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governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

September 2024 :: Issue 69

This digest aggregates and distills key content addressing informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations.

In preparing this digest, we monitor a broad range of academic journals and utilize *Google Scholar* to identify articles referencing informed consent or assent. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic literature globally, including calls for public consultation and symposia/conferences which address consent/assent in whole or in part. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

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

Informed Consent: A Monthly Review is a service of the Center for Informed Consent Integrity (CICI), a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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We organize content in this digest using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. We lead each edition with a spotlight section highlighting content which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, evidence, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

Content Type/Subject Areas	Page
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RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT 19
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No new content was identified for the following established categories:

CAPACITY TO CONSENT
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
GENERAL/OTHER
HUMANITARIAN CONTEXT

Please note that while we strive to identify the primary subject area for the categorization of content, we also recognize that many articles are relevant across other subject areas. We encourage readers to review the entire digest and to utilize the search function on our website where articles are cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the website.

SPOTLIGHT ARTICLES – YOUNG PERSONS

For our *Spotlight* section this month, we feature our full *Young Persons* section, recognizing that the articles included are both important and diverse.

We note in particular, two recent review articles discussed further just below, as well as a position statement from the Malaysian Academy of Medicine for obtaining assent for research involving children in that country, with an interesting set of recommendations. These recommendations include enhancing comprehension, by "…customising assent procedures by integrating visual aids, multimedia resources, verbal explanations and open question sessions. Innovative methods, such as combining images with text or utilising multimedia…" to help "ensure the development of its best practice."

In the *Journal of Adolescent Health* article **Positive Impacts of Adolescent Involvement in Health Research: An Umbrella Review,** Warraitch et al. present the positive impact experienced by adolescents when included in research, as well as the resulting increased quality of the research involved. In their Conclusion, the authors argue that "…Moving forward, rigorous evaluation of adolescent involvement and transparent reporting methods are vital to advancing our understanding of the benefits of engaging youth. By recognizing the transformative potential of adolescent engagement, this review calls for proactive efforts from researchers, institutions, and funding agencies to promote and sustain their active involvement in research initiatives."

In the *AJOB Empirical Bioethics* article **Pediatric Assent in Clinical Practice: A Critical Scoping Review** Wasserman et al. lay out the contextual elements unique to pediatric assent, including its long-term development, and how to approach unique ethical elements involved, such as respect, empowerment and rights. The authors underscore three central themes emerging from their analysis:
[1] Valid pediatric assent depends on the context. It varies by treatment and geographic/cultural setting.
[2] Pediatric assent is conceived as a longitudinal process in two distinct ways. One involves multiple iterations of eliciting the preferences of pediatric patients within the context of a treatment decision or episode of care; the other involves attending to children's developmental maturity over time.
[3] The ethical justifications for pediatric assent are underspecified. Authors often invoked ambiguous notions like "respect" or drew heavily on the concept of autonomy, despite its questionable relevance in many pediatrics cases.

Positive Impacts of Adolescent Involvement in Health Research: An Umbrella Review

Azza Warraitch, Ciara Wackera, Sanjana Biju, Maria Leea, Delali Bruce, Paul Curran, Qusai Khraisha, Kristin Hadfield

Journal of Adolescent Health, August 2024

Open access

Abstract

Despite an increased recognition of the right of adolescents to be involved in decisions that affect them, young people continue to be under-involved in health research. One of the reasons is a lack of awareness among researchers on the current evidence base around the benefits of involving adolescents. To address this, we conducted an umbrella review to synthesize the evidence on the positive impacts of adolescent involvement in health research. This umbrella review was preregistered with PROSPERO (CRD42021287467). We searched 11 databases, Google Scholar, PROSPERO, reference lists, 10 journals, websites of 472 organizations, and sought input from experts. Ultimately, we included 99 review articles. We found that adolescent involvement has many positive impacts on young people, including increased knowledge and skills; personal development; financial benefits; career and academic growth; enhanced relationships; and valuing their experience. The positive impacts of adolescent involvement on the research itself include increased relevance of the study to adolescents, improved recruitment, development of more adolescent-friendly materials, enhanced data collection and analysis, and more effective dissemination. Researchers also benefited from adolescents' involvement through increased knowledge, skills, and a shift in their attitudes. The evidence supporting the positive impacts of adolescent involvement in research is substantial but limited by a lack of rigorous evaluation, inconsistent reporting, and unclear evaluation methods.

Pediatric Assent in Clinical Practice: A Critical Scoping Review

Research Article

Jason Adam Wasserman, Amelia N. Najor, Natalie Liogas, Stephanie M. Swanberg, Abram Brummett,, Naomi T. Laventhal, Mark Christopher Navin

AJOB Empirical Bioethics, 21 August 2024

Abstract

Background

This study assesses how pediatric assent is conceptualized and justified within the therapeutic context. Pediatric ethicists generally agree that children should participate in medical care decisions in developmentally appropriate ways. Much attention has been paid to pediatric assent for research participation, but ambiguities persist in how assent is conceptualized and operationalized in the therapeutic context where countervailing considerations such as the child's best interest and parental permission must also be weighed.

Methods

Searches were conducted in 11 databases including PubMed, Embase, Cochrane Library, and Web of Science. Articles published between 2010 and 2020 were screened in COVIDENCE for meeting each of four criteria: (1) focusing on pediatric assent, (2) focusing on clinical care, (3) including normative claims, and (4) containing substantive statements about the meaning of pediatric assent. Full texts were abstracted for (1) operational definitions of assent, (2) discussion of the temporal nature of assent, (3) description of the concept of "understanding," and (4) ethical justifications for soliciting assent. These excerpts were coded and code patterns formed themes presented in the results.

Results

The final analytic data set contained 29 articles. Analysis yielded three key themes. First, valid assent varies by treatment, population (e.g., younger versus older), and geographic/cultural context. Second, assent represents two distinct longitudinal processes: One involves eliciting preferences over a disease course or care episode; the other focuses on children's developmental maturation. Third, ethical justifications for assent draw variously on instrumental and intrinsic reasons, but often remain ambiguous.

Conclusions

There is widespread agreement that assent is morally valuable, but there remain substantial ambiguities or disagreements about its meaning, process, and ethical justification.

Obtaining assent for research involving children in Malaysia: a position statement from the Academy of Medicine of Malaysia College of Paediatrics

E J Khoo, B A Zilfalil, M K Thong, S C Yong, S C Chee, J K Lee, S H Teh, F Taib, F C Cheah

Medical Journal of Malaysia, July 2024; 79(4) pp 494-497

Abstract

The Academy of Medicine of Malaysia College of Paediatrics acknowledges the role of children in research and this position statement explores the ethical considerations in obtaining assent from minors in the Malaysian context. It highlights the importance in respecting children's agency and navigating cultural complexities. The College proposes flexibility in the minimum age for assent of at least nine years old, while emphasising the need for a tailored assent procedure. Addressing language and cultural diversities and expanding local empirical research on a formal assent process are some building blocks in developing a standardised nationwide process in obtaining assent from children.

Recommendations

Considering the challenges associated with obtaining ethical and effective assent for research involving children in Malaysia, the College proposes several recommendations to address these issues towards best practice.

1. Recognising the importance of respecting children as individuals with their own rights, the College suggests a flexible approach to the minimum age for assent. Specifically, the College recommends raising the minimum age to at least nine years old, guided by current available evidence. Additionally, this flexibility should be applied with consideration for the complexity of the research, ensuring that the assent process is age appropriate. Such an approach not only acknowledges the child's agency but also aids in the development of decision-making skills crucial for adulthood, contributing to the cultivation of trust in an era of evolving healthcare systems.
2. The College emphasises the need for tailored assent procedures that account for varying educational levels among children. To enhance comprehension, the College suggests customising assent procedures by integrating visual aids, multimedia resources, verbal explanations and open question sessions. Innovative methods, such as combining images with text or utilising multimedia, can further ensure the development of its best practice.
3. The College calls attention to the dynamic nature of the assent process, emphasising that obtaining assent is a dialogue. While the College advocate for researchers documenting a child's assent for accountability, the process is not a one-time signature on a form, that could all the more so place a

burden on the child to engage in a significant act they might not fully comprehend. Recognising assent as an ongoing and dynamic process, continuous evaluation is desirable.

