points presented in this session and outline opportunities to promote the design of feasible and generalizable surgical RCTs. In particular, we will review the use of exception from informed consent (EFIC) in surgical trials, central institutional review board (IRB) review for multicenter trials, currently recommended statistical methods to increase clarity of trial findings and avoid dichotomy around the P value, and opportunities to incorporate Bayesian methods into study design and interpretation…

Participant Recruitment, Consent and Post-trial Access to Interventions

Book Chapter
Maru Mormina, Halina Suwalowska, Mira L. Schneiders
Research Ethics in Epidemics and Pandemics: A Casebook, 24 April 2024 [Springer]
Open Access
Abstract
Humanitarian emergencies, including public health crises such as epidemics, can overwhelm local resources and severely disrupt the functioning of communities and societies. Conducting research during or in the immediate aftermath of an emergency poses increased practical and ethical challenges, not least because the need to rapidly generate valuable knowledge must be constantly balanced with the principles of

humanitarian assistance. This chapter provides an overview of key ethical considerations relevant to recruitment, consent and post-trial access to interventions in pandemic contexts, and proposes an "ethics in practice" approach. Research conducted during emergencies is unavoidably context – and time – sensitive, making generalized guidance difficult. The aim of this chapter is thus not to prescribe a checklist for decision-making, but to assist researchers and practitioners to reflect on and discern what constitutes ethical practice during exceptional times. In particular, public health emergencies highlight tensions that can arise between balancing the rights and interests of research participants with the health needs of the population. Careful consideration is also needed of the necessity of minimising risks and maximising benefits, including ensuring that recruitment processes are sensitive to potentially altered risk perceptions and impacts of increased vulnerability on power imbalances. The importance of establishing and maintaining trust is reviewed, particularly when asymmetries in knowledge and access to resources are heightened in complex and challenging pandemic contexts. The five case studies presented in this chapter invite readers to reflect on ethical challenges that research during public health emergencies presents, particularly in connection with processes for communicating with and recruiting participants which have been adapted in pandemic contexts; potential risks to research participants and study staff; and with the rights participants in control groups may have to access experimental products.

Individual consent in cluster randomised trials for non-pharmaceutical interventions: going beyond the Ottawa statement

Research Paper

Marissa LeBlanc, Jon Williamson, Francesco De Pretis, Jürgen Landes, Elena Rocca

Critical Public Health, 18 April 2024

Abstract

This paper discusses the issue of overriding the right of individual consent to participation in cluster randomised trials (CRTs). We focus on CRTs testing the efficacy of non-pharmaceutical interventions. As an example, we consider school closures during the COVID-19 pandemic. In Norway, a CRT was promoted as necessary for providing the best evidence to inform pandemic management policy. However, the proposal was rejected by the Norwegian Research Ethics Committee since it would violate the requirement for individual informed consent. This sparked debate about whether ethics stand in the way of evidence-based health policy, since the Norwegian Research Ethics law's strict requirements for individual consent make it practically impossible to carry out CRTs of public health interventions. We argue that, in the case of the school closure trial, the suggested CRT would not have eliminated an epistemic gap and thus would not have justified the violation of consent rights. First, we focus on the methodological challenges to estimating quantifiable effects of school closures in the specific case of an airborne infectious disease. Second, in line with Evidential Pluralism, we highlight the value of alternative lines of evidence for informing school closure policy in a pandemic. In general, we propose that a trial requiring the waiver of participants' consent rights must be highly likely to eliminate an epistemic gap. We elaborate on the practical aspects of this criterion and discuss the potential advantages of adding it to the *Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials*.

Analysis of informed consent documents for compliance with ICMR guidelines for biomedical and health research

Original Article

Chaitali Ashish Chindhalore, Ganesh N. Dakhale, Snehalata V. Gajbhiye, Ashish Vijay Gupta, Shivam V Khapeka

Perspectives in Clinical Research, 8 April 2024

Abstract

Background
Ethical conduct of research depends on the voluntary expression of consent and adequate disclosure of information about the research in informed consent documents (ICDs).
Objectives
The objective of this study was to analyze ICDs of academic studies for compliance with National Ethical Guidelines for Biomedical and Health Research laid down by the Indian Council of Medical Research (ICMR) and to determine the readability of ICDs using the Flesch–Kincaid Grade Level scale and Flesch reading-ease (FRE) score.
Methodology
ICDs of academic research projects submitted during 2020–22 were retrieved from the IEC office and analyzed for compliance with ICMR 2017 guidelines. The readability of the documents was assessed by the Flesch–Kincaid Grade Level Scale and FRE score.
Results
Among 177 protocols analyzed, the most common were epidemiological studies (36.72%), followed by diagnostic studies (28.81%). Vernacular translations of ICDs were present in significantly more studies in 2022 ($\chi2 = 7.18$, $P = 0.02$) as compared to 2020 and 2021. FREs score was 45.75 ± 10.76, and Flesch–Kincaid Grade Level was 8.67 ± 1.44. Content analysis of participant information sheet (PIS) revealed that significantly more PIS submitted in 2022 mentioned expected duration of participation ($\chi2 = 6.95$, $P < 0.001$), benefit to patient/community ($\chi2 = 26.63$, $P < 0.001$), disclosure of foreseeable risk or discomfort ($\chi2 = 21.72$, $P < 0.001$), payment for participation ($\chi2 = 21.72$, $P < 0.001$), and identity of research team and contact details ($\chi2 = 18.58$, $P < 0.001$). Compliance score was significantly better in 2022 as compared to 2020 and 2021.
Conclusion
Gradually, ICDs became more compliant with ICMR guidelines. Still, there is scope for improvement in ICDs regarding content and readability so that patients can comprehend facts easily to make informed decisions in a real sense.

Alternative consent methods used in the multinational, pragmatic, randomised clinical trial SafeBoosC-III

Research
Maria Linander Vestager, Mathias Lühr Hansen, Gorm Greisen, SafeBoosC-III trial group
Trials, 4 April 2024
Open Access
Abstract
Background
The process of obtaining prior informed consent for experimental treatment does not fit well into the clinical reality of acute and intensive care. The therapeutic window of interventions is often short, which may reduce the validity of the consent and the rate of enrolled participants, to delay trial completion and reduce the external validity of the results. Deferred consent and 'opt-out' are alternative consent methods. The SafeBoosC-III trial was a randomised clinical trial investigating the benefits and harms of cerebral oximetry monitoring in extremely preterm infants during the first 3 days after birth, starting within the first 6 h after birth. Prior, deferred and opt-out consent were all allowed by protocol. This study aimed to evaluate the use of different consent methods in the SafeBoosC-III trial, Furthermore, we aimed to describe and analyse concerns or complaints that arose during the first 6 months of trial conduct.
Methods
All 70 principal investigators were invited to join this descriptive ancillary study. Each principal investigator received a questionnaire on the use of consent methods in their centre during the SafeBoosC-III trial, including the possibility to describe any concerns related to the consent methods used during the first 6 months of the trial, as raised by the parents or the clinical staff.

Results
Data from 61 centres were available. In 43 centres, only prior informed consent was used: in seven, only deferred consent. No centres used the opt-out method only, but five centres used prior and deferred, five used prior, deferred and opt-out (all possibilities) and one used both deferred and opt-out. Six centres applied to use the opt-out method by their local research ethics committee but were denied using it. One centre applied to use deferred consent but was denied. There were only 23 registered concerns during the execution of the trial.
Conclusions
Consent by opt-out was allowed by the protocol in this multinational trial but only a few investigators opted for it and some research ethics boards did not accept its use. It is likely to need promotion by the clinical research community to unfold its potential.

