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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

May 2025 :: Issue 77

The Center for Informed Consent Integrity engages consent as the bulwark of human rights, fundamental freedoms, responsible science, and effective governance. Consent must be exercised in open, non-coercive, supportive, documented contexts and grounded in evidence-based, accessible, understandable and materially complete information. We publish this digest as a key program in our Center's 2040 program of work [link].

Informed Consent: A Monthly Review aggregates and distills key content and analysis around informed consent and assent 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. We directly monitor a wide range of journals and other sources, and utilize *Google Scholar* as a key tool in developing each edition.

As indicated by the thematic sections listed below, our intent is to present a comprehensive digest, including selected content that is arguably controversial and which warrants close scrutiny. We may include "Editor's Notes" or other notations to identify and sometimes challenge such content. We welcome reader comment on any content we include.

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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No new content was identified for the following established categories:

BIOBANKING
CAPACITY TO CONSENT
GENERAL/OTHER
HUMANITARIAN CONTEXT
RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT
SOCIAL SCIENCE RESEARCH

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 posted and cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the Center's website.

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BIOMEDICAL RESEARCH

Disentangling informing participants from obtaining their consent

Experience Report

Patricia Pearl O'Rourke, Joseph Ali, Judith Carrithers, David Magnus, Benjamin S. Wilfond, Sheana Bull, Laura M. Dember, Gail D'Onofrio, Julie Goldman, P. Michael Ho, Edward R. Melnick, Karen L. Staman, James A. Tulsky, Miguel A. Vazquez, Angelo Volandes, David Wendler

Learning Health Systems, 21 April 2025

Open Access

Abstract

Introduction

Pragmatic clinical trials conducted in the context of routine care frequently satisfy the regulatory criteria for a waiver of research consent. When they do, investigators and Institutional Review Boards might assume that there is no reason to communicate any information regarding the study to participants. Yet, this approach ignores the possibility that there may be value in providing information to participants, even when the study does not pose significant risks and researchers are not obtaining their consent.

Methods

Members of the NIH Collaboratory Ethics and Regulatory Core working group used ethical analysis to determine whether there are reasons to provide information to research participants, other than notifying them of significant risks or obtaining their consent. Study team members then provided examples of trials which illustrate the feasibility and different options for providing information to participants in the context of trials conducted with a waiver of research consent.

Results

Communicating information to participants can promote one or more of six goals: respect for persons, participant understanding of the research, participant understanding of their contributions, participant ability to voice any concerns, participant engagement, and trust and trustworthiness. Providing information can also raise potential concerns about feasibility and cost, which need to be balanced against these reasons to inform participants. Depending on the study, a variety of methods can be used to communicate information; for example, letters, email, flyers, posters, as well as brief conversations with clinicians.
Conclusion
Even when researchers are not obtaining participants' consent, communicating information can promote one or more of six important goals. Providing information to participants should thus be the default for trials conducted under a waiver of research consent.

Human artificial placenta technology-trials: counselling and informed consent using healthcare professionals' and parental perspectives

Basic Science Article
Angret de Boer, André Krom, Rania Kalaai, Marieke de Vries, Marije Hogeveen, Sylvia A. Obermann-Borst, Marijn Vermeulen, Juliette S. van Haren, Peter Andriessen, Martine C. de Vries, E. J. T. Verweij, Rosa Geurtzen
Pediatric Research, 16 April 2025
Abstract
Background
The Artificial Amnion and Placenta Technology (AAPT) is developed to improve outcomes of extremely premature birth, with first in-human trials expected in the coming years. Empirical research with key stakeholders is essential for responsibly designing these trials. This study aims to discuss considerations for counselling and informed consent for the first in-human trials of the AAPT, discussing legal and ethical considerations.
Methods
A qualitative study using both individual and focus group interviews with healthcare professionals (HCPs) and parents was performed. Interviews were thematically analysed.
Results
Fifteen parents and 46 HCPs were interviewed. The results are represented into key themes reflecting participants' perspectives on: (I) the moral and legal status of the subject treated in AAPT trials, (II) the first participant: the pregnant person, and (III) the terminology used to describe the technology. Furthermore, considerations around the informed consent process and counselling, including parental hope, are described. The findings suggest these factors are interconnected, as the moral and legal context surrounding AAPT trials influences the approach to counselling and informed consent.
Conclusion
Resolving key ethical and legal issues important for counselling and informed consent is essential for establishing parental right and the development of a responsible, ethically sound informed consent process.
Impact
- Addressing ethical and legal issues surrounding counseling and informed consent is essential to safeguard a responsible and ethically sound consent process for future human artificial amnion and placenta technology (AAPT)-trials.
- This is the first study exploring stakeholder perspectives on the AAPT, highlighting the complexities in counselling and informed consent, such as the moral status of participants and the rights of all parties, which must be carefully navigated before trial designs can progress.
- The article underscores the importance of establishing consensus and maintaining open dialogue among all stakeholders to create a robust, ethically grounded framework for informed consent in future trials.

Towards Excellence: Virtue and the Principle of Autonomy in Informed Consent for Clinical Trials

Alexander Montes

The Journal of Medicine and Philosophy, 1 April 2025

Abstract

In this article, I argue that approximating virtues such as care and respectfulness are necessary to conduct an informed consent discussion for clinical trials adequately. I argue against Beauchamp and Childress' principlism insofar as it claims that virtues do not have "advantages" over the principle of respecting autonomy. When we elaborate what it means to facilitate autonomy in a consent discussion adequately, we find we are describing the virtues. This is because virtues do have an advantage over principles insofar as virtues provide us with rich descriptions of not only what we should do (respect autonomy), but how to do so (with the virtues of respectfulness, care, etc.). Thus, the principle of respecting autonomy points back to the virtues. I conclude by showing how cultivation of these virtues can help rectify well-known shortcomings in the informed consent process.

The Second Legacy of Henrietta Lacks

Viewpoint

Jerry Menikoff

JAMA, 17 February 2025

Abstract

Henrietta Lacks has already provided the world with one extraordinary legacy: her cells were used to create the first cell line, which has produced uncountable medical breakthroughs since 1951. But history also puts her at the center of another important issue: determining the extent to which it is ethical to conduct secondary research on a nonidentified biospecimen without that person's consent. Recent developments create an opportunity for the research community to take an important step forward in clarifying that issue.

Consent to recontact for future research using linked primary healthcare data: Outcomes and general practice perceptions from the ATHENA COVID-19 study

Research Article

Kim Greaves, Amanda King, Zoltan Bourne, Jennifer Welsh, Mark Morgan, Maria Ximena Tolosa, Trisha Johnston, Carissa Bonner, Tony Stanton, Rosemary Korda

Clinical Trials, 29 December 2024

Abstract

Background

The ATHENA COVID-19 study was set up to recruit a cohort of patients with linked health information willing to be recontacted in future to participate in clinical trials and also to investigate the outcomes of people with COVID-19 in Queensland, Australia, using consent. This report describes how patients were recruited, their primary care data extracted, proportions consenting, outcomes of using the recontact method to recruit to a study, and experiences interacting with general practices requested to release the primary care data.

Methods

Patients diagnosed with COVID-19 from 1 January 2020 to 31 December 2020 were systematically approached to gain consent to have their primary healthcare data extracted from their general practice into a Queensland Health database and linked to other datasets for ethically approved research. Patients were also asked to consent to allow future recontact to discuss participation in clinical trials and other research studies. Patients who consented to recontact were later approached to recruit to a long-COVID study. Patients' general practices were contacted to export the patient files. All patient and general practice interactions were recorded. Outcome measures were proportions of patients consenting to data extraction and research, permission to recontact, proportions of general practices agreeing to participate. A thematic

analysis was conducted to assess attitudes regarding export of healthcare data, and the proportions consenting to participate in the long-COVID study were also reported.
Results
Of 1212 patients with COVID-19, contact details were available for 1155; 995 (86%) were successfully approached, and 842 (85%) reached a consent decision. Of those who reached a decision, 581 (69%), 615 (73%) and 629 (75%) patients consented to data extraction, recontact, and both, respectively. In all, 382 general practices were contacted, of whom 347 (91%) had an electronic medical record compatible for file export. Of these, 335 (88%) practices agreed to participate, and 12 (3%) declined. In total, 526 patient files were exported. The majority of general practices supported the study and accepted electronic patient consent as legitimate. For the long-COVID study, 376 (90%) of those patients recontacted agreed to have their contact details passed onto the long-COVID study team and 192 (53%) consented to take part in their study.
Conclusion
This report describes how primary care data were successfully extracted using consent, and that the majority of patients approached gave permission for their healthcare information to be used for research and be recontacted. The consent-to-recontact concept demonstrated its effectiveness to recruit to new research studies. The majority of general practices were willing to export identifiable patient healthcare data for linkage provided consent had been obtained.

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COMPASSIONATE USE/EXPANDED ACCESS

Improving the compliance of informed consent documentation for expanded access patients

Elias Samuels, Misty Gravelin, Ellen Champagne, Haj Ghaffari Dorsa, Jeanne Wright
Journal of Clinical and Translational Science, April 2025
Abstract
Objectives/Goals
The informed consent (IC) process is similar between clinical trials and expanded access (EA), which allows clinical use of investigational products outside studies. Physicians face unique barriers to IC in clinical environments. This project assesses IC documentation, identifies potential barriers, and evaluates efforts to improve compliance.
Methods/Study Population
This is a continuous quality improvement project. To assess the compliance of IC processes for EA patients, informed consent documents signed by EA patients in 2023 were collected and reviewed against institutional standards. Five components of each form were evaluated, and the number and type of noncompliant documentation were tracked. Five physicians who provided EA treatments in 2023 were interviewed and the transcripts were analyzed to identify barriers to physician's and teams' IC processes. Efforts made to address these barriers and improve the compliance of informed consent documentation are being tracked and trends in compliance are being evaluated.
Results/Anticipated Results
Sixty seven (67) signed informed consent documents for EA treatments were systematically reviewed and 34% were found to be compliant in all key aspects assessed. Analyses of interview notes, transcripts, and memos identified barriers to informed consent processes for expanded access treatments, including the infrequent or irregular occurrence of EA treatments making it difficult for care teams to develop and maintain their understanding of IC process and resources. Efforts made to improve compliance by pre-populating available information into informed consent documentation and removing unnecessary boxes in these forms may have driven improvement in compliance with further efforts underway.
Discussion/Significance of Impact

This project evaluated the compliance of IC documentation for EA treatments and identified drivers affecting physicians' IC processes for these patients. Different strategies to improve the compliance of IC documentation were evaluated and potential best practices for EA support were identified.

