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governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

January 2025 :: Issue 73

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 identify 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 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.

Overall, we have elected to be inclusive in our content selection, including articles that may be controversial and warrant closer scrutiny. We may include "Editor's Notes" or other notations to identify such content. This approach aligns with our goal of presenting a holistic landscape of informed consent literature as it is published.

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:

Editor
Paige Fitzsimmons, MA
Associate Director, Center for Informed Consent Integrity
Associate Fellow
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

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 content which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, evidence, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

No new content was identified for the following established categories:

COMPASSIONATE USE/EXPANDED ACCESS
HUMANITARIAN CONTEXT
YOUNG PERSONS

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

To start the new year, we have highlighted an article which broadens our thinking to informed consent at a population level. In the *Public Health Ethics* article **Collective Consent to Xenotransplantation: A Critical Appraisal** Bobier et al. discuss the need to go beyond surveying trends in public attitudes surrounding novel technologies which have the potential to impact the planet on a large scale and actively obtain collective consent for xenotransplantation procedures.

[Extract]

"…solid organ xenotransplantation… involves the transplantation of a genetically engineered porcine organ into a human recipient (Carrier *et al.*, 2022; Fischer and Schnieke, 2022). There is concern, however, that a novel zoonotic disease could be transmitted from the source organ to the human recipient, then from the recipient to others. Theoretically, this could result in an epidemic or pandemic (Fishman, 2022; Thom *et al.*, 2024).

Given the novelty of xenotransplantation and the theoretical potential to cause significant harm, it has been the stated position of the World Health Organization (WHO) since 2008 that any xenotransplantation regulatory system must include ethical assessments that involve the public (WHO, 2008). Public engagement regarding novel medical technology promotes important (i) ethical, (ii) transparent and (iii) inclusive practices (Hurst and Cooper, 2024). However, some have gone further and argued that something more than the assessment of public viewpoints is needed. It has

been argued that collective consent is required in addition to the due diligence of researchers and oversight organizations, such as the US Food and Drug Administration…

While the authors conclude that collective consent is not required in this case to proceed ethically, we have highlighted this article because it engages population level thinking, and is a useful example of a niche area in the informed consent landscape.

Collective Consent to Xenotransplantation: A Critical Appraisal

Christopher Bobier, Adam Omelianchuk, Daniel Rodger, Daniel J Hurst
Public Health Ethics, 12 December 2024
Abstract
Solid organ xenotransplantation may have the potential to help address the shortage of organs for transplantation. There is concern, however, that a novel zoonotic disease could be transmitted from the source organ to the human recipient, and then from the recipient to others. Theoretically, this could result in an epidemic or pandemic. Because of this potential risk, it has been argued that collective consent is required. Our goal is to critically evaluate the claim that collective consent is necessary for xenotransplantation to be ethically permissible. We argue that collective consent is not required and highlight the important roles of public engagement and due diligence in xenotransplant research moving forward.

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BIOMEDICAL RESEARCH

Navigating the consent river: questions to consider before waiving consent requirements in pragmatic cluster randomised trials

Cory E Goldstein, Monica Taljaard, Stephanie N Dixon, Charles Weijer
Journal of Medical Ethics, 18 December 2024
Open Access
Abstract
The robust design and conduct of pragmatic cluster randomised trials may be in tension with the ethical requirement to obtain written informed consent from prospective research participants. In our experience, researchers tend to focus on whether a waiver of consent is appropriate for their studies. However, pragmatic cluster randomised trials raise other important questions that have direct implications for determining when an alteration or waiver of consent is permissible. To assist those involved in the design, conduct and review of pragmatic cluster randomised trials, we outline four critical questions to consider: (1) What is the nature of the intervention being evaluated? (2) Is the choice to use cluster randomisation justified? (3) Can the risk of recruitment bias be addressed? and (4) Is an alteration or waiver of consent appropriately justified? We recommend that researchers and research ethics committees conduct a stepwise analysis of a planned cluster randomised trial using these questions. To illustrate the application of this stepwise analysis, we use three pragmatic cluster randomised trials in the haemodialysis setting as case studies.

Context is key: ethical considerations related to consent and study design in acute cardiac care research

Journal Article
Neal W Dickert, Madeline Meer

European Heart Journal Acute Cardiovascular Care, 28 November 2024

Excerpt

…There is also an important set of ethical issues that arise in cardiac critical care research. By their very nature, acute care studies involve 'high stakes' outcomes such as mortality, organ failure, and other major morbidities. Communicating about study enrolment with patients and family members in the context of life-or-death situations is difficult, and research itself is complex and unfamiliar. To make matters worse, decisions often must be made very quickly, because acute care must be delivered rapidly. These issues make consent processes difficult and, in some cases, impossible. Many patients with severe acute cardiac illness lack capacity to engage in decision-making, and surrogate decision makers are often unavailable and may struggle with having to make research enrolment decisions for someone else. The urgency of these situations only compounds baseline challenges related to deciphering patients' preferences for participating in research.

In this piece, we focus on these ethical challenges and integrate them with practical considerations outlined above. We articulate paths forward for major types of acute cardiac care research, emphasising throughout the importance of attention to critical contextual factors…

On-site electronic consent in pediatrics using generic Informed Consent Service (gICS): Creating a specialized setup and collecting consent data

Research Article

Katharina Danhauser, Larissa Dorothea Lina Mantoan, Jule Marie Dittmer, Simon Leutner, Stephan Endres, Karla Strniscak, Jenny Pfropfreis, Martin Bialke, Dana Stahl, Bernadette Anna Frey, Selina Sophie Gläser, Laura Aurica Ritter, Felix Linhardt, Bärbel Maag, Georgia Donata Emily Miebach, Mirjam Schäfer, Christoph Klein, Ludwig Christian Hinske

PLOS Digital Health, 25 November 2024

Open Access

Abstract

Enrolling in a clinical trial or study requires informed consent. Furthermore, it is crucial to ensure proper consent when storing samples in biobanks for future research, as these samples may be used in studies beyond their initial purpose. For pediatric studies, consent must be obtained from both the child and their legal guardians, requiring the recording of multiple consents at once. Electronic consent has become more popular recently due to its ability to prevent errors and simplify the documentation of multiple consents. However, integrating consent capture into existing study software structures remains a challenge. This report evaluates the usability of the generic Informed Consent Service (gICS) of the University Medicine Greifswald (UMG) for obtaining electronic consent in pediatric studies. The setup was designed to integrate seamlessly with the current infrastructure and meet the specific needs of a multi-user, multi-study environment. The study was conducted in a pediatric research setting, where additional informed consent was obtained separately for the biobank. Over a period of 54 weeks, 1061 children and adolescents aged 3 to 17 years participated in the study. Out of these, 348 agreed also to participate in the biobank. The analysis included a total of 2066 consents and assents, with 945 paper-based and 1121 electronic consents. The study assessed the error susceptibility of electronic versus paper-based consents and found a significant reduction rate of errors of 94.7%. These findings provide valuable insights into the use of gICS in various studies and the practical implementation of electronic consent software in pediatric medicine.

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SOCIAL SCIENCE RESEARCH

"You knew what you were getting into": Perspective differences in gauging informed consent

Rachel Schlund, Vanessa K. Bohns

Organizational Behavior and Human Decision Processes, January 2025

Abstract

We examine differences between perceived and experienced consent in organizational contexts—specifically, the aspect of consent that reflects how informed consenters feel. We theorize that people tasked with soliciting consent overestimate the extent to which consenters feel fully informed of what they are agreeing to and thus feel they have truly consented. We provide support for these predictions across six pre-registered studies (N = 2,993) and eight supplemental pre-registered studies (N = 4,406) that establish causal and mediation evidence, downstream organizational consequences, and real-world relevance. This research reveals that even when an agreement meets the legal criteria for consent, there may be misaligned perceptions of employees' feelings of consent, with consequences for employees' relationship with their organization. The current studies offer a significant step forward in understanding the markedly understudied role of consent in organizations.