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SOCIAL SCIENCE RESEARCH

No recognised ethical standards, no broad consent: navigating the quandary in computational social science research

Research Article
Seliem El-Sayed, Filip Paspalj
Research Ethics, 19 April 2024
Open Access
Abstract
Recital 33 GDPR has often been interpreted as referring to 'broad consent'. This version of informed consent was intended to allow data subjects to provide their consent for certain areas of research, or parts of research projects, conditional to the research being in line with 'recognised ethical standards'. In this article, we argue that broad consent is applicable in the emerging field of Computational Social Science (CSS), which lies at the intersection of data science and social science. However, the lack of recognised ethical standards specific to CSS poses a practical barrier to the use of broad consent in this field and other fields that lack recognised ethical standards. Upon examining existing research ethics standards in social science and data science, we argue that they are insufficient for CSS. We further contend that the fragmentation of European Union (EU) law and research ethics sources makes it challenging to establish universally recognised ethical standards for scientific research. As a result, CSS researchers and other researchers in emerging fields that lack recognised ethical standards are left without sufficient guidance on the use of broad consent as provided for in the GDPR. We conclude that responsible EU bodies should provide additional guidance to facilitate the use of broad consent in CSS research.

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ARTIFICIAL INTELLIGENCE

AI and Ethics: A Systematic Review of the Ethical Considerations of Large Language Model Use in Surgery Research

Sophia M. Pressman, Sahar Borna, Cesar A. Gomez-Cabello, Syed A. Haider, Clifton Haider, Antonio J. Forte
Healthcare, 13 April 2024; 12(8)
Abstract
Introduction

As large language models receive greater attention in medical research, the investigation of ethical considerations is warranted. This review aims to explore surgery literature to identify ethical concerns surrounding these artificial intelligence models and evaluate how autonomy, beneficence, nonmaleficence, and justice are represented within these ethical discussions to provide insights in order to guide further research and practice.

Methods

A systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Five electronic databases were searched in October 2023. Eligible studies included surgery-related articles that focused on large language models and contained adequate ethical discussion. Study details, including specialty and ethical concerns, were collected.

Results

The literature search yielded 1179 articles, with 53 meeting the inclusion criteria. Plastic surgery, orthopedic surgery, and neurosurgery were the most represented surgical specialties. Autonomy was the most explicitly cited ethical principle. The most frequently discussed ethical concern was accuracy (n = 45, 84.9%), followed by bias, patient confidentiality, and responsibility.

Conclusion

The ethical implications of using large language models in surgery are complex and evolving. The integration of these models into surgery necessitates continuous ethical discourse to ensure responsible and ethical use, balancing technological advancement with human dignity and safety.

Investigating the Impact of AI on Shared Decision-Making in Post-Kidney Transplant Care (PRIMA-AI): Protocol for a Randomized Controlled Trial

Bilgin Osmanodja, Zeineb Sassi, Sascha Eickmann, Carla Maria Hansen, Roland Roller, Aljoscha Burchardt, David Samhammer, Peter Dabrock, Sebastian Möller, Klemens Budde, Anne Herrmann

JMIR Research Protocols, 1 April 2024

Abstract

Background

Patients after kidney transplantation eventually face the risk of graft loss with the concomitant need for dialysis or retransplantation. Choosing the right kidney replacement therapy after graft loss is an important preference-sensitive decision for kidney transplant recipients. However, the rate of conversations about treatment options after kidney graft loss has been shown to be as low as 13% in previous studies. It is unknown whether the implementation of artificial intelligence (AI)–based risk prediction models can increase the number of conversations about treatment options after graft loss and how this might influence the associated shared decision-making (SDM).

Objective

This study aims to explore the impact of AI-based risk prediction for the risk of graft loss on the frequency of conversations about the treatment options after graft loss, as well as the associated SDM process.

Methods

This is a 2-year, prospective, randomized, 2-armed, parallel-group, single-center trial in a German kidney transplant center. All patients will receive the same routine post–kidney transplant care that usually includes follow-up visits every 3 months at the kidney transplant center. For patients in the intervention arm, physicians will be assisted by a validated and previously published AI-based risk prediction system that estimates the risk for graft loss in the next year, starting from 3 months after randomization until 24 months after randomization. The study population will consist of 122 kidney transplant recipients >12 months after transplantation, who are at least 18 years of age, are able to communicate in German, and have an estimated glomerular filtration rate <30 mL/min/1.73 m2. Patients with multi-organ transplantation, or who are not able to communicate in German, as well as underage patients, cannot participate. For the primary end point, the proportion of patients who have had a conversation about their treatment options after graft loss is compared at 12 months after randomization. Additionally, 2 different assessment tools for SDM, the

CollaboRATE mean score and the Control Preference Scale, are compared between the 2 groups at 12 months and 24 months after randomization. Furthermore, recordings of patient-physician conversations, as well as semistructured interviews with patients, support persons, and physicians, are performed to support the quantitative results.

Results

The enrollment for the study is ongoing. The first results are expected to be submitted for publication in 2025.

Conclusions

This is the first study to examine the influence of AI-based risk prediction on physician-patient interaction in the context of kidney transplantation. We use a mixed methods approach by combining a randomized design with a simple quantitative end point (frequency of conversations), different quantitative measurements for SDM, and several qualitative research methods (eg, records of physician-patient conversations and semistructured interviews) to examine the implementation of AI-based risk prediction in the clinic.

Monitoring Mental Health: Legal and Ethical Considerations of Using Artificial Intelligence in Psychiatric Wards

Barry Solaiman, Abeer Malik, Suhaila Ghuloum

American Journal Of Law & Medicine, 12 February 2024

Abstract

Artificial intelligence (AI) is being tested and deployed in major hospitals to monitor patients, leading to improved health outcomes, lower costs, and time savings. This uptake is in its infancy, with new applications being considered. In this Article, the challenges of deploying AI in mental health wards are examined by reference to AI surveillance systems, suicide prediction and hospital administration. The examination highlights risks surrounding patient privacy, informed consent, and data considerations. Overall, these risks indicate that AI should only be used in a psychiatric ward after careful deliberation, caution, and ongoing reappraisal.

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HEALTH DATA/DATA

From opt-out to opt-in consent for secondary use of medical data and residual biomaterial: An evaluation using the RE-AIM framework

Research Article

Jennifer E. Lutomski, Peggy Manders

PLOS One, 28 March 2024

Open Access

Abstract

Background

Patient records, imaging, and residual biomaterial from clinical procedures are crucial resources for medical research. In the Netherlands, consent for secondary research has historically relied on opt-out consent. For ethical-legal experts who purport passive consent undermines patient autonomy, opt-in consent (wherein affirmative action is required) is seen as the preferred standard. To date, there is little empirical research exploring patient feasibility, organizational consequences, and the potential risks for research based on secondary data. Thus, we applied the RE-AIM framework to evaluate the impact of migrating from an opt-out to an opt-in consent process.

Methods

This evaluation was carried out in Radboud University Medical Center, a large tertiary hospital located in the southeast of the Netherlands. All non-acute, mentally competent patients ≥16 years of age registered between January 13, 2020 and June 30, 2023 were targeted (N = 101,437). In line with the RE-AIM framework, individual and organizational consequences were evaluated across five domains: reach, efficacy, adoption, implementation, and maintenance.

Results

101,437 eligible patients were approached of whom 66,214 (65.3%) consented, 8,059 (7.9%) refused consent and 27,164 (26.8%) had no response. Of the 74,273 patients with a response, 89.1% consented to secondary use. The migration to an opt-in consent system was modestly successful; yet notably, differential response patterns by key sociodemographic characteristics were observed. Adaptions to the process flow improved its effectiveness and resulted in a reasonable response over time. Implementation was most affected by budgetary restraints, thus impeding the iterative approach which could have further improved domain outcomes.

Conclusion

This evaluation provides an overview of logistical and pragmatic issues encountered when migrating from opt-out to opt-in consent. Response bias remains a major concern. Though not always directly transferable, these lessons can be broadly used to inform other health care organizations of the potential advantages and pitfalls of an opt-in consent system.

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BIOBANKING

GDPR Requirements for Biobanking Activities Across Europe

Book

Valentina Colcelli, Roberto Cippitani, Christoph Brochhausen-Delius, Rainer Arnold

Springer, 2023

About this book

The book deals with the effective operation of the rules related to biomedical research and pays attention to the activities of the national legislatures of the 27 Member States in the field of scientific research. This multilevel system has an impact on biobanking activity. The book answers questions realized by operators on the main biobanks around the EU in the field of GDPR. The authors and editors used the questions born from brainstorming among members of the Association European, Middle East & Africa for Biopreservation and Biobanking (ESBB) to offer to the operators in biobanking activity and researchers quickly answer to their daily questions, but with authors highest quality. Further the book provides a comprehensive review of the rapidly expanding field of biobanking. It provides researchers and scholars working on biobanking and bio-sharing and more in general in the university hospitals and clinical trial consortiums, and companies, biomedical researchers, but also jurists and the professionals (in particular judges, lawyers, officers) an instrument rigorous but easy to use of the GDPR in the case of biobanking activities. The book identifies a methodological path to tackle the legal or ethical problem on a specific scientific-technological to verify existing solutions and give ideas for future applications. The importance of the legal solution influences the implementation of the development of the biobanking activity service itself.