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ARTIFICIAL INTELLIGENCE

Enhancing informed consent in oncological surgery through digital platforms and artificial intelligence

Review Article
Alex Boddy
Clinical Surgical Oncology, June 2025
Open Access
Abstract
Informed consent is a cornerstone of ethical medical practice, particularly in high-stakes oncological surgery where treatment options are complex and risks are significant. This paper explores the potential of digital platforms and artificial intelligence (AI) to enhance the informed consent process. The traditional consent process, reliant on face-to-face interactions and paper-based documentation, is increasingly being supplemented by digital solutions that offer remote consultations, personalized patient information, and electronic consent forms. These digital pathways not only improve accessibility and patient comprehension but also streamline documentation, reducing errors and administrative burdens. AI technologies, including ambient digital scribes and large language models (LLMs), could further augment this process by generating personalized risk assessments, simplifying complex medical information, and facilitating multilingual communication. However, success will also depend on addressing ethical concerns, ensuring equitable access, and preserving the irreplaceable human connection between patients and clinicians. By augmenting rather than replacing clinician expertise, digital platforms and AI can empower patients to make truly informed decisions in oncological care.

The Digital Double: Data Privacy, Security, and Consent in AI Implants

Research Article
Omid Panahi, Soren Falkner
Digital Journal of Engineering Science and Technology, 17 March 2025
Open Access
Abstract
Artificial intelligence (AI) implants are rapidly emerging as a transformative technology with the potential to revolutionize healthcare, enhance human capabilities, and blur the boundaries between humans and machines. However, the integration of AI into the human body raises complex ethical, legal, and social questions, particularly concerning data privacy, security, and consent. This paper explores the concept of the "digital double," a virtual representation of an individual generated from the data collected by AI implants. It examines the potential benefits and risks of creating and utilizing digital doubles, focusing on the implications for data privacy, security, and informed consent. The paper analyses the challenges of protecting sensitive health information, ensuring data security, and obtaining meaningful consent from individuals with AI implants. It also discusses the potential for misuse and abuse of digital doubles, including unauthorized access, surveillance, and discrimination. Finally, the paper proposes a framework for addressing these challenges, emphasizing the need for robust data protection measures, transparent consent processes, and ethical guidelines to safeguard individual autonomy and privacy in the age of AI implants.

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Editor's Note:
The following Barnes et al. article " Enabling Demonstrated Consent for Biobanking with Blockchain and Generative AI" *has been previously shared in this digest. We are sharing it again as this target article in the American Journal of Bioethics has resulted in a number of peer commentaries which follow below. These commentaries offer a range of perspectives on biobanking, blockchain and generative AI and consent. These are areas which we continue to examine in our work.*

Enabling Demonstrated Consent for Biobanking with Blockchain and Generative AI

Caspar Barnes, Mateo Riobo Aboy, Timo Minssen, Jemima Winifred Allen, Brian D. Earp, Julian Savulescu
The American Journal of Bioethics, 5 November 2024
Abstract
Participation in research is supposed to be voluntary and informed. Yet it is difficult to ensure people are adequately informed about the potential uses of their biological materials when they donate samples for future research. We propose a novel consent framework which we call "demonstrated consent" that leverages blockchain technology and generative AI to address this problem. In a demonstrated consent model, each donated sample is associated with a unique non-fungible token (NFT) on a blockchain, which records in its metadata information about the planned and past uses of the sample in research, and is updated with each use of the sample. This information is accessible to a large language model (LLM) customized to present this information in an understandable and interactive manner. Thus, our model uses blockchain and generative AI technologies to track, make available, and explain information regarding planned and past uses of donated samples.

Demonstrated Consent and the Common Good: On Withdrawal of Consent in Stem Cell Research

Open Peer Commentaries
Tijs Rosema, Martine de Vries, Hanna Lammertse, Roland Bertens, Nienke de Graeff
American Journal of Bioethics, 7 April 2025
Excerpt
Barnes et al. (Citation2025) argue that demonstrated consent enhances donor autonomy. This is because demonstrated consent offers donors "ongoing accessibility of information according to donor preferences" and so gives donors "actionable rights to reassess or withdraw consent" (Barnes et al. Citation2025, 99).

Since demonstrated consent uses broad consent as default, it allows researchers to conduct various research projects based on a single initial consent procedure, and so helps contribute to societal interests (Barnes et al. Citation2025). Therefore, demonstrated consent meets the so-called "balance criterion" which Barnes et al. (Citation2025) introduced to underline that informed consent frameworks should also balance donor autonomy with broader societal interests, including progress in science and medicine.

But what does the balance criterion imply for situations in which donor autonomy leads to significant negative consequences for societal interests? This question may arise when donors withdraw their consent. By taking stem cell research as an example, we reason that although demonstrated consent enhances donor autonomy, the exercise of donor autonomy by withdrawing consent should not always lead to the discontinuation of research.

We argue that the right of withdrawal can be limited in stem cell research if a donor is properly informed about limits of withdrawal when providing initial consent. Additionally, we see opportunities for demonstrated consent to compensate for this proposed limitation of donor

autonomy. We thus provide a more detailed elaboration on demonstrated consent and the balance criterion in the context of stem cell research…

On the Complexities of Enabling Demonstrated Consent

Open Peer Commentaries

Panagiotis Alexiou, Joel Azzopardi, Claude Julien Bajada, Jean-Paul Ebejer, Gillian M. Martin, Nikolai Paul Pace

American Journal of Bioethics, 7 April 2025

Excerpt

Barnes et al. (Citation2025) introduce a novel vision for biobanking consent in their article "Enabling Demonstrated Consent for Biobanking with Blockchain and Generative AI." Their concept of "demonstrated consent" leverages blockchain technology and non fungible tokens, along with large language models to enhance transparency and participant engagement. We put this novel framework in context of existing approaches, and highlight some key questions that arise.

The central question that Barnes et al. seek to address is the inherent limitations of the following two traditional consent models in biobanking, namely:

- Study-specific consent: A type of consent where individuals give permission for the use of their bio-samples and data to be used in a single, well defined, research project. While ethically robust, it is often impractical in the context of long-term biobanking due to the increased administrative burden and inflexibility.
- Broad consent: A type of consent where individuals allow their bio-samples and data to be used in future, sometimes unspecified, research projects, with few or no specific restrictions. Importantly, without the need to be re-contacted or consulted. This approach is more efficient, but can undermine the autonomy of participants by failing to provide sufficient information about future research uses. Broad consent needs to be paired with strategies of risk mitigation, and continuous provision of information to participants.

In response to these challenges, various alternative models have been proposed, including tiered informed consent (Tiffin Citation2018), meta-consent (Ploug and Holm Citation2016), and dynamic consent (Kaye et al. Citation2015; Budin-Ljøsne et al. Citation2017) These models try to increase the involvement of participants, but are vulnerable to issues similar to study-specific consent. Dynamic consent in particular, has gained traction as a means of allowing participants to dynamically update their consent preferences in real time, thus tailoring their participation to studies based on their preferences. Individuals however, have to constantly manage their consent, leading to potential choice overload and consent fatigue. The "demonstrated consent" model proposed by Barnes et al. aims to circumvent these issues by providing a secure, transparent, and easily accessible source of information, without requiring participants to continuously manage their preferences. The central contribution of this manuscript is the proposed integration of non-fungible tokens (NFTs) and large language models (LLMs) to tackle these issues…

Challenges to Demonstrated Consent in Biobanking: Technical, Ethical, and Regulatory Considerations

Open Peer Commentaries

Jasmine E. McNealy, Megan Doerr

American Journal of Bioethics, 7 April 2025

Excerpt

We read with interest Barnes and colleagues' recent article, "Enabling Demonstrated Consent for Biobanking with Blockchain and Generative AI" (Barnes et al. 2025). We appreciate their efforts to

succinctly ground their proposal within consent scholarship and their distillation of the ethical challenges of informed consent for repository contexts. Like many, we are vocal advocates for improving the informed consent process, especially within repository enabled research (Doerr et al. 2021). We also strongly support the creative use of technology to mitigate consent's shortcomings (Moore et al. 2017; Kraft and Doerr 2018). However, we are concerned that Barnes et al.'s proposal faces several critical technical challenges to implementation, does not account for key features of repository enabled research, and adds novel regulatory concerns to the mix…

Narrative Transparency in AI-Driven Consent

Open Peer Commentaries

Jarrel De Matas, Jiefei Wang, Vibhuti Gupta

American Journal of Bioethics, 7 April 2025

Excerpt

As artificial intelligence (AI) systems become more prevalent, ethical inquiry into transparency, trust, and patient autonomy must develop with similar pace. One area where such inquiry required is in the process of obtaining informed consent, particularly in a biobanking context, where participants are asked to share their biological data for research purposes. Although Barnes et al. (Citation2025) proposes using blockchain and AI to improve transparency and engagement in biobanking through demonstrated consent, their approach lacks a concrete framework: informed consent should not only be considered a transactional process, as Manson and O'Neill (Citation2007) argue, but more importantly a user-centered, communicative act that requires participants to understand complex information, balance risks and benefits, and make decisions that overlap with their values and preferences. To complement what we identify in Barnes et al. (Citation2025) as an overstatement of the transactional approach to informed consent, we suggest a Narrative Transparency Framework. This framework applies storytelling principles to drive AI-assisted consent processes and aims to improve decision-making, enhance understanding, and foster trust by enhancing personalized, ethically framed, and user-adaptive narratives. In this paper, we explore the theoretical basis of narrative transparency which is premised on the role of narrative structure in shaping participant understanding and decision-making. We also outline the components of the Narrative Transparency Framework and discuss practical strategies for utilizing narrative-driven AI consent interactions…