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ARTIFICIAL INTELLIGENCE

Ethical Challenges in the Integration of Artificial Intelligence in Palliative Care

Abiodun Adegbesan, Adewunmi Akingbola, Olajide Ojo, Otumara Urowoli Jessica, Uthman Hassan Alao, Uchechukwu Shagaya, Olajumoke Adewole, Owolabi Abdullahi

Journal of Medicine, Surgery, and Public Health, December 2024

Abstract

The integration of artificial intelligence (AI) into palliative care offers the possibility of improved patient outcomes through enhanced decision-making, personalized care, and reduced healthcare provider burden. However, the use of AI in this sensitive area presents significant ethical challenges which require serious consideration to ensure that technology serves the best interests of patients without compromising their rights or well-being. This narrative review explores the key ethical issues associated with AI in palliative care, with a focus on low-resource settings where these challenges are often intensified. The review examines essential ethical principles such as autonomy, beneficence, non-maleficence, and justice, and identifies critical concerns including data privacy, informed consent, algorithmic bias, and the risk of depersonalizing care. It also highlights the unique difficulties faced in low-resource environments, where the lack of infrastructure and regulatory frameworks can exacerbate these ethical risks. To address these challenges, the review offers actionable recommendations, such as developing context-specific guidelines, promoting transparency and accountability through explainable AI (XAI), and conducting regular ethical audits. Interdisciplinary collaboration is emphasized to ensure that AI systems are ethically designed and implemented, respecting cultural contexts and upholding patient dignity. This study contributes to the ongoing discourse on ethical AI integration in healthcare, indicating the need for careful consideration of ethical principles to ensure that AI enhances rather than undermines the compassionate care at the heart of palliative care. These findings serve as a foundation for future research and policy development in this emerging field.

Ethical Considerations in Using AI for Mental Health Diagnosis and Treatment Planning: A Scoping Review

Yewande Ojo

Proceedings of the International Conference on Artificial Intelligence and Robotics; Yaba Nigeria, 26-28 November 2024

Abstract

Integrating Artificial Intelligence (AI) with mental healthcare presents a paradigm shift in diagnosis and treatment planning, offering potential efficiency, accuracy, and personalisation improvements. However, this technological advancement allows for the exploration of a complex array of ethical challenges that demand careful consideration. This research explores the vital ethical dimensions surrounding the adoption of AI in mental health contexts, emphasising the reason for a balanced approach that maximises benefits while mitigating risks.

Central to these considerations is the imperative of privacy and data protection. This type of mental health information requires comprehensive robust safeguards to prevent unauthorised access or misuse while allowing for responsible data utilisation to drive AI-powered advancements. The assurance of fairness and non-discrimination in AI systems is critical, as racial bias could exacerbate disparities in mental healthcare access and outcomes. Transparency and explainability emerge as crucial factors in fostering trust and accountability. AI systems must be capable of providing clear rationales for their diagnostic and proposed treatment planning, which aids clinicians and patients to make informed decisions. This transparency is intimately linked to the principles of autonomy and informed consent, requiring that individuals fully understand the role of AI in their treatment and have the agency to accept or decline its use.

The integration of AI also necessitates a reevaluation of professional ethics and responsibilities for mental health practitioners. As AI systems assume more significant roles in diagnosis and treatment planning, the boundaries of professional judgment and accountability must be delineated. Moreover, the broader societal implications, including potential changes in public perception of mental healthcare and shifts in the healthcare workforce, warrant careful consideration.

Regulatory and governance frameworks play a pivotal role in addressing these ethical challenges. Policymakers face the complex task of developing adaptive regulations that foster innovation while ensuring robust ethical safeguards. This requires a collaborative approach involving clinicians, researchers, ethicists, patients, and technology developers.

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TECHNOLOGY/OTHER MEDIATION

Qualitative Assessment of Proposed Visual Key Information Pages for Informed Consent

Krista E. Cooksey, Eliana Goldstein, Clara Lee, Jessica Mozersky, Kimberly A. Kaphingst, Victor Catalan Gallegos, Mary C. Politi

Journal of Clinical and Translational Science, 21 November 2024

Open Access

Abstract

Introduction

The 2018 Common Rule revision intended to improve informed consent by recommending a concise key information (KI) section, yet provided little guidance about how to describe KI. We developed innovative, visual KI templates with attention to health literacy and visual design principles. We explored end users' attitudes, beliefs, and institutional policies that could affect implementing visual KI pages.

Materials and Methods

From October 2023-April 2024, we conducted semi-structured interviews with principal investigators, research staff, institutional review board (IRB) personnel, including those in oversight/management, and community partners. 40 participants from 3 academic institutions (in the Midwest, Southeast, and Mountain West) viewed example KI pages and completed interviews. We coded written transcripts inductively and

deductively based on the capability, opportunity, and motivation to change behavior (COM-B) framework. Data were analyzed using content analysis and organized thematically.

Results

Participants responded positively to the visual KI examples. They discussed potential benefits including improving information processing and understanding of study procedures, diversity in research, trust in research, and study workflow. They also described potential challenges to consider before widespread implementation: IRBs' interpretations of federal guidelines, possible impact on the IRB submission processes, the effort/skill required to develop visuals, and difficulty succinctly communicating study risks. There was no consensus about when to use visual KI during consent, and some wondered if they were feasible for all study types.

Discussion

Visual KI offers a promising solution to long-standing informed consent challenges. Future work can explore resources and training to address challenges and promote widespread use.

