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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

August 2024 :: Issue 68

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

In preparing this digest, we monitor a broad range of academic journals and utilize *Google Scholar* to search articles referencing informed consent or assent. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic 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, some of which may be controversial and warrant closer scrutiny. This approach aligns with our goal of presenting a holistic landscape of informed consent literature as it is being published. We may include "Editor's Notes" or other notations to identify such content.

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

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

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT

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

SPOTLIGHT ARTICLES

In this month's Spotlight, we feature two legal milestones involving consent and social media platforms. One involves the European Commission, its Digital Markets Act, and Meta's "pay or consent" model. The other involves the U.S. state of Texas and a record legal settlement of US$1.4 billion over Meta's deployment of facial recognition software over a decade without consent. We assess that the intersection of consent and advanced data collection technologies implemented on global social media platforms deserves a continuing close examination.

Commission sends preliminary findings to Meta over its "Pay or Consent" model for breach of the Digital Markets Act

Press Release

European Commission, 1 July 2024

Excerpt

Today, the Commission has informed Meta of its preliminary findings that its "pay or consent" advertising model fails to comply with the Digital Markets Act (DMA). In the Commission's preliminary view, this binary choice forces users to consent to the combination of their personal data and fails to provide them a less personalised but equivalent version of Meta's social networks…

Due to their significant position in digital markets, gatekeepers have been able to impose terms of services on their large user base allowing them to collect vast amounts of personal data. This has given them potential advantages compared to competitors who do not have access to such a vast amount of data, thereby raising high barriers to providing online advertising services and social network services.

Under Article 5(2) of the DMA, gatekeepers must seek users' consent for combining their personal data between designated core platform services and other services, and if a user refuses such consent, they should have access to a less personalised but equivalent alternative. Gatekeepers cannot make use of the service or certain functionalities conditional on users' consent…

The Commission takes the preliminary view that Meta's "pay or consent" advertising model is not compliant with the DMA as it does not meet the necessary requirements set out under Article 5(2). In particular, Meta's model:

:: Does not allow users to opt for a service that uses less of their personal data but is otherwise equivalent to the "personalised ads" based service.

:: Does not allow users to exercise their right to freely consent to the combination of their personal data.

To ensure compliance with the DMA, users who do not consent should still get access to an equivalent service which uses less of their personal data, in this case for the personalisation of advertising…

In case of non-compliance, the Commission can impose fines up to 10% of the gatekeeper's total worldwide turnover. Such fines can go up to 20% in case of repeated infringement. Moreover, in case of systematic non-compliance, the Commission is also empowered to adopt additional remedies such as obliging a gatekeeper to sell a business or parts of it or banning the gatekeeper from acquisitions of additional services related to the systemic non-compliance.

The Commission continues its constructive engagement with Meta to identify a satisfactory path towards effective compliance.

"… $1.4 Billion Settlement with Meta Over Its Unauthorized Capture of Personal Biometric Data In Largest Settlement Ever Obtained From An Action Brought By A Single State

Press Release

Attorney General of Texas, 30 July 2024

[Excerpt]

…This settlement is the largest ever obtained from an action brought by a single State…This is the first lawsuit brought and first settlement obtained under Texas's "Capture or Use of Biometric Identifier" Act and serves as a warning to any companies engaged in practices that violate Texans' privacy rights…

In February 2022, Attorney General Paxton sued Meta for unlawfully capturing the biometric data of millions of Texans without obtaining their informed consent as required by Texas law…

In 2011, Meta rolled out a new feature, initially called Tag Suggestions, that it claimed would improve the user experience by making it easier for users to "tag" photographs with the names of people in the photo.

Meta automatically turned this feature on for all Texans without explaining how the feature worked. Unbeknownst to most Texans, for more than a decade Meta ran facial recognition software on virtually every face contained in the photographs uploaded to Facebook, capturing records of the facial geometry of the people depicted. Meta did this despite knowing that CUBI forbids companies from capturing biometric identifiers of Texans, including records of face geometry, unless the business first informs the person and receives their consent to capture the biometric identifier…

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BIOMEDICAL RESEARCH

Quality of Informed Consent in Phase III Clinical Trials in Portugal: The Participants' Perspective

Pedro L. Ferreira, Ana Barradas, Inês Ribeiro

Acta Médica Portuguesa, 19 July 2024

Abstract

Introduction

Some studies show that participants do not always fully understand the informed consent form (ICF), which is one of the reasons for dropouts. This study aimed to adapt the Quality of Informed Consent (QuIC) questionnaire into a valid instrument to be applied to the Portuguese population and to measure its reliability and validity in the Portuguese population, by applying it to a sample of participants in controlled trials.

Methods

The QuIC questionnaire was developed to assess the quality of informed consent in clinical trials and consists of two parts, addressing both the objective (part A) and the subjective (part B) understanding. After being translated and validated into Portuguese, it was implemented in 100 cardiac participants of phase III clinical trials in a University Hospital Center.

Results

The QuIC-PT questionnaire showed excellent stability over time and good validity. All patients evaluated their participation and their health positively and recognized the main purpose of the clinical trial. Almost all participants understood their role in helping future patients and the purpose of the trial and realized that, by signing the ICF, they were participating in a clinical trial. However, none of them knew that their experimental treatment was not proven to be the best alternative for their condition.

