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governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

March 2025 :: Issue 75

This digest aggregates and distills key content and analysis around informed consent and assent including governance, ethics review and oversight, practical approaches, emerging technologies, comprehension aids, and assessment strategies/performance metrics. These come 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. It also identifies societal perspectives on the uses of consent/assent, often embedded in political and legal systems, including their evolution over time and across jurisdictions and diverse cultural, political and economic contexts.

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 are controversial and warrant closer scrutiny. We may include "Editor's Notes" or other notations to identify and challenge such content, and welcome readers' comments to both the article and our comments. This approach aligns with our goal of presenting a holistic landscape of informed consent literature as it is published.

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

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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

JOURNAL LITERATURE

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
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 website.

SPOTLIGHT

This month we highlight an article from the *New England Journal of Medicine*, **Pulling Out the Rug on Informed Consent — New Legal Threats to Clinicians and Patients**, reflecting the impact of changes in US state laws on informed consent. In their perspective piece, Underhill and Nelson examine a change to Utah's Malpractice Act which allows the retroactive withdrawal of consent given as a minor at the point of receiving gender-affirming care, leaving clinicians vulnerable to future litigation. We are highlighting this article as we are concerned about the intersection of political ideology and the protections afforded to patients --and treating physicians -- by effective informed consent. We are reaching out to the authors to explore potential pathways for response and will report on this in future editions of this *Monthly Review***.**

Pulling Out the Rug on Informed Consent — New Legal Threats to Clinicians and Patients

Perspective
Kristen Underhill, Kimberly M. Nelson
New England Journal of Medicine, 1 February 2025

Abstract

A legal technique deployed by Utah to restrict gender-affirming care for minors aims at a core component of the clinician–patient relationship: clinicians' ability to rely on patients' informed consent.

Excerpt

In recent years, state legislators in large portions of the United States have devised and enacted new legal strategies to limit access to health care for transgender people. To date, 26 states have enacted outright bans on gender-affirming care, which thus far apply only to minors. Other state laws create financial or procedural obstacles to this type of care, such as bans on insurance coverage, requirements to obtain opinions from multiple clinicians, or consent protocols that are stricter than those for other health care…

Allowing patients to withdraw their consent retroactively is an acute threat to the legal infrastructure supporting U.S. healthcare. Informed-consent requirements exist to ensure that patients have the information and agency to participate in their own healthcare. They also protect clinicians. In all practice areas, clinicians expect to rely on patients' consent at the time of care, without having to guess which patients will later change their minds. If laws eliminate clinicians' ability to rely on consent at the time of care, the resulting legal instability may undermine access to all types of health care services. Pulling out the rug on informed consent threatens the core of the clinician–patient relationship. Clinicians in every area should recognize that these laws are not just attacking gender-affirming care — they are attacking the foundation of the U.S. health care system.

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BIOMEDICAL RESEARCH

Verbal Consent in Biomedical Research: Moving Toward a Future Standard Practice?

Review Article

Alycia Noe, Emilie Vaillancourt, Ma'n H Zawati

Frontiers in Genetics, 12 February 2025

Abstract

Properly obtaining informed consent is a core obligation for research conducted using human subjects. The traditional informed consent process involves written forms and obtaining signatures. This process remains the standard, but in various research settings, such as COVID-19 and rare disease research, verbal consent has increasingly become the norm. Although verbal consent is used in these settings, its use is still a subject of debate. This article reviews in what medical settings verbal consent is commonly seen today, various advantages and disadvantages of verbal consent, and its legislative and policy ecosystem. In doing so, this review article asserts that it is time for the debate over verbal consent to come to an end and for legislator and policymakers to acknowledge its use and to formalize the process. This will allow verbal consent to be regulated in a similar manner to written consent and will give clinician-researchers guidance on how to better implement verbal consent in their studies to addressing ongoing concerns with the consenting process as a whole**.**

> *Editor's Note: We note that if verbal consent is employed there must also be a record of this transaction, either by way of recording or transcription, to allow for adequate documentation.*

The Use of Electronic Consent (eConsent) Within the Ketamine for Long-Lasting Pain Relief After Surgery (KALPAS) Multicenter Trial

Lisa V Doan, Jeri Burr, Raven Perez, Hamleini Martinez, Randy Cuevas, Kevin Watt, Jing Wang

Journal of Pain Research, 4 January 2025

Abstract

Background

The informed consent process has traditionally taken place in person. The introduction of electronic consent (eConsent) has made remote consenting processes possible. Use of eConsent has increased since the COVID-19 pandemic. It has streamlined the process of consenting patients and has been shown to benefit the research study team and participants.

eConsent in the Ketamine Analgesia for Long-Lasting Pain Relief After Surgery (Kalpas) Study

The KALPAS study is a multicenter, double-blind, randomized controlled study investigating the effectiveness of ketamine in reducing chronic post-mastectomy pain in women undergoing mastectomy for oncologic indication. The study uses a two-part consent form consisting of a master consent with information applicable to all sites and site-specific information. All potential participants receive the full two-part consent form for review. When signing the eConsent, however, all potential participants are provided with a concise summary of the informed consent document, an approach not widely used by multicenter studies. eConsent has been noted to be beneficial to research staff when trying to gather informed consent from participants who live far away from the hospital, want to include their family and friends, and for researchers who can approach patients outside of their clinical appointments.

Conclusion

The ability to consent patients remotely has allowed for a flexible workflow within sites and a more patient-centric process that focuses on including loved ones in the discussion and scheduling time to speak to a principal investigator. Demand for eConsent will likely continue in the post-COVID era, and use of a concise summary can allow for a more efficient consenting process.

Impact of informed consent quality on illness uncertainty among patients with cancer in clinical trials: a cross-sectional study

Original Article

Sihan Kang, Jie Zhang, Dong Pang , Hong Yang, Xiaohong Liu, Renxiu Guo, Yuhan Lu

Asia-Pacific Journal of Oncology Nursing, 20 February 2025

Open Access

Abstract

Objective

This study aimed to examine the level of illness uncertainty and the quality of informed consent among patients with cancer participating in clinical trials and explore their interrelationship.

Methods

A cross-sectional study was conducted with 265 patients with cancer recruited from a tertiary hospital in Beijing, China, from April to November 2023. Participants completed a questionnaire encompassing demographic details, the Mishel Uncertainty in Illness Scale, and the Quality of Informed Consent Questionnaire. Descriptive statistics, correlation analyses, and multiple regression analyses were performed to assess the data.

Results

The mean illness uncertainty score was 40.63 ± 10.12, reflecting a moderately low level of uncertainty, with "Ambiguity" scoring the highest among its dimensions. The mean score for informed consent quality was 3.30 ± 1.20, indicating a moderate level of understanding, with notable gaps in elements such as alternatives and confidentiality. A significant negative correlation was found between the "Foreseeable risks or discomforts" element of informed consent and overall illness uncertainty ($P < 0.05$). Regression analysis revealed that factors such as clinical trial phase, primary caregiver relationship, and health insurance model significantly influenced illness uncertainty and its dimensions.

Conclusions

Enhancing the quality of informed consent can effectively reduce illness uncertainty among patients with cancer in clinical trials. Greater emphasis should be placed on clear communication of risks and discomforts and patient-centered interventions to mitigate psychological stress.

Personal Public Disclosure: A New Paradigm for Meeting Regulatory Requirements Under Exception From Informed Consent

Research Report

Catherine E. Ross, Monica E. Kleinman, Michael W. Donnino

Critical Care Medicine, 12 February 2025

Abstract

Objectives

To describe a novel approach to the requirement for public disclosure under regulations for Exception From Informed Consent (EFIC) in an inpatient clinical trial.

Design

Single-arm intervention study within a clinical trial.

Setting

Medical and medical/surgical PICUs at an academic children's hospital.

Participants

Families of children and young adults younger than 26 years old receiving care in a PICU.

Interventions

As part of a multipronged approach to meeting requirements for public disclosure for EFIC, we developed and implemented a process termed "personal public disclosure," in which a member of the study team notifies all potentially eligible patients/families in-person or by phone about the trial as soon as possible upon PICU admission. Patients/families may choose to opt out of future participation in the trial.

Measurements and Main Results

Over a 16-month period, 1577 potentially eligible patients/families were successfully contacted for personal public disclosure. Of these, 473 (30%) opted out of future participation in the trial. In the same period, 64 patients developed the emergent event of interest for the primary trial. Of these, only 9 (14%) were enrolled. Upon notification of enrollment, all 9 (100%) agreed to continue in the data collection phase of the study. Of the remaining 55 missed enrollments, 38 (69%) were due to the event occurring before personal public disclosure had been completed.

Conclusions

Personal public disclosure supports patient/family autonomy within an EFIC trial; however, this approach is limited by low cost-effectiveness, feasibility and appropriateness in many circumstances.