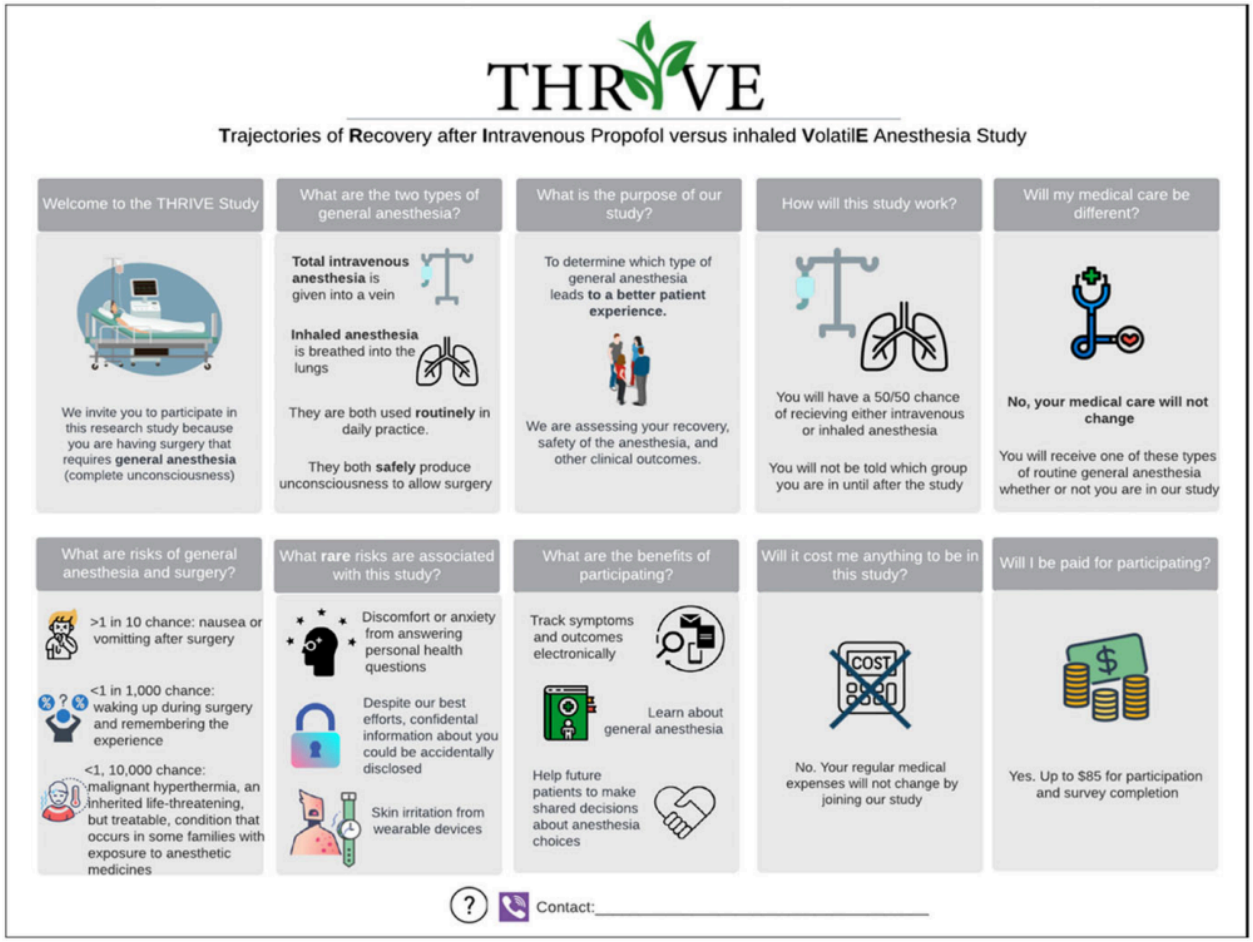

Figure 1. Example 1 displayed during qualitative interviews.

Editor's note: This is an example of a visual KI sheet provided in the article.

Comparison Between Multimedia and Written Informed Consent for Lumbar Transforaminal Epidural Steroid Injection: A Randomized Controlled Pilot Trial

Sunmin Kim, Nam Woo Kim, Francis Nahm, Eun Joo Choi, Pyung Bok Lee

Pain Physician, November 2024; 27(8) pp 529-535

Abstract

Background

Informed consent is a crucial ethical and legal requirement in medical practice to ensure that patients understand the risks, benefits, and alternatives of medical procedures. Recent advances in multimedia technology have facilitated the exploration of multimedia consent, aiming to enhance patient understanding and satisfaction. Ascertaining that patients have full comprehension of the procedures before opting to undergo them is especially important now that instances of such procedures as lumbar transforaminal epidural steroid injections (TESIs) are increasing.

Objectives

To determine the effectiveness of multimedia consent forms for lumbar transforaminal steroid injections.

Study design

Randomized clinical trial.

Setting

Outpatient multidisciplinary pain medicine center of a tertiary hospital.

Methods

A randomized controlled trial was conducted with 30 patients who received lumbar TESIs for lumbar radiculopathy. Patients were randomly assigned to either the multimedia consent group (Group M) or the conventional paper consent group (Group C). This study evaluated patients' comprehension of the procedure, their anxiety levels (using the State-Trait Anxiety Inventory short form), and the patients' post-procedure satisfaction.

Results

Group M showed significantly greater understanding of the procedure and reported lower levels of anxiety than did Group C ($P = 0.041$; $P = 0.03$). However, there were no statistically significant differences in post-procedure satisfaction between the groups ($P = 0.25$). These findings suggest that multimedia consent can effectively improve patient comprehension and reduce anxiety without significantly affecting patient satisfaction.

Limitations

First, the limited sample size of 30 patients restricts the applicability of our findings to a wider population, suggesting a need for larger studies to better assess the effects of multimedia consent. Second, conducting the study in a single hospital might have introduced bias. Multicenter research may provide a more diverse and accurate evaluation of the efficacy of multimedia consent.

Conclusion

This pilot study contributes to the growing evidence supporting the use of multimedia consent to enhance patient understanding and reduce anxiety, marking a promising direction for improving informed consent practices for less invasive procedures, such as lumbar TESIs. Further research is required to fully explore the benefits and limitations of multimedia consent forms in various medical settings.

The Impact of Artistic Representation on Patient Consent and Autonomy

Alberta Jeanne N.

Eurasian Experiment Journal of Scientific and Applied Research, 2024; 6(2)

Open Access

Abstract

Informed consent is fundamental to respecting patient autonomy in healthcare, ensuring that patients make voluntary, well-informed decisions about their treatment. However, consent processes can be hindered by communication barriers, time constraints, and differences in understanding complex medical information. Artistic representations in healthcare ranging from visual arts and music to theater—have emerged as potential tools to enhance patient comprehension and emotional engagement with medical procedures. This paper examines how various forms of art in healthcare environments may influence patient consent and autonomy. It considers the psychological, communicative, and therapeutic impacts of art, proposing that art can support consent by fostering deeper understanding and empathy between patients and healthcare providers. Four theoretical frameworks psychological impact, communicative theory, therapeutic influence,

and autonomy in healthcare are analyzed to assess the efficacy of artistic representations in supporting patient-centered consent. By synthesizing empirical studies on artistic strategies in clinical settings, this article highlights the importance of interdisciplinary approaches to patient autonomy and explores the ethical implications of integrating art into consent processes.

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HEALTH DATA/DATA

Smart contract empowered dynamic consent: decentralized storage and access control for healthcare applications

Aparna Singh, Geetanjali Rathee

Peer-to-Peer Networking and Applications, 10 December 2024

Abstract

The ability to share Electronic Health Records (EHRs) with the right people plays a crucial role in providing on-time diagnosis. The outsourcing of private health data on the cloud, with negligible control in the hands of the data owners, poses a significant challenge for e-healthcare applications. Obtaining the owner's consent is not just essential for data sharing but also to protect the privacy of the data being shared. With the help of Blockchain and Interplanetary File System (IPFS), this research paper proposes a purpose-based framework for obtaining dynamic consent before sharing data among healthcare providers, academicians, etc. The study develops a blockchain system on the Ethereum network to store encrypted EHRs on IPFS. This architecture allows for secure and privacy-enhanced data sharing. The proposed model demonstrates effectiveness in enhancing data security, privacy, scalability, ownership, and integrity of medical records. The cost analysis shows a negligible contract deployment cost of 0.00174363 ETH, equivalent to $2.78. The framework presents a viable solution for securing EHRs and obtaining dynamic consent, ensuring improved healthcare data management. The use of blockchain and IPFS offers a promising avenue for enhancing data security and privacy in e-healthcare applications.

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BIOBANKING

Stakeholder Perspectives on Research Consent and Reconsent for Procedures Involving Biological Samples and Biobanking of Children and Adolescents Living With HIV in Kenya

Research article

Josephine Aluoch, Ashley Chory, Michael Scanlon, Emma Gillette, Hillary Koros, Dennis Munyoro, Celestine Ashimosi, Whitney Beigon, Janet Lidweye, Jack Nyagaya, Allison DeLong, Rami Kantor, Rachel Christine Vreeman, Violet Naanyu, Winstone M. Nyandiko

Journal of the International Association of Providers of AIDS Care, 13 December 2024

Open Access

Abstract

Objective

To explore the perspectives of stakeholders on consenting and reconsenting children and adolescents living with HIV (CALWH) to participate in research involving biological sampling and biobanking. Stakeholders included CALWH, their caregivers, subject matter experts (SMEs) such as Institutional Review Board (IRB) members, Community Advisory Board (CAB) members, Healthcare Providers, researchers, and community leaders.