4. The College addresses the diverse linguistic landscape of Malaysia by recommending proactive language accessibility. This includes addressing translation needs to ensure inclusivity. Furthermore, the College advises granting sufficient time and privacy for consultations with parents, guardians and children. Additionally, extending this process to include discussions with extended family members or community members, as applicable, is deemed crucial. Cultural nuances that may influence the assent process should be acknowledged and navigated accordingly.
5. Given the absence of data on the appropriate age for obtaining assent in Malaysia, the College recommends and supports the conduct of local empirical research in this area. This research aims to better understand the cultural contexts within Malaysia and subsequently formulates the basis for developing assent practices nationwide. Such an approach stresses the importance of tailoring assent procedures to the unique cultural diversity present in Malaysia.

Conclusion

Addressing the challenges of obtaining assent from minors in Malaysia requires a multifaceted approach. This position statement by the College not only delineates its challenges but also outlines a path forward, emphasising the importance of respecting children's developing capacity and ensuring effective communication, while navigating Malaysia's socio-cultural landscape. Establishing local policies and guidelines must be dynamic and responsive to evolving research and societal norms. Advocating for best practices at a local level will deepen understanding and inform the formulation of standardised nationwide assent practices.

Consent for anaesthesia: considerations in children and young people

Niall Tierney, Caoimhe Casby, Barry Lyons

Anaesthesia & Intensive Care Medicine, 9 August 2024

Abstract

The law relating to consent for medical interventions in children is complex. Children, when they are old or mature enough can consent for themselves, but the legal rules around this vary by jurisdiction. When they are unable to consent, this must be sought from someone with parental responsibility. This article discusses consent, and its refusal, to medical interventions by children, adolescents and parents.

Ethical guidelines for human research on children and adolescents: A narrative review study

Review Article

Gholamreza Askari, Mahdi Vajdi, Saeede Jafari-Nasab, Sahar Golpour-Hamedani

Journal of Research in Medical Sciences, August 2024

Abstract

The implementation of human research involving children and adolescents necessitates a nuanced understanding of the distinct ethical complexities and sensitivities that arise. This study aimed to conduct a comprehensive review of ethical guidelines for research with these populations by extensively examining existing standards and applied studies. The review revealed a myriad of challenges inherent in the involvement of children and adolescents as research subjects. The most important ethical challenges relate to the principles of bioethics and their compliance with human studies involving children/adolescents, informed consent, and risk assessment in studies on children/adolescents. To facilitate appropriate participation of youth in research endeavors, meticulous planning is required, in conjunction with a re-examination of the definitions of ethical principles in pediatric research, close monitoring of potential risks and benefits, and the utilization of a combination of innovative and traditional approaches to obtain informed consent that adheres to ethical standards. Performing research with children and adolescents requires special considerations to address the unique ethical issues that can emerge. By adhering to ethical

guidelines tailored specifically to these vulnerable populations, researchers can help ensure that studies are conducted in an appropriate and responsible manner.

Understanding the process of adolescent assent for voluntary male medical circumcision in Zimbabwe: findings from a cross-sectional study

Research

Rebecca L. West, Sunny Sharma, Nisa Hurst, Will Bench, Nehemiah Nhando, Brian Maponga, Lucy Bullock, Darius Egualeonan, Jemma Reast, Sinokuthemba Xaba, Karin Hatzold & Sehlulekile Gumede-Moyo

Discover Public Health, 30 July 2024

Open Access

Abstract

Background

Voluntary medical male circumcision (VMMC) is a method for combination HIV prevention for adolescents > 15 years in settings with generalized epidemics. In Zimbabwe, policy currently allows VMMC in adolescents > 15 years old, but there is consideration to lower the threshold to 13 years old. There is a need to understand current practices in assent/consent, and parents' requirements for assent/consent to inform policy recommendations for the VMMC programme in lowering its age threshold.

Methods

Cross-sectional surveys were conducted in September 2022 using convenience sampling among three respondent groups: uncircumcised adolescents/young men (AYM) aged 13–16 years (n = 881), circumcised AYM aged 13–20 years (n = 247), and parents of uncircumcised adolescents aged 13–16 years (n = 443). Surveys asked about VMMC knowledge, experiences with mobilisers, circumcised AYM's assent/consent experiences, and parents' preferences for assent/consent processes.

Results

Knowledge of VMMC was significantly lower among younger adolescents aged 13–14 than their 15–16 year-old peers. 57% (142/247) of circumcised AYM had a one-to-one discussion with their provider before having the procedure, 32% (80/247) said they were not fully informed about VMMC prior to the procedure, and 54% (134/247) wanted more information about procedure-related pain. Over half (56%, 42/75) of circumcised AYM whose parents had not provided consent in-person for them to receive the procedure reported that their parents had never been contacted to verify consent.

Conclusions

There are gaps in the current assent/consent process for VMMC in Zimbabwe. Providers should be trained to give balanced information on risks and benefits of the procedure, including potential for pain. One-on-one discussions between providers and adolescents prior to the procedure, age-appropriate counselling, and tools for providers to ascertain adolescents' understanding and ability to provide assent are essential processes, especially if the age threshold is lowered to include younger adolescents. it is also imperative to improve communication with parents, particularly to verify consent for their children has been given, per national guidelines.

Obtaining Consent for Research on Risky Behaviours Among Adolescents in Canada: A Scoping Review

Review Article

Lillian MacNeill, A. Luke MacNeill, Shelley Doucet, Alison Luke, Alex Goudreau

Journal of Empirical Research on Human Research Ethics, 15 May 2024

Open Access

Abstract

This scoping review explores current practices for obtaining consent in research on risky behaviours among adolescents in Canada. The JBI methodology for scoping reviews was used. The database search was conducted in August 2021 and updated in November 2022. Papers published in 2010 or later were included. Extracted data included study characteristics, sample characteristics, and consent procedures. The review included 83 reports covering 57 studies. Nearly 60% of studies relied on adolescent self-consent for participation. Adolescent self-consent was more common than parental/guardian consent for studies using in-person research methods, older adolescent groups, and particularly vulnerable populations. Parental/guardian consent was more common for studies using younger age groups and general population samples. Adolescent self-consent was more common than parental/guardian consent for most risky behaviours covered by this review. These results provide insight into current consent practices in this area and offer guidance to researchers and institutional review boards in Canada.

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BIOMEDICAL RESEARCH

Individualized clinical decisions within standard-of-care pragmatic clinical trials: Implications for consent

Research article

Isabel M Astrachan, James Flory, Scott YH Kim

Clinical Trials, 15 August 2024

Abstract

Pragmatic clinical trials of standard-of-care interventions compare the relative merits of medical treatments already in use. Traditional research informed consent processes pose significant obstacles to these trials, raising the question of whether they may be conducted with alteration or waiver of informed consent. However, to even be eligible, such a trial in the United States must have no more than minimal research risk. We argue that standard-of-care pragmatic clinical trials can be designed to ensure that they are minimal research risk if the random assignment of an intervention in a pragmatic clinical trial can accommodate individualized, clinically motivated decision-making for each participant. Such a design will ensure that the patient-participants are not exposed to any risks beyond the clinical risks of the interventions, and thus, the trial will have minimal research risk. We explain the logic of this view by comparing three scenarios of standard-of-care pragmatic clinical trials: one with informed consent, one without informed consent, and one recently proposed design called Decision Architecture Randomization Trial. We then conclude by briefly showing that our proposal suggests a natural way to determine when to use an alteration versus a waiver of informed consent.