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ARTIFICIAL INTELLIGENCE

Potential role of ChatGPT in simplifying and improving informed consent forms for vaccination: a pilot study conducted in Italy

Original Research

Claudia Cosma, Alessio Radi, Rachele Cattano, Patrizio Zanobini, Guglielmo Bonaccorsi, Chiara Lorini, Marco Del Riccio

BMJ Health & Care Informatics, 22 February 2025

Open Access

Abstract

Objectives

Informed consent forms are important for assisting patients in making informed choices regarding medical procedures. Because of their lengthy nature, complexity and specialised terminology, consent forms usually prove challenging for the general public to comprehend. This pilot study aims to use Chat Generative Pretrained Transformer (ChatGPT), a large language model (LLM), to improve the readability and understandability of a consent form for vaccination.

Methods

The study was conducted in Italy, within the Central Tuscany Local Health Unit. Three different consent forms were selected and approved: the standard consent form currently in use (A), a new form totally generated by ChatGPT (B) and a modified version of the standard form created by ChatGPT (C). Healthcare professionals in the vaccination unit were asked to evaluate the consent forms regarding adequacy, comprehensibility and completeness and to give an overall judgement. The Kruskal–Wallis test and Dunn's test were used to evaluate the median scores of the consent forms across these variables.

Results

Consent forms A and C achieved the top scores in every category; consent form B obtained the lowest score. The median scores were 4.0 for adequacy on consent forms A and C and 3.0 on consent form B. Consent forms A and C received high overall judgement ratings with median scores of 4.0, whereas consent form B received a median score of 3.0.

Conclusions

The findings indicate that LLM tools such as ChatGPT could enhance healthcare communication by improving the clarity and accessibility of consent forms, but the best results are seen when these tools are combined with human knowledge and supervision.

Analyzing patient perspectives with large language models: a cross-sectional study of sentiment and thematic classification on exception from informed consent

Scientific Reports

Aaron E. Kornblith, Chandan Singh, Johanna C. Innes, Todd P. Chang, Kathleen M. Adelgais, Maija Holsti, Joy Kim, Bradford McClain, Daniel K. Nishijima, Steffanie Rodgers, Manish I. Shah, Harold K. Simon, John M. VanBuren, Caleb E. Ward, Catherine R. Counts

Nature, 20 February 2025

Open Access

Abstract

Large language models (LLMs) can improve text analysis efficiency in healthcare. This study explores the application of LLMs to analyze patient perspectives within the exception from informed consent (EFIC) process, which waives consent in emergency research. Our objective is to assess whether LLMs can analyze patient perspectives in EFIC interviews with performance comparable to human reviewers. We analyzed 102 EFIC community interviews from 9 sites, each with 46 questions, as part of the Pediatric Dose Optimization for Seizures in Emergency Medical Services study. We evaluated 5 LLMs, including GPT-4, to assess sentiment polarity on a 5-point scale and classify responses into predefined thematic classes. Three human reviewers conducted parallel analyses, with agreement measured by Cohen's Kappa and classification accuracy. Polarity scores between LLM and human reviewers showed substantial agreement (Cohen's kappa: 0.69, 95% CI 0.61–0.76), with major discrepancies in only 4.7% of responses. LLM achieved high thematic classification accuracy (0.868, 95% CI 0.853–0.881), comparable to inter-rater agreement among human reviewers (0.867, 95% CI 0.836–0.901). LLMs enabled large-scale visual analysis, comparing response statistics across sites, questions, and classes. LLMs efficiently analyzed patient perspectives in EFIC interviews, showing substantial sentiment assessment and thematic classification performance. However, occasional underperformance suggests LLMs should complement, not replace, human judgment. Future work should evaluate LLM integration in EFIC to enhance efficiency, reduce subjectivity, and support accurate patient perspective analysis.

Transforming Informed Consent Generation Using Large Language Models: Mixed Methods Study

Qiming Shi, Katherine Luzuriaga, Jeroan J Allison, Asil Oztekin, Jamie M Faro, Joy L Lee, Nathaniel Hafer, Margaret McManus, Adrian H Zai

JMIR Medical Informatics, 13 February 2025

Abstract

Background

Informed consent forms (ICFs) for clinical trials have become increasingly complex, often hindering participant comprehension and engagement due to legal jargon and lengthy content. The recent advances in large language models (LLMs) present an opportunity to streamline the ICF creation process while improving readability, understandability, and actionability.

Objectives

This study aims to evaluate the performance of the Mistral 8x22B LLM in generating ICFs with improved readability, understandability, and actionability. Specifically, we evaluate the model's effectiveness in generating ICFs that are readable, understandable, and actionable while maintaining the accuracy and completeness.

Methods

We processed 4 clinical trial protocols from the institutional review board of UMass Chan Medical School using the Mistral 8x22B model to generate key information sections of ICFs. A multidisciplinary team of 8 evaluators, including clinical researchers and health informaticians, assessed the generated ICFs against human-generated counterparts for completeness, accuracy, readability, understandability, and actionability. Readability, Understandability, and Actionability of Key Information indicators, which include 18 binary-scored items, were used to evaluate these aspects, with higher scores indicating greater accessibility, comprehensibility, and actionability of the information. Statistical analysis, including Wilcoxon rank sum tests and intraclass correlation coefficient calculations, was used to compare outputs.

Results

LLM-generated ICFs demonstrated comparable performance to human-generated versions across key sections, with no significant differences in accuracy and completeness ($P>.10$). The LLM outperformed human-generated ICFs in readability (Readability, Understandability, and Actionability of Key Information score of 76.39% vs 66.67%; Flesch-Kincaid grade level of 7.95 vs 8.38) and understandability (90.63% vs 67.19%; $P=.02$). The LLM-generated content achieved a perfect score in actionability compared with the human-generated version (100% vs 0%; $P<.001$). Intraclass correlation coefficient for evaluator consistency was high at 0.83 (95% CI 0.64-1.03), indicating good reliability across assessments.

Conclusions

The Mistral 8x22B LLM showed promising capabilities in enhancing the readability, understandability, and actionability of ICFs without sacrificing accuracy or completeness. LLMs present a scalable, efficient solution for ICF generation, potentially enhancing participant comprehension and consent in clinical trials.

ChatGPT's role in alleviating anxiety in total knee arthroplasty consent process: a randomized controlled trial pilot study

Randomised Controlled Trial

Wenyi Gan, Jianfeng Ouyang, Guorong She, Zhaowen Xue, Lingxuan Zhu, Anqi Lin, Weiming Mou, Aimin Jiang, Chang Qi, Quan Cheng, Peng Luo, Hua Li, Xiaofei Zheng

International Journal of Surgery, 4 February 2025

Open Access

Abstract

Background

Recent advancements in artificial intelligence (AI) like ChatGPT have expanded possibilities for patient education, yet its impact on perioperative anxiety in total knee arthroplasty (TKA) patients remains unexplored.

Methods
In this single-blind, randomized controlled pilot study from April to July 2023, 60 patients were randomly allocated using sealed envelopes to either ChatGPT-assisted or traditional surgeon-led informed consent groups. In the ChatGPT group, physicians used ChatGPT 4.0 to provide standardized, comprehensive responses to patient queries during the consent process, while maintaining their role in interpreting and contextualizing the information. Outcomes were measured using Hospital Anxiety and Depression Scales (HADS), Perioperative Apprehension Scale-7 (PAS-7), Visual Analogue Scales for Anxiety and Pain (VAS-A, VAS-P), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and satisfaction questionnaires.
Results
Of 55 patients completing the study, the ChatGPT group showed significantly lower anxiety scores after informed consent (HADS-A: 10.48 ± 3.84 vs 12.75 ± 4.12, P = .04, Power = .67; PAS-7: 12.44 ± 3.70 vs 14.64 ± 2.11, P = .01, Power = .85; VAS-A: 5.40 ± 1.89 vs 6.71 ± 2.27, P = .02, Power = .75) and on the fifth postoperative day (HADS-A: 8.33 ± 3.20 vs 10.71 ± 3.83, P = .01, Power = .79; VAS-A: 3.41 ± 1.58 vs 4.64 ± 1.70, P = .008, Power = .85). The ChatGPT group also reported higher satisfaction with preoperative education (4.22 ± 0.51 vs 3.43 ± 0.84, P<.001, Power = .99) and overall hospitalization experience (4.11 ± 0.65 vs 3.46 ± 0.69, P = .001, Power = .97). No significant differences were found in depression scores, knee function, or pain levels.
Conclusions
ChatGPT-assisted informed consent effectively reduced perioperative anxiety and improved patient satisfaction in TKA patients. While these preliminary findings are promising, larger studies are needed to validate these results and explore broader applications of AI in preoperative patient education.

Artificial Intelligence and Informed Consent: an information science perspective on privacy policies and terms of use in major AI platforms

Conference Presentation
Jonas Ferrigolo Melo, Moises Rockembach
Artificial Intelligence in Library and Information Science: Exploring the Intersection, January 2025; Istanbul, Turkey
Abstract
This study examines how AI platforms incorporate the principles of informed consent (IC) concerning transparency, privacy, and user autonomy. The research aims to identify areas of convergence, divergence, and potential integration between the conceptual framework of IC in Information Science and the Privacy Policies of ChatGPT, Gemini, and Co-pilot. By analyzing these policies, the study explores how these platforms communicate data practices, ensure user control over personal information, and align with ethical standards of informed decision-making. The findings contribute to a broader understanding of AI governance and user rights in digital environments.