Study design
This qualitative study was conducted at the Academic Model Providing Access to Healthcare (AMPATH) in Kenya. Semi-structured interviews were conducted with CALWH, their caregivers, and SMEs. Audio recordings were transcribed, thematically analyzed, and emerging themes derived.
Results
In total, 99 participants were interviewed, of which the majority (52%) were female; 50% of CALWH were female with a median age of 17.5 years (range 11-24); 70% of caregivers and 44% of SMEs were female. All SMEs, CALWH, and caregivers emphasized that recontacting and reconsenting were their strong preferences for the use of biospecimens and also an essential procedure to address legal and ethical considerations and confidentiality. All CALWH wanted consent to detail how they will be informed about research findings and emphasized making their results available to them. Caregivers highlighted the importance of trust in the use of the stored samples to be maintained as per the consents.
Conclusion
Our findings revealed that CALWH and their caregivers want researchers to go beyond the typical information provided about biospecimen storage and use. They desire to be recontacted and reconsented as well as maintain ongoing communication with the research team about the research findings.

Patient Reflections on the Consent Process for Donating Extra Bone Marrow Research Samples to a Hematology Biobank: A Qualitative Interview Study

Madeleine Gordon, Oksana Motalo, Erika Camilleri, Taryn Chesser, Gary Davis, Grace Fox, Katya Godard, Caryn Y Ito, Jocelyn Lepage, Krystina B. Lewis, Wendy Nuttall, Craig Peloshok, Stuart Nicholls, Mitchell Sabloff
Blood, 5 November 2024
Abstract
Background
Bone marrow samples taken at the time of diagnosis are essential for early diagnosis and treatment of acute leukemia (AL) and additionally can be used to understand the underlying biology. This requires bone marrow samples to be taken for clinical purposes as well as for research. Due to the rapid onset and progression of AL, there is a narrow time frame from initial disease suspicion to diagnosis confirmation and treatment initiation. This can present challenges with consenting patients for additional, research-specific bone marrow samples to be obtained during the diagnostic procedure. While patients with cancer are generally positive towards contributing to medical research, recruitment rates for bone marrow samples are low, hindering translational research aimed at improving patients' outcomes in AL. Little is known about patient perspectives with respect to the informed consent process under these time-sensitive circumstances, or how these processes can improve research sample provision while also maintaining respect for patient autonomy and supporting their decision-making during a stressful time. The current study is aimed to better understand the experiences of patients with AL in relation to consenting to provide extra bone marrow samples for research during the diagnostic procedure.
Methods
Semi-structured interviews were conducted with patients treated for AL between January 1, 2017 and December 31, 2021 at The Ottawa Hospital. Patients were eligible if they were admitted to hospital urgently to confirm AL diagnosis, received intensive induction chemotherapy and spoke English or French. Interviews proceeded until data saturation was reached.
Results
Seventeen patients were interviewed. Patient experiences centred on three key areas within the consent process: Preparation and awareness of research, logistical challenges related to obtaining consent within the limited time frame and having emotional and psychological support. Patients were supportive of increasing public knowledge about research and noted the important roles that friends and family members played in providing support and retaining information. Despite the time pressure and anxiety that came with a diagnosis of AL, the decision to give a research sample did not in itself require much deliberation. Decisions

were informed by proximal factors such as impact on patient health and family, the anticipated pain associated with the bone marrow procedure and its duration, as well as distal factors such as altruism and trust in the healthcare team. Patients valued as much time as possible between the consent process and the bone marrow extraction. Further, they valued information about the level of anticipated procedure-associated pain, the purpose of ongoing research and its use of samples, and details regarding the privacy and security of the research samples.

Conclusion

Our findings suggest that the success of consenting for additional bone marrow samples for research may be optimised through multiple changes, such as those pertaining to the environment where the consent discussion takes place as well as a period of time for reflection on the discussion prior to the procedure, in addition to the type of information provided, the recognition of patient concerns surrounding discomfort and how it will be mitigated and, finally, the value of current and future research.

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GENOMIC MEDICINE/GENE EDITING

What does a consent conversation for whole genome sequencing look like in the NHS Genomic Medicine Service? An observational study

Holly Ellard, Huda Alfardus, Saskia Sanderson, Celine Lewis

European Journal Of Human Genetics, 26 November 2024

Open Access

Abstract

Patient choice consent for whole genome sequencing (WGS) through the Genomic Medicine Service in England covers consent to diagnostic testing and an invitation to the National Genomic Research Library (NGRL). Little is known about what consent conversations for WGS look like in practice. We audio-recorded and analysed the content and structure of consent appointments (n = 26) between healthcare professionals (HCPs) and parents of children with rare disease across seven NHS Trusts. Appointments frequently covered the potential findings from testing, implications for family members, and DNA storage, but often omitted that data may be reanalysed in the future if a diagnosis is not made. Consent to the NGRL was typically sought during the same appointment; these discussions varied in content, but frequently included a background to the NGRL and data security. HCPs often tempered expectations around what WGS can achieve and asked questions to clarify parents' understanding, but less commonly elicited parents' values and concerns. Administrative tasks were time-consuming, but took less time when consent was recorded digitally. Future training should emphasise how to elicit patients' values and concerns. Digital infrastructure and hiring roles such as genomic associates to support consent may be important strategies to meet the workload demands of WGS.

Variance of Consent for Genetic Return of Results Across Sociodemographic Traits

Christine Jovanovic, Brynn Mayer

University of Illinois Library, 25 November 2024

Abstract

There is a gap in the literature assessing whether demographic variables are associated with uptake of genetic testing in the absence of identified barriers of referral and cost. Because the All of Us Research Program offers genetic testing and counseling at no cost, we propose to address this gap using data from the University of Illinois Chicago All of Us Research Program, which includes over 16,000 individuals. This study will aim to assess whether consent to receive genetic return of results (GRoR) varies significantly across

relevant sociodemographic factors among the diverse participants in the University of Illinois Chicago (UIC) All of Us cohort.

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CAPACITY TO CONSENT

Obtaining Informed Consent From People With Dyslexia: The Role Of Easy Language

Marija Jozipović, Mirjana Lenček
Croatian Journal of Rehabilitation Research, 19 December 2024
Open Access
Abstract
Obtaining informed consent is a standard procedure in research practice. However, it is not sufficient, even if an individual chooses to participate voluntarily in research process, for the researchers to be able to claim that they have obtained informed consent. The consent must be of sufficiently 'high quality': it must not only be informed, but also valid, i.e., it must contain the following three elements: adequate information, voluntariness, and competence. Although preparing informed consent is a difficult process in general, it is particularly challenging when working with certain populations, such as clinical groups who have language and literacy difficulties, e.g., dyslexia. A lack of understanding of the basis and specific characteristics of this disorder can have negative effects on people with dyslexia (PwD) such as in the form of unwanted misunderstandings, psychological stress, negative effects on their learning processes, as well as unethical treatment in the research process. Studies have shown that PwD can be particularly vulnerable to research that might exploit, imply, or attribute unsafe practices to them and their difficulties, especially in connection with research recommendations that require written informed consent. Easy language refers to the language adaptation of a text to facilitate both reading and comprehension, particularly for PwD. Therefore, the use of the easy language guidelines for language adaptation and graphical adjustment is important when obtaining informed consent from PwD.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

What Is Truly Informed Consent in Medical Practice and What Has the Perception of Risk Got to Do with It?

Catherine Jane Calderwood, Geir Sverre Braut, Siri Wiig
Healthcare, 24 December 2024
Abstract
Making decisions about risk, describing and appropriately explaining risk in medical practice is complex for patients and professionals. In this paper, we investigate how the concept of consent is practiced differently in the UK and Norway and discuss pros and cons of the chosen approaches from a patient safety culture perspective. We argue that consent is a fundamental part of the safety culture and influence on health system functioning and patient and staff safety. Examples from the UK and Norway are used and discussed in terms of how risk perception influences consent processes and practices.