Evaluation of a group-based online informed consent conversation (eConsent) in participants from a low-risk vaccination clinical trial

Research

Ngoc H. Tan, Melvin Lafeber, Roos S. G. Sablerolles, Isabelle Veerman Roders, Anna van de Hoef, Karenin van Grafhorst, Leo G. Visser, Douwe F. Postma, Abraham Goorhuis, Wim J. R. Rietdijk, P. Hugo M. van der Kuy

Trials, 7 August 2024

Open Access

Abstract

Background

Electronic informed consent (eConsent) usage has expanded in recent years in Europe, especially during the pandemic. Slow recruitment rate and limitations in participant outreach are the challenges often faced in

clinical research. Given the benefits of eConsent and group counselling reported in the literature, group eConsent was implemented in recruitment for the SWITCH-ON study. We aim to explore the experience of participants who attended group eConsent for the SWITCH-ON study and evaluate its potential for future use.

Methods

SWITCH-ON study aims to analyse the immunogenicity of a healthy population following bivalent COVID-19 booster vaccination. Four hundred thirty-four healthcare workers aged 18–65 were successfully recruited and sent a questionnaire about their experience with group eConsent. Out of 399 completed questionnaires (response rate 92%), 39 participants did not join group eConsent. The remaining 360 responses were included in the final analysis. Quantitative and qualitative data were reported using descriptive statistical analysis and thematic analysis respectively.

Results

Participants found that group eConsent was an efficient method that it allowed them to hear each other's questions and concerns and created a sense of togetherness. However, limited privacy, barriers to asking questions in a group, and peer pressure can limit the use of group eConsent. One hundred sixty-five (46%) participants thought that group eConsent was suitable to recruit participants with diseases or conditions, while 87 (24%) reported limitations with this method. The remaining participants suggested that applicability of group eConsent depended on the diseases or conditions of the study population, and one-to-one conversation should always be available. Participants who had experienced both one-to-one and group eConsent shared different preferred consent formats for future studies.

Conclusion

Group eConsent was positively evaluated by the participants of a low-risk vaccination study. Participants advised using webinars to provide general information about the study, followed by an individual session for each participant, would retain the benefits of group eConsent and minimise the limitations it posed. This proposed setting addresses privacy questions and makes group eConsent easier to implement.

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SOCIAL SCIENCE RESEARCH

IRB Consent Guidelines: Potential Barriers to Diversity in Research

Research Article

Evan Decker, Tana Chongsuwat

Health Promotion Practice, 2 August 2024

Abstract

Despite initiatives aimed at improving study participation and inclusion among ethnic and racially minoritized and marginalized populations, participation remains low. While necessary to ensure ethical practice in human participant research, certain Institutional Review Board (IRB) guidelines may introduce additional barriers in research involving these populations. This work outlines guidelines pertaining to consent translation for non-English speaking populations and offers discussion on a greater emphasis for more inclusive methods for marginalized communities. The University of Wisconsin's IRB approved alternative oral consent processes after the community partner determined that standard translation processes would be inefficient. Researchers used translated consent materials for four different ethnic groups (Hmong, Karen, Karenni, and Burmese). We provided recorded consents in each respective language to participants before study participation and obtained verbal consent prior to study participation at the study location. We experienced time and resource constraints in both access to translators and the consent-translation process itself. Furthermore, many participants were unable to read in their native language making standard written consent processes both difficult and impractical. Oral discussion and verbal consent processes were efficient.

Adjustments to consent-related guidelines may prevent and eliminate time and resource-related barriers in consent processes. In eliminating such barriers, subsequent improved efficiency in both study design and study promotion areas can work to better promote diversity in research among populations that emphasize oral language and in instances where literacy rates in written non-English language may be lower.

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ARTIFICIAL INTELLIGENCE

Meaningful and Informed Consent and Satisfactory Education for Physicians Using AI in Radiology

Katerina Kapotas Tapas

Journal of Health Care Compliance, 2024

Abstract

The article explores the use of artificial intelligence (AI) in radiology and the challenges it poses in terms of transparency and understanding. It emphasizes the importance of human oversight and control over AI systems, as well as the principles of prudence, human autonomy, and responsibility. The article also highlights the need for informed consent and adequate education and training for physicians using AI. While AI has the potential to improve diagnostic accuracy and patient outcomes in radiology, ethical considerations must be carefully addressed. The text includes a list of sources and covers various topics related to Medicare Advantage, improper payments, compliance audits, online trackers, HIPAA compliance, challenges in healthcare operations, business formation, and compliance program fundamentals. It provides factual information and insights without expressing personal judgments or opinions.

Safeguarding Data Privacy and Informed Consent: Ethical Imperatives in AI-Driven Mental Healthcare

Souvik Dhar, Utsa Sarkar

Intersections of Law and Computational Intelligence in Health Governance, 2024 [IGI Global]

Abstract

This chapter explores the ethical challenges surrounding data privacy and informed consent in artificial intelligence (AI)-driven mental healthcare in India. The integration of AI technologies in mental health services offers potential for enhanced patient outcomes, but also raises significant ethical issues. Emphasizing patient autonomy and the protection of personal information, the chapter examines the complexities of informed consent and data privacy. It highlights the importance of transparent communication and robust regulatory frameworks to safeguard patient rights. By analysing key principles and the Digital Personal Data Protection Act 2023, the chapter provides insights into balancing technological advancements with ethical imperatives. It advocates for comprehensive ethical guidelines and collaborative efforts among stakeholders to foster a responsible and patient-centred AI-driven mental healthcare system. The chapter emphasizes the need for education on AI's impact, potential biases, and the significance of maintaining trust and accountability in patient care.

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HEALTH DATA/DATA

Privacy, Data Protection and Data-driven Technologies

Book

Martin Ebers, Karin Sein
Routledge, 2025
Description
This book brings together contributions from leading scholars in law and technology, analysing the privacy issues raised by new data-driven technologies. Highlighting the challenges that technology poses to existing European Union (EU) data protection laws, the book assesses whether current legal frameworks are fit for purpose, while maintaining a balance between supporting innovation and the protection of individual's privacy. Data privacy issues range from targeted advertising and facial recognition, systems based on artificial intelligence (AI) and blockchain, and machine-to-machine (M2M) communication, to technologies that enable the detection of emotions and personal care robots. The book will be of interest to scholars, policymakers and practitioners working in the fields of law and technology, EU law and data protection
[Chapters Relating to Consent]
Part II: Consent, Data Protection and New Technologies
Chapter 2: Dark Patterns and the Scraping Consumer Consent: Comparative Remarks on More Effective Legal Compliance, Giorgia Guerra
Chapter 3: The Consent Service in Estonia: Enhancement of State-held Data Sharing vs Privacy Risks, Karin Sein
Chapter 4: Consent to Data Processing in Biobanking: Regulatory Challenges of Data Processing in Biobanking, Using the Estonian Example, Kärt Pormeister

Retrospective Radiology Research: Do We Need Informed Patient Consent?

Original Research
Yfke Ongena, Thomas C. Kwee, Derya Yakar, Marieke Haan
Journal of Bioethical Inquiry, 19 August 2024
Open Access
Abstract
While knowledge of the population's view on the need for informed consent for retrospective radiology research may provide valuable insight into how an optimal balance can be achieved between patient rights versus an expedited advancement of radiology science, this is a topic that has been ignored in the literature so far. To investigate the view of the general population, survey data were collected from 2407 people representative of the Dutch population. The results indicate that for non-commercial institutions, especially hospitals (97.4 per cent), respondents agree with the retrospective use of imaging data, although they generally indicate that their explicit consent is required. However, most respondents (63.5 per cent) would never allow commercial firms to retrospectively use their imaging data. When including only respondents who completed the minimally required reading time of 12.3 s to understand the description about retrospective radiology research given in the survey (n = 770), almost all (98.9 per cent) mentioned to have no objections for their imaging data to be used by hospitals for retrospective research, with 57.9 per cent indicating their consent to be required and 41.0 per cent indicating that explicit patient consent to be unnecessary. We conclude that the general population permits retrospective radiology research by hospitals, and a substantial proportion indicates explicit patient consent to be unnecessary when understanding what retrospective radiology research entails. However, the general population's support for the unrestricted retrospective use of imaging data for research purposes without patient consent decreases for universities not linked to hospitals, other non-commercial institutions, government agencies, and particularly commercial firms.