Conclusion

The QuIC-PT questionnaire seems to be a valid and useful instrument to evaluate the participants' understanding of the ICF. In this study, we found that some concepts, like 'study protocol' or 'randomization', were not well understood by participants when signing the ICF, especially by participants with lower education levels. They also believed that the experimental intervention would solve their health condition. Greater awareness about the importance of the informed consent process and ICF is necessary so that participants can fully understand the protocol, especially the risks involved, and their rights as participants.

Characteristics, consent patterns, and challenges of randomized trials using the Trials within Cohorts (TwiCs) design A scoping review

Original Research

Alain Amstutz, Christof M. Schönenberger, Benjamin Speich, Alexandra Griessbach, Johannes M. Schwenke, Jan Glasstetter, Sophie James, Helena M. Verkooijen, Beverley Nickolls, Clare Relton, Lars G. Hemkens, Frédérique Chammartin, Felix Gerber, Niklaus D. Labhardt, Stefan Schandelmaier, Matthias Briel

Journal of Clinical Epidemiology, 19 July 2024

Open Access

Abstract

Objective

Trials within Cohorts (TwiCs) is a pragmatic design approach that may overcome frequent challenges of traditional randomized trials such as slow recruitment, burdensome consent procedures, or limited external validity. This scoping review aims to identify all randomized controlled trials using the TwiCs design and to summarize their design characteristics, ways to obtain informed consent, output, reported challenges and mitigation strategies.

Study design and setting

Systematic search of Medline, Embase, Cochrane, trial registries and citation tracking up to December 2022. TwiCs were defined as randomized trials embedded in a cohort with post-randomization consent for the intervention group and no specific post-randomization consent for the usual care control group. Information from identified TwiCs were extracted in duplicate from protocols, publications, and registry entries. We

analyzed the information descriptively and qualitatively to highlight methodological challenges and solutions related to non-uptake of interventions and informed consent procedure.

Results

We identified a total of 46 TwiCs conducted between 2005 and 2022 in 14 different countries by a handful of research groups. The most common medical fields were oncology (11/46; 24%), infectious diseases (8/46;17%), and mental health (7/46; 15%). A typical TwiCs was investigator-initiated (46/46;100%), publicly funded (36/46; 78%), and recruited outpatients (27/46; 59%). Excluding eight pilot trials, only 16/38 (42%) TwiCs adjusted their calculated sample size for non-uptake of the intervention, anticipating a median non-uptake of 25% (interquartile range 10%-32%) in the experimental arm. Seventeen TwiCs (45%) planned analyses to adjust effect estimates for non-uptake. Regarding informed consent, we observed three patterns: 1) three separate consents for cohort participation, randomization, and intervention (17/46; 37%); 2) combined consent for cohort participation and randomization and a separate intervention consent (10/46; 22%); and 3) consent only for cohort participation and intervention (randomization consent not mentioned; 19/46; 41%).

Conclusions

Existing TwiCs are globally scattered across a few research groups covering a wide range of medical fields and interventions. Despite the potential advantages, the number of TwiCs remains small. The variability in consent procedures and the possibility of substantial non-uptake of the intervention warrants further her research to guide the planning, implementation, and analysis of TwiCs.

Waiving the consent requirement to mitigate bias in observational precision medicine research

Comment

Ruifeng Song

International Journal for Equity, 18 July 2024

Open Access

Abstract

Consent bias is a type of selection bias in biomedical research where those consenting to the research differ systematically from those not consenting. It is particularly relevant in precision medicine research because the complexity of these studies prevents certain subgroups from understanding, trusting, and consenting to the research. Because consent bias distorts research findings and causes inequitable distribution of research benefits, scholars propose two types of schemes to reduce consent bias: reforming existing consent models and removing the consent requirement altogether. This study explores the possibility of waiving consent in observational studies using existing data, because they involve fewer risks to participants than clinical trials if privacy safeguards are strengthened. It suggests that data protection mechanisms such as security enhancement and data protection impact assessment should be conducted to protect data privacy of participants in observational studies without consent.

> *Editor's note: In reflecting on the argument as presented in the abstract, we are reaching out to explore and assess further in dialogue with the author.*

Coerced consent in clinical research: study protocol for a randomized controlled trial

Study Protocol

Connor T. A. Brenna, Nancy Walton, Melanie Cohn, Urooj Siddiqui, Ella Huszti, Richard Brull

Trials, 4 July 2024

Open Access

Abstract

Background

Despite the low-risk nature of participation in most clinical anesthesia trials, subject recruitment on the same day as surgery is often restricted due to the concerns of researchers and local research ethics boards that

same-day consent may not afford adequate time and opportunity for patients to weigh and make decisions, as well as perceptions of patient vulnerability immediately prior to surgery that could impact the voluntary nature and the rigor of the informed consent process. However, specialties such as anesthesiology, critical care, interventional radiology, and emergency medicine have a varied pattern of practice and patient acquaintance that does not typically afford the luxury of time or, in many cases, advance consent for participation in research. Indeed, the initial encounter between anesthesiologists and patients undergoing elective procedures routinely occurs on the day of surgery. Concerns of coercion related to same-day consent for clinical anesthesia research trials have not been borne out in the literature, and represent a significant obstacle to clinical researchers, as well as to the patients who are denied opportunities for potential benefit through participation in research studies.