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GENOMIC MEDICINE/GENE EDITING

Analysis of informed consent forms of patients undergoing cancer genetic testing in the era of next-generation sequencing

Research
Tina Kerševan, Tina Kogovšek, Ana Blatnik, Mateja Krajc
Hereditary Cancer in Clinical Practice, 21 February 2025

Open Access
Abstract
Background

The Department of Clinical Cancer Genetics at the Institute of Oncology Ljubljana offers genetic counselling and testing to cancer patients and their relatives. Before undergoing genetic testing, patients sign the informed consent form. In addition to giving consent for collection of biological material and genetic testing, patients decide about storage of biological material and participation in international databases. Furthermore, patients decide whether the information regarding their test results may be revealed to their blood relatives and whether they want to be informed about secondary findings.

Methods

Using the signed consent forms, we investigated the effect of selected factors on patients' decisions. Using different statistical methods, we tried to determine the proportion of patients who opted for different items and the effect of gender, age and cancer diagnoses on their decisions.

Results

Nearly all (99.6%) patients, regardless of gender, age, and presence of oncological diagnosis, consented to the storage of their biological material, 98.4% of patients, regardless of gender, age, and presence of oncological diagnosis, wanted to be included in international databases in a pseudo-anonymised form, 98.8% of patients, irrespective of gender, age, and presence of oncological diagnosis, allowed blood relatives to see their results, and 98.4% of patients, irrespective of gender, age and presence of oncological diagnosis, wanted to know whether secondary findings were detected when genetic analysis of their biological material was performed. Men are, on average, more likely to consent but the difference between genders is not statistically significant. Patients without oncological disease were more likely to agree to be included in international databases than patients with a confirmed oncological diagnosis.

Conclusions

Our results show that the vast majority of patients were in favour of the options they were offered. Most importantly, the majority of them allow their genetic test results be revealed to their blood relatives when needed and would participate in international databases. Research in rare diseases, including rare cancer genetic predisposition syndromes, is crucial for optimal diagnostic, prevention and treatment options for patients with rare genetic disorders. The results are also important for refining the approach to pre-and post-test cancer genetic counselling.

New Online Consent Tool for Patients

Australian Genomics, 23 January 2025

Abstract

Informed consent is a critical component of genomic and genetic testing. It is a process whereby a patient agrees to undergo genomic testing in full knowledge of the potential risks, benefits and outcomes. It is therefore essential that they are given clear and transparent information to support their decision. A new interactive online tool developed by Australian Genomics provides easy and accessible information in bite-sized chunks to guide patients through the key concepts of genomic testing. It is designed to complement the updated genetic and genomic clinical consent package released by Australian Genomics earlier last year. "These consent materials are among the most popular resources we have produced," said Project Lead Professor Julie McGaughran. "This is another step forward in our work to provide accurate and engaging material to help people better understand the often-complex process of genomic testing." The tool is designed to provide key details upfront and then options for users to explore more information based on their interests.

Looking Beyond the IRB

Editorial

Quinn Waeiss, Margaret Levi, Leif Wenar, David Magnus

The American Journal of Bioethics, 29 January 2025

Excerpt

…Looking to the informed consent process to address group harms also brings serious complications. The first is defining the groups that could experience harm. Without careful thought to the identification of these groups, researchers run the risk of using social groups as inappropriate proxies for the groups actually under study—and those ultimately at risk of harm (Juengst Citation1998). Blanket calls for community engagement in data-centric research without careful consideration of the communities in question seems likely to reinforce the incorrect use of population descriptors in fields like genomics. Doerr and Meeder (Citation2025) highlight several additional complexities with appropriately demarcating groups in data-intensive research, including groups that researchers can analyze into existence. Even if groups are properly identified, we still need to consider the additional burdens placed on communities and their members through community engagement in the research process, and how burdens could compound if such engagement were mandatory…

Consideration and Disclosure of Group Risks in Genomics and Other Data-Centric Research: Does the Common Rule Need Revision?

Target Article

Carolyn Riley Chapman, Gwendolyn P. Quinn, Heini M. Natri, Courtney Berrios, Patrick Dwyer, Kellie Owens, Síofra Heratyf Birkbeck, Arthur L. Caplan

The American Journal of Bioethics, 2025

Abstract

Harms and risks to groups and third-parties can be significant in the context of research, particularly in data-centric studies involving genomic, artificial intelligence, and/or machine learning technologies. This article explores whether and how United States federal regulations should be adapted to better align with current ethical thinking and protect group interests. Three aspects of the Common Rule deserve attention and reconsideration with respect to group interests: institutional review board (IRB) assessment of the risks/benefits of research; disclosure requirements in the informed consent process; and criteria for waivers of informed consent. In accordance with respect for persons and communities, investigators and IRBs should systematically consider potential group harm when designing and reviewing protocols, respectively. Research participants should be informed about any potential group harm in the consent process. We call for additional public discussion, empirical research, and normative analysis on these issues to determine the right regulatory and policy path forward.

Beyond Individual Consent: The Hidden Crisis of Group Harm in the AI and Genomics Era

Open Peer Commentaries

Y. Tony Yang

The American Journal of Bioethics, 29 January 2025

Excerpt

…Chapman and colleagues' analysis highlights critical gaps in current regulatory frameworks, particularly around institutional review board (IRB) assessment of group risks, informed consent requirements, and criteria for consent waivers. Their work connects to and builds upon several themes identified in earlier work: the increasing salience of group risks in data-centric research, as highlighted by analyses of algorithmic harm and bias in big health data research (Obermeyer et al. Citation2019); the challenges of prospectively identifying group harms, emphasized in studies of genetic research with Indigenous communities (Garrison et al. Citation2019); and the limitations of individual-focused protections in addressing collective risks, a theme present across multiple analyses…

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TECHNOLOGY/OTHER MEDIATION

The Impact of Video Consent on Patient Satisfaction When Undergoing Percutaneous Nephrolithotomy: A Randomized Control Trial

Kartik Sharma, Gautam Ram Choudhary, Shiv Charan Navriya, Jeena Raju Kudunthail, Deepak Prakash Bhirud, Mahendra Singh, Arjun Singh Sandhu

Société Internationale d'Urologie Journal, 12 February 2025

Abstract

Introduction

Consent-taking for surgery evolved from a historical paternalistic approach to informed consent in the mid-20th century. Modern healthcare models prioritize patient-centric care, and the use of multimedia tools may overcome challenges such as language barriers and complex medical surgical steps. This study evaluates the impact of an educational video on patient satisfaction for those undergoing percutaneous nephrolithotomy (PCNL), a procedure where explaining complexities verbally can be challenging.

Materials and Methods

A randomized control trial was conducted at a tertiary care center in India from July 2022 to April 2024. A total of 232 adult patients scheduled for PCNL were randomly assigned to a study group (Group A) or a control group (Group B). Group A viewed an educational video about PCNL, while Group B provided standard written consent. The video, presented in patients' native languages, covered procedural details, potential outcomes, and post-operative care. Patient satisfaction was assessed using a 10-question questionnaire at discharge, with scores ranging from one (poor) to five (best). Statistical analysis was performed using SPSS software to compare outcomes between the two groups.

Results

The study found that Group A exhibited significantly higher satisfaction compared to Group B across all domains. Group A demonstrated a better understanding of the procedure, improved knowledge of post-operative care, reduced anxiety, and a greater awareness of potential complications. Specifically, the mean satisfaction scores for Group A were higher in understanding the procedure (13.15 vs. 10.00), post-operative care (8.46 vs. 6.84), and overall anxiety (8.65 vs. 6.96). The video also improved patients' comprehension regarding potential complications and the need for further procedures. Complication rates and hospital stay durations were similar between both groups.

Discussion

The educational video significantly enhanced patient satisfaction and the understanding of PCNL. This multimedia approach provided a consistent, clear explanation of the procedure, which improved patient comprehension and reduced anxiety, irrespective of literacy levels. These findings support the integration of video-assisted consent in pre-operative education to enhance patient engagement and satisfaction.

Conclusions

The use of an educational video for consent in PCNL improves patient understanding and satisfaction. This method effectively complements traditional consent processes, providing a valuable tool for patient education in complex procedures.

Improving Endoscopy Room Efficiency: Evaluation of a Video as a Supplementary Tool for Informed Consent

A Kyei, O esenwa, C Tan, D Llovet, M Bernstein, B Mannino, L Cohen, N Griller, F Saibil, P Tartaro, E Yong, J Tinmouth

Journal of the Canadian Association of Gastroenterology, 10 February 2025

Abstract

Background

Endoscopy unit efficiency is critical because of the need to provide timely and quality care, despite limited resources. In previous work, obtaining informed consent negatively impacted efficiency. We developed a 3-minute animated video to facilitate the consent process, including describing colonoscopy, its purpose and potential risks/benefits.

Aims

1) Assess the ability of the video to support the informed consent process; 2) Determine the effectiveness of the video as a communication tool.