Statistical Analysis of Abilities to Give Consent to Health Data Processing

Antonella Massari, Biagio Solarino, Paola Perchinunno, Angela Maria D'Uggento, Marcello Benevento, Viviana D'Addosio, Vittoria Claudia De Nicolò, Samuela L'Abbate

Applied Mathematics, August 2024

Abstract

The recent pandemic crisis has highlighted the importance of the availability and management of health data to respond quickly and effectively to health emergencies, while respecting the fundamental rights of every individual. In this context, it is essential to find a balance between the protection of privacy and the safeguarding of public health, using tools that guarantee transparency and consent to the processing of data by the population. This work, starting from a pilot investigation conducted in the Polyclinic of Bari as part of the Horizon Europe Seeds project entitled “Multidisciplinary analysis of technological tracing models of contagion: the protection of rights in the management of health data”, has the objective of promoting greater patient awareness regarding the processing of their health data and the protection of privacy. The methodology used the PHICAT (Personal Health Information Competence Assessment Tool) as a tool and, through the administration of a questionnaire, the aim was to evaluate the patients’ ability to express their consent to the release and processing of health data. The results that emerged were analyzed in relation to the 4 domains in which the process is divided which allows evaluating the patients’ ability to express a conscious choice and, also, in relation to the socio-demographic and clinical characteristics of the patients themselves. This study can contribute to understanding patients’ ability to give their consent and improve information regarding the management of health data by increasing confidence in granting the use of their data for research and clinical management.

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BIOBANKING

Developing Informed Consent for Academic Hospital-Based Biobank Modeling: An Experience from Indonesia

Research Article

Wika Hartanti, Amirah Ellyza Wahdi, Tika Prasetiawati, Qurry Amanda Izhati, Jajah Fachiroh

Biopreservation and Biobanking, 21 August 2024

Abstract

Background

Informed consent (IC) for biobank practice is vital to ensure that sample collection, storage, and utilization are ethical. However, the standard practices in biobanking in upper-middle-income countries such as Indonesia often rely on specific consent, leading to restricted sample use and ethical concerns. This article describes the development of an IC model that meets ethical standards and yet is acceptable for biobanking practice in an Indonesian academic hospital.

Method

We conducted a study involving Universitas Gadjah Mada (UGM) Biobank Unit and the UGM Academic Hospital, Yogyakarta, Indonesia, between 2019 and 2021. The IC development process consisted of four stages: (1) conceptualization, (2) preparation, (3) pilot, and (4) evaluation. These activities were part of a more extensive pilot study for an academic hospital-based biobank (Medical Biobank for Research in Indonesia (MBRIO) study).

Result

We conceptualized a broad consent model, consisting of an information sheet, comprehension test, agreement sheet, and exit survey. We tested and revised the broad consent document to ensure readability, trained 10 consenting staff (1 surgeon and 9 nurses), and then piloted the IC procedure on 24 patients with elective surgery. The evaluation showed that patients understood the information objectively and subjectively. Consenting staff considered the broad consent model acceptable for the academic hospital

setting and suggested improvements to increase the readability of information sheets and have more trained staff for better coordination.
Conclusion
The IC development process and model consent are ethically sufficient, acceptable and feasible to be implemented in academic hospital-based biobanks in Indonesia adjusted to the business processes.

Dynamic governance: A new era for consent for stem cell research

Perspective
Rosario Isasi, Heidi B. Bentzen, Morris Fabbri, Antonie Fuhr, Joel C. Glover, Nancy Mah, Deborah Mascalzoni, Sabine Mueller, Stefanie Seltmann, Andreas Kurtz
Stem Cell Reports, 15 August 2024
Open Access
Summary
Governance infrastructures streamline scientific and ethical provenance verification of human pluripotent stem cell (SC) lines. Yet, scientific developments (e.g., SC-derived embryo models, organoids) challenge research governance approaches to stored biospecimens, questioning the validity of informed consent (IC) models. Likewise, e-health platforms are driving major transformations in data processing, prompting a reappraisal of IC. Given these developments, participatory research platforms are identified as effective tools to promote longitudinal engagement, interactive decision-making, and dynamic governance. Learning from European initiatives piloting dynamic IC for biobanking and SC research, this Perspective explores the benefits and challenges of implementing dynamic IC and governance for SC.

Consent to Data Processing in Biobanking: Regulatory Challenges of Data Processing in Biobanking, Using the Estonian Example

Book Chapter
Kärt Pormeister
Privacy, Data Protection and Data-driven Technologies, 2024 [Taylor&Francis]
Abstract
Under European Union (EU) data protection law, consent can generally only be relied upon as a legal basis for processing personal data if the consent has been given for one or more specified purposes. The fact is that in the world of scientific research, this is not always possible or feasible, is recognized in the recitals of the General Data Protection Regulation. Unfortunately, the European Data Protection Board has rendered this recognition in the recitals effectively moot by maintaining that even in research, a broader consent to data processing could only go as far as to cover multiple pre-defined projects, but not undefined future projects. This 'one-size-fits-all' stance on consent to data processing is a problem for biobanks, the existence and data processing purposes of which cannot be confined to pre-defined research projects. In the first part of this chapter, the author explores the evolution of consent to data processing for research purposes in EU data protection law and the interpretations given to it by a number of data protection institutions, and contrasts these to other emerging regulatory regimes within the EU concerning the (secondary) research use of personal data. In the second half of the chapter, the author exemplifies the previously explored theoretical problems using the Estonian Biobank as a practical example.

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GENOMIC MEDICINE/GENE EDITING

Genomic sequencing in newborn screening: balancing consent with the right of the asymptomatic at-risk child to be found

Bartha Maria Knoppers, Ana Eliza Bonilha, Anne-Marie Laberge, Arzoo Ahmed, Ainsley J. Newson

European Journal of Human Genetics, 12 August 2024

Open Access

Abstract

In this paper, we explore key aspects of the complex ethical and legal landscape surrounding consent in the context of incorporating genomic sequencing into existing newborn bloodspot screening programs. In particular, we consider the potential impact of genomic sequencing on the health rights of the child in relation to existing consent practices in newborn screening. We begin with an introduction to newborn screening programs and their population health goals. We then discuss public health ethics as a rationale underpinning newborn screening before turning to consent. We go on to describe seven current research projects on genomic sequencing in newborn screening and then introduce the 'right of the asymptomatic at-risk child to be found' as a useful concept to draw on when considering consent to newborn screening. We draw on this novel right to argue for the adoption of "appropriate consent" when it comes to certain uses of genomics in newborn screening. We contend that, for 'virtual panels' at least, appropriate consent proportionately balances the ongoing universality of newborn screening for important health conditions with an acknowledgement of the complex outcomes that bringing a complicated diagnostic technology into the screening domain will generate.

Editor's Note: After assessing the observations and arguments made in this paper, we are reaching out to the corresponding author for clarification.

Australian Attitudes Towards Waivers of Consent Within the Context of Genomic Data Sharing

Lyndsay Newett, Rebekah McWhirter, Lisa Eckstein, Vanessa Warren, Dianne Nicol

Journal Of Empirical Research on Human Research Ethics, 2 August 2024; 19(3) pp 113–123

Abstract

This research identifies the circumstances in which Human Research Ethics Committees (HRECs) are trusted by Australians to approve the use of genomic data – without express consent – and considers the impact of genomic data sharing settings, and respondent attributes, on public trust. Survey results (N = 3013) show some circumstances are more conducive to public trust than others, with waivers endorsed when future research is beneficial and when privacy is protected, but receiving less support in other instances. Still, results imply attitudes are influenced by more than these specific circumstances, with different data sharing settings, and participant attributes, affecting views. Ultimately, this research raises questions and concerns in relation to the criteria HRECs use when authorising waivers of consent in Australia.