'Some parts of the consent form are written using complex scientific language': community perspectives on informed consent for research with pregnant and lactating mothers in Uganda

Research

Adelline Twimukye, Sylvia Nabukenya, Aida N. Kawuma, Josephine Bayigga, Ritah Nakijoba, Simon Peter Asiimwe, Fredrick Byenume, Francis Williams Ojara, Catriona Waitt

BMC Medical Ethics, 21 December 2024

Open Access

Abstract

Background

Appropriate language use is essential to ensure inclusion of diverse populations in research. We aimed to identify possible language-related barriers regarding the informed consent process and propose interventions to improve clarity and understanding of pregnant and breastfeeding women participating in research.

Methods

A cross-sectional qualitative study employing focus group discussions (FGD) was conducted in Uganda from August 2023 to September 2023, involving a diverse group of stakeholders from the community, including community members, research participants, and Community Advisory Board members. 19 FGD comprised adult participants representing at least six different mother tongues (Luganda, Acholi, Runyankole, Runyoro, Lugbara and English). An inductive thematic approach was utilized for data analysis using NVivo version 12 software to identify language factors that influence informed consent. A series of community validation workshops ensured concurrence.

Results

At the individual level, language barriers, and low levels of literacy contributed to poor comprehension, thus hindering ability to achieve genuine informed consent. At the health facility level, participants reported that there was use of inappropriate, unclear language including inaccurate translations, with poor and complicated grammar in some consent forms. Participants reported that complex medical terminologies are difficult to translate to local languages. Community members highlighted that social/cultural norms in language use affected cultural perceptions of informed consent. To enhance understanding for individuals without education in science, participants suggested simplification of terminologies and avoidance of complex medical jargon. Researchers should identify participants' preferred languages and communicate in those languages whenever possible. If researchers are not fluent, trained interpreters should be identified. Informed consent documents must be translated into local languages to ensure participants comprehend the study's purpose, procedures, risks, and benefits. Involving community members during development and translation of these documents can provide valuable insights into local dialects and culturally specific concepts, ensuring that study tools like surveys and consent forms are accurate and respectful.

Conclusion

Language barriers influence the informed consent process within communities in Uganda. These can potentially be resolved at individual, health system and community levels. Consideration of locally understandable terms in community-facing study documentation is likely to enhance understanding and could improve research participation, although further studies are needed to assess these. The use of appropriate language ensures that informed consent is genuine in keeping with principles of Good Clinical Practice, and developing a research communication strategy should be part of inclusive research design.

Patients' satisfaction with the preoperative informed consent in elective gynecological surgery in a tertiary hospital, BMA

Thossaporn Chuaysatit, Apichaya Pradyachaipimol, Jiraporn Luengmettakul

Thai Journal of Obstetrics and Gynaecology, 18 December 2024

Abstract

Objectives
This study aimed to evaluate patients' satisfaction with the preoperative informed consent process in elective gynecological surgery.
Materials and Methods
This cross-sectional study was conducted at Charoenkrung Pracharak Hospital, Bangkok, Thailand, from October 2023 to May 2024. Personal data and satisfaction with the preoperative informed consent process were collected on the second postoperative day. The Thai version of the Decisional Satisfaction Scale (DSS) was used to measure the satisfaction and the Informed Consent Process Questionnaire was used to assess knowledge of surgery and perception of informed consent process. Bivariate associations between highly satisfied and not highly satisfied groups were tested using Fisher's exact test.
Results
A total of 178 participants were enrolled, with mean age of 42.48 years. Most participants agreed or strongly agreed with the statements on the DSS, a mean total score was 27.87, indicating high overall satisfaction. 135 patients (75.8%) were highly satisfied with the informed consent process. There were several factors with significant differences between the highly satisfied group and not highly satisfied group. These included being informed about the consequences of not undergoing the procedure, knowing enough about the procedure to explain it, being informed about the reasons for prolonged urine catheterization and being given the opportunity to refuse the procedure.
Conclusion
This study highlights the critical role of an effective informed consent process in elective gynecological surgery. High patient satisfaction is achieved when communication and patient participation are prioritized. Future research should explore these dynamics in different settings and diverse populations.

Assessing informed consent in surgical patients at Queen Elizabeth Central Hospital in Blantyre, Malawi: a cross-sectional study

Lucy Kaomba, Wakisa Mulwafu
Malawi Medical Journal, December 2024; 36(4) pp 249-254
Abstract
Introduction
Informed consent is critical to medical practice, and a clearly outlined process that results in signing the consent form may improve the validity of the given consent. There is a paucity of studies in Malawi that have assessed the informed consent process in surgical patients.
Aim
To assess the informed consent process for patients undergoing surgery at QECH in Malawi.
Methods
A cross-sectional quantitative descriptive study was conducted among postoperative patients in the adult surgical wards at QECH through face-to-face interviews. The calculated sample size was 235. A consecutive sampling technique was used. Those below 18 years and those who didn't or couldn't consent were excluded. Data was entered and analyzed in Microsoft Excel 2016 and IBM SPSS 25.0. The level of significance was considered as $P<0.05$.
Results
A total of 222 patients were interviewed. The age range was 21 to 75 years, with a median of 38.5. Two hundred and twelve (95%) patients signed a consent form before surgery, and 21 (9%) knew the content of the form. Most patients, 100 (47%) had a primary school education, and 156 (70%) could read and write. Those with secondary or tertiary education were more likely to want to ask a question given the opportunity (OR 2.82, p= 0.0012), but there was no significant difference in the likelihood of being given time to ask questions between the two groups who had primary and no formal education vs those who had secondary and tertiary education (OR 1.4, p=0.3367)
Conclusion

This study highlights the necessity of employing effective communication strategies during the consent process for surgical procedures and the need to tailor the consent form to the patient's education level.

Awareness of consent among Nigerian orthodontic patients; a study of perceptions and practices

Sylvia Simon Etim, Onyinye Dorathy Umeh

Acta Stomatologica Marisiensis, December 2024

Abstract

Introduction

Orthodontic treatment is elective but not without risks. Prospective patients need to be fully informed of their treatment options and understand the associated risks and benefits.

Aim of the study

To assess the perception of Nigerian orthodontic patients regarding the consent and assent-giving process before orthodontic treatment.

Material and Methods

A total of 349 patients from the University of Port Harcourt Teaching Hospital and Lagos University Teaching Hospital, who received orthodontic treatment between December 2023 and May 2024, participated in this study. A 21-item questionnaire was administered via Google Forms. The questionnaire contained demographic questions and items assessing knowledge, perception, and practice of consent in orthodontics. Data were analyzed using IBM SPSS Version 26, employing descriptive statistics (frequencies and percentages).

Results

Of the 349 participants, 99 (28.4%) were male, and 250 (71.6%) were female, with a mean age of 23.43 ± 10.49 years. Of the study population, 88% of female and 91.9% of male participants had heard of consent before treatment. A total of 93.1% of participants gave consent, with 78.5% of these being verbal. Pain (45.6%) was the most commonly explained complication, while infection (6.9%) was the least. In terms of satisfaction, 92% of participants were satisfied with the consent process.

Conclusion

Most Nigerian orthodontic patients are aware of the consent process and are generally satisfied with it. Orthodontists in Nigeria should prioritize obtaining written informed consent to ensure patient protection and avoid potential legal issues.

Editor's note: Acta Stomatologica Marisiensis is the Journal of George Emil Palade University of Medicine, Pharmacy, Science, and Technology in Romania.