Methods

Using a critical case sample design with maximum variation, 12 participants completed pre- and post-colonoscopy 1:1 semi-structured interviews after viewing the video. Questions evaluated whether key components of informed consent were conveyed and assessed the video using principles of learner verification (attractiveness, usability, comprehension, impact on self-efficacy, acceptability). Interviews were recorded and transcribed. The data were coded inductively and deductively.

Results

Regarding components of informed consent, most participants understood the purpose and nature of a colonoscopy, but alternatives, including the right to refuse, were less effectively communicated. As a communication tool, the animations engaged participants and aided comprehension of complex material. The language was accessible, however, some participants found the video too fast and the font too small. Most participants found the video acceptable and characters relatable. Some identified information gaps included sedation level and procedure duration.

Conclusions

Endoscopy unit efficiency may be improved by providing consent information via video to patients scheduled for colonoscopy to supplement current approaches to informed consent. Our findings will inform revisions of the video and subsequent implementation into clinical practice.

How Inclusive Are Patient Decision Aids for People with Limited Health Literacy? An Analysis of Understandability Criteria and the Communication about Options and Probabilities

Research Article

Romy Richter, Jesse Jansen, Josine van der Kraan, Wais Abbaspoor, Iris Bongaerts, Fleur Pouwels, Celine Vilters, Jany Rademakers, Trudy van der Weijden

Medical Decision Making, 14 December 2024

Abstract

Objective

Patient decision aids (PtDAs) can support shared decision making. We aimed to explore how inclusive PtDAs are for people with limited health literacy (LHL) by analyzing 1) the understandability of PtDAs using established criteria, 2) how options and probabilities of outcomes are communicated, and 3) the extent to which risk communication (RC) guidelines are followed.

Methods

In a descriptive document analysis, we analyzed Dutch PtDAs available in 2021 that met the International Patient Decision Aid Standards. We developed and pilot tested a data extraction form based on key RC and health literacy literature.

Results
Most PtDAs (151/198) met most of the understandability criteria on layout (7–8 out of 8 items) such as font size but not on content aspects (121/198 PtDAs scored 5–7 out of 12 items) such as defining medical terms. Only 31 of 198 PtDAs used a short and simple sentence structure. Most PtDAs presented 2 to 4 treatment options. Many followed RC recommendations such as the use of numerical RC strategies such as percentages or natural frequencies (160/198) and visual formats such as icon arrays (91/198). Only 10 used neutral framing (10/198). When presented, uncertainty was presented verbally (134/198) or in ranges (58/198). Four PtDAs were co-created together with patients with LHL and used only verbal RC or no RC.

Conclusion
Most PtDAs met most of the understandability criteria on layout, but content aspects and adherence to RC strategies can be improved. Many PtDAs used long sentences and mostly verbal RC and are therefore likely to be inappropriate for patients with LHL. Further research is needed on PtDA characteristics and RC strategies suitable for people with LHL.

Highlights

- Despite meeting most criteria for understandability, many of the Dutch PtDAs use long sentences, which likely impede comprehension for patients with LHL.
- Most of the Dutch PtDAs follow established recommendations for risk communication, with room for improvement for some strategies such as framing and a clear reference to the time frame.
- Overall, more research is needed to tailor PtDAs to the needs of people with LHL.

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HEALTH DATA/DATA

Exploring Consent to Use Real-World Data in Lung Cancer Radiotherapy: Decision of a Citizens' Jury for an 'Informed Opt-Out' Approach

Arbaz Kapadi, Hannah Turner-Uaandja, Rebecca Holley, Kate Wicks, Leila Hamrang, Brian Turner, Tjeerd van Staa, Catherine Bowden, Annie Keane, Gareth Price, Corinne Faivre-Finn, David French, Caroline Sanders, Søren Holm, Sarah Devaney

Health Care Analysis, 10 February 2025

Abstract

An emerging approach to complement randomised controlled trial (RCT) data in the development of radiotherapy treatments is to use routinely collected 'real-world' data (RWD). RWD is the data collected as standard-of-care about all patients during their usual cancer care pathway. Given the nature of this data, important questions remain about the permissibility and acceptability of using RWD in routine practice. We involved and engaged with patients, carers and the public in a two-day citizens' jury to understand their views and obtain decisions regarding two key issues: (1) preferred approaches to consent for the use of RWD within the context of patients receiving radiotherapy for lung cancer in RAPID-RT and (2) how RWD use should be best communicated to patients. Individual views were polled using questionnaires at various stages of the jury, whilst group discussion activities prompted further dialogue about the rationale behind choices of consent. Key decisions obtained from the jury include: (1) an opt-out approach to consent for the use of RWD; (2) the opt-out approach to consent should be informed. Furthermore, it was advised that information and communication regarding the consent process and use of RWD should be accessible, clear and available in a variety of formats. It is important that the consent process for patient data use is underpinned by principles of autonomy and transparency with clear channels of communication between those asking for and giving consent. Moreover, the process of seeking consent from patients should be proportionate to the risks presented from their participation.

Using dataflow diagrams to support research informed consent data management communications: participant perspectives

Brian J McInnis, Ramona Pindus, Daniah H Kareem, Julie Cakici, Daniela G Vital, Eric Hekler, Camille Nebeker

Journal of the American Medical Informatics Association, 4 February 2025

Abstract

Objectives

Digital health research involves collecting vast amounts of personal health data, making data management practices complex and challenging to convey during informed consent.

Materials and Methods

We conducted eight semi-structured focus groups to explore whether dataflow diagrams (DFD) can complement informed consent and improve participants' understanding of data management and associated risks (N = 34 participants).

Results

Our analysis found that DFDs could supplement text-based information about data management and sharing practices, such as by helping raise new questions that prompt conversation between prospective participants and members of a research team. Participants in the study emphasized the need for clear, simple, and accessible diagrams that are participant centered. Third-party access to data and sharing of sensitive health data were identified as high-risk areas requiring thorough explanation. Participants generally agreed that the design process should be led by the research team, but it should incorporate many diverse perspectives to ensure the diagram was meaningful to potential participants who are likely unfamiliar with data management. Nearly all participants rejected the idea that artificial intelligence could identify risks during the design process, but most were comfortable with it being used as a tool to format and simplify the diagram. In short, DFDs may complement standard text-based informed consent documents, but they are not a replacement.

Discussion

Prospective research participants value diverse ways of learning about study risks and benefits. Our study highlights the value of incorporating information visualizations, such as DFDs, into the informed consent procedures to participate in research.

Conclusion

Future research should explore other ways of visualizing consent information in ways that help people to overcome digital and data literacy barriers to participating in research. However, creating a DFD requires significant time and effort from research teams. To alleviate these costs, research sponsors can support the creation of shared infrastructure, communities of practice, and incentivize researchers to develop better consent procedures.

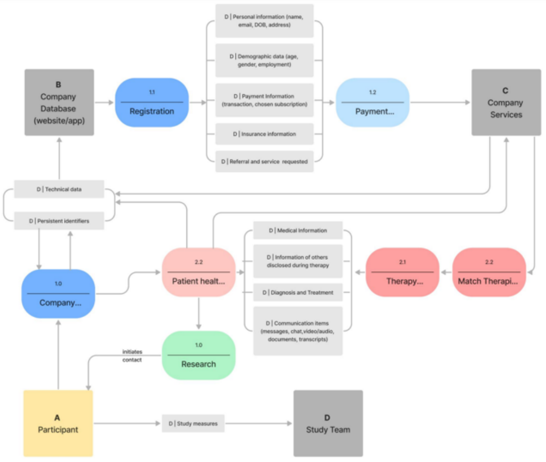

Figure 1. Baseline design for the Commercial DFD is based on the data privacy policy documents published on the company's website. This Commercial DFD included a legend describing entities and processes depicted in this visualization.

Example dataflow diagram from the article

Technological Adjuncts to Streamline Patient Recruitment, Informed Consent, and Data Management Processes in Clinical Research: Observational Study

Jodie Koh, Stacey Caron, Amber N Watters, Mahesh Vaidyanathan, David Melnick, Alyssa Santi, Kenneth Hudson, Catherine Arguelles, Priyanka Mathur, Mozziyar Etemadi

JMIR Formative Research, 29 January 2025

Abstract

Background

Patient recruitment and data management are laborious, resource-intensive aspects of clinical research that often dictate whether the successful completion of studies is possible. Technological advances present opportunities for streamlining these processes, thus improving completion rates for clinical research studies.

Objective

This paper aims to demonstrate how technological adjuncts can enhance clinical research processes via automation and digital integration.

Methods

Using one clinical research study as an example, we highlighted the use of technological adjuncts to automate and streamline research processes across various digital platforms, including a centralized database of electronic medical records (enterprise data warehouse [EDW]); a clinical research data management tool (REDCap [Research Electronic Data Capture]); and a locally managed, Health Insurance Portability and Accountability Act–compliant server. Eligible participants were identified through automated queries in the EDW, after which they received personalized email invitations with digital consent forms. After digital consent, patient data were transferred to a single Health Insurance Portability and Accountability Act–compliant server where each participant was assigned a unique QR code to facilitate data collection and integration. After the research study visit, data obtained were associated with existing electronic medical record data for each participant via a QR code system that collated participant consent, imaging data, and associated clinical data according to a unique examination ID.