Methods

We describe the protocol for a prospective randomized controlled trial examining the voluntariness of patient consent, solicited either in advance of surgery or on the same day, to participate in an anesthesia research study at Women's College Hospital [Toronto, Canada]. One hundred fourteen patients scheduled to undergo ambulatory anterior cruciate ligament repair facilitated by general anesthesia with an adductor canal block will be randomized for recruitment either (a) in the pre-operative assessment clinic before the day of surgery or (b) on the day of surgery, to be approached for consent to participate in a fabricated research study of adjunct medications in adductor canal blocks. Regardless of allocation, patients in both groups will receive the same routine standard of care and will complete a post-operative questionnaire to signal perceptions of undue influence in the process of providing informed consent for the fabricated trial.

Discussion

This study will inform trial design and practice guidelines surrounding the amount of time patients ought to be afforded in order to make durable decisions to participate (or not) in clinical research studies. This is expected to impact trial recruitment in a variety of clinical settings where researchers have only brief opportunities to interface with patients.

Interactive Media-Based Approach for an Exception From Informed Consent Trial Involving Patients With Trauma

Shannon W. Stephens, Christy Carroll-Ledbetter, Sarah Duckert, Tanner Coffman, Margaret Nelson, Karen N. Brown, Joel Rodgers, Russell L. Griffin, Amy Suen, Jeremy Casey, Steven R. Sloan, Brahm Goldstein, Adam Joseph McClintock, Sara F. Goldkind, Luke Gelinas, Amanda E. Higley, Bellal A. Joseph, John B. Holcomb, Jan O. Jansen

JAMA Surgery, 3 July 2024

Abstract

Importance

Exception From Informed Consent (EFIC) research requires community consultation (CC) and public disclosure (PD). Traditional methods of conducting CC and PD are slow, expensive, and labor intensive.

Objective

To describe the feasibility and reach of a novel interactive, media-based approach to CC and PD and to identify the similarities and differences between trial sites in website views, survey responses, online community forum attendance, and opt-out requests.

Design, Setting, and Participants

This survey study analyzed the CC and PD campaigns conducted for the TAP trial (Evaluation of BE1116 in Patients With Traumatic Injury and Acute Major Bleeding to Improve Survival), an EFIC trial of the early administration of prothrombin complex concentrate in patients with trauma. The CC and PD campaigns consisted of social media advertisements, linked websites, community surveys, and online community forums. These activities were coordinated from a central site and approved by a central institutional review board. This study focused on the first 52 of 91 TAP trial sites (level I trauma centers) in the US to have

completed their CC and PD campaigns. Community members in the catchment areas of the participating trauma centers were targeted. Data analysis was conducted between October 2023 and February 2024.
Exposure
Social media advertisements, surveys, and online community meetings conducted as part of the CC and PD campaign for the TAP trial.
Main Outcomes and Measures
Social media campaign reach and engagement, web page views, survey results, online community forum attendance, and opt-out requests.
Results
Fifty-two trial sites were approved for participant enrollment. Social media advertisements were displayed 92 million times, reaching 11.8 million individuals. The median (IQR) number of people reached in each location was 210 317 (172 068-276 968). Site-specific websites were viewed 144 197 times (median [IQR] viewings per site, 2984 [1267-4038]). A total of 17 206 fully or partly completed surveys were received, and survey respondents had a median (IQR) age of 40.1 (15-65) years and included 10 444 females (60.7%). Overall, 60.6% survey respondents said they would want to be entered into the trial even if they could not give consent, 87.7% agreed that emergency care research was necessary, and 88.0% agreed that the TAP trial should be conducted in their community. Online community forums were attended by a median (IQR) number of 38 (20-63) people. Four opt-out requests were received.
Conclusions and Relevance
The interactive media-based approach to CC and PD for the ongoing TAP trial showed the feasibility and benefits of executing an efficient, coordinated, centrally run series of locally branded and geographically targeted CC and PD campaigns for a large EFIC study.

Exception From Informed Consent—A Model for Donor Intervention Research

Invited Commentary
Anji E. Wall, Giuliano Testa
JAMA Surgery, 3 July 2024
Abstract
In their article “Interactive Media-Based Approach for an Exception From Informed Consent Trial Involving Patients With Trauma,” Stephens and colleagues demonstrate the feasibility of a multicenter community consultation and public disclosure campaign for exception for informed consent for the Trauma and Prothrombin Complex Concentrate (TAP) trial.1 The unique interactive media-based approach resulted in widespread reach to the community through social media and active community participation through surveys, virtual forums, and opt-out requests. Over 50 level 1 trauma centers adopted this approach, which demonstrated the feasibility of a centrally run, locally branded, and geographically targeted campaign.