Consent Is Dead, Long Live Ethical Oversight: Integrating Ethically Sourced Data into Demonstrated Consent Models

Open Peer Commentaries

Jean-Christophe Bélisle-Pipon, Vardit Ravitsky

American Journal of Bioethics, 7 April 2025

Excerpt

Barnes et al. (Citation2025) propose a demonstrated consent model that seeks to address challenges in modern biomedicine by transforming consent from a static, one-time transaction into a dynamic process. Their model integrates blockchain technology with generative artificial intelligence (AI) to allow donors to monitor the use of their biological samples in real time and adjust their preferences as research evolves. This approach helps to respond to the limitations of traditional consent frameworks—a concern echoed by Evans and Bihorac (Citation2024), who note that "informed consent for data use, as conceived in the 1970s, seems dead." They argue that modern computational methods introduce privacy risks not only through direct data breaches but also via inferences drawn from aggregated data, affecting even those who have not directly consented. Barnes and colleagues' model embeds increased transparency and user agency into consent processes. However, it also raises ethical questions: Does this approach truly empower donors, or

might it overwhelm them with technical complexity? Can blockchain's transparency and AI's capacity to personalize consent overcome systemic inequities, or will they obscure deeper structural imbalances? These questions are essential to assessing whether demonstrated consent can adequately safeguard autonomy, privacy, and justice in biomedical research…

Informed Consent: An Essential Tool for Medical Practice and Research

Review Article

Sukhvinder Singh Oberoi, Nilima Sharma, Sweta Rastogi, Sunil Kumar, Anand Suresh

Amrita Journal of Medicine, April-June 2025

Abstract

The concept of informed consent regulates the relationship between medical practice and patients, promoting human rights and dignity. It serves as both a legal and ethical mechanism for ensuring autonomy and self-determination. This review examines the concept of informed consent as it applies to both medical research and clinical practice, addressing its types, prerequisites, limitations, and challenges. Additionally, it explores waiver of consent and the concept of minimal risk in research. The review highlights the importance of shared decision-making (SDM), the barriers to informed consent, and the role of comprehension in the consent process. The discussion emphasizes the need for improvements in informed consent procedures, particularly in enhancing patient understanding and addressing legal and ethical gaps. Future research should focus on refining consent mechanisms to improve their effectiveness in modern healthcare.

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GENOMIC MEDICINE/GENE EDITING

Health system-led early consent and direct contact of at-risk relatives: Pilot study results

Nora B Henrikson, Aaron Scrol, Jamilyn M Zepp, Melissa L Anderson, Paula R Blasi, John J Ewing, Jane Grafton, James D Ralston, Stephanie M Fullerton, Kathleen A Leppig

Public Health Genomics, 3 April 2025

Abstract

Introduction

At-risk relatives of probands with genetic variants associated with hereditary cancer risk should receive cascade genetic testing. In the U.S., probands are expected to notify their own at-risk relatives, but many relatives never learn of their risk, representing missed opportunity to reduce morbidity and mortality associated with hereditary cancers. Direct contact of relatives could reach relatives not contacted by the proband. We conducted a single-arm, prospective pilot evaluation of a direct contact intervention based on patient and family preferences. Here we report the study's quantitative results, measured by proband and relative participation in the intervention follow-up survey.

Methods

We recruited adults receiving genetic counseling for inherited cancer risk at one U.S. integrated health system. A genetic counselor offered to contact at-risk relatives. We surveyed probands and relatives at study enrollment and 6-8 weeks and evaluated administrative data to assess the program's outreach to probands and relatives, its acceptability, and its limited efficacy.

Results

We approached 148 probands before their genetic counseling appointment. 55 (37%) consented to study participation. Of these, 31 completed genetic testing, 29 of whom provided consent to contact 101 relatives. 44% (n=45) of relatives consented to be contacted by the study genetic counselor. Acceptability was high for

both groups and no harms were reported. All relatives reached (n=43) received their proband's test results, including 6 pathogenic/likely pathogenic findings.
Conclusion
A direct contact program was acceptable, reached at-risk relatives and communicated proband test results. Direct contact with early consent of relatives holds promise for future research.

Editor's Note: Our Center is examining the nuanced underlying issues raised by this important article.

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HEALTH DATA/DATA

Challenges and Solutions in Implementing Informed Consent in Digital Environments: A Scoping Review

Ramona Schmidt, Ina Schiering, Harald Zwingelberg, Michael Friedewald
IEEE Access, 30 April 2025
Abstract
In times of ubiquitous data collection and processing, the need for privacy and control is stronger than ever. The implementation of informed consent is becoming increasingly important. The obligation to obtain informed consent and the user's right to information and to refuse or withdraw consent is already defined in the GDPR. Particularly within the mHealth [mental health] sector, where the collection of particularly sensitive health data occurs, the realisation of informed consent presents an important challenge. However, many applications are still not compliant, and companies seem to struggle with the implementation of effective informed consent. This scoping review analyses how the technical implementation of informed consent has been addressed in the literature to date, what challenges need to be overcome when implementing informed consent, and what solutions are proposed and discussed in the current literature on the implementation of informed consent.

Toward Ethical Digital Practices: Guidelines for Consent, Accountability, and Transparency in Anthropology

Amber M Plemons, Micayla C Spiros
American Journal of Biological Anthropology, April 2025
Abstract
Objectives
Digital tools and imaging are now common practice in biological anthropology research. Ethical concerns around the management, use, and display of digital human remains are a budding topic of discussion. Currently, there are no formalized discipline-wide guidelines or standards for digital ethics in biological anthropology. To bridge the gap between ethical standards and digital practices, we need to gauge current digital tools and resources used by professionals, as well as the state of ethical codes for professional organizations regarding digital media in biological anthropology.
Materials and methods
This study reviews ethical statements from five professional organizations and survey responses from biological anthropologists on their use and opinions of digital remains. Text analyses were performed on ethics statements to identify terms related to digital remains and on survey responses to identify key themes in opinions of digital ethics.
Results

Results demonstrated that only one organization mentions digital ethics while survey results indicate researchers are creating and using digital tools in their research. Thematic text analyses underline the need for consent, digital ethical guidelines, anonymity, data security, and cultural sensitivity and respect.
Discussion
These results highlight the gap in practice and guidelines for digital ethics. We propose immediate action items, including the development of a cross-cultural, disciplinary working group to generate cohesive digital ethics standards, explicit statements on digital human remains in donor forms, the addition of digital best practice standards into organizations' ethics codes, and ethics statements added to current digital platforms. These proposed ethical guidelines and questions for donor forms are provided for these action items.

> *Editor's Note: "Digital remains" refers to the digital data and information a person leaves behind after death, including online accounts, emails, social media posts, documents, and other digital assets.*

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TECHNOLOGY/OTHER MEDIATION

Co-designing and pilot-testing an infographic to support the consent process in an adaptive platform trial for adults in ICU with community-acquired pneumonia or COVID-19: a mixed methods study within a trial (SWAT)

Research
Heather K. O'Grady, Kathy Smith, Sandra Dalziel, Barbara Dolanjski, Gyan Sandhu, Marlene Santos, Jackie Bosch, Lyn S. Turkstra, Srinivas Murthy, John C. Marshall, Michelle E. Kho
Research Involvement and Engagement, 25 April 2025
Open Access
Abstract
Background
Informed consent documents educate patients and families about research participation and alternatives. However, given their length and complexity, consent documents can be challenging to understand, particularly in high-stress environments such as the Intensive Care Unit (ICU) and for complex study designs such as platform trials.
Methods
This is an exploratory sequential mixed methods study-within-a-trial (SWAT) of REMAP-CAP (Randomized, Embedded, Multifactorial, Adaptive Platform Trial for Community-Acquired Pneumonia). Phase 1: We conducted focus groups with individuals with lived experience, including ICU survivors, substitute decision makers (SDMs) and research coordinators (RCs) to refine an infographic to augment a priori REMAP-CAP consent encounters. We analyzed data using inductive content analysis. Phase 2: We piloted the infographic with patients/SDMs approached a priori to participate in REMAP-CAP, who could communicate in English, at five sites in Ontario, Canada. We assessed implementation according to 1) eligible consent encounters (number of patients/SDMs eligible for SWAT / approached for REMAP-CAP), 2) receipt of infographic (number of patients/SDMs who received the infographic / eligible consent encounters), 3) consent to participation in this SWAT by patients/SDMs (number of patients/SDMs who consented / those approached), and 4) feedback questionnaire completion (number of patients/SDMs who completed the questionnaire / those who received it).
Results
Phase 1: We conducted two, two-hour focus groups with 5 participants (10 participants total). Participants identified important infographic design considerations (visual presentation, language) and content (study details, participation in research).
Integration: Results from Phase 1 were used to develop a final consent infographic.

Phase 2: Sixty-three patients were eligible for REMAP-CAP during the study period; 21 were eligible (33%) for the SWAT. Of these, 18 patients/SDMs (86%) received the infographic, 17 consented to the SWAT (94%) and 15 (88%) completed questionnaires. RCs completed case report forms for each consent encounter (n = 18, 100%).

Conclusions

We engaged individuals with lived experience to co-design a consent infographic. We achieved three of four pre-specified feasibility objectives during pilot testing of the infographic for a priori REMAP-CAP consent encounters. Although there were fewer eligible consent encounters than anticipated, we identified acceptable rates of infographic delivery, consent to SWAT participation and questionnaire completion.