The Role of Informed Consent in Medical Disputes at State University Hospitals

Putu Agus Prawira Eka Putra, Gusti Ayu Putri Kartika, R.A. Tuty Kuswardhani

Unram Law Review, 11 November 2024

Abstract

The research aims to understand how informed consent functions in the context of medical disputes at state university hospitals in Indonesia. The main benefit of the study is to provide an overview of how informed consent offers legal protection to the medical profession, particularly in resolving disputes that may arise in the hospital setting. The research utilizes a normative legal research method, focusing on the examination of written laws, regulations, and legal materials applicable in Indonesia. The research concludes that the thoroughness of informed consent documentation is crucial, especially for medical procedures that carry high risks. This thoroughness serves as a legal safeguard for medical professionals, ensuring their protection in case of disputes. Enhanced attention to the completeness of informed consent is necessary to mitigate the risks for doctors and provide legal security within the medical field at state university hospitals.

Barriers to Familial Consent in Deceased Organ Donation among Racialized and Indigenous Communities in Canada: A Qualitative Study

Simran Sandhu, Jagbir Gill, Reetinder Kaur

Journal of the American Society of Nephrology, October 2024

Poster

Metrics

Background

In Canada, over 3700 people are on the organ transplant list, with deceased donor kidney transplants making the majority of transplants completed annually. Despite the increasing numbers of transplants, populations marginalized by race and ethnicity have lower rates of organ donation registration and are less likely to consent to donation. Gaining insight into barriers to providing consent is critical in developing strategies to address disparities. This study aimed to identify barriers to familial consent among members of racialized and Indigenous communities.

Methods

48 participants were recruited through community-based organizations in British Columbia (BC) and included BC residents, aged over 19, who spoke English. 31 participants completed interviews and 17 completed focus groups. Participants were oversampled for members of racialized and Indigenous communities. A case vignette was used to collect data with data analyzed using summative content analysis.

Results

Four overarching barriers were identified: 1) system-level; 2) community-based; 3) related to decision-making; and 4) informational. System-level barriers highlighted mistrust of Canadian healthcare institutions, perceived coercion, and the role of language in consent. Community-based barriers involved ideas around the deceased body, funeral, afterlife, and general perceptions of organ donation. Decision-making was affected by family dynamics and donor and recipient identity. Informational barriers such as age eligibility also influenced consent. Facilitators to address barriers include culturally diverse resources, increasing community knowledge, and providing language, cultural, and religious support to build trust and facilitate discussions.

Conclusion

This study highlights barriers and modifiable determinants to familial consent in deceased organ donation among members of racialized and Indigenous communities. Although it examines barriers to familial consent for all organ donation, findings are of significant relevance to kidney care, as patients waiting for kidney transplants constitute the majority of patients on transplant waitlists. Education and engagement initiatives must be targeted at the health system and community levels to fully address barriers to consent and reduce racial and ethnic disparities in organ transplantation.

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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].

Informed consent in global outreach

Book Chapter
Meseret E. Kassa, Morris E. Hartstein
Global Oculoplastics: A Guide to the Care of Patients in Resource-Poor Environments, 2025; pp 93-95
Abstract
Informed consent in resource-poor settings is equally important as in Western settings. However, language and cultural barriers exist, making it much more challenging to obtain. This chapter will discuss the potential barriers, enhance understanding and respect of the culture, and discuss methods to modify the process in order to successfully obtain informed consent in resource-poor environments.

Editor's note: The barriers discussed in this chapter include understanding and respecting community norms, cultural and religious variations, communities with strong social interdependence family structure, informed consent for women, deference to physician, rejection of medical interventions, confidentiality, justice, and patient anonymity, and language and illiteracy.

Women's Decision-Making Autonomy and Free and Informed Consent in Accessing Reproductive Health Care in Community Settings: A Qualitative Study in the N'djili Health Zone (Kinshasa City, Democratic Republic of the Congo)

Bertine Mbongopasi Ekeni, Koto-Te-Nyiwa Ngbolua, Bernard Ntoto Nkunzi, Félicien Mukandu Basua Babintu
Mechanisms and Machine Science, 14 November 2024
Abstract
The aim of this study is to identify factors influencing the improvement of decision-making autonomy and free, informed consent among women in the N'djili Health Zone. A cross-sectional analytical study was conducted from September 25 to October 26, 2022. Results revealed that participants faced challenges in exercising autonomy over reproductive health decisions, impacting their capacity to give informed consent. Additionally, a lack of information and awareness about reproductive health rights and options perpetuates existing inequalities. Developing educational and awareness programs that inform women of their rights, while involving the community and health professionals, are crucial to fostering sustainable change.

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RIGHTS/LEGAL/LEGISLATIVE

How Much Is Enough?: Informed Consent in Healthcare Minimal-Risk Research and Quality Improvement

Book Chapter
Paula Garcia McAllister
IRB, Human Research Protections, and Data Ethics for Researchers, 2025 [IGI Global]
Abstract

This chapter provides key takeaways for investigators and clinical researchers in healthcare settings doing minimal-risk research and quality improvement. Following an in-depth overview of the current regulations for informed consent (IC) with a focus on the 2018 regulatory revisions, it then describes the current state of IC in quality improvement activities commonly employed in learning healthcare systems and the ethical challenges they present. This chapter does not address the complexities of IC in clinical trials or in research with greater than minimal risk because the IC processes in such activities are well established. Instead, the focus is on what the regulations state regarding the requirements of informed consent; when and how consent can be waived; how research and quality improvement activities differ from the viewpoint of IC; and what information potential research subjects need to make decisions about participating in minimal-risk research and quality improvement in healthcare settings.

Increased Infectious Risk Donor Status and Equity-Relevant Predictors of Organ Donation Organization Approach and Caregiver Consent for Deceased Organ Donation in a Canadian Province (2015-2021)

Murdoch Leeies, Karen Doucette, Brenden Dufault, Tricia Carta, Owen Mooney, Carmen Hrymak, Nicolette Balzer, Ben Borys, Yasmine El-Salakawy, Mirna Ragheb, Davie Xie, Emily Christie, David Collister, Matthew J Weiss, Sonny Dhanani, Julie Ho

Clinical Transplantation, 2 December 2024

Open Access

Abstract

Background

Current donor risk assessments to identify risk of infectious transmission through transplantation have been criticized as unnecessarily discriminatory for sexual and gender minorities. Little is known about how increased infectious risk donor (IIRD) patients transition through the deceased donation system. We sought to evaluate how IIRD status and other equity-relevant identities impacted the likelihood of a caregiver of a deceased donor being approached for organ donation and the likelihood of caregiver consent.

Methods

We conducted a retrospective, observational cohort study of potential deceased donors referred to a Canadian provincial organ donation organization (ODO) from 2015 to 2021. Our primary outcome is the difference in the likelihood of being approached by the ODO for organ donation for IIRDs compared to baseline risk donors, amongst referred potential deceased organ donors. Secondary outcomes include the difference in caregiver consent for donation for IIRDs compared to baseline risk donors, amongst approached deceased organ donors. We built multivariable logistic regression models to evaluate these outcomes.

Results

Amongst all referred potential deceased organ donors, IIRD status did not impact the likelihood of being approached by our ODO for deceased organ donation compared to baseline risk donors (OR 1.695, 95% CI 0.902-3.197). Amongst approached deceased organ donors, there was no significant difference in caregiver consent for donation between IIRD and baseline risk donors (OR 1.854, 95% CI 0.902-3.929). Approached eligible IIRDs were younger with fewer comorbidities, lower KDPI scores, were more likely to have died from anoxic brain injuries and have death determined by neurologic criteria, and more likely to have non-medical injection drug use than baseline risk donors. There were no cases of donor-derived human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) reported for any donors included, regardless of IIRD status, during the study period.