The ethical value of consulting community members in non-emergency trials conducted with waivers of informed consent for research

Emily A Largent, Steven Joffe, Neal W Dickert, Stephanie R Morain
Clinical Trials, 25 June 2024
Abstract
There is growing interest in using embedded research methods, particularly pragmatic clinical trials, to address well-known evidentiary shortcomings afflicting the health care system. Reviews of pragmatic clinical trials published between 2014 and 2019 found that 8.8% were conducted with waivers of informed consent; furthermore, the number of trials where consent is not obtained is increasing with time. From a regulatory perspective, waivers of informed consent are permissible when certain conditions are met, including that the study involves no more than minimal risk, that it could not practicably be carried out without a waiver, and

that waiving consent does not violate participants' rights and welfare. Nevertheless, when research is conducted with a waiver of consent, several ethical challenges arise. We must consider how to: address empirical evidence showing that patients and members of the public generally prefer prospective consent, demonstrate respect for persons using tools other than consent, promote public trust and investigator integrity, and ensure an adequate level of participant protections. In this article, we use examples drawn from real pragmatic clinical trials to argue that prospective consultation with representatives of the target study population can address, or at least mitigate, many of the ethical challenges posed by waivers of informed consent. We also consider what consultation might involve to illustrate its feasibility and address potential objections.

Consent Form Reporting on ClinicalTrials.Gov, 2013-2023

Research Letter

Sydney A. Axson, Reshma Ramachandran, Alexa Lisenby, Nicholas A. Giordano

JAMA Open, 21 June 2024; 7(6)

Introduction

Informed consent documentation is legally, ethically, and scientifically imperative for research and provides prospective trial participants key study information. Historically, consent documents have been difficult to obtain and not consistently publicly available. As of July 21, 2019, and after a 2-year voluntary period, the revised Common Rule required select federally funded interventional trials to publicly post consent forms no later than 60 days after the last participant visit. The revision intends to increase research transparency and inform consent development. Although transparency efforts addressing trial registrations and results are well studied, less is known about public availability of consent forms in the context of the revised rule's recent implementation. This cross-sectional analysis examined National Institutes of Health (NIH)–funded trial consent form availability on ClinicalTrials.gov.

Reshaping consent so we might improve participant choice (III) – How is the research participant's understanding currently checked and how might we improve this process?

Research Article

Hugh Davies, Simon E Kolstoe, Anthony Lockett

Research Ethics, 24 February 2024

Open Access

Abstract

Valid consent requires the potential research participant understands the information provided. We examined current practice in 50 proposed Clinical Trials of Investigational Medicinal Products to determine how this understanding is checked. The majority of the proposals (n = 44) indicated confirmation of understanding would take place during an interactive conversation between the researcher and potential participant, containing questions to assess and establish understanding. Yet up until now, research design and review have not focused upon this, concentrating more on written material. We propose ways this interactive conversation can be documented, and the process of checking understanding improved.

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SOCIAL SCIENCE RESEARCH

Communication in healthcare contexts: Multilingual technological resources to improve the communicative effectiveness of the Informed Consent

Isabel García-Izquierdo, Anabel Borja Albi
Cadernos de Tradução, September 2024
Abstract
Scientific advances and the complexity of the sociological context in which medicine is practised in an increasingly globalised and interconnected world raise new ethical and legal questions about the rights and obligations of patients, health professionals and public health care services. Despite the significant and undeniable progress brought about by the paradigm shift in the doctor-patient relationship and the great development of medical law and bioethics in recent years, patients continue to encounter serious linguistic and cultural obstacles to exercising their right to information and decision-making in relation to their health. In this paper we present part of the results of the HIPOCRATES research project of the Spanish GENTT group, aimed at humanising health care by improving doctor-patient communication in multilingual environments. Specifically, we will focus on the advances made in the textual analysis of the Informed Consent (IC), a medical genre of great relevance in clinical translation and writing due to its ethical and legal implications. Its lexical-syntactic complexity and the lack of standardised patterns in its writing hinder its comprehensibility and makes it difficult to identify the rhetorical sequences in which the communicative and legal functions of this genre are embodied. We present a textual analysis tool (ProText GENTT), which uses machine learning to exploit corpora with traditional techniques and artificial intelligence and with which we have analysed a multilingual (Spanish, Catalan and English) corpus of IC texts compiled by our research group (GENTT_Corpus). This analysis has allowed us to identify the linguistic-textual and rhetorical elements that hinder comprehension. From these results, our team is currently working on proposing optimized models with different levels of complexity both in printed and digital formats (e-consent).

Editor's note: Cadernos de Tradução is published by the Federal University of Santa Catarina, Brazil.

Words, words, words: participants do not read consent forms in communication research

Research Article
Daria Parfenova, Alina Niftulaeva, Caleb T. Carr
Communication Research Reports, 22 July 2024
Abstract
Informed consent is an essential part of conducting human subjects research; but its utility is dependent on participants actually reading the consent forms provided. This research conducted secondary analysis of data (N = 1,283) to assess how long participants spent on the consent forms. Participants spent an average of 35.4 seconds on consent documents: not a nonsignficant amount of time (i.e., different from 0 seconds), but insufficient to read or even skim consent forms. Women spent slightly less time on consent forms. Neither the length nor readability of a consent form predicted time spent reading, and neither readability nor gender moderated the relationship between word count and time spent reading. Results suggest participants in communication studies do not spend enough time on a consent document to be able to read it, and therefore modern practices of informed consent do not ensure informed participation in research.