A Randomized Controlled Trial of Video-Assisted Electronic Consent Versus Standard Consent for Percutaneous Kidney Biopsy

Pedro H Franca Gois, Vera Y Miao, Rebecca B Saunderson, Marina Wainstein, Julia Jefferis, Rebecca Hudson, Shaun Chandler, Kylie-Ann Mallitt, Martin Wolley, Belinda Elford, Ann Bonner, Helen G Healy

Clinical Journal of the American Society of Nephrology, 9 April 2025

Abstract

Background

Informed consent is crucial in healthcare, as it respects and honors patient autonomy. However, the process of consenting a patient to a procedure or intervention is often unstandardized, leading to gaps in comprehension, which in turn affects decision-making. This study aimed to assess the patient-reported benefits of video-assisted electronic consent (eConsent) compared with the usual consent practices for percutaneous kidney biopsies (PKB).

Methods

In this single-center, open-label, randomized controlled trial, consecutive patients undergoing PKB between July 2021 and January 2024 were randomized (1:1) to either video-assisted eConsent (intervention) or usual practice of consent (control). The intervention group accessed an eight-minute explanatory animation on an online platform covering the procedure, its risks, and pre- and post-biopsy care before providing digital consent. The control group was consented to by clinicians in the usual manner and signed a paper form. The primary outcome was questionnaire-based patient comprehension, with secondary outcomes including patient-reported experience, anxiety, and satisfaction with the consent process.

Results

Of 178 eligible patients, 120 were enrolled (60 in each group), with a median age of 52 (IQR 34-65) years, 56% were female, and 59% had less than 12 years of education. Comprehension scores were significantly higher in the eConsent group, with participants answering on average three more questions correctly out of nine compared to the control group ($p<0.001$). Comprehension did not differ significantly by sex or education level, but younger patients scored higher. The eConsent group also had better comprehension of pre- and post-PKB care. No significant differences were observed in patient-reported experience, anxiety, or satisfaction between groups.

Conclusions

Video-assisted eConsent improves patient comprehension of PKB compared to usual consent practice without affecting patient experience, anxiety, or satisfaction.

An informational video for informed consent improves patient comprehension before total hip replacement- a randomized controlled trial

Research

Sebastian von Hertzberg-Boelch, Konrad Fuchs, Johanna Schubring, Dominik Rak, Kilian List, Konstantin Horas, Axel Jakuscheit, Maximilian Rudert

International Orthopaedics, 2 April 2025

Open Access

Abstract

Purpose

Effective patient comprehension is critical for informed consent, particularly in Total Hip Arthroplasty (THA), a globally prevalent procedure. This study evaluates the efficacy of an informational video to improve the patients' understanding, self-perceived knowledge, and emotional comfort in the context of THA informed consent. This randomized controlled trial investigates the impact of an additional informational video on (I) the patients' understanding, (II) self-precepted knowledge and (III) emotional comfort during the informed consent process for THA.

Methods

Participants were randomized to receive either the standard informed consent procedure or the standard procedure supplemented with an informational video. The effect of the video was tested with post-consent questionnaires.

Results

The informational video significantly ($p = 0.014$) improved the patients' understanding from 78.6% to 86.5%. Self-precepted knowledge and Emotional comfort was not effected by the video ($p = 0.986$; $p = 0.333$).

Conclusions

The informational video significantly improved patient comprehension during the informed consent process before THA.

Comprehension and Satisfaction with Informed Consent for Hip Arthroscopy Using Supplemental Online Educational Materials

Molly Piper, Kira Smith, Margaret Sinkler, Michael Salata, Jacob Calcei

Journal of Hip Preservation Surgery, 27 March 2025

Abstract

Background

Informed consent is a crucial component of building the patient-physician relationship, and it typically involves a conversation between patient and provider along with a written document. The purpose of this study was to determine whether the use of electronic educational resources in addition to paper handouts would improve patient comprehension and retention of informed consent for hip arthroscopy procedures.

Methods

Patients undergoing hip arthroscopy were enrolled prospectively, and they were randomized into two groups at their preoperative visit. The first group of patients received a handout discussing their procedure following the informed consent process with the physician, while the second group received the handout as well as access to an online educational forum. The online educational materials included information regarding the procedure, risks, benefits, and alternative options to surgery. The patient’s comprehension, retention, and satisfaction were assessed with a survey on their day of surgery prior to the hip arthroscopy procedure.

Results

There were 26 patients who completed the survey preoperatively, and 65% of those patients were females (n= 17). The average age was 30 ± 9.6 years. 13 of those patients accessed the online educational materials, and 13 patients only had a paper copy of the information. There was no significant difference in the proportion of patients who were very or extremely informed of their procedure ($p > 0.99$). Additionally, there was not a significant difference in the awareness of the risks, benefits, and alternatives to hip arthroscopy between patient groups ($p > 0.99$). Over 75% of patients in each group were very or extremely satisfied with the information and teaching they received during the informed consent, but there was not a significant difference between groups ($p= 0.59$). Of the patients who utilized the online educational materials, 62% agreed that the materials helped improve their understanding of the surgery (n= 8).

Conclusion

Despite an additional online educational forum, there was not a difference in patients' comprehension of information from the informed consent process for those undergoing hip arthroscopy. There was also not a difference in patient satisfaction between patients receiving only a paper handout versus the additional online educational forum.

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YOUNG PERSONS

Pediatric Acute Appendicitis as a Model for Shared Decision-Making

Book Chapter
Lindsay A. Gil, Loren Berman, Peter C. Minneci
Difficult Decisions in Pediatric Surgery, 28 March 2025 [Springer]
Abstract
Shared Decision-Making (SDM) in pediatric surgery is challenging given that the treatment decision typically involves three parties (surgeon, caregiver, and patient), and at least one of the treatment choices usually involves an operative intervention. There has been mounting evidence to support the safety and efficacy of non-operative management of pediatric uncomplicated acute appendicitis with antibiotics alone, making SDM an essential and valuable tool for pediatric surgeons. This chapter highlights both the importance and challenges of applying SDM in pediatric surgery by exemplifying its application to the treatment choice between non-operative and operative management of pediatric uncomplicated acute appendicitis. The appendicitis example is one of several in which SDM has the potential to reduce healthcare resource utilization and costs by increasing uptake of non-operative conservative treatments.

Ethical Considerations in the Surgical Care of Children: Balancing the Interests of the Child, the Family, and the Surgeon

Book Chapter
Johnathan Kent, Miranda Ortega, Manish Tushar Raiji
Difficult Decisions in Pediatric Surgery, 28 March 2025 [Springer]
Abstract
Pediatric surgeons take part in the care of children across a wide spectrum of development and maturity. The relationships between patients, their families, and their surgeons can form an inclusive and supportive team to help children navigate complex health concerns. However, these relationships can also form the basis of complex ethical challenges. The care of children involves an understanding of the development of a child's maturity and subsequent ability to participate in medical decision making. Under specific circumstances, adolescents can become fully independent to make medical decisions. But in the vast majority of instances, children and adolescents require surrogate decision makers to choose for them. This chapter explores several of the tensions that may arise when considering medical and surgical care for children.

> *Editor's note: We note the authors' assertion that "…in the vast majority of instances, children and adolescents require surrogate decision makers…" We express concern about the imprecision and underlying assumptions of this assertion and continue to examine issues around assent, capacity and children's rights in our Center for Informed Consent Integrity work.*

Navigating consent and dissent in early childhood research: An Australian perspective

Katie Fielding, Karen Murcia, Madeleine Dobson, Geoffrey Lowe
Issues in Educational Research, March 2025; 35(1)

Open Access

Abstract

Notions of consent, including assent and dissent, are paramount ethical considerations in human research, but have different connotations in research involving young children (aged 3 to 8). While discussion surrounding consent in the early childhood literature has progressed from paternalistic views surrounding the need to protect the child, to recognising their capacity to make decisions in line with their rights, needs and interests, some studies suggest that the application of this change may still be problematic in practice. Many researchers still grapple with notions of who provides consent, what consent may look like, and how it is applied both before and during research. This article reports on the practical application of consent, framed by the hierarchy of Children's Participation Rights (Mayne et al., 2018), within a study into young children's demonstration of creative thinking behaviours when using digital technologies. It provides a brief overview of contemporary views of children's rights and consent for context before outlining the study itself and how consent was applied throughout, informed by the Mayne et al. (2018) framework. It presents a series of vignettes describing elements of consent as they arose in practice and discusses them in relation to the literature. The article concludes by considering rights-based consent in contemporary early childhood research in terms of study design for future researchers to consider.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Editor's note: We recognize that a number of articles in this section deal with consent in various country contexts which make arguments that may warrant closer scrutiny.

Readability of health research informed consent forms: case of the National Health Research Ethics Committee in Tanzania

Renatha Kato, Renatha Joseph, Lazaro Haule, Mwanaidi Kafuye

BMC Medical Ethics, 22 April 2025

Open Access

Abstract

Background

Obtaining informed consent is the practice of respect for persons that gives the right to participants to make autonomous decisions about research participation. The difficult-to-read research informed consent forms (RICFs) hinder comprehension and can expose participants to harm. This study aims to assess the readability of health RICFs for studies approved by the National Health Research Ethics Committee (NatHREC) in Tanzania.

Methods

We used a retrospective cross-sectional study design. A total of 266 RICFs were sampled from the NatHREC database using stratified and systematic random sampling strategies. The readability of RICFs was assessed using the Flesch Reading Ease (FRE) and Flesch-Kincaid Readability Grade Level (FKRGL) formulas available in Microsoft Word Office and by manual check. Data were collected using the assessment checklist, analyzed, and presented with SPSS and MS Excel software.

Results

Out of 266 RICFs assessed, 65.4% had the recommended page numbers, 81.6% had longer sentences, and 80.5% were difficult to read, necessitating a person to acquire a US grade 10 (Form Four educational level in Tanzania) to understand the presented information. Pearson's correlation coefficient with p-values of < 0.001 and 95% confidence level disclosed that sentence lengths in the RICFs had a statistical association with the difficult reading levels obtained.

Conclusion

Findings from this study showed that most of the RICFs were concise in terms of page numbers and word count but had long and difficult sentences. Researchers should assess the readability of RICFs before submitting them for ethical approval. Research Ethics Committees (RECs) should consider inclusion of RICFs readability measurements in the Ethics Guidelines for Health Research. The study recommends further studies to assess the Kiswahili versions of RICFs to determine if the results obtained in this study apply to Kiswahili texts.