Results

Over a 19-month period, automated EDW queries identified 20,988 eligible patients, and 10,582 patients received personalized email invitations. In total, 1000 (9.45%) patients signed consents to participate in the study. Of the consented patients, 549 unique patients completed 779 study visits; some patients consented to the study at more than 1 time period during their pregnancy.

Conclusions

Technological adjuncts in clinical research decrease human labor while increasing participant reach and minimizing disruptions to clinic operations. Automating portions of the clinical research process benefits clinical research efforts by expanding and optimizing participant reach while reducing the limitations of labor and time in completing research studies.

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YOUNG PERSONS

Consenting for themselves: A qualitative study exploring a Gillick Competence assessment to enable adolescents to self-consent to low-risk online research

Maria Loades, Lara Willis, Emma Wilson, Grace Perry, Melanie Luximon, Christy Chiu, Nina Higson-Sweeney

BMJ Open, 13 February 2025

Abstract

Background

Providing digital mental health interventions online could expand access to help for young people, but requiring parental consent may be a barrier to participation. We therefore need a method that enables young people <16 years old (i.e. presumed competent in the UK) to demonstrate Gillick Competence (understanding of purpose, process, potential benefits, and potential harms) to self-consent to online, anonymous, low-risk studies.

Aim

To explore whether a new method for assessing Gillick Competence to participate in low risk, anonymous online studies is acceptable to both young people and parents.

Method

We interviewed 15 13–15-year-olds and 12 parents of this age group in the UK. Using a qualitative approach, we explored the acceptability of a series of multiple-choice questions (MCQs) designed to assess understanding of a specific online self-help research study testing a self-kindness intervention.

Results

The MCQ answers that participants gave mostly corresponded with their narrative explanations of their understanding during interviews. Young people and parents thought that the process was empowering and could increase access to research whilst also promoting independence. However, they emphasised the importance of individual differences and different research contexts and highlighted the need for safeguards to be in place.

Conclusions

The MCQs were acceptable to both young people and parents, providing preliminary evidence for the potential of this process for allowing <16's to self-consent to online, anonymous, low-risk mental health research. Further research is needed to validate the effectiveness of this process among a diverse range of populations and research contexts.

Between Protection and Participation: Informed Consent, Ethics and Play in Research With Children and Youth

Original Article

Maria V. Barbero

Children & Society, 11 February 2025

Abstract

While a robust scholarly dialogue has emerged in recent decades surrounding child and youth-centred research methods, less attention has been paid to how other elements of research design can better account for the needs, vulnerabilities, and perspectives of children and youth. In this article, I discuss challenges tied to informed consent processes and inflexible ethical guidelines in social science research with minors. Drawing from the child and youth studies literature as well as my past research experiences, I explore what it means to develop ethical approaches that are situated, responsive, and relational and which focus not only on the protection of minors but also their inclusion and full participation in research. In doing so, I develop the concept of "playful consent checkpoints" and argue that playful approaches can offer interesting and flexible possibilities for responding to ongoing ethical challenges in research with young people.

Ascribed Agency, Denied Influence: How Adult Narratives Shape and Constrain the Right of Children in the Justice System to be Heard

Mark Yin

The International Journal of Children's Rights, 17 December 2024

Abstract

Following McMellon and Tisdall's (2020) literature review on children's participation rights, as embodied in the Convention on the Rights of the Child, Article 12, this narrative review considers how access to these rights is affected by children’s involvement in the criminal justice system. Based on 30 papers relating to youth participation in youth justice, it is argued that adult-driven narratives of criminalised children as “risky”, “self-interested” or “vulnerable” variously undermine their right to be heard, while children’s narratives about themselves are often neglected. This suggests that the “perennial” implementation solutions identified by McMellon and Tisdall belie more fundamental questions about the very idea of childhood – as exemplified by children in conflict with the law – which warrant their own analysis.

Giving Due Weight to Children and Young People in Australian Policy Making

Meaghan Vosz, Anne Graham, Mark Hughes

The International Journal of Children's Rights, 17 December 2024

Abstract

While Article 12 of the Convention on the Rights of the Child is often cited to assure children’s right to express their views freely in all matters affecting them, little is known about the practices associated with giving due weight to their views in policy-making that impacts their lives. This paper reports on critical-participatory research exploring the practices of more than 100 policy actors, conducted with five young co-researchers with lived experience of Australian child protection and out-of-home care systems. Practices associated with giving due weight included: involving children as policy actors, listening, giving feedback and reporting back, and amplifying their views. Practices were constrained by discourses of authenticity/tokenism; bureaucracy and jurisdiction; the attribution of expertise; and limited funding and time. Research demonstrated opportunities for realising Article 12 through intergenerational dialogue and valuing the lived experience and agency of young people as policy actors.

A New Approach for Investigating Children’s Participation Rights in Early Childhood Education: Listening to Voices in Interaction for Participation (LViIP)

Cynthia Hicban, Maryanne Theobald, Julia Mascadri

The International Journal of Children's Rights, 17 December 2024

Abstract

Research into children’s participation rights has largely focused on the challenges for early childhood educators to navigate children’s participation rights enactment. The aim of this article is to show how the enactments of children’s participation rights in an educational setting can be identified using a new approach, Listening to Voices in Interaction for Participation (LViIP).

LViIP is based on Lundy’s (2007) conceptualisation of Article 12(1) and combines with conversation analysis (ca) to identify how rights enactment sequentially unfolds and how the interactants mobilise (or gatekeep) opportunities for children to have a say.

A step-by-step worked example of LViIP shows in detail how participatory approaches by educators and children are built in early childhood education, thus demonstrating which interactional practices contribute towards the co-construction of children’s participation rights and how early childhood professionals can listen, be and do as duty-bearers of children’s rights in their daily practice.

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CAPACITY TO CONSENT

Guidelines for the Creation of Accessible Consent Materials and Procedures: Lessons from Research with Autistic People and People with Intellectual Disability

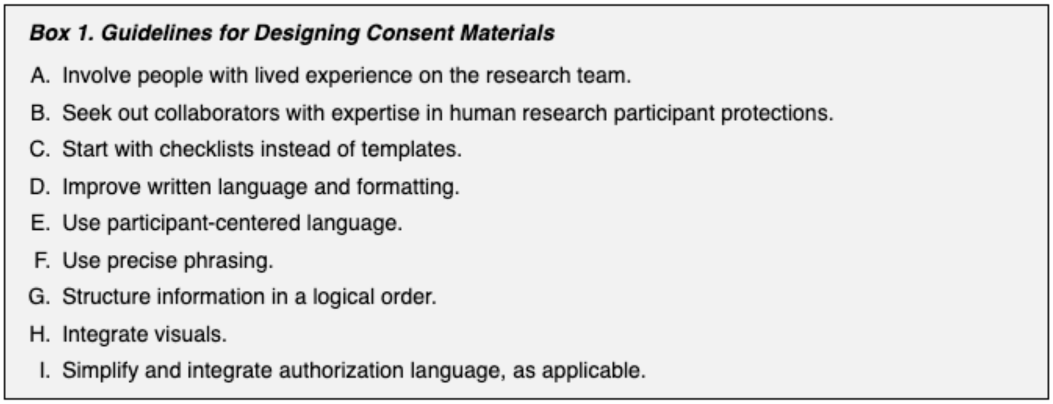
Research Article

Kelly B. Beck, Kristen T. MacKenziem, Anne V. Kirby, Katherine McDonald, Ian Moura, Kaitlyn Breitenfeldt, Elizabeth Rutenberg, Tanvi Kumar, Juliet Mancino, Maya Sabatello, Shannon Roth, Christina Nicolaidis

Autism in Adulthood, 19 February 2025

Abstract

Informed, voluntary, ongoing consent is a central tenet of ethical research. However, consent processes are prone to exclusionary practices and inaccessibility. Consent materials are often too long and complex to foster understanding and ensure that people make truly informed decisions to participate in research. While this complexity is problematic for all people, these challenges are compounded for autistic people and people with intellectual disability. Consent materials and procedures rarely incorporate accommodations for processing and communication differences common in autism and intellectual disability. Failure to provide such accommodations ultimately threatens the conduct of ethical research. We describe lessons learned across multiple major U.S. research institutions that improved informed consent materials and procedures, with the goal of fostering responsible inclusion in research for autistic people and people with intellectual disability. We used these alternative materials and procedures in multiple research projects with samples of autistic people and people with intellectual disability. Each contributing team partnered with university human research participant protections personnel, accessibility experts, community members, and researchers to develop rigorous procedures for improving the readability and accessibility of informed consent materials. We present guidelines for designing consent materials and procedures and assert that participatory methods are vital to the success of ongoing accessibility initiatives. Adoption of understandable consent materials and accessible consent procedures can cultivate more equitable, respectful, and inclusive human research practices. Future work should expand on this work to design inclusive practices for populations with additional considerations.