Responsible inclusion: A systematic review of consent to social-behavioral research with adults with intellectual disability in the US

Katherine E. McDonald, Ariel E. Schwartz, Robert Dinerstein, Robert Olick, Maya Sabatello
Disability and Health Journal, 2 July 2024
Abstract
Background
In recognition of their status as a health disparities population, there is growing emphasis on conducting research inclusive of adults with intellectual disability to generate new knowledge and opportunities to

improve health and equity. Yet they are often excluded from research, and human research participant protection experts and researchers lack agreement on effective consent protocols for their inclusion.
Objective
We sought to identify approaches to consent in US-based social-behavioral research with adults with intellectual disability.
Methods
We conducted a systematic review on approaches to self-consent with adults with intellectual disability published between 2009 and 2023, identified via searching eight databases and reference list hand searches. We identified 13 manuscripts and conducted a thematic analysis.
Results
Our analysis identified themes related to guiding principles, strategies to enhance informed and voluntary consent, approaches to consent capacity, involving individuals subject to guardianship, and strategies for expressing decisions and enhancing ongoing decisions.
Conclusions
Manuscripts largely reflected an emphasis on identifying approaches to consent that reflect disability rights principles to promote the right to be included and make one's own decisions based on assessment of relevant information, risks and benefits, and to employ reasonable modifications to achieve inclusion. To avoid the risks of exclusion and advance the responsible inclusion of adults with intellectual disability, we make recommendations to align consent approaches anchored in contemporary thinking about human research participant protections, including through integration with disability rights.

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ARTIFICIAL INTELLIGENCE

Artificial intelligence and the law of informed consent

Book Chapter
I. Glenn Cohen, Andrew Slottje
Research Handbook on Health, AI and the Law, 16 July 2024 [Elgar]
Introduction
A patient is diagnosed with stage I non-small-cell lung cancer. The patient's physician recommends surgery and adjuvant chemotherapy, explaining the benefits and risks of each. The physician does not explain, however, that standard treatment guidelines for the patient would counsel against chemotherapy, and that more aggressive treatment has been recommended for the patient by an artificial intelligence (AI) system based on the patient's imaging data. Only after the course of treatment is completed does the patient learn of the AI's involvement in the care decision. The patient is distressed that, as he sees it, he underwent a potentially unnecessary treatment because his physician outsourced decision-making to a machine without letting him know.

Artificial Intelligence as a Consent Aid for Carpal Tunnel Release

Original Research
James Brock, Richard Roberts, Matthew Horner, Preetham Kodumuri
Cureus, 24 June 2024
Open Access
Abstract
Background

Hand surgeons have been charged with the use of diverse modalities to enhance the consenting process following the Montgomery ruling. Artificial Intelligence language models have been suggested as patient education tools that may aid consent.

Methods

We compared the quality and readability of the Every Informed Decision Online (EIDO) patient information leaflet for carpal tunnel release with the artificial intelligence language model Chat Generative Pretrained Transformer (GPT).

Results

The quality of information by ChatGPT was significantly higher using the DISCERN score, 71/80 for ChatGPT compared to 62/80 for EIDO (p=0.014). DISCERN interrater observer reliability was high (0.65) using the kappa statistic. Flesch-Kincaid readability scoring was 12.3 for ChatGPT and 7.5 for EIDO, suggesting a more complex reading age for the ChatGPT information.

Conclusion

The artificial intelligence language model ChatGPT produces high-quality information at the expense of readability when compared to EIDO information leaflets for carpal tunnel release consent.

Safe and Equitable Pediatric Clinical Use of AI

Viewpoint

Jessica L. Handley, Christoph U. Lehmann, Raj M. Ratwani

JAMA Pediatrics, 13 May 2024; 178(7) pp 637-638

Excerpt

Use of artificial intelligence (AI) in pediatric clinical settings has the potential to improve diagnosis, treatment, and quality of care. However, most pediatric AI products tend to be in an early stage—mainly to predict risks using patient data (eg, kidney injury, clinical deterioration, and mortality). AI may also lead to unintended patient safety and equity issues harmful to children. US President Biden's October 2023 AI executive order calls for an AI safety framework. As guidelines, standards, and policies are formulated to guide safe and equitable AI use, the application of AI in pediatrics must be recognized as imbued with distinctly different risks and mitigation needs for children than in adults…

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HEALTH DATA/DATA

Dynamic consent: a royal road to research consent?

Extended essay

Andreas Bruns, Eva C Winkler

Journal of Medical Ethics, 24 July 2024

Abstract

In recent years, the principle of informed consent has come under significant pressure with the rise of biobanks and data infrastructures for medical research. Study-specific consent is unfeasible in the context of biobank and data infrastructure research; and while broad consent facilitates research, it has been criticised as being insufficient to secure a truly informed consent. Dynamic consent has been promoted as a promising alternative approach that could help patients and research participants regain control over the use of their biospecimen and health data in medical research. Critical voices have focused mainly on concerns around its implementation; but little has been said about the argument that dynamic consent is morally superior to broad consent as a way to respect people's individual autonomy. In this paper, we identify two versions of this argument—an information-focused version and a control-focused version—and then argue that both fail to establish the moral superiority of dynamic over broad consent. In particular, we argue that since

autonomous choices are a certain species of choices, it is neither obvious that dynamic consent would meaningfully enhance people's autonomy, nor that it is morally justifiable to act on every kind of consent choice enabled by dynamic consent.