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TECHNOLOGY/OTHER MEDIATION

Improving Patient Information and Enhanced Consent in Urology: The Impact of Simulation and Multimedia Tools. A Systematic Literature Review from the European Association of Urology Patient Office

Review – Education

Carlotta Nedbal a b, Patrick Juliebø-Jones c d, Eamonn Rogers e, James N'Dow f, Maria Ribal g, Jens Rassweiler h, Evangelos Liatsikos i, Hein Van Poppel j, Bhaskar

European Urology, 25 April 2024

Abstract

Background and objective

Discussions surrounding urological diagnoses and planned procedures can be challenging, and patients might experience difficulty in understanding the medical language, even when shown radiological imaging or drawings. With the introduction of virtual reality and simulation, informed consent could be enhanced by audiovisual content and interactive platforms. Our aim was to assess the role of enhanced consent in the field of urology.

Methods

A systematic review of the literature was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, using informed consent, simulation, and virtual reality in urology as the search terms. All original articles were screened.

Key findings and limitations

Thirteen original studies were included in the review. The overall quality of these studies was deemed good according to the Newcastle-Ottawa Scale. The studies analysed the application of different modalities for enhanced consent: 3D printed or digital models, audio visual multimedia contents, virtual simulation of procedures and interactive navigable apps. Published studies agreed upon a significantly improved effect on patient understanding of the diagnosis, including basic anatomical details, and surgery-related issues such as the aim, steps and the risks connected to the planned intervention. Patient satisfaction was unanimously reported as improved as a result of enhanced consent.

Conclusions and clinical implications

Simulation and multimedia tools are extremely valuable for improving patients' understanding of and satisfaction with urological procedures. Widespread application of enhanced consent would represent a milestone for patient-urologist communication.

Patient summary

Several multimedia tools can be used to improve patients' understanding of urological conditions and procedures, such as simulation and models. Use of these tools for preoperative discussion enhances knowledge and patient satisfaction, resulting in more realistic patient expectations and better informed consent.

Enhancing comprehension of online informed consent: the impact of interactive elements and presentation formats

Research Article

Bree Holtz, Katharine Mitchell, Robyn Adams, Caitlin Grier, Jason Wright

Ethics & Behavior, 29 March 2024

Abstract

Informed consent, a cornerstone of research ethics, ensures participant protection and informed participation, particularly in online settings. Despite its significance, engagement with online consent forms remains low, underscoring the need for improved presentation strategies. This study investigates the impact of interactive elements and diverse presentation formats on the comprehension and engagement of online informed consent documents among a broad demographic beyond the commonly studied student populations. Employing a between-subjects experimental design, we explored six versions of online consent

forms varying in interactivity, readability, and visual formatting to identify optimal strategies for enhancing participant comprehension and engagement. Our findings reveal that interactive formats significantly improve comprehension and perceived readability, highlighting the pivotal role of design in facilitating informed consent. The study also examines the influence of individual differences, such as self-efficacy and trust in science, on the effectiveness of consent forms, providing insights into the nuanced dynamics between participant characteristics and consent form engagement. These results advocate for integrating interactive elements and thoughtful design in consent forms to foster a more informed and engaged participant base. Implications for research ethics, best practices in consent form development, and future research directions are also discussed, emphasizing the need for ongoing innovation in the consent process to adapt to the evolving landscape of online research. This study contributes to the body of knowledge on research ethics by offering evidence-based recommendations for enhancing the informed consent process, ultimately promoting participant-centered research practices.

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YOUNG PERSONS

Closing the gaps: consent and preoperative assessment for children and young people

Editorial
Hugo Wellesley, Simon P. Courtman
British Journal of Anaesthesia, 15 April 2024
Summary
The changing ethical and legal landscape in the UK means that anaesthetists should routinely be discussing the risk of death during the consent process. To do this effectively means expanding anaesthetic preassessment services for children and young people, something that has been recognised as a priority, but which still needs investment and an appreciation of its value at the trust level.

Consent and assent in paediatric practice: it's the conversation that matters

Viewpoint
Hugh T Davies, Jenny Preston
Archives of Disease in Childhood, 4 April 2024
Excerpt
In paediatric medical research, across jurisdictions, parental consent and the assent of their child will usually come from a shared conversation between the researcher and family. This is how a study is introduced, information delivered, uncertainties addressed and understanding confirmed. Evidence indicates the crucial importance of the dialogue1 yet it currently goes unguided, undocumented, and often unchecked as review and research design continue to focus on the Participant Information Sheets (PIS).2 We propose that it's time to move our focus on to this conversation to help families make their decision and in this viewpoint we suggest how this can be realised working within the constraints that researchers face. We address consent to research, but would contend that this idea has equal applicability in clinical practice…

From vulnerable subjects to research partners: a critical policy analysis of biomedical research ethics guidelines and regulations

Research Article
Maria Cristina Murano
Research Ethics, 29 March 2024

Open Access
Abstract
Over the last three quarters of a century, international guidelines and regulations have undergone significant changes in how children are problematised as participants in biomedical research. While early guidelines enacted children as vulnerable subjects with diminished autonomy and in need of special protection, beginning in the early 2000s, international regulatory frameworks defined the paediatric population as vulnerable due to unaddressed public health needs. More recently, ethical recommendations have promoted the active engagement of minors as research partners. In this paper, I adopt a post-structuralist approach to policy analysis to examine deep-seated assumptions and presuppositions underlying the changes in the problematisation of children as biomedical research participants over time. While biomedical research ethics focuses on the autonomy and vulnerability of minors, ethical guidelines are situated in specific sociocultural contexts, shaped, among other things, by contingent public health needs and changing conceptions of the value of research and science for society. In the process, I demonstrate the challenge of moving away from an approach that in taking adults as the model overshadows the complexity of children's lived experiences as well as their personal, cultural, and social lives. The lack of acknowledgement of this complexity makes children vulnerable to epistemic injustice, which is particularly crucial to address in public involvement initiatives.

Navigating Theoretical, Methodological, and Ethical Interdependences in Researching Children

Book Chapter
Chikezie E. Uzuegbunam
Children and Young People's Digital Lifeworlds, 27 March 2024; pp 55–75
Abstract
This chapter discusses the theoretical, methodological, and ethical approaches to conducting research with children in specific, local contexts. It is a journey from negotiating theories and methodological decision-making to data collection, while highlighting the various processes and challenges involved in negotiating access to the actual participants used in both the focus groups and the surveys conducted. There is a conscious and deliberate decision to foreground the entire research on a child-centred approach, from theory, methodology, and ethics to analyses, making all of these components interdependent. Due to contextual differences and the nascent nature of digital media and youth research in Nigeria, conducting research with children and young people in such contexts can present unique ethical and methodological challenges. Such dilemmas dealt with include adult–child power relationships, gendered and group dynamics, problems of language and cognition, techno-shame, shy and assertive participants, the challenges of conducting fieldwork in school settings, and absentee participants.

Reconciling Children's Best Interests and Right to be Heard

Hege Stein Helland
The International Journal of Children's Rights, 6 March 2024
Abstract
This article explores the tension between the child's best interests principle and children's participation and examines the inherent challenges and different approaches to reconcile the dilemma in law and practice: how can children's best interests be reconciled with their right to be heard? By exploring different systems' institutional approaches and empirical ability to implement and honour children's right to participation in national contexts, this article reviews the literature and suggests a framework for understanding participation through a lens of a global typology of child protection systems. Drawing on the conceptual and empirical reviews and elements from the deliberative ideal for decision-making, the article concludes by drawing up a sketch for a best interest model for meaningful, respectful and successful participation with

global applicability. The model aims to enhance children's citizenship and legitimacy of decision-making in child protection.