Informed Consent in Tertiary Care Hospitals of Pakistan; The Moral Magic of Consent

Nargis Khan, Gul Hassan Sethar, Zia Ullah Khan, Lubna Meraj, Nadia Shams, Farhat Bashir

Journal of Rawalpindi Medical College, 29 March 2025

Abstract

Objective

This study aimed to assess whether standard international guidelines obtain informed consent and to identify potential contributing factors.

Methodology

This Questionnaire descriptive cross-sectional study was conducted at public sector hospitals of Karachi (October 2021-Aug. 2022) after ethical approval. A 12-point questionnaire was developed based on three categories, first to assess awareness & significance of IC, second regarding elements of IC & third for administrative part of IC. Indoor adult patients ≥18 years of age, who have undergone any surgical or medical procedures were included. The critically ill, unconscious and those unable to give consent were excluded. Data was analyzed by SPSS version 23.

Results

A total of 587 subjects were included, with a mean age of 43. There were 340(57.9%) males & 247(42.1%) females. 51.7% of respondents had an education level of <10 years. 51.1% & 48.9 % of subjects underwent medical related & surgical related procedures respectively. 426(72.6%) patients were aware of IC and 318(54.2%) responded affirmative to significance of IC. 407(69.3%) subjects were informed about treatment options prior to procedure, 349(59.5%) were informed about complications, while risks & benefits of procedure were discussed with 294(50.1%). 281(47.9%) of the patients were satisfied with the information about the procedure, and 288(49.1%) subjects understood the information. Of the respondents, 356(60.6%) stated that the language used wasn't appropriate for comprehension, 200(34.1%) identified language as a barrier, 185(31.5%) pointed to cultural factors, and 202(34.4%) believed that both language and culture were barriers to IC. 368(62.7%) of the subjects signed the IC, while the IC was signed by a family member in 219(37.3%). Only a minority of patients, 199(33.9%), felt that the consent process was free and fair, while 388(66.1%) believed their decision was influenced. Among them, 233(39.7%) felt influenced by the doctor, and 155(26.4%) attributed the influence to a family member.

Conclusion

There is significant room for improvement in achieving legally and ethically valid informed consent (IC). Literacy, language barriers, and cultural beliefs are major factors influencing patient's understanding of IC. Higher levels of education were associated with better comprehension of IC. The majority of patients reported that the consent process was neither free nor fair, with language and cultural barriers being significant obstacles. Enhancing the communication skills of healthcare professionals and incorporating formal training on obtaining IC at all levels, from undergraduate education to consultant training, is suggested.

Informed Consent as a Fundamental Principle of Medical Ethics: An Examination of its Application in Nigerian Healthcare Settings

Onyegbule Kelechi Goodluck

Journal of Commercial and Property Law, 23 March 2025

Abstract
The patient's right of consent to any medical treatment recommended by a medical practitioner is now internationally recognised. This consent is required by the premise of the individual's inviolable right to choose and control his own health-care situations. Consent must be free, prior, and informed. Free indicates that permission is invalid if obtained through manipulation or coercion. Consent gained unwillingly, under duress or coercion, may result in a battery lawsuit. The consent must be granted voluntarily by a patient who has capacity to so do. Prior means that consent must be obtained adequately in advance of any authorisation granted by medical or hospital authorities, or the initiation of hospital activities that influence the patient's health. Informed means that the patient's agreement must be obtained only after complete and legally accurate disclosure of information about the proposed medical operation. The disclosure must be in a form that is both accessible and clear to the patient, including the nature, scope, duration, potential hazards, and foreseeable consequences of the medical operation. There must be complete disclosure of information about the treatment, benefit, danger, complications, and repercussions of such a procedure. Regarding a procedure or therapy that needs to be administered to the patient, the doctor gives all the information that is required. In Nigeria, the idea of informed, prior, and free consent is not widely recognized in the medical field. This is caused by multiple variables. First, there is the issue of Nigeria's low literacy rate. Patients with limited literacy typically depend solely on the doctor's judgement. The second factor is the lack of enforcement of the right to informed consent. Under Nigerian law, patients whose rights to informed consent have been violated have little recourse options. Bureaucracy also hinders the processes that are in place to enforce the right to informed consent. This article makes the case that the legal and institutional regimes for Nigeria’s informed consent laws are insufficient.

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RIGHTS/LEGAL/LEGISLATIVE

Expectations for meaningful free, prior, and informed consent: an exploration by the Little Salmon/Carmacks First Nation

Original Article
Emily Martin, The Little Salmon Carmacks First Nation, Ben Bradshaw
The Extractive Industries and Society, September 2025
Abstract
Indigenous self-determination plays an increasingly prominent role in lands and resources development decisions. One way of operationalizing self-determination is through the realization of free, prior, and informed consent (FPIC) for development impacting Indigenous Peoples and their lands, as recognized in the United Nations Declaration on the Rights of Indigenous peoples (UNDRIP). In the Yukon, Canada, where some consent and consent-like rights are held by First Nations, few First Nations have formally articulated their expectations for the meaningful expression of their consent. This paper begins to address this gap based on a case study by the Little Salmon/Carmacks First Nation (LS/CFN), a self-governing, Northern Tutchone Yukon First Nation located proximate to past, present, and potentially future mineral development. Though LS/CFN's expectations of FPIC are not formalized today, this exploratory research presents that LS/CFN participants expect: early engagement; to be fully informed; space for self-defined internal processes; ongoing engagement with proponents and the Crown; mitigation of resource barriers; enforceability of commitments; contextually relevant processes; appropriate representation; agreed upon definitions of terminology; mitigation of power imbalances; and mutual agreement on the consent process itself. More broadly this article makes a case for a covenantal, rather than a solely contractual, approach to make FPIC meaningful.

Beyond Consent: Ensuring Meaningful Protection of Genetic Data Under India's Digital Personal Data Protection Act, 2023

Review Article

RK Singh, Vini Singh

Journal of Indian Academy of Forensic Medicine, 10 April 2025

Open Access

Abstract

India's Digital Personal Data Protection Act (DPDPA) adopts a notice-and-consent-based framework for data protection; it treats all personal data, including genetic data, as a singular category without accounting for its unique characteristics. Unlike ordinary personal data, genetic data is inherently relational; it reveals information not just about an individual but also their biological relatives. Moreover, the risks associated with the processing of genetic data extend beyond identifiability, such as the potential for its misuse in law enforcement or to discriminate in matters of employment or insurance. Despite these concerns, the DPDPA fails to offer a nuanced regulatory approach, lacks a clear definition of genetic data, and does not impose heightened safeguards for its processing.

This article identifies the limitations of the DPDPA's notice-and-consent-based model in regulating genetic data processing and argues for a shift toward a harm-based framework. It proposes key reforms, such as the classification of genetic data into categories based on sensitivity, an expanded definition of the data principal to include affected blood relatives, and risk-based processing guidelines that categorize genetic data processing into prohibited, high-risk, medium-risk, and low-risk processing. Additionally, this article advocates for stronger privacy by design and by default requirements, mandatory data protection impact assessments (DPIAs), and the introduction of rights such as data portability and right to restrict processing.

Further, to ensure effective enforcement, it recommends strengthening grievance redressal mechanisms, introducing compensation for privacy harms, and imposing proportionate criminal liability for negligent handling of sensitive genetic data.

By addressing these gaps, this article underscores the need for a strong legal framework that moves beyond notice and consent to provide meaningful privacy protections for genetic data in India's evolving digital landscape.

Patient's Right to Consent to Medical Procedures from the Perspective of Health Law, Bioethics, and Human Rights

Ni Putu Parvathi Priyadarshini, Gusti Ayu Putri Kartika

Journal of Law Politic and Humanities, March 2025

Abstract

The patient's right to consent to medical procedures is a vital element in the relationship between patients and healthcare providers, connected to health law, bioethics, and human rights, all focusing on the protection of patient autonomy. This study analyzes the patient's right to consent from the perspectives of health law, bioethics, and human rights, and identifies challenges in its implementation in Indonesia. A normative method is employed with legislative, conceptual, and comparative approaches. Data is gathered by analyzing national regulations, bioethical principles, and literature on human rights. Descriptive-analytical analysis was used to explore the synergy between these three perspectives in medical consent implementation. Findings reveal that the patient's right to consent is regulated by Law No. 17 of 2023 and other relevant regulations. Bioethics stresses respecting patient autonomy, while human rights ensure access to information and the freedom to consent. Challenges include paternalistic cultural attitudes, low public awareness, and inadequate healthcare facilities. Recommendations include strengthening regulations, providing bioethics training for healthcare professionals, and educating the public to safeguard patient rights in medical procedures in accordance with health law, bioethics, and human rights.

On the Legal Dilemma and the Way Out of Revocation of Consent by Living Organ Transplant Donors

Jie Xi, Lei Feng

Open Access Library Journal, March 2025

Abstract

This paper's purpose is to discuss the legal dilemma arising from the revocation of consent by donors in living organ transplantation, analyze its jurisprudential basis and practical impact, and propose a solution to balance the rights and interests of donors and recipients, so as to promote the healthy development of the organ transplantation cause. Through the analysis of typical cases, it reveals the real harm of revocation of consent; combined with the legislative status of China's Human Organ Transplantation Regulations, it points out the deficiencies of the current law in the definition of conditions, procedures and consequences of the exercise of the right of revocation; from the perspective of jurisprudence, it demonstrates the legitimacy of the revocation of consent, and emphasizes that it is in line with the principle of voluntariness, personal autonomy, and social adaptability of the law; through the comparative study, it compiles the legal difficulties in the protection of donor autonomy, information and notification mechanism, and psychological and social impacts in the US and Germany. Through comparative legal research, the practical experience of the United States and Germany in protecting the autonomy of donors, the information mechanism and the psychological counseling system is examined**;** specific conditions limiting the exercise of the right of revocation are proposed, including time, form and force majeure factors, and a framework of legislative proposals is constructed based on them.