Genetic Data Privacy and 'Legitimate Interest' in Genetic Research: Is consent still a relevant narrative within the realm of big data research under the European data protection regime?

B Bak

PhD Thesis, University of Reading, 2024

Abstract/Summary

The processing of genetic data in scientific research delivers substantial benefits, striving for better well-being and healthcare for the public. The collection of genetic data stored in research repositories or biobanks for future research use, where researchers and research subjects do not engage, has become commonplace. However, the research use of genetic data also raises controversial questions regarding data protection. Genetic data uniquely distinguishes individuals from others and provides sensitive information about them and their relatives, concerning their current and future health status. Hence, its commercial misuse, leading to unethical discriminatory practices, and the reidentification of individuals must be prevented. This study

aims to strike a balance between the public's interest in genetic research and the protection of genetic privacy, by focusing on the General Data Protection Regulation (GDPR). Specifically, it assesses the degree to which individual consent, one of the GDPR bases for justifying research and the traditional research method, can effectively establish this delicate balance. It argues that the legitimate interest ground, an alternative GDPR basis, offers certain advantages over consent and the public interest ground—another GDPR basis. Contrary to the dominant opinion, the legitimate interest basis may effectively establish an equilibrium between this public/private divergence for certain genetic research activities. This is a consequence of the shift towards big data research and contemporary dynamics in the biomedical field, and it occurs without necessarily compromising data protection principles and research ethics. The study introduces a novel perspective on genetic research, aiming to catalyse transformative changes in both legal frameworks and societal norms from a standpoint of solidarity. This unconventional approach is offered as a topic for further research.

Editor's Note: After assessing the observations and arguments made in this paper, we are reaching out to the corresponding author for clarification.

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TECHNOLOGY/OTHER MEDIATION

Use of E-Consent in Healthcare Settings: A Scoping Review

Haris Obaidi, Youssef Elkhyatt, Mahmood Alzubaidi, Mowafa Househ

Studies In Health Technology and Informatics, 22 August 2024

Abstract

Electronic consent is a technology-driven approach that remains challenging in various healthcare settings. Transitioning from paper-based to electronic consent (e-consent) has streamlined the consent process. This scoping review explores patients' electronic consent in different healthcare settings. We searched four databases and selected 14 studies that met our inclusion criteria. Our results show that E-consent is associated with key measures such as sufficient information, accuracy, enhanced shared decision-making, and efficiency. The majority of studies used a comparative design model to contrast paper-based consent with E-consent. Our findings provide an overview of the current state of E-consent use in healthcare settings.

Examining Introduction of E-consent in The Neurosurgical Caseload: Understanding The Barriers to Implementation

Original Article

Daniele S.C. Ramsay, Virensinh Rathod, Sami Rashed, Sohani Dassanayake, Santhosh Thavarajasingam, Nigel Mendoza, Ali R. Haddad

World Neurosurgery, 12 August 2024

Open Access

Abstract

Objective

To evaluate current usage and barriers of e-consent implementation in neurosurgical practice. Electronic consent (e-consent) forms provide an alternative method for conducting the informed consent (IC) procedure. IC requires an ability to understand, retain, weigh up and communicate decisions regarding the proposed procedure. Currently, e-consent has shown promise as a method of improving IC, yet barriers to implementation exist.

Methods

A comparative analysis regarding procedural and consent data was collected over six months in two neurosurgical centres with elective and emergency caseloads. These were evaluated for changes over time

following e-consent introduction. Clinicians were surveyed for their experience using of e-consenting to understand the barriers to implementation.

Results

Over half (55.6%) of neurosurgical procedures made use of e-consent for IC. Lower rates of e-consent were used in trauma related procedures (38.38%) as compared to elective procedures. This did not increase significantly over the study period. Positive clinician survey feedback indicated e-consenting reduces the time required to perform IC, with 50% of respondents strongly agreeing. Barriers to implementation were reported on free-text entry pertaining largely to difficulties in emergency situations due to form complexity. The inability to create and edit templates for personalised e-consent delivery was a further limitation.

Conclusion

Despite the advantages conferred by e-consent for the administration of IC in neurosurgical procedures, reflected in our survey data, there remains limited use of the technology. Limitations remain relating to ease of access and complexity of use in trauma scenarios.

Enhancing patient informed consent in elective skin cancer surgeries: a comparative study of traditional and digital approaches in a German public hospital

Research

Alexandra Schulz, Sabine Bohnet-Joschko

BMC Health Services Research, 2 August 2024

Open Access

Abstract

Background

This study aims to investigate the integration of modern sources of patient information, such as videos, internet-based resources, and scientific abstracts, into the traditional patient informed consent process in outpatient elective surgeries. The goal is to optimize the informed consent experience, enhance patient satisfaction, and promote shared decision making (SDM) between patients and surgeons. By exploring different patient informed consent formats and their impact on patient satisfaction, this research seeks to improve healthcare practices and ultimately enhance patient outcomes. The findings of this study will contribute to the ongoing efforts to improve the informed consent process in public hospitals and advance patient-centred care.

Methods

Data collection occurred at the day care clinic of a prominent German public hospital, forming an integral component of a prospective clinical investigation. The study exclusively focused on individuals who had undergone surgical intervention for skin cancer. For the purpose of meticulous data examination, the statistical software SPSS version 21 was harnessed. In the course of this study, a chi-square test was aptly employed. Its purpose was to scrutinize the nuances in patient experiences pertaining to informed consent across four distinct categories, viz., oral informed consent discussion (Oral ICD), written informed consent discussion (Written ICD), video-assisted informed consent discussion (video-assisted ICD), and digitally assisted informed consent discussion (digital-assisted ICD). The primary dataset of this inquiry was diligently gathered via a structured questionnaire administered to a targeted cohort of 160 patients. Within this sample, a balanced representation of genders was observed, encompassing 82 males and 78 females. Their collective age span ranged from 18 to 92 years, with an average age of 71 years. A randomized selection methodology was employed to include participants in this study during the period spanning from July 2017 to August 2018.

Results

Significant differences were observed across the groups for all research questions, highlighting variations in patient responses. Video-assisted and digital-assisted IC were rated as superior in patient satisfaction with information compared to written and oral IC. Demographic profiles of the four study groups were found to be comparable.

Conclusion
The findings of this study indicate that the incorporation of digital technologies in the informed consent process can enhance patient understanding during outpatient elective skin cancer surgeries. These results have important implications for increasing patient satisfaction and improving the SDM process within the hospital environment.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Compromised informed consent due to functional health literacy challenges in Chinese hospitals

Research
Dangui Zhang, Zhilin Hu, Zhuojia Wu, Ting Huang, Tingting Huang, Junhao Liu, Hongkun Sun, William Ba-Thein
BMC Medical Ethics, 23 August 2024
Open access
Abstract
Background
Medical informed consent stands as an ethical and legal requisite preceding any medical intervention. Hospitalized patients face functional health literacy (FHL) challenges when dealing with informed consent forms (ICFs). The legitimacy of ICFs and informed consent procedures in China remains substantially undisclosed. The study's aim was to investigate if Chinese patients have adequate FHL to be truly informed before providing medical consent.
Methods
In this cross-sectional, structured interview-based study, FHL was assessed within the context of the informed consent scenarios in two teaching hospitals (a 1500-bed general tertiary hospital and a 700-bed cancer hospital) affiliated with Shantou University Medical College. Twenty-seven patients admitted across clinical departments, along with their relatives (n = 59), were enrolled in the study after obtaining informed consent. The participants underwent a three-step assessment with two selected ICFs —teach-back skills, perceived understanding (perception), and informed knowledge (cognizance), with each component carrying a maximum score of 10. Data were analyzed with SPSS (version 22.0) for descriptive and inferential statistics, with consideration of significant P values as < 0.05.
Results
The median age (IQR and range) of participants was 35.5 (28 – 49 and 13 – 74) years. Most participants had only high school education (24.4%, 21/86) or below high school education (47.7%, 41/86). The median score (IQR) of FHL assessments—teach-back, perception, and cognizance—was 4.0 (2.5, 5.8), 8.0 (6.8, 8.8), and 6.5 (5.5, 8.0) out of 10, respectively. A moderate correlation was observed between the scores of cognizance and teach-back ($r = 0.359$, $P = 0.002$) or perception ($r = 0.437$, $P < 0.001$). Multivariate linear regression analysis predicted being a patient and having lower education levels as independent risk factors of inadequate FHL (Ps = 0.001). Lack of patient-centeredness in ICFs, time constraints, and poor clinical communication were identified as barriers impeding informed consent.
Conclusions
This study demonstrates inadequacy in personal FHL and impaired organizational HL, resulting in compromised informed consent in Chinese teaching hospitals. As a remedy, we propose improving the quality of ICFs and institutionally mandated outcome-focused training on informed consent for all concerned clinicians to enhance medical ethics, ensure quality health care, address patient values, and mitigate potential medical conflicts.