[Key considerations in the process of assent in children and adolescents: an integrative review]

Vega Vega P, Miranda Castillo C, Vargas Celis I

Revista Chilena de Pediatria, 1 February 2024; 95(1) pp 91-106

Abstract

The participation of children and adolescents in research requires bioethical measures to safeguard their autonomy and well-being through the application of the informed consent process.

Objective

To critically analyze the factors involved in the process of assent/consent in children and adolescents in research.

Methodology

Integrative review of scientific evidence carried out between April and June 2023, from manuscripts published between 2014 and 2023 in Web of Science, PubMed, CUIDEN, and CINAHL databases, using the descriptors Process Assessment OR Assent AND Informed Consent AND Bioethics AND Minors OR Child OR Children AND adolescent OR teenage AND Pediatrics AND Research. Twenty primary articles were found, and the results were subjected to content analysis.

Result

Three categories were identified: shared consent/assent; child-specific factors for giving assent (age of the child to give assent and autonomy of the child to give assent), and key aspects of the assent process (assent form format; assent form content, and context for applying the assent process).

Conclusions

The assent process is a key tool for legal and ethical compliance with the rights of children and adolescents in clinical trial participation. In addition to favoring participation in informed decision-making together with the parents, it is also an instance where the participant's competencies, capacity for understanding, and autonomy are valued.

Editor's note: This is a Spanish language publication.

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CAPACITY TO CONSENT

Consent-as-Method: Capacity to Consent of Cognitively Disabled People and Research Ethics Review

Hannah Quinn, Rebecca-Eli M. Long

Canadian Journal of Disability Studies, 22 April 2024

Abstract

Informed consent is a core ethical principle informing research conduct. Yet, normative consent culture– often grounded in ableist understandings of capacity, rationality, and independence– exclude people with cognitive disabilities. The adjudication of consent capacity in research can be a source of harm, requiring researchers to enact lateral ableism against research participants and, potentially, themselves. As anthropologists conducting ethnographic research with intellectually and developmentally disabled participants in Canada and the U.S., we argue for the creation of an anti-ableist consent culture in the context of research. In exploring alternative ways of doing consent, we turn to the etymology of "feeling-with"–the collaborative, multi-sensory, and embodyminded experience of giving, getting, and living consent– as this can inform more ethical and anti-ableist notions of consent. We propose "consent-as-method" as part of a larger conversation about the methodological challenges and potentials of doing research as and with

people with non-normative bodyminds. Drawing on our research and lived experiences of cognitive ableism, we theorize consent practices that consider disabled people's felt knowledges of denial of consent capacity and coercion to inform anti-ableist, relational ways of doing consent. We focus on capacity because it structures the kinds of bodyminds that are seen as capable of being consenting subjects. We build on existing scholarship that considers how critically engaging with disability as a lived experience and orientation fundamentally crips our methodological and ethical commitments. Attending to consent capacity through consent-as-method treats consent as not only a means to an end but as an anti-ableist research ethic.

Essentials of Informed Consent to Psychedelic Medicine

Special Communication

Mason Marks, Rebecca W. Brendel, Carmel Shachar, Glenn Cohen

JAMA Psychiatry, 10 April 2024

Abstract

Importance

Interest in administering psychedelic agents as mental health treatment is growing rapidly. As drugmakers invest in developing psychedelic medicines for several psychiatric indications, lawmakers are enacting legal reforms to speed access globally, and health agencies are preparing to approve these treatments. Meanwhile, US states, such as Oregon and Colorado, are making psychedelics available for supervised use outside the conventional health care system.

Observations

Despite legal change and potentially imminent regulatory approval in some countries, standards for integrating psychedelics into health care have lagged, including norms for designing and implementing informed consent processes. Informed consent is complicated by the unique features of psychedelics and their means of administration. Because no governments have approved any classic psychedelics for general medical or psychiatric use, only clinical researchers have obtained informed consent from trial participants. Accordingly, there is an unmet need for informed consent processes tailored to the challenges of administering psychedelics in nonresearch settings.

Conclusions and Relevance

Analysis of the challenges of designing and implementing psychedelic informed consent practices revealed 7 essential components, including the possibility of short- and long-term perceptual disturbances, potential personality changes and altered metaphysical beliefs, the limited role of reassuring physical touch, the potential for patient abuse or coercion, the role and risks of data collection, relevant practitioner disclosures, and interactive patient education and comprehension assessment. Because publicly available informed consent documents for psychedelic clinical trials often overlook or underemphasize these essential elements, sample language and procedures to fill the gap are proposed.

Informed Consent to Psychedelic Treatment—A Work in Progress

Editorial

Paul S. Appelbaum

JAMA Psychiatry, 10 April 2024

Excerpt

Psychedelic compounds appear to be moving toward approval for clinical use, with early studies suggesting therapeutic efficacy for conditions ranging from depression to alcohol use disorder to traumatic brain injury. However, obtaining meaningful informed consent to psychedelic treatment will be challenging, given the unique effects of the drugs—including what are often described as the ineffable elements of the psychedelic experience, such as ego dissolution. Although some commentators have suggested that informed consent to psychedelic treatment, in the usual sense of that term, is simply unattainable, a growing consensus has

coalesced around the notion that with proper attention to content and presentation, clinicians will be able to obtain meaningful and valid consent from patients…

Informed Consent for Psychotherapy: The Moderating Role of Therapeutic Alliance, Prior Knowledge and Autonomous Motivation on Decision-Making and Treatment Expectation

Sönke Ladwig, Franz Pauls, Leonie Gerke, Yvonne Nestoriuc

Clinical Psychology & Psychotherapy, March-April 2024

Abstract

Background

Informed consent is an ethical prerequisite for psychotherapy. There are no routinely used standardized strategies for obtaining informed consent. A new optimized informed consent consultation (OIC) strengthened treatment-relevant aspects. It remains unclear which factors influence the OIC efficacy regarding clinical and decision-related outcomes.

Methods

N = 122 adults were included in a randomized controlled online trial. Participants received an information brochure on psychotherapy (TAU; n = 61) or OIC + TAU (n = 61). The main and interaction effects of group allocation, therapeutic alliance, prior knowledge about psychotherapy and treatment motivation on treatment expectations, decisional conflict and capacity to consent were tested. Floodlight analyses were conducted for significant interactions.

Results

Large interaction effects were shown between treatment motivation and group allocation on treatment expectations (β = -0.53) and between prior knowledge and group assignment on capacity to consent (β = 0.68). The interaction between treatment motivation and group allocation was significant up to a motivation score of 5.54 (range: 1-7). The interaction between prior knowledge and group assignment was significant up to a knowledge score of 14.38 (range: 5-20).

Conclusion

Moderator analyses indicated varying efficacy degrees for the OIC regarding decisional outcomes and expectation. Especially patients with little treatment motivation or low prior knowledge benefited from optimized information about the efficacy and possible side effects of psychotherapy.

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RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT

Editor's Note:

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].

Consent-as-Method: Capacity to Consent of Cognitively Disabled People and Research Ethics Review

Hannah Quinn, Rebecca-Eli M. Long

Canadian Journal of Disability Studies, 22 April 2024

Abstract

Informed consent is a core ethical principle informing research conduct. Yet, normative consent culture– often grounded in ableist understandings of capacity, rationality, and independence– exclude people with cognitive disabilities. The adjudication of consent capacity in research can be a source of harm, requiring researchers to enact lateral ableism against research participants and, potentially, themselves. As anthropologists conducting ethnographic research with intellectually and developmentally disabled participants in Canada and the U.S., we argue for the creation of an anti-ableist consent culture in the context of research. In exploring alternative ways of doing consent, we turn to the etymology of "feeling-with"–the collaborative, multi-sensory, and embodyminded experience of giving, getting, and living consent– as this can inform more ethical and anti-ableist notions of consent. We propose "consent-as-method" as part of a larger conversation about the methodological challenges and potentials of doing research as and with people with non-normative bodyminds. Drawing on our research and lived experiences of cognitive ableism, we theorize consent practices that consider disabled people's felt knowledges of denial of consent capacity and coercion to inform anti-ableist, relational ways of doing consent. We focus on capacity because it structures the kinds of bodyminds that are seen as capable of being consenting subjects. We build on existing scholarship that considers how critically engaging with disability as a lived experience and orientation fundamentally crips our methodological and ethical commitments. Attending to consent capacity through consent-as-method treats consent as not only a means to an end but as an anti-ableist research ethic.