Box 1. Guidelines for Designing Consent Materials

A. Involve people with lived experience on the research team.
B. Seek out collaborators with expertise in human research participant protections.
C. Start with checklists instead of templates.
D. Improve written language and formatting.
E. Use participant-centered language.
F. Use precise phrasing.
G. Structure information in a logical order.
H. Integrate visuals.
I. Simplify and integrate authorization language, as applicable.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Consent Mechanisms and Default Effects in Health Information Exchange in Japan

Original Research

Atsushi Ito, Fumihiko Nakamura

Frontiers in Digital Health, 3 February 2025

Background

Health information exchange (HIE) is an information system that efficiently shares patient information across medical institutions. However, traditional consent methods, represented by opt-in and opt-out, face a trade-off between efficiency and ethical, making it difficult to fundamentally improve consent rates. To address this issue, we focused on default settings and proposed an innovative approach called the "two-step consent model," which leverages the advantages of existing models using utility theory. We evaluated the acceptability of this method.

Methods

An online survey was conducted with 2,000 participants registered with Japan's largest internet survey company. We compared and analyzed the consent rates of the opt-in, opt-out, and two-step consent models. Results: The opt-in model had a 29.5% consent rate, maximizing patient autonomy but increasing the burden and reducing efficiency. The opt-out model had a 95.0% consent rate but raised concerns among half of the respondents. The two-step consent model had a 68.5% consent rate, demonstrating its cost-effectiveness compared with traditional models

Discussion

The two-step consent model, involving implicit and explicit consent when needed, ensures efficient consent acquisition while respecting patient autonomy. It is a cost-effective policy option that can overcome the ethical issues associated with the opt-out model. Introducing methods that leverage both opt-in and opt-out advantages is expected to address HIE stagnation.

Conclusion

The two-step consent model is expected to improve consent rates by balancing the efficiency and quality of consent acquisition. To achieve this, patient education is crucial for raising awareness and understanding of HIE and its consent methods.

Surgical informed consent practice and associated factors among adult postoperative patients in public hospitals of Mekelle, Tigray, Ethiopia 2023/2024

Research Article

Fiseha Abadi Gebreanenia, Hailemarim Berhe Kahsay, Desta Siyoum Belay, Binyam Gebrehiwet Tesfay, Fissha Brhane Mesele, Mamush Gidey Abirha

PLOS One, 3 February 2025

Open Access

Abstract

Background

Substantial weaknesses and omissions of surgical informed consent are evident and the current elements of the surgical informed consent process are largely neglected in daily practice. This study aimed to assess surgical informed consent practice and associated factors among adult postoperative patients in public hospitals of Mekelle, Tigray, Ethiopia.

Methods

Institution based cross-sectional study was conducted among 314 adult postoperative patients in public hospitals of Mekelle, Tigray, Ethiopia. Participants were selected using systematic random sampling. A pretested interviewer-administered questionnaire was used to collect data. Descriptive, Descriptive, bivariate and multivariable logistic regression analyses were performed using statistical package for social science version 27.

Result

Only 35.8% (CI 95%, 30.6, 41) of the respondents were identified to have received the recommended (6 or more) components of surgical informed consent. Educational level [AOR 5.76 (1.02, 32.6)], timing of surgical informed consent delivery [AOR 3.27 (1.5, 7.11)], qualification of counselor who took surgical informed consent them [AOR3.185 (1.21, 8.38)], hospital type [AOR 2.85 (1.26, 6.46)], and duration of counseling [AOR 6.9 (3.33, 14.3)] were statistically significant at $P<0.05$.

Conclusion

Majority of participants did not receive comprehensive information during the surgical informed consent process in the study hospitals. To improve the delivery it is suggested that health professionals; create rapport with patient, spend more time during counseling.

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RIGHTS/LEGAL/LEGISLATIVE

A Critical Appraisal of Informed Consent in English Medical Law: A Patient-Centred Approach Against Medical Paternalism: Who Gets to Decide What Is Best for Me?

Lisa Kachina Poku

European Journal of Health Law, 18 February2025

Abstract

This article seeks to discuss informed consent in English law. The attitudes on informed consent have shifted to a more patient-centred approach following Montgomery v Lanarkshire Health Board [2015] UKSC 11, [2015] AC 1430, as opposed to the long-standing Bolam decision where clinical judgment was more widely accepted. Thus, following on from the decision in Montgomery a patient is required to know about material risks regarding the proposed treatment and not what the doctor thinks would be the best practice as has been the long-standing consensus since Bolam was decided back in 1957 with subsequent cases following suit. The Montgomery principle has allowed more transparency in the patient–doctor relationship, allowing for a discussion between the doctor and the patient to be the central focus. The outcome of Montgomery was a much needed change in healthcare because prior to this it could be seen that patients were having decisions made on their behalf, and if they had been informed accordingly regarding the risks involved may have decided not to go ahead with the procedure. In the case of Diamond v Royal Devon & Exeter NHS Foundation Trust [2019] EWCA Civ 585 the case highlights the issue of causation in medical negligence action if a doctor does not warn of risks and advise treatment alternatives this would not result in a claim for damages because the patient in this case as was held would have gone ahead with the mesh repair in any case, and thus failing to establish causation could result in no remedy as it did in Diamond. Furthermore, the recent case of McCulloch and others v Forth Valley Health Board [2023] UKSC 26 adds a bit of salt to the wounds of those who had thought or believed that Montgomery had already clarified the position regarding disclosure of alternative treatments to a patient, and to our dismay to learn of that once again English courts have ruled in favour of 'Bolam'.

Informed consent in neurosurgery with particular reference to alternatives to proposed surgery. Updated case law including McCulloch.

Research Article

Nicholas Todd, James Wright-Todd

Medico-Legal Journal, 11 February 2025

Abstract

Introduction

Informed consent is a crucial element in neurosurgical practice; failures of the consenting process are a common cause of litigation in neurosurgery and judgments that have particular relevance to neurosurgical practice will be reviewed here. Guidance for consent based upon current case law is discussed.

*Method*s

The legal databases BAILII and WestLaw were searched using the search term "informed consent". The BAILII search yielded 86 abstracts, WestLaw yielded 33. There were 15 duplicates. Ten of the remaining 104 abstracts were commentaries, leaving 94 judgments. From those judgments a further 21 cases were added. A total of 115 judgments were reviewed by both authors.

Results

A total of 23 judgments dealing with issues of informed consent in neurosurgical and other surgical practice were selected. The cases and their implications for neurosurgical consent are discussed below.

Discussion

When proposing a surgical procedure to a competent adult, the treating surgeon must discuss the benefits, risks and alternatives to treatment with the patient. The surgeon can be guided by professional guidance from the GMC, or another professional body, and/or case law. Relevant issues include: (i) the risks and benefits of surgery; (ii) information that is accurate (or inaccurate, incorrect, missing or late information); (iii) established practice; (iv) the current state of knowledge; (v) reasonable alternative treatments; and (vi) surgery performed on a different day or by a different surgeon.

Perceptions and experiences of healthcare professionals of implementing the Organ Donation (Deemed Consent) Act in England during the Covid-19 pandemic

Research

Mustafa Al-Haboubi, Leah McLaughlin, Lorraine Williams, Jane Noyes, Stephen O'Neill, Paul Boadu, Jennifer Bostock, Nicholas Mays

BMC Health Services Research, 31 January 2025

Open Access

Abstract

Context

In May 2020 during the COVID-19 pandemic, England implemented a 'soft' opt-out system of consent to deceased organ donation. As part of a wider evaluation, this analysis focused on the perceptions of health care professionals, specifically their experiences of implementation.

Methods

Mixed-methods study informed by Normalisation Process Theory, based on two national surveys of health care professionals and interviews, observations and document analysis, across two case study sites. Routine NHS Blood and Transplant's audit data provided context.

Findings

70 interviews with 59 staff and 244 first and 738 second surveys. COVID-19 affected every aspect of implementation. Although supportive in principle, many staff were unconvinced that legislative changes alone would increase consent rates. Many staff were redeployed or left their jobs. As a result, staff were not able to work collectively as intended for implementation. Staff received routine donor audit data suggesting the law was yet to make a difference to consent rates, reducing their enthusiasm and commitment.

Conclusions

Implementation could have been more impactful if delayed. The National Health Service needs to reprioritise organ donation and relaunch the implementation plan in the post-pandemic period, though it is unlikely the changes will bring about a significant increase in consent rates.

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MEDICAL/SURGICAL

Role and Complexities of Informed Consent in Vascular Surgery

Editorial

Himanshu Verma

Indian Journal of Vascular and Endovascular Surgery, January – March 2025; 12(1)

Open Access

Introduction

Informed consent is a cornerstone of ethical medical practice, emphasizing the patient's right to autonomy and the alignment of medical care with their values and preferences. Over the past century, this principle has evolved from a procedural formality to an essential process enabling shared decision-making (SDM). Patients now actively participate in treatment decisions, weighing the risks, benefits, and alternatives of interventions to ensure their choices reflect personal goals and priorities.