Conclusions

We found no significant difference in the likelihood of ODO approach in IIRDs compared to baseline risk donors. There was no difference in caregiver consent for donation in IIRDs compared to baseline risk donors. A greater proportion of IIRDs became successful donors compared to baseline risk donors.

Free, prior, and informed consent, local officials, and changing biodiversity governance in Hin Nam No, Laos

Peter Bille Larsen, Chantaly Chanthavisouk

Conservation Biology, December 2024; 38(6)

Abstract

Free, prior, and informed consent (FPIC) is now a globally established norm and is a condition of equitable engagement with Indigenous peoples and local communities in biodiversity conservation. However, implementation is frequently questioned in terms of its efficacy in top-down-driven governance contexts. Local officials represent core voices often absent from mainstream discourse. Conservation practices are framed by local discourses, value frameworks, and relationships that offer critical opportunities to tailor localized consent processes. Relative to an FPIC process for a prospective World Heritage Site in Hin Nam No National Park, Laos, we examined the importance of mediation by local officials in a comanagement context. The mediation led to commitments to address long-standing community grievances and reconcile conservation and development relationships in the area. Building the capacity of local officials as critical duty-bearers helped shape rights-based conservation and development outcomes. Enhancing nonconfrontational mechanisms for rights holders to air concerns and dialogue spaces for duty-bearers to respond plays a key role in this respect.

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COVID-19

When Understanding Fails: How Diverging Norms in Medicine and Research Led to Informed Consent Failures During the Pandemic

Daniel Pinto

Journal of Medical Ethics, 18 December 2024

Abstract

During the COVID-19 pandemic, there were many vaccine trials which had significant purposes which participants needed to understand to validly consent. For example, participants needed to understand that the purpose of dose-escalation vaccine trials was to give incremental doses of vaccine until participants became ill. Likewise, participants needed to understand that if they received placebos, they could no later take a genuine vaccine to preserve the integrity of the trials. Yet, these intuitive judgements about what participants need to understand to validly consent are rejected by recent accounts of consent. According to these accounts, as long as participants were given a good opportunity to learn these purposes, they do not need to actually understand them to consent. In this paper, I reject this consensus, and I argue that participants who failed to understand these aims associated with vaccine trials failed to provide legitimate consent. I defend this claim by developing and defending a new understanding condition for valid consent. According to this understanding condition, a participant must understand when a consent transaction has features which violate the norms which govern the medical practice with which they are acquainted. I argue that this condition is independently plausible and best explains why participants needed to understand these aims associated with vaccine trials to validly consent.

Medical Ethics and Informed Consent to Treatment: Past, Present and Future

Alan Mordue, Elizabeth A Evans, James T Royle, Clare Craig

Cureus, 9 December 2024; 16(12)

Open Access

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.

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MEDICAL/SURGICAL

Consent to medical student teaching: an observational, cross-sectional study exploring the patient view

Research

Niki Newman, Fraser McKenzie, Jonathan M. Wells, Tim Wilkinson, John Dean, Matthew Doogue, Lutz Beckert

BMC Medical Education, 24 December 2024

Open Access

Abstract

Background

New Zealand guidelines stipulate that patient consent is obtained for medical student involvement in clinical care, however, patients' preferences regarding consent for medical student teaching have not been widely explored. This study examined patient preferences for consent for medical student teaching with the aim to increase patient empowerment, to optimise care and to reflect societal expectations more accurately.

Method

Observational, semi-qualitative, cross-sectional study of in-patients. Each participant was presented with a series of nine hypothetical clinical scenarios and were allowed a limited number of responses. For each scenario the participants completed a short questionnaire about their preferences for consent. These included their preferred mode of consent (implicit, verbal or written), timing of consent, and who should take their consent. The analysis used descriptive statistics and ordinal logistic regression mixed models to investigate associations between patient characteristics and chosen mode of consent.

Results

There were 123 participants (50% male), median age was 64 years. Patients were admitted to either medical (69%), surgical (22%) or women's health (9%). Increasing age was statistically significantly associated with a preference for verbal and implicit rather than written consent with the exception of 'breaking bad news' and 'bedside teaching'. The majority of patients preferred verbal consent across all nine clinical scenarios (57–82%), including two surgical scenarios where verbal consent was preferred by 59%. Most patients preferred the supervising doctor to take consent, with no clear preference about the timing.

Conclusions

This study identifies the patient voice in the consent process for the involvement of medical students in clinical care. Although the patients' views generally align with an existing national consensus statement, there is variability in the expectations of the patients suggesting flexibility in the consent process is still needed. The preference for older patients for verbal or implicit consent compared with younger patients for more invasive scenarios highlights the need for consideration of inter-generational differences. Most patients in this study were willing to contribute to student learning in all scenarios.

The German Medical Informatics Initiative Broad Consent in the Emergency Department: A Single Centre Prospective Observational Study to Assess Consenting Mode Dependent Success Rates

Felix Patricius Hans, Jan Kleinekort, Melanie Boerries, Alexandra Nieters, Gerhard Kindle, Micha Rautenberg, Laura Bühler, Gerda Weiser, Michael Clemens Röttger, Carolin Neufischer, Matthias Kühn, Julius Wehrle, Anna Christine Slagman, Antje Fischer-Rosinsky, Larissa Eienbröker, Frank Hanses, Gisbert Wilhelm Teepe, Hans-Jörg Busch, Leo Benning

JMIR Medical Informatics, 19 November 2024

Abstract

Background

The Broad Consent (BC) by the German Medical Informatics Initiative (MII) was developed to serve as a national blueprint for consenting patients for the use of routinely collected medical-, insurance- and contact data and biomaterials for research purposes, ensuring compliance with European General Data Protection Regulation (GDPR). Emergency departments (EDs) are characterized by a broad and unselected patient population that provides the opportunity to include patients from different demographic and socioeconomic groups, as well as from different disease groups. While also posing regulatory and ethical challenges, obtaining BC in an ED environment presents a promising opportunity to increase the availability of ED data for research.

Objective

This study aimed to evaluate the success rate of obtaining BC through different consenting approaches in a tertiary ED. The study also explored factors influencing consent and dropout rates.

Methods

A single-center prospective observational study was conducted in a German tertiary ED from September to December 2022. Patients were randomly selected (every 30th patient) and screened for eligibility to be informed about BC. Eligible patients were informed through one of three modalities: (a) directly in the ED, (b) during inpatient stay on the ward, or (c) via telephone after discharge. The primary outcome was the success rate of obtaining BC within 30 days of ED presentation. Secondary outcomes included analysis of potential influences on the success- and dropout rate concerning patient characteristics, information mode, and the interaction time applied for the information.

Results

Out of 11,842 ED visits in the study period, 419 patients were randomly screened for BC eligibility, with 151 meeting the inclusion criteria. Of these, 68 patients (45.0 %) consented to at least one BC module, while 24 (15.9 %) refused participation. The overall dropout rate was 39.1 %, with the highest dropout occurring in the telephone-based group (52.3 %) and lowest in the ED group (7.1 %). Patients who were informed face-to-face during the inpatient stay following their ED treatment had the highest consent rate (85.2 %), while those approached in the ED or by telephone consented in 69.2 %. Logistic regression analysis indicated that longer interaction time was significantly associated with higher consent rates, whereas female gender was associated with increased dropout rates. No significant differences were found between consenting and non-consenting groups concerning age, triage category, billing details (inpatient treatment), or diagnosis distribution.

Conclusions

Obtaining BC in an ED environment is feasible, and showed representative inclusion of the ED-population. However, discharge from the ED and female gender negatively influenced the odds of obtaining consent to the BC. Face-to-face interaction significantly improves consent rates and seems to be the most promising approach for consenting inpatients. Telephone-based approaches, conversely, resulted in higher dropout rates but equal consent rates as the direct consenting in the ED. The study highlights the need for tailored consent strategies, indicating a benefit to maintain staff in EDs and on wards to provide information on BC and obtain consent from eligible patients.