The importance of global bioethics to paediatric health care

Viewpoint

Karel-Bart Celie, Joseph W Mocharnuk, Ulrick S Kanmounye, Ruben Ayala,Tahmina Banu, Kokila Lakhoo

Lancet Child & Adolescent Health, 23 February 2024

Summary

The paradigm of values adopted by the global health community has a palpable, albeit often unseen, impact on patient health care. In this Viewpoint, we investigate an inherent tension in the core values of medical ethics and clinical practice that could explain why paediatric health care faces resource constraints despite compelling economic and societal imperatives to prioritise child health and wellbeing. The dominant narrative in the philosophy of medicine tends to disproportionately underscore values of independence and self-determination, which becomes problematic in the context of paediatric patients, who by their very nature epitomise vulnerability and dependence. A double-jeopardy situation arises when disadvantaged children see their inherent dependence leveraged against them. We illustrate this predicament through specific examples relating to rights and obligations and to autonomy. Alternative value perspectives—communitarianism and relational autonomy—might offer more robust protection for vulnerable children. A shift away from the dominant narrative towards a more explicit and inclusive discussion of values is necessary. Such a shift requires giving a legitimate platform to diverse perspectives, with the presumption that collective moral progress is possible; this endeavour is embodied by global bioethics. Successful

implementation of global bioethics, in turn, hinges on close collaboration between practicing clinicians and bioethicists. Taking global bioethics seriously and actively pursuing collaboration could help the global health community achieve more equitable health care.

A cultural-historical exploration of relational ethics in research involving children

Gloria Quinones, Niina Rutanen, Yaiza Lucas Revilla

Learning, Culture and Social Interaction, October 2023

Abstract

Participatory studies involving children are a growing topic of debate concerning research on early childhood education and care (ECEC). Developments in ethnographic methods and the use of video recordings to collect data have raised new challenges for researchers who study children regarding such issues as formal procedures for informed consent and obtaining children's assent to research encounters. A growing number of studies have explored children's and researchers' relationships, as well as the ethical aspects of research encounters. We contribute to this discussion by adopting a cultural-historical (wholeness) approach to research that involves children, partnering as researchers with a child participant. By using a cultural-historical approach, we analyzed a critical incident that involved a child's assent and dissent process through dynamic motive orientations. We focused on the importance of considering dynamic motive orientation as researchers navigate new ethical challenges. Our findings reveal that adopting a wholeness approach requires researchers to serve as activity partners, reflecting on and recalibrating their own motives and centering child participants in the research process.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Understanding the language barriers to translating informed consent documents for maternal health trials in Zambia: a qualitative study

Original Research

Alice Beardmore-Gray, Musonda Simwinga, Bellington Vwalika, Sebastian Chinkoyo, Lucy Chappell, Jane Sandall, Andrew Shennan

BMJ Open, 5 April 2024

Abstract

Objective

Providing comprehensible information is essential to the process of valid informed consent. Recruitment materials designed by sponsoring institutions in English-speaking, high-income countries are commonly translated for use in global health studies in other countries; however, key concepts are often missed, misunderstood or ‘lost in translation’. The aim of this study was to explore the language barriers to informed consent, focusing on the challenges of translating recruitment materials for maternal health studies into Zambian languages.

Design

We used a qualitative approach, which incorporated a multistakeholder workshop (11 participants), in-depth interviews with researchers and translators (8 participants) and two community-based focus groups with volunteers from community advisory boards (20 participants). Content analysis was used to identify terms commonly occurring in recruitment materials prior to the workshop. The framework analysis approach was used to analyse interview data, and a simple inductive thematic analysis approach was used to analyse focus group data.

Setting

The study was based in Lusaka, Zambia.

Results
The workshop highlighted difficulties in translating research terms and pregnancy-specific terms, as well as widespread concern that current templates are too long, use overly formal language and are designed with little input from local teams. Framework analysis of in-depth interviews identified barriers to participant understanding relating to design and development of recruitment materials, language, local context and communication styles. Focus group participants confirmed these findings and suggested potential solutions to ensure the language and content of recruitment materials can be better understood.
Conclusion
Our findings demonstrate that the way in which recruitment materials are currently designed, translated and disseminated may not enable potential trial participants to fully understand the information provided. Instead of using overly complex institutional templates, recruitment materials should be created through an iterative and interactive process that provides truly comprehensible information in a format appropriate for its intended participants.

Informed consent in cancer clinical care: Perspectives of healthcare professionals on information disclosure at a tertiary institution in Uganda

Research Article
Rebecca Kampi, Clement Okello, Joseph Ochieng, Erisa Sabakaki Mwaka
PLOS One, 4 April 2024
Open Access
Abstract
Introduction
While there have been several studies examining the understanding and quality of informed consent in clinical trials of cancer therapies, there is limited empirical research on health practitioners' experiences on the informed consent process in cancer care, especially from low resource settings. This study explored health professionals' perspectives on information disclosure during the consenting process in cancer care.
Methods
A qualitative descriptive approach was used to collect data. Face to face interviews were conducted with 10 purposively selected healthcare professionals who were actively involved in soliciting informed consent at a cancer treatment centre in Uganda. A thematic approach was used to interpret the results.
Results
There were five key themes, and these included information disclosure to patients; assessment of patients' cancer awareness, treatment preferences and expectations; informed consent practices; barriers to optimal informed consent and information disclosure; and recommendations for improving the consenting process. All respondents appreciated the value of disclosing accurate information to patients to facilitate informed decision making. However, the informed consent process was deemed sub-optimal. Respondents asserted that the psychological wellbeing of patients should be protected by mentally preparing them before disclosing potentially distressing information. All healthcare professionals were appreciative of the central role the family plays in the consenting process.
Conclusion
Overall, informed consent practices were not ideal because of the several challenges. Inadequate time is devoted to information disclosure and patient education; there is lack of privacy; and informed consent documentation is poor. There is a need for significant improvement in informed consent practices and healthcare professional-patient communication.

Obligation, Informed Consent, and Health-Care Reforms in China

Jia Liu
Asian Journal of Law and Society, 1 April 2024

Abstract
Drawing on recent jurisprudential literature that emphasizes the role and function performed by obligation, this article examines how the ethical doctrine of informed consent has been implemented in the context of health-care reforms in China. It argues that, while the Chinese incorporation of informed consent has sought to empower patients, the major medical laws and social policies fail to instantiate the obligations. Along with this failure, the Chinese medical laws have also failed to secure the bond of trust between them. This article also points out that a rounded analysis of the implementation of informed consent in China must take into account the obligation and function of the major components of the health-care delivery system other than physicians and hospitals, such as health-care insurance schemes.

Patients' comprehension and satisfaction with informed consent at day surgery unit at King Khalid University Hospital, Riyadh, Saudi Arabia

Original Article
Sulaiman A Alshammari, Suliman Ahmed Aldhalaan, Abdulaziz Mohammed Alqahtani, Ahmed Tawfik Khoja, Ghaith Uthman Alkhulayfi, Meshal Abdulaziz Aljudai
International Journal of Medicine in Developing Countries, 12 February 2024
Open Access
Abstract
Background
Informed Consent (IC) is a crucial element in medical practice and research. However, additional research is needed to assess the quality of IC in Middle Eastern regions, including Saudi Arabia. This study aimed to measure surgical patients' comprehension and satisfaction with IC and related factors at King Khalid University Hospital (KKUH).
Methods
This cross-sectional study investigated postsurgical patients' satisfaction and comprehension of IC at the day surgery unit at KKUH from August to December 2022. Data collection was done through an online questionnaire.
Results
A total of 387 patients participated in this study, with over half (56.1%) being women (mean age = 41.4 ± 13.4). More than 88% of the patients were satisfied with all IC components. Patients aged 26-45 reported the highest levels of IC understanding (54.9%, $p < 0.05$), and female patients demonstrated higher overall comprehension compared to male patients ($p = 0.088$). Those with higher education and income had the highest comprehension scores (61.2%, $p < 0.05$) and (28.4%, $p < 0.05$), respectively. Only 54% of patients read the IC form and were aware of who provided them with the forms. Approximately 92% of the patients signed the IC form themselves, and 72% required less than an hour to consent.
Conclusion
Middle-aged patients, women, and those with a high level of education exhibited the highest overall IC comprehension and satisfaction. The findings underscore the importance of personnel delivering therapy introducing themselves and indicating their involvement in the team. The future of the IC process lies in electronic standardization through the use of "Esihi," KKUH's current electronic record system.