While patient comprehension remains a critical element of informed consent, studies reveal significant gaps in understanding.[4] Patients often struggle to recall or fully grasp essential details, including diagnoses, procedural risks, benefits, and alternatives.[5,6] Consequently, informed consent has transitioned from being a mere legal safeguard to an interactive dialog fostering patient engagement and trust.[7,8] This editorial explores the nuances of informed consent, particularly within the context of vascular surgery, where challenges are multifaceted and deeply rooted in both medical complexity and patient perception.

Broad consent in the emergency department: a cross sectional study

Research

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

Archives of Public Health volume, 18 February 2025

Open access

Abstract

Background

The Medical Informatics Initiative (MII) introduced a broad consent form (MII-BC) encompassing clinical, insurance, and biomaterial data, along with re-contacting options. In the emergency department (ED), outpatient and inpatient patients of all illnesses and severity could be reached early in their treatment course. The BC-ED (Broad Consent in the Emergency Department) project uniquely investigated the implementation of MII-BC in EDs, exploring feasibility, selection bias and patients' perceptions of voluntariness, information recall, motivation, and satisfaction.

Methods

The BC-ED project involving four university hospital EDs in Germany, is part of CODEX+ (Collaborative Data Exchange and Usage), an initiative within the Network University Medicine (NUM). To minimize selection bias, a systematic sampling approach (every 5th/30th patient) was applied, with patient recruitment and consent processes adapted to local conditions and therefore varying among sites. Data collection included patient questionnaires, surveys completed by study nurses, and routine clinical data. Analysis was conducted descriptively using SPSS.

Results

Of 1,138 patients approached, 553 (48.6%) were capable of giving consent. Of 353 patients who could not consent, primary reasons included language barriers (35.4%) and inability to grasp study details (21.5%). Of all eligible patients, 3.3% could not be contacted. Of 535 (47.0%) patients able to consent and contacted, 313 consented to the MII-BC. Resulting in a consent rate of 27.5% corresponding to the baseline population and 58.5% of those contacted. Motivations for consenting were general support for research (85.3%) and the desire to help future patients (78.2%). Patients generally reported a high level of understanding and satisfaction with the consent process, reporting comprehensive understanding of scientific data use (89.8%) and associated risks (82.2%). However, discrepancies were noted between consented options and patient recall.

Conclusions

This study is the first to investigate the implementation of the MII-BC in the challenging ED environment. With a consent rate of 27.5% total baseline population and 58.5% of those contacted, it demonstrates that patients were able and willing to participate in research. Reasons for non-consent were barriers like language and medical conditions. Strategies to address these barriers are crucial for inclusivity. Although patients generally understood the consent process, discrepancies in recall highlight the need for improved comprehension strategies.

Advance Consent for Interventional Radiology Procedures: Quality Improvement Project

Rohan Shankarghatta, Alexandra Garnett

The Physician, 17 February 2025

Abstract

Background

Advance consent is crucial for patients undergoing Interventional radiology (IR) procedures with potential serious harm. Two previous audits at our hospital revealed issues with obtaining consent before the day of the procedure, leading to the implementation of a consent clinic. Subsequently, a new electronic patient record (EPR) system was introduced. This third audit cycle assessed whether these changes improved the advance consent rates for vascular IR procedures.

Method

We retrospectively reviewed 53 patients who underwent vascular IR procedures in January 2023, noting whether each procedure was inpatient or outpatient, urgent or elective, and the procedure type. These results were compared with previous cycles to evaluate adherence to consent standards.

Results

Among the 53 patients, there was an even split between inpatient and outpatient procedures, as well as between urgent and elective procedures. 27 patients underwent lower limb angiogram/angioplasty, 19 had fistula work, and 7 underwent other procedures. 77% of patients consented in advance or had the consent process initiated beforehand.

Conclusion

An improvement in advance consent rates was noted compared to previous cycles (14% → 63% → 77%) following the implementation of consent clinics and the new EPR system. However, 33% of patients, primarily those undergoing fistula work, still consented on the day of the procedure. This audit highlights the benefit of the new EPR system and the need to continue consent clinics, emphasizing the importance of advance consent, especially for fistula procedures.

Is informed consent correctly obtained for vaccinations?

Dhriti Jagadish, Nathaniel Mamo, Felicia Pasadyn, Arthur Caplan

Human Vaccines & Immunotherapeutics, 16 February 2025

Abstract

Informed consent is an integral tenet of medical ethics. However, the United States lacks a standardized consent process for immunizations, with states and private companies instead reliant on Vaccine Information Statements (VISs) introduced by the 1986 National Childhood Vaccine Injury Act. VISs, rather than being developed with patient autonomy in mind, were a response to excessive vaccine injury litigation and resulting vaccine supply shortages. VISs do not provide meaningful information disclosures, with its producer - the Centers for Disease Control and Prevention - itself admitting that VISs should not be mistaken for informed consent forms. In its content, the VIS is too complex in its readability, does not situate immunization in a public health context, and does not present all alternatives. VIS delivery is also inadequate, with limited time given for patients to digest vaccine information and no documentation required to ensure that VISs were presented at all. Simply put, VISs do little to spark deliberation and increase vaccine confidence. This article recommends minor improvements to VIS content, delivery, and accountability mechanisms to ensure distribution. The authors argue that these patient-provider moments - for patients to better understand their health, the threat of disease, and the weight of their contribution to the public - should not be squandered.

Consent: risk assessment, risk communication and shared decision making

Catherine Rimmer

Surgery, 10 February 2025

Abstract

The consent process is the foundation of the modern doctor–patient relationship, and can present a significant challenge to doctors. The consent process can be complex, and often involves the interaction of many different factors, including ethical and legal considerations. A shared decision-making process allows for full consideration of the treatment options available, and takes into account individual patients' values and preferences. Ensuring that the patient is fully informed requires a thorough understanding of the risks of an intervention for that particular patient; therefore, individualized risk assessment is of fundamental importance. Using a combination of individual patient information, formal investigations and population data gives the most complete assessment of risk. Communicating that risk information to patients is key, and the doctor should always use clear language and avoid bias. The use of visual aids and information leaflets and the avoidance of vague language and complex statistical terms will all help the patient to develop a more complete understanding of the risks they face.

The impact of obtaining explicit informed consent for medical student participation in the pelvic examination under anesthesia: A qualitative interview study

Hannah C Milad, Katie Watson, Patrick F Eucalitto, Ricky Hill, Alithia Zamantakis, Marlise Jeanne Pierre-Wright, Adaeze A Emeka, Susan Tsai, Susan Goldsmith, Magdy P Milad

International Journal of Gynaecology and Obstetrics, 4 February 2025

Abstract

Objective

To examine patient, physician, and operating room (OR) staff perceptions at an academic institution following the introduction of an explicit, written consent form for medical student participation in the pelvic examination under anesthesia (EUA).

Methods

The study was performed at one urban academic medical center between May 2021 and May 2023. Thirty-one individuals including patients, OR staff, and physicians were interviewed to better understand their perspectives regarding an initiative to explicitly consent patients for the student pelvic EUA. Northwestern University Institutional Review Board approval was obtained.

Results

Patients appreciated being asked to explicitly consent to or refuse the student pelvic EUA and having a dedicated consent form left them with a positive feeling about the hospital and their healthcare providers. OR staff and physicians agreed that the student pelvic EUA is necessary, and almost all supported an explicit consent form. Physicians did not find the additional consent form burdensome and noted only a modest decline in learning opportunities.

Conclusion

Patients and healthcare providers agreed that requiring explicit written consent for the student pelvic EUA respected patient autonomy, improved healthcare quality, and caused minimal disruption to medical education. Our data support the use of an explicit written consent form as standard practice.

Informed Consent in Pelvic Reconstructive Surgery: Patients’ Perspective of a Tertiary Service Process

Original Article

Vandna Verma, Hayser Medina Lucena, Ivilina Pandeva, Ashish Pradhan

International Urogynecology Journal, 31 January 2025

Abstract

Introduction and Hypothesis

Obtaining informed consent to surgery is essential for ethical, legal, and quality-care reasons. This study evaluates patients' understanding, experience, and satisfaction with the informed consent process prior to pelvic reconstructive surgery.

Methods

A prospective study was conducted from April 2021 to April 2022, registered as a service evaluation project. It included all consenting women undergoing pelvic reconstructive surgery. A standardised questionnaire with closed and open-ended questions assessed patients' experiences and decision-making evaluated using the Decisional Conflict Scale (DCS). Satisfaction was evaluated through a five-point Likert scale and a ten-point visual analogue scale (VAS) for response reliability.

Results

The study included 87 patients with a mean age of 61.4 years (SD 11.4). A significant 96.6% read the consent form thoroughly, 98% affirmed detailed explanations by staff, and 88.5% found the explanation clear. Although 83.9% considered the surgery details sufficient, 16.1% found the information overly detailed or too brief. Most patients (91.9%) felt that they had ample time to think before signing, and 75.9% deemed both oral and written information helpful. Only 13.8% preferred medical staff to decide for them, whereas 55.2% valued being included in decision making. Key factors influencing satisfaction were detailed procedure information (72.4%) and reading the consent form (51.7%). The mean DCS score was 7, indicating a high level of satisfaction. Overall, 85% were very satisfied or satisfied with the consent process, with 89.7% scoring 8–10 on the VAS scale.