Editor's note: In reflecting on the argument as presented in the abstract, we are reaching out to explore and assess further in dialogue with the authors.

Contours of data protection in India: the consent dilemma

Research Article

Aafreen Mitchelle Collaco

International Review of Law, Computers & Technology, 26 June 2024

Abstract

Amid the rapid advancement of digital technology in India, there is a growing concern regarding data protection and digital privacy. The recent DPDP Act 2023 also reflects the significant emphasis on a robust privacy practice. This paper examines the effectiveness of consent, a crucial principle and a subject of many debates in data privacy regimes. Despite being a cornerstone of privacy regimes globally, the consent-based approach has significant limitations. For instance, its binary character allows for a yes or no response and its inability to guarantee data subjects to make an informed choice. The study is set against the prominent data breaches and the Indian Government's effort to strengthen data protection measures. The study also examines the theoretical and legal aspects of consent by analysing the fundamental ideas that form the basis of the DPDP Act, 2023, protecting the consent framework. It questions whether the current form of the Act aligns with the landmark Privacy Judgement. It concludes by exploring alternative and more adaptable mechanisms for implementing informational privacy that might effectively address the specific issues in the Indian context while taking inspiration from other jurisdictions like the EU.

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GENOMIC MEDICINE/GENE EDITING

SecureConsent: A Blockchain-Based Dynamic and Secure Consent Management for Genomic Data Sharing

Ibrahim Tariq Javed, Victoria Lemieux, Dean A. Regier

International Conference on Smart Communications and Networking, 28-30 May 2024

Abstract

The potential of precision oncology initiatives heavily relies on sharing and analyzing genomic data across diverse patient groups. However, the sensitivity of genomic data raises concerns about consent, and data control, hindering patient participation in such initiatives. Existing healthcare data-sharing methods are unable to fully address these issues, and they also do not take into account patient preferences and requirements within their models. Therefore in this paper, we introduce "SecureConsent", a Patient-Centric consent management system designed for sharing genomic data. SecureConsent caters to patient preferences, allowing them to have control over how their genomic data is shared and used within precision oncology initiatives. It facilitates patients to make informed decisions and modify their consent at any moment through the implementation of dynamic informed consent. Moreover, it integrates a decentralized access control mechanism to establish a robust and patient-centric framework. SecureConsent also presents a user-friendly interface for simple interaction between patients and those requesting data. We conduct a performance evaluation of our blockchain-based model to establish its system efficiency, which includes analyzing gas cost, latency, and transaction throughput.

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TECHNOLOGY/OTHER MEDIATION

Comparison of the Response to an Electronic Versus a Traditional Informed Consent Procedure in Terms of Clinical Patient Characteristics: Observational Study

Anna G M Zondag, Marieke J Hollestelle, Rieke van der Graaf, Hendrik M Nathoe, Wouter W van Solinge, Michiel L Bots, Robin W M Vernooij, Saskia Haitjema

Journal of Medical Internet Research, 11 July 2024

Abstract

Background

Electronic informed consent (eIC) is increasingly used in clinical research due to several benefits including increased enrollment and improved efficiency. Within a learning health care system, a pilot was conducted with an eIC for linking data from electronic health records with national registries, general practitioners, and other hospitals.

Objective

We evaluated the eIC pilot by comparing the response to the eIC with the former traditional paper-based informed consent (IC). We assessed whether the use of eIC resulted in a different study population by comparing the clinical patient characteristics between the response categories of the eIC and former face-to-face IC procedure.

Methods

All patients with increased cardiovascular risk visiting the University Medical Center Utrecht, the Netherlands, were eligible for the learning health care system. From November 2021 to August 2022, an eIC was piloted at the cardiology outpatient clinic. Prior to the pilot, a traditional face-to-face paper-based IC approach was used. Responses (ie, consent, no consent, or nonresponse) were assessed and compared between the eIC and face-to-face IC cohorts. Clinical characteristics of consenting and nonresponding patients were compared between and within the eIC and the face-to-face cohorts using multivariable regression analyses.

Results

A total of 2254 patients were included in the face-to-face IC cohort and 885 patients in the eIC cohort. Full consent was more often obtained in the eIC than in the face-to-face cohort (415/885, 46.9% vs 876/2254, 38.9%, respectively). Apart from lower mean hemoglobin in the full consent group of the eIC cohort (8.5 vs 8.8; P=.0021), the characteristics of the full consenting patients did not differ between the eIC and face-to-face IC cohorts. In the eIC cohort, only age differed between the full consent and the nonresponse group (median 60 vs 56; P=.0002, respectively), whereas in the face-to-face IC cohort, the full consent group seemed healthier (ie, higher hemoglobin, lower glycated hemoglobin [HbA1c], lower C-reactive protein levels) than the nonresponse group.

Conclusions

More patients provided full consent using an eIC. In addition, the study population remained broadly similar. The face-to-face IC approach seemed to result in a healthier study population (ie, full consenting patients) than the patients without IC, while in the eIC cohort, the characteristics between consent groups were comparable. Thus, an eIC may lead to a better representation of the target population, increasing the generalizability of results.