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GENERAL/OTHER

Consent under Duress

Book

Tom Dougherty

Oxford Academic, 31 December 2024

Abstract

Consent can make actions morally permissible. But consent can lose its moral force when it is given under duress. Understanding how this happens requires answering the question of which types of duress undermine consent. Uncontroversially, severe coercion, like threats of violence, can prevent consent from creating moral permissions. But what about minor duress? Duress from natural causes? Duress from social norms? Duress that is merely apparent to the consent-giver with no objective basis in reality? To answer these questions, Consent under Duress defends an account that follows two key approaches. First, it adopts an expansive approach that broadens the class of misconduct that is constituted by acting on someone's consent that is given under duress. Second, it adopts a scalar approach that allows that consent can be invalidated to varying degrees, which in turn can track the degrees of the severity of the duress to which the consent-giver is subject. The expansive and scalar approaches work in tandem. Once there is an expansion of the aforementioned class of misconduct, additional theoretical resources are needed to draw moral distinctions within this heterogeneous class. By providing these resources, the scalar approach supplements the expansive approach. Meanwhile, once it is recognized that consent can be partially invalidated by minor duress, it is necessary to expand the class of what constitutes misconduct that is constituted by acting on someone's consent that is given under duress. By arguing independently for these mutually reinforcing approaches, Consent Under Duress offers a robust defense of their combination.

Scaffolding Informed Consent

Extended Essay

Dominic Wilkinson, Neil Levy

Journal of Medical Ethics, 20 December 2024

Abstract

The principle of respecting patient autonomy underpins the concept and practice of informed consent. Yet current approaches to consent often ignore the ways in which the exercise of autonomy is deeply epistemically dependent.

In this paper, we draw on philosophical descriptions of autonomy 'scaffolding' and apply them to informed consent in medicine. We examine how this relates to other models of the doctor–patient relationship and other theories (eg, the notion of relational autonomy). A focus on scaffolding autonomy reframes the justification for existing ways of supporting decisions. In other cases, it suggests a need to rethink how, when and where professionals obtain consent. It may highlight the benefit of technology for supporting decisions.

Finally, we consider the implications for some high-stakes decisions where autonomy is thought to be critical, for example, termination of pregnancy. We argue that such decisions should not be free from all sources of influence—rather they should be protected from undesired influence.

Excerpt

…In what we might call a socially supported model of decision making, individuals make their decisions with input from others. They seek opinions and advice from family and friends, and information from medical professionals, and then attempt to weigh that information in coming to a decision that reflects their own values and outlook. Such socially supported decisions are very plausibly better for the input of others: a broader range of considerations are brought to bear than the individual could marshal on their own. But the final decision-making reflects cognition that is fully the individual's own. Properly scaffolded models, however, go beyond socially supported models. On the latter, decision-making reflects cognition that is

distributed across agents and across the environment. Scaffolded autonomy draws its inspiration from distributed models of cognition…

"Informed" consent? Ethical considerations for clinicians using therapy-matching platforms

Colette N. Delawalla, Lorenzo Lorenzo-Luaces

Journal of Consulting and Clinical Psychology, 2024; 92(12)

Abstract

Mental health care in the United States is prohibitively difficult to access. Barriers of entry include a shortage of providers, high cost of services, insufficient insurance coverage, and layers of bureaucracy. This problem of low supply and high demand created a unique environment for capitalist problem solvers to enter the therapeutic market, via "therapy-matching platforms." Several ethically related Federal Trade Commission (FTC) complaints and independent investigations into these platforms highlight that the forward progress is not without growing pains. This commentary focuses on ensuring proper informed consent when providing services on therapy-matching platforms (e.g., BetterHelp, TalkSpace).

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PRE-PRINT SERVERS [*all subject areas*]

Empowering Patients for Disease Diagnosis and Clinical Treatment: A Smart Contract-Enabled Informed Consent Strategy

Md Al Amin, Hemanth Tummala, Rushabh Shah, Indrajit Ray

arXiv, 13 December 2024

Open Access

Abstract

Digital healthcare systems have revolutionized medical services, facilitating provider collaboration, enhancing diagnosis, and optimizing and improving treatments. They deliver superior quality, faster, reliable, and cost-effective services. Researchers are addressing pressing health challenges by integrating information technology, computing resources, and digital health records. However, digitizing healthcare introduces significant risks to patient data privacy and security, with the potential for unauthorized access to protected health information. Although patients can authorize data access through consent, there is a pressing need for mechanisms to ensure such given consent is informed and executed properly and timely. Patients deserve transparency and accountability regarding the access to their data: who access it, when, and under what circumstances. Current healthcare systems, often centralized, leave much to be desired in managing these concerns, leading to numerous security incidents. To address these issues, we propose a system based on blockchain and smart contracts for managing informed consent for accessing health records by the treatment team members, incorporating safeguards to verify that consent processes are correctly executed. Blockchain's inherent immutability ensures the integrity of consent. Smart contracts automatically execute agreements, enhancing accountability. They provide a robust framework for protecting patient privacy in the digital age. Experimental evaluations show that the proposed approach can be integrated easily with the existing healthcare systems without incurring financial and technological challenges.

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CURRENT 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].

Ethical Guidelines for Research Using Pervasive Data

A Notice by the U.S. National Telecommunications and Information Administration on 12/11/2024
Public comment period that ends 01/15/2025.
SUMMARY:

The National Telecommunications and Information Administration (NTIA) is seeking public input on the potential writing of ethical guidelines for the use of "pervasive data" in research. "Pervasive data" refers to data about people gathered through online services. NTIA will rely on these comments, along with stakeholder engagements, in considering whether to draft and issue non-binding guidelines to assist researchers working with pervasive data. Such guidelines, if warranted, would detail how independent third-party researchers [3] can work with pervasive data while meeting ethical expectations of research and protecting individuals' privacy and other rights...

The goal of ethical guidelines would be to outline principles and best practices that researchers, research institutions, data intermediaries,[4] and online service providers can choose to follow when involved in research with pervasive data…

Pervasive data can be drawn from global networks and may be analyzed by an international community of researchers. Therefore, **it is increasingly important to use a global lens to address ethical issues in pervasive data.** Advancements in research using pervasive data may benefit from international collaboration and agreed-upon norms for ethical research and the protection of privacy and other rights…

Risks to data subjects presented by research with pervasive data include reidentification of anonymous user accounts; release or inference of information that can be used to perpetuate a range of privacy and other individual-level harms, including fraud, impersonation, discrimination, reputational harms, and emotional distress; and decreased willingness to post and access information online and engage in the digital economy...

Sample Questions:

6**. Consent and autonomy are key principles in human subjects research ethics. However, users of online services may be required to divulge certain personal information and/or have no ability to freely make decisions about its use.[44] How should researchers working with pervasive data consider consent and autonomy?**

a. What, if any, would be an appropriate consent model for research with pervasive data? How and how often should consent occur?

b. Are there alternative models to traditional consent that either support autonomy or provide protections for data subjects in cases where autonomy is limited?

c. How, if at all, is user autonomy influenced by context, such as the need to use online services for school, work,[45] or socializing?

11**. What existing ethical frameworks, such as those from professional organizations [64] or government agencies,[65] should be considered when drafting national-level ethical guidelines for research with pervasive data?**

a. To what extent do existing frameworks apply to the collection and use of pervasive data?

b. What modifications of existing frameworks might be necessary to ensure that those frameworks are applicable to the needs of research with pervasive data?

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NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

No new normative or regulatory guidance or analysis referencing consent identified.

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SYMPOSIA/CONFERENCES/WEBINARS

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 relevant events identified.

# # # #

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

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