Conclusions

A thorough consent process is associated with high patient satisfaction and facilitates shared decision making.

Informed Consent Challenges in Frail Surgical Patients

Book Chapter

Alessandro Feola, Antonietta Porzio, Mariavictoria De Simone, Omero Pinto, Graziamaria Corbi, Carlo Pietro Campobasso

The Frail Surgical Patient, 28 January 2025 [Springer]

Abstract

Informed consent is an essential aspect of medical ethics and the foundation of patient-centered healthcare. It represents the principles of autonomy, self-determination, dignity, and patient rights. Physicians are responsible for acquiring informed consent or dissent before conducting any medical procedure and should provide comprehensive information about potential benefits, risks, and alternatives while also encouraging patient participation in their care whenever possible. The historical evolution of informed consent has led to a new definition of the doctor-patient relationship, shifting from a paternalistic approach to one that valorizes the individual’s decision-making capacity and will. For many years, the definition of “frailty” has not been uniform: several authors consider frailty as a condition where an inadequate response to stress and a high risk of adverse outcomes, such as the onset of disabilities, illnesses, institutionalization, or mortality. Frail surgical patients encounter unique ethical and legal challenges due to their increased vulnerability. Because of their cognitive limitations, physical disabilities, and comorbidities, these patients may face complex decisions about surgical procedures. Their limited capacity to comprehend the risks, advantages, and alternatives related to surgical intervention may compromise their ability to make informed choices. To ensure the best possible outcomes, healthcare providers should conduct a preoperative frailty assessment, implement perioperative management with a multidisciplinary approach, and reduce the risk of future complications to improve postoperative care. Informed consent in frail surgical patients is a challenging aspect of medical practice that requires a patient-centered approach based on adequate information and respect for patient autonomy. Healthcare professionals must ensure that patients and their caregivers are adequately informed and supported during the decision-making process and that all discussions related to informed consent are thoroughly documented.

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GENERAL/OTHER

EXPRESS: Beyond Opt-Out: How Presumed-Consent Language Shapes Persuasion

Research article
Romain Cadario, Jenny Zimmermann, Bram Van den Bergh
Journal of Marketing, 16 February 2025
Abstract
When using opt-out (vs. opt-in) policies, choice architects presume that people consent, rather than explicitly asking them to state their consent. While opt-out policies often increase compliance, they are also associated with managerial issues such as ethical considerations, legal regulations, limited public support, and increased no-show rates. This research demonstrates that choice architects can also establish presumed-consent through the language they use, holding the opt-in policy constant. Seven studies in various health domains indicate that presumed-consent language (e.g., "a vaccine was arranged for you") rather than explicit-consent language (e.g., "you can choose to get a vaccine") increases persuasion (i.e., behavioral intentions, actual behaviors). This effect occurs through perceived endorsement: Decision makers infer through the presumed-consent language that the desired health behavior (e.g., vaccination) is the recommended course of action. Furthermore, this research examines the proposed endorsement process under various conditions. When product tangibility is low (e.g., a flu shot), the effectiveness of presumed-consent language stems primarily from perceived endorsement rather than psychological ownership or perceived ease. In contrast, when product tangibility is high (e.g., a sunscreen lotion), the effect stems primarily from psychological ownership rather than perceived endorsement or perceived ease.

Informed Consent, Autonomy, False Beliefs, and Ignorance

James Stacey Taylor
Social Philosophy and Policy, 6 February 2025
Abstract
It is widely believed that health policy should take care to ensure that persons are informed about the expected risks as well as the anticipated advantages of medical procedures. This is often justified by a concern for the moral value of personal autonomy, as it is widely believed that to the extent that a person makes decisions on the basis of false beliefs or ignorance her autonomy with respect to them is compromised. This essay argues against this widespread claim. A person's autonomy with respect to her decisions will not be compromised by either ignorance or false beliefs. However, it does not follow that there is no reason to provide persons with the opportunity to have access to the available information relevant to their decisions concerning their medical treatment. The epistemic requirements for a person to give her consent to her treatment are more stringent than those that must be met for her to be autonomous with respect to her consent. Consent, not autonomy, can be undermined by ignorance or false belief. It is a concern for consent, not a concern for autonomy, that justifies providing people with information about their prospective medical procedures.

Pragmatic Clinical Research, Informed Consent, and Clinical Equipoise

Lynn A. Jansen
Social Philosophy and Policy, 6 February 2025
Abstract

There is a growing movement within contemporary medical ethics to blur the boundaries between clinical medicine and clinical research. Some writers now argue that the research-practice distinction is outdated and the importance of distinguishing between research and medicine is no longer as pressing as it once was or seemed to be. Instead, we are now urged to view the health-care system as a dynamic "learning health-care system" in which research components are embedded within standard clinical care. This essay defends the ethical significance of the research-practice distinction while acknowledging the reality and usefulness of integrated health care. A key claim that this essay advances is that the principle of clinical equipoise, which has largely been rejected by research ethicists, can be reinterpreted and repurposed to help distinguish medical practices that call for more demanding forms of informed consent from those that do not.

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PRE-PRINT SERVERS [*all subject areas*]

A pilot study to explore utility of electronic informed consent in a low- income setting; the case of a Controlled human infection study in Blantyre, Malawi

Clara Ngoliwa, Chikondi Chakwiya, Joel Gondwe, Edna Nsomba, Vitumbiko Nkhoma, Modesta Reuben, Linda Chantunga, Pemphero Liwonde, Edward Mangani, Evaristar Kudowa, Lumbani Makhaza, Neema Toto, Tiferanji Sochera, Tarsizio Chikaonda, Ben Morton, Marc Y.R. Henrion, Dingase Dula, Stephen B. Gordon, Anthony E. Chirwa

Wellcome Open Research, 5 February 2025

Abstract

Background

Electronic informed consent can improve accuracy, workflow, and overall patient experience in clinical research but has not been used in Malawi, owing to uncertainty about availability, utility, patient data security and technical support.

Objectives

We aimed to explore the utility of electronic consent (e-consent) in an ongoing human infection study in Blantyre, Malawi.

Methods

The approved paper consent forms were digitized using Open Data Kit (ODK). Following participant information giving by the research staff, healthy literate adult participants with no audio-visual impairments completed a self-administered e-consent and provided an electronic signature. We dual-consented participants by both paper-based and electronic-consenting. Signed e-consent forms were uploaded to a secure study server. Utility of e-consenting was observed by participation rate, user-friendliness, documentation error rate, and staff perception of the overall consenting process.

Results

All 109 participants offered e-consenting accepted participation. E-consenting was user-friendly, had no identifiable documentation errors as compared to 43.1% (n 47/109) error rate with paper-based consenting, and ensured data safety, and unravelled areas for consideration. Challenges with e-consenting included difficult digitization of ethics stamped documents, as well as present but infrequent delays of retrieval of e-consent forms.

Conclusion

E-consenting is feasible, has a utility benefit in a controlled human infection study in Malawi; a low-income country, and can supplement paper-based consenting. Its usefulness can improve the consenting process in research conducted in such settings. Additionally, success of e-consenting requires a careful consideration.

Integrating a conceptual consent permission model from the informed consent ontology for software application execution

Muhammad "Tuan" Amith, Yongqun He, Elise Smith, Marceline Harris, Frank Manion, Cui Tao

MedRxiv, 2 February 2025

Abstract

We developed a simulated process to show a software implementation to facilitate an approach to integrate the Informed Consent Ontology, a reference ontology of informed consent information, to express implicit description and implement conceptual permission from informed consent life cycle. An early study introduced an experimental method to use Semantic Web Rule Language (SWRL) to describe and represent permissions to computational deduce more information from the Informed Consent Ontology (ICO), demonstrated by the use of the All of Us informed consent documents. We show how incomplete information in informed consent documents can be elucidated using a computational model of permissions toward health information technology that integrates ontologies. Future goals entail applying our computational approach for specific sub-domains of the informed consent life cycle, specifically for vaccine informed consent.

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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].

No new calls for public consultation referencing consent identified.

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NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

GA4GH Policy Brief: children's data protection and genomic research (part 2: consent and lawful bases)

Global Alliance for Genomics and Health, 4 February 2025

Abstract

Following discussion of general considerations related to protection of children's genomic and health data, part two of this two-part Policy Brief further explores considerations with respect to consent and lawful bases under the General Data Protection Regulation (GDPR). This two-part Policy Brief is published as part of the GA4GH Health Data Sharing, Privacy, and Regulatory Forum's work to explore laws and regulations that have an impact on genomic and related health data sharing. The GA4GH Health Data Sharing, Privacy, and Regulatory Forum publishes Policy Briefs to explore laws and regulations that have an impact on genomic and related health data sharing. Following discussion of general considerations related to protection of children's genomic and health data, published on 23 January, part two of this two-part Policy Brief, by Michael J. S. Beauvais, further explores considerations with respect to consent and lawful bases under the General Data Protection Regulation (GDPR).

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SYMPOSIA/CONFERENCES/WEBINARS

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

No new relevant events identified.

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

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