Editor's Note: The revocation of consent referred to in this article occurs prior to surgery taking place.

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MEDICAL/SURGICAL

A cross-sectional analysis of the reliability, content and readability of orthodontic retention and retainer informed consent forms

Original Article

Maurice J. Meade, Sven Jensen, Xiangqun Ju, David Hunter, Lisa Jamieson

International Orthodontics, September 2025

Open Access

Summary

Objective

The aim of the study was to determine the reliability, quality and readability of content contained within informed consent forms concerning orthodontic retention and retainers provided by orthodontic treatment providers.

Methods

An online search strategy identified informed consent forms for evaluation. The DISCERN instrument was used to determine content reliability. Each form was assessed for the presence of pre-determined content regarding 11 domains. Analysis for quality of the domain content was via a 4-point scoring scale. The Simple Measure of Gobbledegook (SMOG) and the Flesch-Kincaid Grade-Level (FKGL) were employed to determine readability.

Results

Thirty-four forms satisfied selection criteria. The majority (n = 20; 58.8%) were sourced from websites in the US, with most (n = 22; 64.7%) from specialist orthodontist websites. The mean (SD) DISCERN score per form was 31.9 (4.5). The mean (SD) number of domains present within each form was 7.76 (1.65). The mean (SD) number of points scored per form was 14.82 (3.01) from a maximum of 33. Information regarding retainer

review and relevant potential impacts on quality-of-life was lacking and scored poorly. The requirement for lifetime retention was stated in 25 (73.5%) forms. Forms sourced from specialist orthodontist websites scored higher (P = 0.016) than those sourced from general dentist and multi-disciplinary clinic websites. The median (IQR) SMOG and FKGL scores were 10.11 (9.55) and 9.95 (9.18) respectively.

Conclusions

The reliability and quality of the informed consent forms concerning orthodontic retention and retainers was generally poor. The readability of the forms failed to meet recommended guidelines, meaning that many are likely not to comprehend the information provided.

Permission to Die? The Conflict of Consent in Brain Death Testing

Karrah St. Laurent-Ariot, George Clement, Bailey Brislin, Paul Zimmerman, Laura Hanson

Journal of Pain and Symptom Management, May 2025

Outcomes

1. Understand the ethics and laws regarding brain death testing.
2. Understand processes of brain death testing in ventilated patients and how these interact with patient and family values.

Key Message

Brain death testing can be inconsistent with patient's cultural beliefs. While consent is not required to evaluate for brain death, apnea testing for a ventilated patient is an involved process which can be traumatic for families. Moral distress can be reduced by using thorough communication early on to establish a care plan that incorporated her spiritual and cultural beliefs.

Abstract

While there is ongoing debate about the need for consent for brain death testing, American Academy of Neurology guidelines state there is “no obligation to obtain consent”. However, familial objection to brain death testing can present care teams with unique challenges.

Case

An 18-year-old woman was found unresponsive after going to sleep with a severe headache. Evaluation at a local hospital showed respiratory arrest triggering intubation, GCS 3, unresponsive pupils, and hypothermia; CT head demonstrated a large intracranial hemorrhage and evidence of brain herniation. She was transferred to a tertiary medical center where brain death testing was recommended once hypothermia resolved. Her father was initially amenable, but after consultation with faith leaders, declined apnea testing, the remaining step to diagnose brain death. Her hospitalization was complicated by substantial barriers to trust and communication. Her family recounted inconsistent information and policies, over-adherence to algorithms, and shades of historical manipulation of minorities. They employed video surveillance and threats of litigation and requested transfer to New Jersey where brain death criteria are not endorsed. Ultimately, the patient received tracheostomy and PEG and was discharged to a long-term acute care hospital.

Discussion

Apnea testing for a ventilated patient can be traumatic for families. Both the family and the medical team experienced immense moral distress which may have been ameliorated by early and thorough communication to establish a care plan that incorporated her spiritual and cultural beliefs. Only one state in the U.S, New Jersey, allows for religious exemptions to Death by Neurologic Criteria under its Declaration of Death Act. It is often helpful to let family witness serial neurological exams to better understand the condition of their loved ones. Lastly, incorporating palliative care and chaplaincy services can decrease moral distress of both families and medical teams.

> *Editor’s note: We note the reference to the American Academy of Neurology guidelines and it’s apparent treatment of consent, which we will be examining further within our Center for Informed Consent Integrity.*

Standardization of written informed consent forms to improve patient care, a quality improvement project

Jaweria Akram, Madeha Khalid, Rawand Abdelnaser Jebril, Isra Saleh Alsheikh, Amina Bougaila, Esha Subhash, Muhammed Zahid

BMJ Open Quality, 23 April 2025

Open Access

Abstract

Background

Informed consent taken by inadequately explaining the procedure to the patient or patient representative, along with incomplete documentation of the process, can have ethical, legal and administrative implications. We conducted a baseline survey from the patient's representative admitted to the Acute Medical Assessment Unit (AMAU), Hamad General Hospital (HGH) [Doha, Qatar], and their representatives to assess the level of satisfaction and understanding with the current informed consent taking process for thoracocentesis, ascitic tapping, lumbar puncture, blood, and blood product transfusion. It showed only 64% were satisfied. We conducted a Quality Improvement project to standardize the process of taking informed consent for the above-mentioned procedures in order to improve patient satisfaction from 64% to 80% by December 2021 by providing them with individualized informed consent forms along with patient information template in their preferred language.

Methods

A thorough process mapping showed different factors that can lead to inadequate informed consent. We introduced the use of individualized informed consent forms for each above-mentioned procedure with the already printed complications along with patient information template in their preferred language with pictorial presentation of the procedure. Ten Plan/Do/Study/Act (PDSA) cycles were conducted with each cycle lasting four weeks. Before each cycle, the quality team conducted extensive training sessions for the residents and nurses. Different reinforcements were provided with each cycle to ensure the utilization of the interventions.

Results

After 10 PDSA cycles, the level of satisfaction with the process of taking informed consent improved from 64% to 94%.

Conclusion

A standardized informed consent form, along with a patient information template written in their preferred language, improves patients' understanding to make a well-informed decision and therefore improves their satisfaction with the process, acting as a marker of quality improvement.

Legal Implication in Utilizing Automated Robots: A Written Informed Consent Form Proposal

Maria Teresa Contaldo, Sonia Triggiani, Giacomo Vignati, Daniele Bracchi, Gianpaolo Carrafiello

International Journal of Medical Robotics and Computer Assisted Surgery, 22 April 2025

Abstract

Background

Robotic systems enhance physicians' capabilities by replicating hand movements in real-time, ensuring precise control and a quick return to conventional procedures if patient safety is compromised. Physicians performing robot-assisted procedures bear ultimate responsibility, sharing potential liability with manufacturers for malfunctions.

Methods

This study, conducted by a transdisciplinary team of interventional radiologists and a legal expert, evaluates the integration of robotic systems in interventional radiology through a comprehensive literature review, addressing potential legal contingencies.

Results

This paper aims to define liability in this context and examines how workflows and doctor-patient relationships might be reshaped: patients must be informed about treatment options, including details about robot-assisted procedures and associated risks.

Conclusions

These systems could significantly impact interventional radiology practice. A dedicated informed consent process is necessary to ensure clear communication and protect the decision-making process and patient-centred care; thereby, an informed consent is proposed to comprehensively address these needs.

Informed Consent Practices for Publication of Patient Images in Dermatology Journals

Toluwani Taiwo, Bianca Obiakor, Sarah McClung, Kanade Shinkai

JMIR Dermatology, 18 April 2025

Introduction

Clinical images play an important role in informing clinical care and education in dermatology. Standardized informed consent for publishing patient images is an important concern regarding patient privacy, especially given increasing avenues for dissemination (eg. online publication and social media). Protecting patient privacy is a critical aim for dermatologists, as publishing images with potentially identifiable features is often necessary. Establishing trust between dermatologists and patients is imperative when complete anonymity cannot be guaranteed. Clear guidelines and thorough consent practices can ensure that authors are accountable for upholding patients' privacy and are transparent when obtaining photo consent, thereby empowering patients to make informed decisions about sharing their images. This study assesses current informed consent practices in image publication for top dermatology journals, examining author-facing guidelines and patient consent forms.

Rethinking the Burden of Traditional Informed Consent Prior to Prenatal Genetic Screening

Megan Allyse, Kirsten Riggan, Natasha Bonhomme, Marsha Michie

Hastings Center Report, 17 April 2025

Abstract

The ethics literature and professional guidelines call for extensive discussions prior to prescreening consent to prenatal cell-free DNA screening to, theoretically, allow patients to make decisions that match their values and goals of care. Most patients, however, actively avoid in-depth moral deliberation when consenting to prenatal screening and then receive a screen-negative result, suggesting that an information-heavy process is irrelevant for average-risk pregnancies. In addition, extensive information-based consent procedures are not feasible in many resource-limited contexts. Meanwhile, patients and families with screen-positive results frequently report minimal support following screening, resulting in long-term distress and suboptimal outcomes. We argue for a fundamental shift to an approach we call "just-in-time consent": identifying the essential information for values-based decisions prior to screening while relocating resources and moral deliberation to when families receive screen-positive results. This model both ensures that patients and families receive support when they most need it and maintains high standards for the ethical provision of prenatal genetic screening.

> *Editor's Note: We recognise that the "just-in-time consent" model proposed in this article could be very problematic. We will be examining this further in our Center for Informed Consent Integrity work.*

Challenges in Obtaining Informed Consent for Endovascular Thrombectomy in Acute Stroke: A Survey of Providers

Ali Alsarah, Amir Mbonde, Adam Dmytriw, Joshua Hirshch, Aneesh Singhal, Thabele Leslie-Mazwi, Anna Bonkhoff, Natalia Rost, Aman Patel, Michael Young, Robert Regenhardt

Neurology, 8 April 2025

Abstract

Objective

To identify challenges that providers face when obtaining informed consent (IC) for endovascular thrombectomy (EVT).