A Survey Of Awareness And Practices Of Informed Consent Among Dentists In Rawalpindi And Islamabad, Pakistan

Shaista Rafi, Hina Khan, Muhammad Hamza Hussain, Hira Aslam, Yousra Khan, Hala Hidayat
Pakistan Oral & Dental Journal, 29 March 2024
Abstract
Objective

The aim was to determine the awareness and practices of dental professionals about informed consent among various levels of qualification. A total of 129 dentists from Rawalpindi and Islamabad were included by convenience sampling technique.

Methodology

Dentists practicing clinically in Rawalpindi and Islamabad were included. Undergraduate dental students, dental technicians and dental assistants were excluded.

Results

Data was collected using an especially developed questionnaire, and analyzed using SPPS through chi-square tests. The mean age was 33.89±7.57 years. A total of 126 dentists (96.67%), including 45 females (34.88%) and 84 males (65.12%), were familiar with informed consent. The most frequently reported "basic element of Informed Consent" was confidentiality (n=50, 38.76%), followed by treatment alternatives (n=33, 25.58%), and all of these (n=29, 22.48%). The most frequently reported "main purpose of Informed Consent" was legal (n=128, 18.12%), followed by ethical (n=45, 35.16%), and all of these (n=51, 39.72%). Most of the participants said they take Informed Consent prior to treatment (n=103, 79.84%), stating that it is not a waste of time (n=69, 53.49), that they take it verbally (n=107, 82.95%), and that the minimum age to sign Informed Consent by oneself is above 18 years (n=109, 84.5%). Only 6 (4.65%) said they provide a copy of Informed Consent to patients.

Conclusion

There was lack of awareness and good practices among dental professionals regarding the process of taking informed consent. More qualified dentists reported better awareness and practices compared to less qualified dentists. Only few dental professionals have the habit of obtaining written Informed Consent.

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RIGHTS/LEGAL/LEGISLATIVE

Michigan: Parental Consent Law for Abortion Harms Young People - New Report Examines Law and Calls for Repeal

Human Rights Watch, 28 March 2024

Summary

- A Michigan law that requires a young person to obtain parental consent to have an abortion threatens the health and safety of youth in the state and violates their human rights.
- In some cases, disclosing a pregnancy to a parent will result in abuse or being forced to leave home or continue the pregnancy, and judicial bypass can be subjective and cause delays.
- Michigan's forced parental consent for abortion law should be immediately repealed to ensure young people's safety and dignity.

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MEDICAL/SURGICAL

Informed Consent and Digit Replantation: Current State and Recommendations for Ethical Patient Care

Emily Gudbranson, Adnan Prsic, Ashley Pistorio, David L. Colen

The Journal of Hand Surgery, 18 April 2024

Abstract

The importance of informed consent and the value of shared decision-making in hand surgery are well-established and particularly critical in the setting of digit amputation when considering replantation. Informed consent requires an understanding of not only the immediate and long-term risks and benefits of surgery, as well as the risks and alternatives involved, but also the capacity of the patient to make a medical decision. However, patients who have acutely sustained a disfiguring trauma are often in distress and may not fully process the consent discussion. Digit replantation is an "elective emergency"—the decision must be made immediately but is not lifesaving—which poses a difficult dilemma: are surgeons acting in patients' best interests by pursuing replantation if we engage those patients in informed consent discussions when they may not have capacity? This article explores the relevant bioethical principles associated with digit replantation, summarizes updated literature regarding informed consent and shared decision-making, and provides recommendations for patient education materials to standardize informed consent discussions for surgeons approaching patients at this unique intersection of considering revision amputation versus replantation.

Informed consent in clinical practice: Old problems, new challenges

Research Article

Isaac KS Ng

Journal of the Royal College of Physicians of Edinburgh, 14 April 2024

Abstract

Informed consent is a fundamental tenet of patient-centred clinical practice as it upholds the ethical principle of patient autonomy and promotes shared decision-making. In the medicolegal realm, failure to meet the accepted standards of consent can be considered as medical negligence which has both legal and professional implications. In general, valid consent requires three core components: (1) the presence of mental capacity – characterised by the patient's ability to comprehend, retain information, weigh options and communicate the decision, (2) adequate information disclosure – based on the 'reasonable physician' or 'reasonable patient' standards and (3) voluntariness in decision-making. Nonetheless, in real-world clinical settings, informed consent is not always optimally achieved, due to various patient, contextual and systemic factors. In this article, I herein discuss three major challenges to informed consent in clinical practice: (1) patient literacy and sociocultural factors, (2) psychiatric illnesses and elderly patients with cognitive impairment and (3) artificial intelligence in clinical care, and sought to offer practical mitigating strategies to address these barriers.

Preparing Patients for Oral Immunotherapy (PPOINT): International Delphi consensus for procedural preparation and consent

Douglas P. Mack, Timothy E. Dribin, Paul J. Turner, Richard L. Wasserman, Mariam A. Hanna, Marcus Shaker, Mimi L.K. Tang, Pablo Rodríguez del Río, Brad Sobolewski, Elissa M. Abrams, Aikaterini Anagnostou, Stefania Arasi, Sakina Bajowala, Philippe Bégin, Scott B. Cameron, Edmond S. Chan, Sharon Chinthrajah, Andrew T. Clark, Paul Detjen, George du Toit, Matthew Greenhawt

Journal of Allergy and Clinical Immunology, 8 April 2024

Abstract

Background

Despite the promise of oral immunotherapy (OIT) to treat food allergies, this procedure is associated with potential risk. There is no current agreement about what elements should be included in the preparatory or consent process.

Objective

We developed consensus recommendations about the OIT process considerations and patient-specific factors that should be addressed before initiating OIT and developed a consensus OIT consent process and information form.

Methods
We convened a 36-member Preparing Patients for Oral Immunotherapy (PPOINT) panel of allergy experts to develop a consensus OIT patient preparation, informed consent process, and framework form. Consensus for themes and statements was reached using Delphi methodology, and the consent information form was developed.
Results
The expert panel reached consensus for 4 themes and 103 statements specific to OIT preparatory procedures, of which 76 statements reached consensus for inclusion specific to the following themes: general considerations for counseling patients about OIT; patient- and family-specific factors that should be addressed before initiating OIT and during OIT; indications for initiating OIT; and potential contraindications and precautions for OIT. The panel reached consensus on 9 OIT consent form themes: benefits, risks, outcomes, alternatives, risk mitigation, difficulties/challenges, discontinuation, office policies, and long-term management. From these themes, 219 statements were proposed, of which 189 reached consensus, and 71 were included on the consent information form.
Conclusion
We developed consensus recommendations to prepare and counsel patients for safe and effective OIT in clinical practice with evidence-based risk mitigation. Adoption of these recommendations may help standardize clinical care and improve patient outcomes and quality of life.

Valid consent in the acute hospital setting: perspectives of patients and members of the public

Original Article
Živa Kovic, Motheo Kobua, Mary Fogarty, Claire L. Donohoe, Michael E. Kelly, Gerard J. Fitzmaurice, Mella Fitzgerald, Paul Zambra, Una Geary, Marie E. Ward
Irish Journal of Medical Science, 5 April 2024
Open Access
Abstract
Background
People who interact with healthcare services have an ethical and legal right to control their own lives, to make informed decisions, and to consent to what happens to them. For consent to be considered ethically and legally valid, three key criteria must be met: consent must be given voluntarily; people must be sufficiently informed of all options; and people should have capacity to make the decision to give or withhold their consent.
Aim
This study set out to explore, through the use of surveys, the perspectives of patients and public in relation to consent.
Method
Surveys were developed for patients and the public and administered paper based (patients) and through social media (public).
Results
One hundred and forty surveys were posted to patients, with a 38% response rate; 104 responses were received from the public. Ninety-six percent of patients were satisfied that the decision they made was informed; 100% felt they had made a voluntary decision; 98% felt the clinician seemed knowledgeable about the procedure. What matters most to the public were being informed about the risks associated with the proposed procedure and being assured that whatever choice they make they will receive the best care possible.
Conclusions
The results highlight interesting similarities and differences in relation to consent between members of the public thinking about a possible treatment, surgery, or procedure and those patients who have actually been

through the process in the past 12 months. Recommendations have been developed on the basis of these findings to co-design improvements in consent practices.