CLARA-MeD Tool - A System to Help Patients Understand Clinical Trial Announcements and Consent Forms in Spanish

Leonardo Campillos-Llanos, Federico Ortega-Riba, Ana R Terroba, Ana Valverde-Mateos, Adrián Capllonch-Carrión

Studies In Health Technology and Informatics, 22 August 2024

Abstract

We present an NLP web-based tool to help users understand consent forms (CFs) and clinical trial announcements (CTAs) in Spanish. For complex word identification, we collected: 1) a lexicon of technical terms and simplified synonyms (14 465 entries); and 2) a glossary (70 547 terms) with explanations from sources such as UMLS, the NCI dictionary, Orphadata or the FDA. For development, we extracted entities from 60 CTAs, 60 CFs and 60 patient information documents (PIDs). To prepare definitions for new terms, we used ChatGPT and experts validated them (28.99% needed to be fixed). We tested the system on 15 new CTAs, 15 CFs, and 15 PIDs, and we achieved an average F1 score of 82.91% (strict match) and of 94.65% (relaxed). The tool is available at: http://claramed.csic.es/demo.

The Role Of Husbands And Midwives' Motivation For Compliance With Providing Informed Consent In Cito Sc Actions At Merauke Regional Hospital

Hermin Langdo Layuk, Reny Yuli Astutik, Eri Puji Kumalasari, Devy Putri Nursanti

Journal Of Health Science Community, August 2024; pp70-78

Abstract

Informed consent is a critical aspect of medical practice, including emergency caesarean section (SC) or Cito. Compliance with informed consent becomes more complex because it involves quick decisions in emergency situations, Informed consent compliance with Cito SC actions can be influenced by the husband's role and midwife's motivation. This study aims to determine the influence of the role of husbands and midwives' motivation on compliance with the provision of informed consent in cito SC actions at Merauke Regional Hospital. This study used an Observational Analytics research design with a cross sectional approach. Sampling was carried out using the total sampling technique and a sample of 15 respondents was obtained, the independent variable consists of the role of the husband and the motivation of the midwife then the dependent variable used is the adherence of giving informed consent. The Chi-Square test is used to determine the relationship between two categorical variables. The results of the study of 15 respondents were obtained, most respondents had supporting husband role criteria, namely as many as 8 respondents (53.3%), Most respondents received poor midwife motivation which was as many as 8 respondents (53.3%) and most respondents included the criteria for compliance with informed concent on Cito SC Actions. The results of the analysis using the Chi-Square statistical test obtained the results of $p = 0.005$ and $0.019 < 0.05$, then H0 was rejected and H1 was accepted, which means that there is an influence on the role of the husband and the motivation of midwives on Compliance with Giving Informed Consent to Pregnant Women Who Perform Cito SC Actions at Merauke Regional Hospital. The role of the husband and the motivation of midwives play a very significant role in shaping the compliance of informed consent to pregnant women. Collaboration between patients, husbands, medical teams is the main key.

Editor's note: Merauke Regional Hospital is located in Indonesia.

Surfactants and the importance of informed consent: Nurturing culturally competent care in healthcare settings

Priyanka Gupta, Vishwajeet Singh, Prince Pareek

Indian Journal Of Medical Ethics, July-September 2024

Abstract

Background

Culturally competent healthcare improves patient satisfaction and clinical outcomes. Many drugs, dressings and implants have human or animal-derived content which may conflict with patients' religious beliefs, and may even have medicolegal implications.

Methods

This cross-sectional study (anonymous web-based survey) was done to understand the informed consent process followed by paediatricians and neonatologists in India, their views regarding disclosure pertaining to the animal origin of exogenous surfactants to patients' families, and their willingness and ability to provide alternative surfactants based on parental preferences.

Results

A total of 114 neonatologists/paediatricians involved in neonatal care and using surfactants in their practice responded to the survey. Although 61(53.5%) neonatal care units stocked two or more brands of surfactant in their inventory, only 38(33.3%) units had both bovine and porcine preparations. Most (104, 91.2%) of the doctors always take parental consent before administering surfactants; but only a few (12,10.5%) said they always inform parents about its animal origin. None of the respondents offer parents a choice between bovine or porcine-origin surfactants, most (73, 64%) presuming that it would be irrelevant for the parents. However, many respondents (27, 23.7%) mentioned that they want to offer the choice to parents but are unable to do so because they do not stock both bovine and porcine preparations.

Conclusion

Although most parents might agree to a life-saving medicine in emergency situations, this does not mean they do not want to be informed. Healthcare professionals should not have a dismissive attitude to parental belief systems. They must use the antenatal period to take the cultural/spiritual history and the necessary consent.

Research to Establish a Common Standard for Assent by Assessing the Current State of the Assent Process and Conducting Interviews with Pediatrician/Pediatric Neurologist

Yoon Jin Lee, Sun Ju Lee, Su Jin Kang, Dae Ho Lee, Kyun-Seop Bae, Jong Woo Chung, Byung Soo Kim, Byung Soo Kim, Jin Seok Kim, Myung Ah Lee

Journal of KAIRB, 2024; 6(1) pp 5-16

Abstract

Purpose

The purpose of this study is to investigate the current status of pediatric assent in nationwide hospitals and to assess the children’s comprehension for pediatric assent by interviewing pediatricians/pediatric neurologists to determine whether children of the age (elementary and middle school students) can understand the purpose, risks, benefits, and concepts of voluntary participation in clinical research described in the assent form, and to help improve the administrative efficiency of multicenter clinical trials.

Methods

The status of pediatric assent was surveyed online using Google Forms at 141 university hospitals with administrative staff who are members of the Institutional Review Board (IRB) administrative staff subcommittee with in Korean Association of Institutional Review Boards (KAIRB). Additionally, face-to-face interviews were conducted with 7 pediatricians/pediatric neurologists. Survey and interview responses were summarized using descriptive statistics.

Results

Out of the 141 institutions surveyed, 35 institutions (24.8%) responded. Among them, 30 institutions (85.7%) reported having age criteria for acquiring pediatric assent forms in the case of children. The age range for pediatric assent acquisition have been from 7 years old to 12 years old (15 institutions, 50%), and from 7 years old to 15 years old (7 institutions, 23.3%). Nine institutions (25.7%) have had criteria for obtaining both parents' consent in cases involving the participation of children. Nineteen institutions (54.3%) have had checklists or guidelines available for use by IRB members in study protocols involving vulnerable research subjects. Three pediatricians/pediatric neurologists have believed that upper-grade elementary school

students (5th–6th grade) could comprehensively understand informed consent forms. Two have believed that middle school students would be able to understand them if they included personal information. Two pediatricians/pediatric neurologists have believed that even lowergrade elementary school students (1st–4th grade) could understand the explanations if they were made simpler.