Background

IC is viewed as integral to medical practice and clinical research, particularly when procedures are involved. However, the process can be fraught with significant challenges, especially for time sensitive emergency treatments such as EVT.

Design/Methods

Healthcare providers involved in acute stroke care were surveyed from July to December 2023. The questionnaire was created using Qualtrics and distributed via institutional networks, professional societies including the American Academy of Neurology and StrokeNet, and social media.

Results

Among 391 total respondents, 74% were staff physicians, predominantly from the United States (70%) and employed at academic medical centers (76%). The mean duration in clinical practice was 13.1 ±10.6 years. When asked how often there was uncertainty regarding the optimal approach to IC for EVT, responses stated: "never" (35%), "sometimes" (52%), "often" (9%), and "always" (4%). Respondents answered “no” (21%), “yes” (56%), or “unsure” (23%), when asked if their institutions had policies around IC for EVT. Furthermore, 83% stated they never received training at their institutions on the topic. In free-text responses about perceived challenges to IC for EVT, several key themes emerged: time constraints in emergency settings (40%), lack of patient capacity (20%), availability of surrogates/family (15%), communication barriers (10%), institutional practices/policies (10%), and legal/ethical considerations (5%). Respondents stated: “time is brain,” “seems excessive like consent for CPR,” “overly ambitious to provide EVT even outside of guidelines,” “wildly different physician opinions,” and “patients are unusually incapacitated.”

Conclusions

This study underscores the provider uncertainty, lack of specific training, and challenges associated with obtaining IC for EVT in acute stroke care. To address these specific challenges, there is a critical need for standardized training, protocols, and guidelines that can be applied across varied geographical regions and multidisciplinary environments.

The role of the enrolling clinician in emergency research conducted under an exception from informed consent

Katherine Sahan, Ethan Cowan & Mark Sheehan

Theoretical Medicine and Bioethics, 1 April 2025

Open Access

Abstract

The Exception from Informed Consent (EFIC) permits patient enrolment into therapeutic emergency research where obtaining informed consent is challenging. Yet this fails to resolve a core ethical conflict in the research and has generated controversy. This is because existing justification and practice has relied on applying EFIC per study—a wholesale permission to enroll irrespective of circumstance—instead of per patient. Our novel justification for enrolment centers on applying EFIC per patient, which empowers the enrolling clinician to judge whether to enroll patients with an Exception. This contrasts with the idea that clinician judgment is surplus to the judgements already made by institutions in deciding the research may proceed. Instead, we show that enrolling clinician’s judgment is ethically significant and should not be overlooked: attending to this strengthens the research ethically and reduces controversy. There should be a bigger role for the clinician in the research enrolment space.

An Iterative Model of Informed Consent: A Trauma-Informed Approach to Consent in Gender-Affirming Surgery

Elijah R. Castle, Rey L. Daigle, Andres Cazares, Nathan Levitt, Augustus Klein

Transgender Health, 31 March 2025

Abstract

Discourse regarding informed consent in trans health care generally addresses overarching interventions (hormones, surgery) and not specific details of these interventions (who will be involved, what kind of and where touch is required), which threatens patient autonomy and bodily agency and reinforces power imbalances inherent in health care. Pelvic care has made the case for a trauma-informed approach to informed consent, which offers a strategy to discuss these specific details and mitigate such threats. In this article, we provide guidance for how clinicians working in gender-affirming surgery can implement a trauma-informed approach to informed consent through an iterative model of informed consent.

> *Editor's Note: The article states that "Principles of trauma-informed care stipulate that the clinician should seek consent for each part of the exam and, importantly, that the patient can stop the exam at any time."*

Feasibility, comprehension and applicability of broad consent in the emergency department: an exploratory mixed-methods study

Extended essay

Larissa Eienbröker, Antje Fischer-Rosinský, Martin Möckel, Frank Hanses, Felix Patricius Hans, Sebastian Wolfrum, Johannes Drepper, Daniela Krüger, Philipp Heinrich, Liane Schenk, Anna Slagman

Journal of Medical Ethics, 26 March 2025

Abstract

Background

The German Medical Informatics Initiative (MII) introduced a standardised Broad Consent (BC) form encompassing medical data, insurance data, contact information and biomaterials for health data research. This study assesses the feasibility of MII-BC in emergency departments (EDs), examining patient understanding and identifying implementation facilitators and barriers. Recommendations for implementation of MII-BC in EDs will be derived.

Methods

Mixed-method data were collected in EDs of four German university hospitals (UHs) using pseudonymised participant observation with a focus on patient perspective and surveys from patients. Data included MII-BC acceptance rates, patient understanding, motivation to consent and implementation facilitators and barriers. Quantitative data were analysed descriptively; qualitative data underwent content analysis with deductive–inductive category formation.

Results

The exploratory study involved 12 participant observations from four tertiary UHs, surfacing five key themes: (1) MII-BC patient information in the ED, (2) facilitators and (3) barriers in obtaining MII-BC in the ED, (4) patient perspectives on MII-BC and (5) recommendations for implementing MII-BC in EDs. Survey results (n=225) showed that most patients (89.8%) demonstrated high understanding of MII-BC patient information. Facilitators include empathetic engagement, clear communication and encouragement for questions. Hindering factors include estimating study time frames, ambient noises and study procedure interruptions. Adequate resources, such as trained staff and suitable premises, are crucial.

Conclusion

Implementing MII-BC in the ED is feasible with appropriate resources, though ED-specific challenges must be addressed. Successful MII-BC implementation in EDs hinges on ensuring access to comprehensible information materials, transparent communication and a calm recruitment environment.

Valid and Informed Consent in Orthopaedic Surgery: A Multicentre, Regional Service Evaluation of Current UK Practice

R Mills, M Sohail, H Sadique, O Adebayo, K Shanmuganathan, G Mamarelis, S Ali, A Sanalla, F Acquaah, A Ali, S Subhash, M Archunan, S Janjua, O Toma, V Matera, A Al-Sukaini, G Hourston, J Barwell, A Adeyeye, A Genena, M Lebe, S Towell, Ch Chan, A MacDowell, P Novak, W Khan, F Bhatti, A Iqbal, H Fawi, J Patel, M Begum, I Marciulynaite, N De Reock, R Tansey, S Hussein, Z Elgheriany, R Munni, T Sandhu, J Rahman, M Popescu, M Loeffler

Georgian Medical News, January 2025

Abstract

Background

In recent years, there has been increasing focus upon tailoring the consent process to reflect patients' individual needs and concerns. Meanwhile, clinical litigation costs for 'failure to warn' as part of 'informed consent' remain staggeringly high. We aimed to investigate the validity of the patient consent process in elective lower limb arthroplasty surgery regionally, with a view to ascertaining how it could be improved.

Methods

Regional data across the East of England was collected retrospectively from seven hospital trusts (fifty data sets per hospital) in 2021 and analyzed against predetermined criteria. Data analyzed included operation notes, patient records and clinic letters.

Results

A total of 165 elective knee and 173 elective hip replacement cases were included in the final analysis. Capacity criteria (defined as the ability to understand, retain, weigh up and communicate a decision) were fulfilled in 11.6% of hip and 13.9% of knee replacement surgeries, despite Consent Form 1 (a form commonly used in England to consent adults, deemed to have capacity, for surgical procedures) being completed in 94.8% and 88.5% of these same cases. Procedure-specific consent was obtained in 74.0% and 72.1% of cases, respectively, whilst 'Type' and 'Brand' of implant were rarely consented for. Alternative treatment options were offered in 67.1% of hips and 62.1% of knee cases. Separate consent clinics were offered in 55.5% of hip and 57.6% of knee cases.

Conclusions

This study demonstrates that there is room for improvement within the current consent process. We propose digitalization, utilizing interactive multimedia and audio-visual demonstrations to explain surgical procedures, as a dynamic and versatile adjunct to the consent process.

Informed Consent Regarding Risk of Stroke from Cervical Spine Manipulation: A Narrative Review

Steven Brown, James J. Lehman

Journal of the International Academy of Neuromusculoskeletal Medicine, 2025

Open Access

Abstract

Objective

Although the incidence of stroke following cervical spine manipulation (CSM) is low, the potential outcomes are serious. The objective of this study was to perform a narrative review to assess whether informed consent to the risk of stroke from CSM is recommended by chiropractic researchers and practice guidelines.

Methods

An electronic literature search was conducted in February 2025 using PubMed, Google Scholar, and the Index to Chiropractic Literature, covering 1989 to March 2025. Search terms included chiropractic, cervical spine manipulation, stroke, informed consent, and risk. English language peer reviewed studies by chiropractic physicians, along with practice guidelines written in whole or in part by chiropractic physicians, were considered.

Results

There was unanimous support for informed consent to the risk of stroke from CSM in the results. We identified two practice guidelines, two case control studies, three narrative reviews, and one case series authored by chiropractic physicians that recommend such informed consent. We did not find any peer reviewed studies that argued against such informed consent.
Conclusions
Informed consent to the risk of stroke from CSM is recommended by practice guidelines and chiropractic researchers. This lends weight to the view that such informed consent is the standard of care for the chiropractic profession.

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PRE-PRINT SERVERS

InformGen: An AI Copilot for Accurate and Compliant Clinical Research Consent Document Generation

Zifeng Wang, Junyi Gao, Benjamin Danek, Brandon Theodorou, Ruba Shaik, Shivashankar Thati, Seunghyun Won, Jimeng Sun
arXiv, 2 April 2025
Open Access
Abstract
Leveraging large language models (LLMs) to generate high-stakes documents, such as informed consent forms (ICFs), remains a significant challenge due to the extreme need for regulatory compliance and factual accuracy. Here, we present InformGen, an LLMdriven copilot for accurate and compliant ICF drafting by optimized knowledge document parsing and content generation, with humans in the loop. We further construct a benchmark dataset comprising protocols and ICFs from 900 clinical trials. Experimental results demonstrate that InformGen achieves near 100% compliance with 18 core regulatory rules derived from FDA guidelines, outperforming a vanilla GPT-4o model by up to 30%. Additionally, a user study with five annotators shows that InformGen, when integrated with manual intervention, attains over 90% factual accuracy, significantly surpassing the vanilla GPT-4o model's 57%-82%. Crucially, InformGen ensures traceability by providing inline citations to source protocols, enabling easy verification and maintaining the highest standards of factual integrity.