Protocol for a hybrid effectiveness-implementation clinical trial evaluating video-assisted electronic consent vs standard consent for patients initiating and continuing haemodialysis in Australia (eConsent HD)

Protocol

Pedro Henrique Franca Gois, Rebecca B Saunderson, Marina Wainstein, Chenlei Kelly Li, Matthew J Damasiewicz, Vera Y Miao, Martin Wolley, Kirsten Hepburn, Clyson Mutatiri, Bobby Chacko, Ann Bonner, Helen Healy

BMJ, 11 July 2024

Abstract

Introduction

Communicating complex information about haemodialysis (HD) and ensuring it is well understood remains a challenge for clinicians. Informed consent is a high-impact checkpoint in augmenting patients' decision awareness and engagement prior to HD. The aims of this study are to (1) develop a digital information interface to better equip patients in the decision-making process to undergo HD; (2) evaluate the effectiveness of the co-designed digital information interface to improve patient outcomes; and (3) evaluate an implementation strategy.

Methods and analysis

First, a co-design process involving consumers and clinicians to develop audio-visual content for an innovative digital platform. Next a two-armed, open-label, multicentre, randomised controlled trial will compare the digital interface to the current informed consent practice among adult HD patients (n=244). Participants will be randomly assigned to either the intervention or control group. Intervention group: Participants will be coached to an online platform that delivers a simple-to-understand animation and knowledge test questions prior to signing an electronic consent form. Control group: Participants will be consented conventionally by a clinician and sign a paper consent form. Primary outcome is decision regret, with secondary outcomes including patient-reported experience, comprehension, anxiety, satisfaction, adherence to renal care, dialysis withdrawal, consent time and qualitative feedback. Implementation of eConsent for HD will be evaluated concurrently using the Consolidation Framework for Implementation Research (CFIR) methodology. Analysis: For the randomised controlled trial, data will be analysed using intention-to-treat statistical methods. Descriptive statistics and CFIR-based analyses will inform implementation evaluation.

Ethics and dissemination

Human Research Ethics approval has been secured (Metro North Health Human Research Ethics Committee B, HREC/2022/MNHB/86890), and Dissemination will occur through partnerships with stakeholder and consumer groups, scientific meetings, publications and social media releases.

Interactive Health Technology Tool for Kidney Living Donor Assessment to Standardize the Informed Consent Process: Usability and Qualitative Content Analysis

Fernanda Ortiz, Juulia Grasberger, Agneta Ekstrand, Ilkka Helanterä, Guido Giunti

JMIR Formative Research, 9 July 2024

Abstract

Background

Kidney living donation carries risks, yet standardized information provision regarding nephrectomy risks and psychological impacts for candidates remains lacking.

Objective

This study assesses the benefit of interactive health technology in improving the informed consent process for kidney living donation.

Methods

The Kidney Hub institutional open portal offers comprehensive information on kidney disease and donation. Individuals willing to start the kidney living donation process at Helsinki University Hospital (January 2019-January 2022) were invited to use the patient-tailored digital care path (Living Donor Digital Care Path) included in the Kidney Hub. This platform provides detailed donation process information and facilitates communication between health care professionals and patients. eHealth literacy was evaluated via the eHealth Literacy Scale (eHEALS), usability with the System Usability Scale (SUS), and system utility through Likert-scale surveys with scores of 1-5. Qualitative content analysis addressed an open-ended question.

Results

The Kidney Hub portal received over 8000 monthly visits, including to its sections on donation benefits (n=1629 views) and impact on donors' lives (n=4850 views). Of 127 living kidney donation candidates, 7 did not use Living Donor Digital Care Path. Users' ages ranged from 20 to 79 years, and they exchanged over 3500 messages. A total of 74 living donor candidates participated in the survey. Female candidates more commonly searched the internet about kidney donation (n=79 female candidates vs n=48 male candidates; P=.04). The mean eHEALS score correlated with internet use for health decisions (r=0.45; P<.001) and its importance (r=0.40; P=.01). Participants found that the Living Donor Digital Care Path was technically satisfactory (mean SUS score 4.4, SD 0.54) and useful but not pivotal in donation decision-making. Concerns focused on postsurgery coping for donors and recipients.

Conclusions

Telemedicine effectively educates living kidney donor candidates on the donation process. The Living Donor Digital Care Path serves as a valuable eHealth tool, aiding clinicians in standardizing steps toward informed consent.

Enhancing Informed Consent through Multimedia Tools in Pediatric Spinal Surgery: A Comprehensive Review

Marina Rosa Filezio, Nishan Sharma, Jennifer Thull-Freedman, Fabio Ferri, Maria Jose Santana

Frontiers in Pediatrics, 28 June 2024

Abstract

Pediatric spine surgery is a high complexity procedure that can carry risks ranging from pain to neurological damage, and even death. This comprehensive mini review explores current best practice obtaining valid and meaningful informed consent (IC) prior to pediatric spinal surgery, including modalities that support effective comprehension and understanding. An evaluation of the literature was performed to explore understanding of surgical IC by patients or their guardians and the role of multimedia tools as a possible facilitator. The evidence discussed throughout this review, based on legal and ethical perspectives, reveals challenges faced by patients and guardians in achieving comprehension and understanding, especially when facing stressful medical situations. In this context, the introduction of multimedia tools emerges as a patient-centered strategy to help improve comprehension and decrease pre-operative uncertainty. This review highlights the need for a tailored approach in obtaining IC for pediatric patients and suggests a potential role of shared decision-making (SDM) in the surgical discussion process.