Standardized Informed Consent Form for Clinicians Administering Platelet-Rich Plasma

Satvik N. Pai, Naveen Jeyaraman, Ravichandran Venkatasalam, Ravi VR, Swaminathan Ramasubramanian, Sangeetha Balaji, Arulkumar Nallakumarasamy, Shilpa Sharma, Bishnu P. Patro, Madhan Jeyaraman

Cureus, 3 April 2024; 16(4)

Abstract

Introduction

When it comes to medico-legal malpractice suits, lawyers and insurers tend to focus on informed consent documentation. Unfortunately, there is no standard protocol for obtaining informed consent for the use of platelet-rich plasma (PRP) injections, which might cause problems. This study aimed to mitigate this concern through the development of a standardized informed consent document for PRP injections, grounded in evidence-based practices.

Materials and methods

An examination of databases was conducted to explore the medico-legal ramifications associated with PRP injections, as well as the broader topic of informed consent, with a particular focus on the context of PRP injections. Moreover, interviews were carried out with healthcare providers and individuals who had received PRP injections within the preceding year, utilizing a semi-structured methodology.

Results

We developed an evidence-based informed consent document tailored for PRP injections. To guarantee its legal validity, the document underwent review by a legal specialist. Subsequently, our institutions implemented the finalized form for PRP injection procedures over one year.

Conclusion

A legally valid and evidence-based informed consent form for PRP injections would ensure patient's rights, and encourage open communication and transparency between them and the doctor. Moreover, if a lawsuit were to arise, it would serve as a critical document in the doctor's defense and withstand scrutiny from lawyers and the judiciary.

Informed consent in endoscopy: read, understood, or just signed?

Ana Catarina Carvalho, Ricardo Cardoso, Hugo Marcelo Vieira, Américo Silva

iGIE, 2 April 2024

Abstract

Background And Study Aims

While informed consent is a requirement for all interventional procedures such as those in gastrointestinal endoscopy, its standardization is a challenge. While very thorough documents have been proposed, it is unknown whether patients actually read them. We intended to evaluate if patients read and understand informed consent forms and information leaflets for gastrointestinal endoscopy.

Patients And Methods

This single center prospective observational study was performed between April 2021 and April 2022 and included adult patients proposed for outpatient elective esophagogastroduodenoscopy and colonoscopy. Informed consent forms and information leaflets were mailed to patients, with a small text instruction added to the informed consent form. Prior to endoscopy it was assessed whether patients adequately read the informed consent form, based on patient signature, table questionnaire completion and performance of the text instruction.

Results

The study included 232 patients (50.6% males, mean age 63.8±12.76 years). Most had only basic education (78.0%) and had previously undergone gastrointestinal endoscopy (90.6%). 86.6% of patients stated they had

read the form while 13.4% did not. While most signed the form (83.6%), only 24.6% adequately read and understood it. No statistically significant association between informed consent form adequate reading and any of the assessed variables was found.

Conclusions

Despite the timely provision of information, most patients do not read or adequately understand the provided documents. It is necessary to develop new strategies to enhance patients' involvement in decision making, improving the doctor-patient relationship in obtaining informed consent.

Editor's note: iGIE is published by Elsevier Inc. on behalf of American Society for Gastrointestinal Endoscopy.

Moral Dilemmas Regarding Physical Restraints in Intensive Care Units: Understanding Autonomy, Beneficence, Non-Maleficence and Justice in the Use of Physical Restraints

Zhou J, Qin Q, Chen S, Zhang H

Journal of Multidisciplinary Healthcare, 28 March 2024

Abstract

In intensive care units, patients are often restrained to ensure their safety, with physical restraints being the most commonly used method. However, physical restraints compromises the patient's freedom, health and comfort, and nurses often face moral dilemmas when deciding whether to use physical restraints. This article examines physical restraints through the four universal principles of autonomy, beneficence, non-maleficence and justice. Through these principles, the authors will critically explore whether the physical restraints of patients by nurses is ethical in practice and what moral issues exist. This paper also explores conflicts and moral dilemmas for nurses in this context. Finally, suggestions are made on changes to education and clinical practice.

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PRE-PRINT SERVERS

Medical Ethics and Facilitating Fully Informed Consent to Treatment

Alan Mordue, Evans E A, Royle T J, Clare Craig

OSF Preprints, 24 April 2024

Abstract

It has been asserted that there was an erosion of medical ethics during the Covid-19 pandemic and a departure from the principle of obtaining fully informed consent from patients before treatment. In light of these assertions, this article reviews the historical development of medical ethics and the approach to obtaining informed consent, and critiques the consent practices before and during the pandemic. It then describes a new tool for displaying key statistics on the benefits and risks of interventions to help explain them to patients and suggests a more rigorous process for seeking fully informed consent in the future.

Editor's note: OSF Preprints is published by the Center for Open Science.

Responsible Governance of Genomics Data and Biospecimens in the Context of Broad Consent: Experiences of a Pioneering Access Committee in Africa

Rebai A, Abayomi A, Andanda P, Bukini D, Kerr R, Herbst K, Mabuka J, Wamuyu R, Dandara C

Qeios, 24 April 2024

Abstract

International collaboration in genomic research is gaining momentum in African countries and is often supported by external funding. Over the last decade there has been an increased interest in African genomic data. The contribution of this rich data resource in understanding diseases predominant in both African and global populations has been limited to date. Although There has been some non-governmental funding dedicated to the advancement of genomic research and innovation by African-based and African-led research groups, but the impact of these initiatives is hard to quantify. However, there is now opportunity for the global research community to leverage decades of genomic data and biospecimens originating from African populations. The experience we describe in this paper is of an access governance framework established under the Human, Heredity, and Health in Africa (H3A) consortium, given the task of managing wider access to the data and biospecimen resources collected via its various projects. The function of the Data and Biospecimen Access Committee (DBAC) is to facilitate the advancement of medicine and health, whilst fostering the development bioinformatics capabilities at Africa-based institutions or regional hubs. Our collective experiences and lessons learned as a committee provide examples of nuanced considerations when evaluating access to African data. The committee was semi-autonomous in its establishment and has independence in decision-making. The DBAC continually advocates for responsible use of genomic data and biospecimens that were obtained from African research participants, under broad consent, by primary researchers who no longer have oversight over future use of these resources.

Advancing a Consent-Forward Paradigm for Digital Mental Health Data

Sachin R. Pendse, Logan Stapleton, Neha Kumar, Munmun De Choudhury, Stevie Chancellor

arXiv, 22 April 2024

Abstract

The field of digital mental health is advancing at a rapid pace. Passively collected data from user engagements with digital tools and services continue to contribute new insights into mental health and illness. As the field of digital mental health grows, a concerning norm has been established -- digital service users are given little say over how their data is collected, shared, or used to generate revenue for private companies. Given a long history of service user exclusion from data collection practices, we propose an alternative approach that is attentive to this history: the consent-forward paradigm. This paradigm embeds principles of affirmative consent in the design of digital mental health tools and services, strengthening trust through designing around individual choices and needs, and proactively protecting users from unexpected harm. In this perspective, we outline practical steps to implement this paradigm, toward ensuring that people searching for care have the safest experiences possible.

Editor's note: arXiv is published by Cornell University.