Co-designing the consent process of critical care trials with patients and the public: Project protocol

Timo Tolppa, Arishay Hussaini, Vrindha Pari, Nikhat Ahmed, Arjen Dondorp, Shehla Farooq, Madiha Hashmi, Monaza Khan, Adnan Masood, Saima Saleem, Zahyd Shuja, Marianne Vidler, Shahnaz Zaman, Srinivas Murthy
Wellcome Open Research, 31 March 2025
Abstract
Background
Informed consent processes in critical care trials can be overwhelming for patients and their families as decisions about participation need to be made under distressing circumstances. Existing consent processes have been developed for and by White Western populations, making them less relevant for racialized groups from low- and middle-income countries. One solution is involving patients, their relatives and members of the public from diverse backgrounds in co-designing informed consent processes.
Methods
This project aims to co-design the consent materials and processes for two ongoing critical care trials with an existing Patient and Public Involvement and Engagement group at Ziauddin University in Pakistan. Using

experience-based co-design and participatory action research, the process will follow six stages for each trial: (i) Introduction to trial and consent, (ii) Review of existing materials, (iii) Process mapping & recommendations, (iv) Creation of new materials, (v) Vetting, and (vi) Finalization. The final two steps involve collaboration with clinicians, trial teams, sponsors, and members of ethics review boards.

Expected Outcomes

The co-design process will produce new consent materials, aligned with patient and substitute decision-maker needs, that can be implemented to improve the conduct of two active trials. Deliverables include an informed consent process map, recommendations for revising consent materials, and guidelines on patient-centred formats. Additionally, training patient and public members in co-design will build capacity and enable the group to contribute to the design of consent processes of future trials.

Conclusion

Collaboration between patients, researchers and the public has the potential to promote ethical conduct of critical care trials in Pakistan and elsewhere by supporting patient-centered informed decision-making. This co-design process represents the first step towards achieving this goal, with future work evaluating the impact of the new consent materials and processes on trial enrolment rates, participant diversity and consent experiences.

Data sharing in child and adolescent psychiatry research: Key challenges (and some potential solutions)

Case Study

Beth Oakley, Alexandra Lautarescu, Tony Charman, Christopher Chatham, Eva Loth, Christian Beckmann, Thomas Bourgeron, Florence Campana, Rosie Holt, Eliza Eaton, Pierre Violland, Katrien Van den Bosch, Siofra Heraty, Scott Wagers, Jan Buitelaar, Declan Murphy, Amy Goodwin, Emily Jones

Open Research Europe, 31 March 2025

Open Access

Abstract

Background

The field of biomedical research is entering a new era, in which public data sharing is increasingly the norm. There are many advantages of embracing data sharing initiatives, including tackling the replication crisis through enhanced transparency and publication of null findings, facilitating global collaborations to accelerate research progress, enhancing cost-effectiveness by reducing duplication of efforts, and making scientific advances more accessible to the public. However, there are also several crucial ethical and logistical challenges that must be addressed to maximise the benefits of data sharing and minimise risks. The potential, and increasingly recognised, risks of unregulated data sharing (e.g., data reidentification, misuse, and lack of representativeness due to variability in who agrees to share data) have also been exemplified by high profile data breaches and directly clash with efforts to make research more robust, accessible, and global.

Methods/Results

Here, we narratively outline current challenges for data sharing from the perspective of child and adolescent psychiatry, one area where they may be particularly acute. For example, child and early adolescent research often requires caregivers to consent on behalf of a minor – increasing the responsibility of researchers to consider how the science of today may evolve into the future (when those individuals are no longer minors). We use data from our research consortium Autism Innovative Medicines Study - 2 - Trials (AIMS-2-TRIALS; https://www.aims-2-trials.eu/) to illustrate the points raised in this perspective piece.

Conclusions

We also propose some potential solutions to begin to address current challenges for data sharing, focusing on key priorities, including shared control of data curation between researcher and participant communities

and equity of access by research groups to the tools and resources needed to conduct responsible and sustainable data sharing.

Improving shared decision-making between paediatric haematologists, children with sickle cell disease and their parents: an observational post-intervention study

Ricardo Orlando Wijngaarde, Samantha C. Gouw, Dirk T. Ubbink

Research Square, 31 March 2025

Abstract

Background

Children with sickle cell disease (SCD) suffer from a chronic disease that can lead to serious co-morbidity and impacts their quality of life. During the course of their disease, a variety of health-related decisions need to be made for and by SCD-patients, depending on their age and health status, together with their parents and paediatric haematology clinicians. Shared decision-making (SDM) may improve health outcomes of chronically ill children but is still not commonly applied. We assessed the level of SDM among paediatric haematologists after the introduction of SDM-interventions.

Methods

An observational post-intervention study was conducted in a paediatric outpatient clinic of a university hospital. After an SDM consultation training of the three paediatric haematologists and introduction of SDM-supporting tools for both paediatricians and (parents of) patients with SCD, two evaluators independently and objectively analysed the level of patient involvement in decision-making from audio-recordings of the consultations using the OPTION-5 instrument. SDM-Q-9 and SDM-Q-Doc questionnaires were used to measure the level of SDM as perceived by patients/parents and paediatricians, respectively. Scores were expressed as a percentage, ranging from 0% (no SDM observed) to 100% (exemplary level of SDM).

Results

Participants were 9 female and 9 male patients between 3 months and 17 years old, with a mean age of 7.6 years (SD 5.5). Eighteen consultations (six per paediatrician) in which a decision was to be made about SCD treatment options were analysed. Median OPTION-5 score was 50 (Interquartile Range [IQR] 40–65%). Median SDM-Q-9 and SDM-Q-Doc scores were 73% (IQR 52.2–91) and 62.2% (IQR 55.6–71.1), respectively.

Conclusion

After the introduction of SDM training and tools, paediatric haematologists reached a moderately good level of SDM. This level had doubled as compared to the baseline level, as assessed in a previous study.

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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].

Call for submissions for Open-ended intergovernmental working group on an optional protocol to the Convention on the Rights of the Child

Issued by Working Group on an optional protocol to the Convention on the Rights of the Child

Deadline 18 May 2025

Background

On 10 July 2024, the Human Rights Council adopted resolution 56/5, in which it decided to establish an openended intergovernmental working group of the Human Rights Council with the mandate of exploring the possibility of, elaborating and submitting to the Human Rights Council a draft optional protocol to the Convention on the Rights of the Child with the aim to:

a. Explicitly recognize that the right to education includes early childhood care and education;
b. Explicitly state that, with a view to achieving the right to education, States shall:
    1. Make public pre-primary education available free to all, beginning with at least one year;
    2. Make public secondary education available free to all;
c. Recall that States shall promote and encourage international cooperation in matters relating to education;
d. Consider a provision that would allow for States parties to the Convention on the Rights of the Child to incorporate all reporting on their obligations under the optional protocol into their reports submitted under article 44 of the Convention, eliminating the need for an initial or other separate reports.

Key questions and types of input/comments sought

Respondents are requested to limit their comments to a maximum of 5 pages. Additional supporting materials, such as reports, academic studies, and other types of background materials may be annexed to the submission.

1. What are the main barriers to public pre-primary education available free to all in law, policy, and practice in your country and what is their impact on the rights of the child? Please consider the specific situation of marginalized children and those in vulnerable situations in your response.
2. What are the main barriers to public secondary education available free to all in law, policy, and practice in your country and what is their impact on the rights of the child? Please consider the specific situation of marginalized children and those in vulnerable situations in your response.
3. What are examples of innovative and sustainable financial mechanisms to support the full and effective implementation of public pre-primary and secondary education available free to all children in your country?
4. What steps is the Government taking to remove barriers and make public pre-primary and secondary education available free to all, including through the allocation of adequate resources and cross-sectoral and international cooperation? Please provide examples of specific laws and regulations, measures, policies, and programmes.

Call for submissions: draft of general comment No. 27 on children's right to access to justice and to an effective remedy

Issued by CRC

Deadline 30 June 2025

Background

During its 95th session in January 2024, the Committee on the Rights of the Child decided to draft a general comment on children's right to access to justice and to an effective remedy. The concept note of the general comment is here.

Consultations on the concept

- In May 2024, the Committee issued a call for submissions inviting all interested parties to provide contributions to clarify terms, approaches and actions States should take in order to implement the right of all children to access justice and effective remedies.
- The consultation guidance from UNICEF was available here, and information from Child Rights Connect for organizers of focus group discussions or consultations with children was available here. Stakeholders specified their plans for consultations here to promote collaboration.
- The Committee received 315 submissions as well as outcomes from over 141 consultations held on the general comment, of which over 82 consultations involved the participation of at least 7,215 children.

Call
The Committee on the Rights of the Child now seeks contributions from all interested stakeholders on the draft of the general comment. The draft is available here. Information for children by Child Rights Connect and UNICEF is available here. Background information about the general comment here.

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NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

No new normative guidance 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.

Mining Companies Must Obtain Free, Prior, Informed Consent, Partner with Indigenous Peoples to Ensure Responsible, Ethical Land Use, Speakers Tell Permanent Forum

United Nations: Meetings Coverage and Press Releases, 23 April 2025
Excerpt
Mining companies must obtain free, prior and informed consent from Indigenous Peoples when pursuing projects on their ancestral lands, speakers emphasized at the 2025 session of the Permanent Forum on Indigenous Issues — a high-level advisory body to the Economic and Social Council. Participants also discussed how partnerships can mobilize adequate development finance for Indigenous communities… The Permanent Forum has before it a related study (document E/C.19/2025/6), titled "The rights of Indigenous Peoples in the context of critical minerals to ensure a just transition"…

# # # #

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