Conclusion

It is suggested that not only elementary school students (7–12 years old) but also middle school students (13–15 years old) should receive pediatric assent forms, as it would facilitate a comprehensive understanding of the forms. To enhance the comprehension of assent form content, it is necessary to use age-appropriate words, language, and expressions in the forms. It is also recommended to create comics or videos to make the content of the assent forms more accessible for children.

> *Editor's note: This is a Korean language publication of the Korean Association of Institutional Review Boards.*

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RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT

Editor's Note:

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

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

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

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

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

Review Article

Richard Appiah, Giuseppe Raviola, Benedict Weobong

Journal of Empirical Research on Human Research Ethics, 18 March 2024

Open Access

Abstract

Objective

This review explores the ethico-cultural and implementation challenges associated with the individual-based informed consent (IC) model in the relatively collectivistic African context and examines suggested approaches to manage them.

Methods

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

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RIGHTS/LEGAL/LEGISLATIVE

Free, Prior, and Informed Consent Principles as Indigenous Peoples' Right: Soft Law or Hard Law?

Retno Kusniati
Jambe Law Journal, 23 August 2024; 7(1) Pp 169-193
Abstract
Ensuring conformity between national laws and international law principles is crucial for states, particularly concerning the adoption of the Free, Prior, and Informed Consent (FPIC) principle to safeguard the natural resource rights of Indigenous Peoples. Numerous development initiatives proceed without indigenous consent, resulting in significant harm. Policies impacting indigenous communities should be established through prior consultation and their explicit endorsement to align with local wisdom and values. This paper explores the imperative to reevaluate the FPIC principle within legal frameworks. Using both conceptual and statutory analyses, it assesses whether FPIC constitutes a binding obligation with legal ramifications that necessitate incorporation into national law (hard law) or remains a nonbinding guideline (soft law). The State's role in implementing this principle to shield indigenous groups from detrimental development projects affecting their natural resources and cultures is scrutinized. The foundational ethos of FPIC is rooted in defending Indigenous Peoples' entitlements to natural resources. Lastly, legislative recommendations are offered to define FPIC as a legal norm, ensuring legal certainty and guiding judicial decisions in upholding these rights.

Editor's note: This journal is published by the Faculty of Law at Jambi University, Indonesia.

Informed consent form for platelet rich plasma injections: evidence-based and legally guide for orthopaedic surgeons

Research
Madhan Jeyaraman, Satvik N. Pai, Migliorini Filippo, Naveen Jeyaraman, Ravichandran Venkatasalam, Arulkumar Nallakumarasamy, Manish Khanna, Bishnu Prasad Patro, Shilpa Sharma, Ravi Velamor Rangarajan
European Journal of Medical Research, 17 August 2024
Open Access
Abstract
Regarding medico-legal malpractice suits, lawyers and insurers focus on informed consent documentation. Unfortunately, there is no standard protocol for obtaining informed consent for platelet-rich plasma (PRP) injections. The objective of the present study was to create a pre-designed, evidence-based informed consent form specifically for PRP injections. The current evidence on the medico-legal implications of PRP injections was accessed, as well as informed consent in general and specifically informed consent in PRP

injections. Additionally, we interviewed orthopaedic surgeons and patients who had undergone PRP injections in the past year using a semi-structured approach. A legally valid and evidence-based informed consent form for PRP injections ensures rights, encouraging open communication and transparency between the patient and surgeon. Moreover, if a lawsuit arose, informed consent would be a critical document in surgeons' defence and would withstand scrutiny from lawyers and the judiciary. An evidence-based informed consent form for PRP injections was elaborated and reviewed by a legal expert to ensure adherence to legal proprieties. The final form of the informed consent for PRP injection was administered for one year and validated at our institution.

Shared Decision-Making and Informed Consent Legislation in Clinical Decision Making

Yeoran Yoon, Hyuna Bae

Korean Journal of Medical Ethics, 30 June 2024; 27(2) pp 71-87

Abstract

This article examines shared decision-making, a concept that extends beyond informed consent to safeguard patients' right to self-determination in medical decision-making, emphasizing mutuality with patients. After reviewing the relevant legislation concerning consent, we argue that there are limitations to using this legislation as a basis for integrating shared decision-making across various medical domains. We assess the applicability, acceptability, and consistency of this legislation within the medico-legal system. In particular, we scrutinize the roles of so-called "participants" in shared decision-making, the content of shared information, and potential legal liabilities stemming from deficiencies in this process. Through this examination, we analyze legal precedents concerning the duty to inform and propose policy adjustments necessary for the institutionalization of shared decision-making within the medico-legal framework.

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

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MEDICAL/SURGICAL

Deferred Consent in Emergency Trauma Research: A Qualitative Study Assessing the Healthcare Professional's Opinions

Injury, 15 August 2024

Zynab Noori, Niek J. Vianen, Esther M.M. Van Lieshout, Erwin J.O. Kompanje, Iscander M. Maissan, Michiel H.J. Verhofstad, Mark G. Van Vledder

Abstract

Introduction

Severely injured patients are often incapacitated to provide informed consent for clinical studies. Deferred consent could facilitate unbiased enrollment in studies involving these patients. Little is known about how healthcare professionals (HCPs) perceive deferred consent and how this impacts patient enrollment. The aim of this study was to identify factors that could influence HCPs decision-making during recruitment of patients for interventional studies in (pre)hospital emergency trauma research.

Methods

This was a qualitative study in which physicians and nurses working in prehospital or in-hospital care were interviewed using a semi-structured interview guide. Interviews were audio-recorded, transcribed, and analyzed according to thematic analysis as described by Braun and Clarke.

Results

Ten semi-structured interviews were conducted with six physicians and four nurses. Eight themes were identified as being relevant consent related factors influencing HCPs' decision-making during patient recruitment in studies using deferred consent: 1) HCPs' lack of knowledge; 2) Patients' and proxies' inability

to be informed; 3) Practical (im)possibilities for informed consent; 4) Nature of intervention; 5) HCPs' personal beliefs; 6) Importance of emergency care research; 7) HCPs' trust in legal base; and 8) Communication and collaboration.
Conclusions
Eight consent-related factors influencing HCPs' decision making were identified. Insufficient knowledge about consent procedures among HCPs leads to significant negative attitudes towards deferred consent.

Follow Informed Patient Consent in Clinical Teaching in Order to Achieve a Truly Patient-Centered Approach

Research Article
Hongnan Ye
Journal of Patient Experience, 14 August 2024
Open Access
Abstract
Patient- and disease-focused clinical teaching is considered the cornerstone of medical education. Current clinical teaching is increasingly taking place in outpatient settings, but this can cause discomfort to patients. Although many professional organizations have developed a set of ethical considerations in response to this issue to use these considerations to guide clinics in their outpatient procedures, these guidelines are not well adhered to in outpatient practice. My experience as an eczema patient in a dermatology outpatient is good evidence of this. In my opinion, there is nothing inherently wrong with the pedagogy of medical students observing clinical interactions in outpatient settings; the real problem lies in not informing the patient of the medical student's presence or allowing the patient to exercise his or her right of refusal. Therefore, the following recommendations are made: First, academic medical centers should provide regular training to doctors and medical students to ensure that they are fully aware of what is contained in the ethical guidelines established by the professional organizations and that they recognize the importance of adhering to these guidelines in clinical practice. Second, each clinical teaching activity should have the informed consent of the patient and be based on the patient's wishes. Finally, it is recommended that hospitals establish appropriate evaluation mechanisms to assess doctors' compliance with the ethical guidelines and provide continuing education and training for doctors and medical students who fail to comply.