An ethical analysis of human fetal and embryological collections and informed consent: a focus group study

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BMC Medical Ethics Preprint, 19 April 2024

Abstract

Background

Human fetal and embryological collections refer to repositories or archives that house remains of human fetuses and embryos at different stages of development. Previous studies have highlighted that most remains in these collections have been obtained without informed consent from the next of kin, thus reflecting a time in history where this may have been acceptable. Previous studies seeking stakeholder perceptions towards these collections suggest that there is misalignment with the values of society today, and the current guiding frameworks pertaining to these collections. The aim of this study was to explore and

analyse the perceptions of key stakeholders regarding fetal collections with a particular focus on informed consent.

Methods

Through conducting focus group interviews of 25 participants, the study sought to provide an in-depth exploration of how stakeholders perceive the value of fetal and embryological collections, and the importance of informed consent.

Results

The mean age of participants was 29.1 years of age with a gender distribution of 40% men and 55.6% of women. Thematic analysis identified four themes: Consent; preparation for clinical practice; 3. equity and fairness; and 4 educational value, with several subthemes identified at macro, meso, and micro ethical levels. Macro subthemes included importance of informed consent, and equity and fairness, and genetic composition. Meso subthemes included respect and privacy, and legal and institutional considerations. Micro subthemes included emotional considerations, preparation for clinical practice, and educational value.

Conclusions

The study advocates for consideration of the ethical issues surround human fetal and embryological collections from the macro, meso, and micro ethical frameworks.

Editor's note: This preprint is Under Review at BMC Medical Ethics.

Evolution of informed consent in research: From the Hippocratic Oath to the tailored consent

Essay

Jaime Fons-Martinez, Carlos Murciano-Gamborino, Javier Diez-Domingo

Open Research Europe, 17 April 2024

Abstract

Background

Informed consent (IC) is essential in defending the autonomy of potential participants in clinical research. Despite the advances in research ethics, particularly in IC, the different guidelines and codes have not been fully implemented. Several studies have presented consent deficiencies that have resulted in unethical practices or poor understanding of the IC.

Main body

This article reviews the evolution of IC, from its philosophical origins and initial use in the Ottoman Empire (16th century) to its use in clinical research today. It also presents the vision of the European project i-CONSENT (Grant Agreement number: 741856), whose main purpose is to improve the understanding of ICs in research and identifies the key components of a new paradigm to develop patient-centred ICs.

Conclusions

In many cases, the IC has served to protect the investigator or sponsor from complaints. Different ethical guidelines have sought to make the IC a more useful tool, with little success. Today's IC is mainly a bureaucratic and legal process that fails to consider the patient's point of view. In this context, the Guidelines for Tailoring the Informed Consent Process in Clinical Studies provide alternatives to the current IC process, focusing on the patient's opinions and making them part of the process, thereby improving clinical research quality.

Assessment of the knowledge, attitude and practices of the informed consent process in oral healthcare among dental students in Makerere University Dental Hospital, Uganda

Research Article

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BMC Medical Education Preprint, 11 April 2024

Abstract
Introduction
Informed consent is an ethical and legal component of healthcare. It ensures patient autonomy and allows patients to make decisions regarding their treatment. In dental care, informed consent is particularly important because most dental procedures are invasive. Since dental students are future dentists, they need to learn about their ethical obligations and accountability through the informed consent process as this is critical to the patient's well-being. The present study aimed to determine dental students' knowledge, attitudes, and practices of informed consent for oral health care in Makerere University Dental Hospital, Uganda.
Study Methodology
This was a descriptive cross-sectional quantitative study that was carried out at Makerere University Dental Hospital. Third, fourth, and fifth-year students (n = 102) pursuing a Bachelor of Dental Surgery programme took part in a survey. A self-administered structured questionnaire was used to assess their knowledge, attitudes, and practices of informed consent for oral health care. Collected data were entered into Epi-data version 3.1, where it was cleaned, coded, and imported to STATA version 14 software for statistical analysis.
Results
Of the 102 participants, 65.7% were males. The mean age was 25 (SD = 3.21) years. The majority (90%) of the students had a high level of knowledge of the informed consent process. About 80% had a positive attitude towards informed consent and 85% most often practiced the informed consent process. Based on bi-variate analysis, training on informed consent, year of study, age, and sex were significantly associated with the informed consent process. However, there was no significant risk factor associated with informed consent in multiple logistic regression analysis.
Conclusion
The study findings highlighted high levels of knowledge, positive attitude, and practice of the informed consent process among the clinical dental students. Continuous in-service training for dentists and other oral healthcare workers on the informed consent process is highly recommended.

Editor's note: This preprint is Under Review at BMC Medical Education.

Considerations for the design of informed consent in digital health research: Participant perspectives

Research Methods & Evaluation
Brian McInnis, Ramona Pindus, Daniah Kareem, Camille Nebeker
Advance, 1 April 2024

Abstract
The research team, prospective participants, and written materials all influence the success of the informed consent process. As digital health research becomes more prevalent, new challenges for successful informed consent are introduced. This exploratory research utilized a human centered design process where 19 people were enrolled to participate in one of 4 online focus-groups. Participants discussed their experiences with informed consent, preferences for receiving study information and ideas about alternative consent approaches. Data were analyzed using qualitative methods. Six major themes and sixteen sub-themes were identified that included study information that prospective participants would like to receive, preferences for accessing information and a desire to connect with research team members. Specific to digital health, participants expressed a need to understand how the technologies worked and how the volume of granular personal information would be collected, stored, and shared.

Editor's note: Advance is a sage preprint publication.

Mental capacity assessment in the multi-professional real world: a qualitative study of six areas of uncertainty

Research Article

Andrew McWilliams, Kevin Ariyo, Anthony S. David, Gareth S. Owen

Wellcome Open Research, 2024

Open Access

Abstract

Background

The Mental Capacity Act 2005 of England and Wales is a ground-breaking piece of legislation with reach into healthcare, social care and legal settings. Professionals have needed to develop skills to assess mental capacity and handle malign influence, but it is unclear how assessments are implemented in real world settings. Our previously reported survey found professionals juggling competing resources in complex systems, often struggling to stay up to date with law. The current follow-up study uses one-to-one interviews of professionals to characterise in detail six areas of uncertainty faced when assessing mental capacity, whilst suggesting ways to make improvements.

Methods

Forty-four healthcare, social care and legal professionals were interviewed, using a semi-structured topic guide. Transcripts were analysed using framework analysis: a qualitative technique built to investigate healthcare policy.

Results

Our topic guide generated 21 themes. In relation to the six areas of uncertainty: 1) Many participants stressed the importance of capturing a holistic view, adding that their own profession was best-placed for this - although a medical diagnosis was often needed. 2) The presumption of capacity was a laudable aim, though not always easy to operationalise and occasionally being open to abuse. 3) There was cautious interest in psychometric testing, providing a cognitive context for decisions. 4) Undue influence was infrequent, but remained under-emphasised in training. 5) Multi-professional assessments were common, despite doubts about fitting these within local resources and the law. 6) Remote assessment was generally acceptable, if inadequate for identifying coercion.

Conclusions

Practical constraints and competing demands were reported by professionals working within real world systems. Assessment processes must be versatile, equally applicable in routine and emergency settings, across diverse decisional types, for both generalist and specialist assessors, and able to handle coercion. Recognising these challenges will guide development of best practices in assessment and associated policy.

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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].

Invitation for Public Comment: WHO principles for human genome access, use and sharing

8 April 2024 Consultation Period: 8th April 2024 – 3 May 2024

Background

For the potential of genomics to be realized, access to, use, and the sharing of human genome data is critical. Following the WHO's Science Council 2022 Report on Accelerating access to genomics for global health: promotion, implementation, collaboration, and ethical, legal, and social issues, WHO is implementing a programme of activities to promote equitable and fair access to genomics technologies for the benefit of people worldwide. As part of this, WHO is developing guiding principles for human genome data access, use and sharing. To develop these principles, a virtual consultation was held in January 2024 with an interdisciplinary group of participants. This consultation discussed the diverse perspectives on issues related to human genome data access, use and sharing; how a global set of principles from WHO may enable data access, use and sharing; and proposed initial principles. This was followed by an in-person meeting in March 2024 that considered in detail the proposed principles. Following this meeting, a draft document was developed and comments on this document and the principles are now invited.
Feedback on the WHO Principles for human genome data access, use, and sharing
Public feedback on this document is being solicited through this public consultation using the comment form.

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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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