Consent for interventions during childbirth: A national population-based study

Clinical Article
Marianne Jacques, Anne Alice Chantry, Anne Evrard, Nathalie Lelong, Camille Le Ray, the ENP2021 Study Group
Gynecology & Obstetrics, 2 August 2024
Open Access
Abstract
Objective
To assess the frequency and determinants of medical interventions during childbirth without women's consent at the population level.
Methods
The nationwide cross-sectional Enquête Nationale Périnatale 2021 provided a representative sample of women who delivered in metropolitan France with a 2-month postpartum follow-up (n = 7394). Rates and 95% confidence intervals (CI) of interventions during childbirth (oxytocin administration, episiotomy or emergency cesarean section) without consent were calculated. Associations with maternal, obstetric, and organizational characteristics were assessed using robust variance Poisson regressions, after multiple imputation for missing covariates, and weighted to account for 2-month attrition.
Results

Women reporting failure to seek consent were 44.7% (CI: 42.6–47.0) for oxytocin administration, 60.2% (CI: 55.4–65.0) for episiotomy, and 36.6% (CI: 33.3–40.0) for emergency cesarean birth. Lack of consent for oxytocin was associated with maternal birth abroad (adjusted prevalence ratio [aPR] 1.20; 95% CI: 1.06–1.36), low education level, and increased cervical dilation at oxytocin initiation, whereas women with a birth plan reported less frequently lack of consent (aPR 0.79; 95% CI: 0.68–0.92). Delivery assisted by an obstetrician was more often associated with lack of consent for episiotomy (aPR 1.46; 95% CI: 1.11–1.94 for spontaneous delivery and aPR 1.39; 95% CI: 1.13–1.72 for instrumental delivery, reference: spontaneous delivery with a midwife). Cesarean for fetal distress was associated with failure to ask for consent for emergency cesarean delivery (aPR 1.58; 95% CI: 1.28–1.96).

Conclusion

Women frequently reported that perinatal professionals failed to seek consent for interventions during childbirth. Reorganization of care, particularly in emergency contexts, training focusing on adequate communication and promotion of birth plans are necessary to improve women's involvement in decision making during childbirth.

Enhancing Patient Understanding of Cardiac Catheterisation Prior to Procedural Consent

J. Reynolds, R. Newcombe, G. Armstrong, S. El-Jack, T. Wijohn

Heart, Lung and Circulation, August 2024

Abstract

Background

People with reduced health literacy are at higher risk of not sufficiently understanding informed consent prior to procedures. Approximately 44% of adults read at or below the age of an average 12-13-year-old, indicating they may struggle to understand basic health information during the consent process. This is magnified in indigenous peoples, older adults and those with English as a second language in both countries.

Methods

We designed a procedural graphic comic booklet to be shared prior to the consent process, aiming to increase understanding in all patient groups. Pilot research on patients' understanding of basic probability was conducted using non-medical questions confirmed poor understanding of risk. The comic booklet was developed with patient and health literacy group input and subjected to several cycles of feedback to reach the final version utilised in our audit.

Results

We audited patient and staff perceptions of the graphic comic booklet to the commonly used Heart Foundation information booklet. In 15 patients and 12 health-workers, the graphic comic booklet format was felt to be more succinct and understandable and was preferred by the majority of respondents. A small group preferred more detailed information.

Discussion

The use of a graphic comic booklet can therefore be an important educational tool, aiding patient understanding of procedures prior to the consent process. We intend to use it in addition to the current pre-angiography education provided to patients.

Informed consent in neurosurgery - Evaluation of current practice and implementation of future strategies

Francesca Colombo, Ross McLeod, Rohit Ravindranath Nambiar, Helen Maye, Sam Dickens, K Joshi George

Surgical Neurology International, 19 July 2024

Abstract

Background

In recent times, clinical negligence claims against National Health Service hospitals have doubled, with 8% of claims being made due to "failure to warn/informed consent." This study aimed to assess the current

compliance of the neurosurgical division within a large tertiary neuroscience center with the national legal framework and professional guidelines around the issue of surgical consent and to develop strategies to improve the consent process.
Methods
Electronic patient records (EPR) were accessed to collect demographic data and information regarding the surgical procedures. Telephone questionnaires were carried out. Neurosurgical registrars were interviewed. The author met with the trust's Legal team, the neuropsychology lead, and the trust's consent lead.
Results
Fifty-eight patients were included in the analysis. Of the respondents to the questionnaire, 98% felt that they were adequately informed during the consent process. When consenting patients, all registrars felt that they explained the reason for the procedure, detailed benefits, and major risks, including uncommon and rare risks. However, 50% admitted to not specifically discussing the postoperative recovery time or alternatives. Only 15% admitted to documenting on the EPR or through a letter to the patient's General Practitioner.
Conclusion
Informed consent is a delicate moment of communication between a clinician and the patient. Regular training and good communication skills help staff to focus on the most relevant aspects of consent, which should be delivered in an appropriate environment and with family support. Audio-visual aids can support the process but do not replace good communication.

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PRE-PRINT SERVERS

LLM Doc: An Assessment of ChatGPT's Ability to Consent Patients for IR Procedures

Research Article
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CVIR Endovascular, 17 June 2024
Abstract
Purpose
The study aims to evaluate how current interventional radiologists view ChatGPT in the context of informed consent for interventional radiology (IR) procedures.
Methods
ChatGPT-4 was instructed to outline the risks, benefits, and alternatives for IR procedures. The outputs were reviewed by IR physicians to assess if outputs were 1) accurate, 2) comprehensive, 3) easy to understand, 4) written in a conversational tone, and 5) if they were comfortable providing the output to the patient. For each criterion, outputs were measured on a 5-point scale. Mean scores and percentage of physicians rating output as sufficient (4 or 5 on 5-point scale) were measured. A linear regression correlated mean rating with number of years in practice. Intraclass correlation coefficient(ICC) measured agreement among physicians.
Results
The mean rating of the ChatGPT responses was 4.29, 3.85, 4.15, 4.24, 3.82 for accuracy, comprehensiveness, readability, conversational tone, and physician comfort level, respectively. Percentage of physicians rating outputs as sufficient was 84%, 71%, 85%, 85%, and 67% for accuracy, comprehensiveness, readability, conversational tone, and physician comfort level, respectively. There was an inverse relationship between years in training and output score (coeff = -0.03413, p=0.0128); ICC measured 0.39 (p=0.003).
Conclusions
GPT-4 produced outputs that were accurate, understandable, and in a conversational tone. However, GPT-4 had a decreased capacity to produce a comprehensive output leading some physicians to be uncomfortable providing the output to patients. Practicing IRs should be aware of these limitations when counseling patients as ChatGPT-4 continues to develop into a clinically usable AI tool.

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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].

Agency Information Collection Request; 30-Day Public Comment Request

A Notice by the Health and Human Services Department on 08/19/2024 Comments on the ICR must be received on or before **September 18, 2024.**

[IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation]

Abstract:

The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990-0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research; and determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Patient Engagement Advisory Committee; Notice of Meeting-Patient-Centered Informed Consent in Clinical Study

A Notice by the Food and Drug Administration on 08/28/2024

Written submissions may be made to the contact person on or before October 3, 2024. Oral presentations on or before September 25, 2024

The meeting will be held on October 30, 2024, from 10 a.m. to 5 p.m. Eastern Time.

Agenda:

On October 30, 2024, the Committee will discuss and make recommendations on "Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products." The individuals who volunteer to participate in clinical research play an integral role in advancing scientific knowledge and supporting the development of potentially life-saving therapies for patients in need. Informed consent is a key element in clinical studies and can be one of a patient's first interactions with the clinical community. Too often, however, informed consent forms are lengthy and difficult for potential research participants to understand. FDA has worked to improve informed consent over the years, including several recent activities such as developing a draft guidance in identifying key information in informed consent.

The Committee will provide recommendations on the informed consent process and the areas of focus of the informed consent. The Committee will also provide recommendations on factors to consider when

communicating informed consent to clinical study participants to increase the likelihood of participants understanding the key elements of research.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting.

Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*

Procedure:

Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before October 3, 2024. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 25, 2024. Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993-0002, *Letise.Williams@fda.hhs.gov*.

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NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

No new guidance or analysis referencing consent identified.

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SYMPOSIA/CONFERENCES

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

No new symposia/conferences identified.

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