Video consent significantly improves patient knowledge of general surgery procedures

Kristin Bremer, Emily Brown, Rachel Schenkel, Ryan W. Walters, Kalyana C. Nandipati

Surgical Endoscopy, 26 June 2024

Open Access

Abstract

Introduction

Informed consent is essential in ensuring patients' understanding of their medical condition, treatment, and potential risks. The objective of this study was to investigate the impact of utilizing a video consent compared to standard consent for patient knowledge and satisfaction in selected general surgical procedures.

Methods and procedures
We included 118 patients undergoing appendectomy, cholecystectomy, inguinal hernia repair, and fundoplication at two hospitals in Omaha, NE. Patients were randomized to either a standard consent or a video consent. Outcomes included a pretest and posttest objective knowledge assessment of their procedure, as well as a satisfaction survey which was completed immediately after consent and following discharge. Given the pre-post design, a linear mixed-effect model was estimated for both outcomes. A two-way interaction effect was of primary interest to assess whether pre-to-post change in the outcome differed between patients randomized to standard or video consent.
Results
Baseline characteristics were mostly similar between groups except for patient sex, $p = 0.041$. Both groups showed a statistically significant increase in knowledge from pretest to posttest (standard group: 0.25, 95% CI 0.01 to 0.51, $p = 0.048$; video group: 0.68, 95% CI 0.36 to 1.00, $p < 0.001$), with the video group showing significantly greater change (interaction $p = 0.043$) indicating that incorporating a video into the consent process resulted in a better improvement in patient's knowledge of the proposed procedure. Further, both groups showed a decrease in satisfaction post-discharge, but no statistically significant difference in the magnitude of decrease between the groups (interaction $p = 0.309$).
Conclusion
Video consent lead to a significant improvement in a patient's knowledge of the proposed treatment. Although the patient satisfaction survey didn't show a significant difference, it did show a trend. We propose incorporating videos into the consent process for routine general surgical procedures.

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YOUNG PERSONS

Research Ethics of Involving Adolescents in Health Research Studies: Perspectives From Australia

Original Article
Neha Faruqui, Angus Dawson, Katharine Steinbeck, Elizabeth Fine, Julie Mooney-Somers
Journal of Adolescent Health, 11 July 2024
Open Access
Abstract
Purpose
Adolescent participation in health research studies is critical yet complex given the lack of clarity around issues such as consent. This study aimed to understand how those conducting research in Australia navigate research ethics in health research involving adolescents, through qualitative interviews.
Methods
Purposive sampling was used to recruit 23 researchers involved in adolescent health research using semi-structured in-depth interviews. Interviews were conducted via Zoom and audio-recorded after obtaining informed consent. Thematic analysis was used to construct themes and data were organised using NVivo.
Results
Two contrasting positions emerged from the data: (1) framing of adolescents as inherently vulnerable, their participation in research understood in terms of risk and protection and (2) adolescent engagement in research is understood in terms of empowerment, emphasising their capacity to make decisions about research participation. We traced these positions through three key themes, particularly in relation to the role of ethics committees: (1) competing positions as a result of inferior or superior knowledge about adolescent lives, (2) competing positions resulting in a risk averse or an empowerment approach, and (3) reflections on processes of obtaining consent which involves gatekeeping and tokenism.
Discussion

Our study highlights the contentious topic of navigating ethics committee requirements for the needs of adolescents. Majority of participants felt the current research ethics establishment is not favourable for researchers or adolescents themselves. While it is imperative that perceptions of ethics committees also be studied in the future, our study provides preliminary understanding of how experiences and perceptions shape how researchers interact with the research ethics establishment.

Informed Consent and Adolescents with Cancer: Challenges and Tools in Online Studies

Research Article

Maria Carolina Neves, Sara Monteiro, Judith B. Prins, Célia

Journal of Adolescent and Young Adult Oncology, 3 July 2024

Introduction

Adolescents and young adults (AYAs) with cancer are defined as those diagnosed between 15 and 39 years. Estimates suggest 1,335,100 new AYAs were diagnosed in 2019, but this population is still underrepresented in research. Some challenges to investigating this population are the differences in cancer types between younger and older AYAs; they are difficult to track and easily lost at follow-up; and they are difficult to find at the hospital since they are divided between the pediatric and adult clinics. This article will focus on adolescents 15–17 years old since these are the ones who might need parental consent to participate in research.

Online research has increased in popularity in the last decades, and in 2017, it was the primary way of collecting quantitative data worldwide. Recruiting minors through online methods was shown to be more efficient and cost-effective than offline methods while still allowing researchers to have representative sample. Research shows that adolescents use the internet frequently, making it a good place when investigating adolescents. Regarding cancer research, some studies have used online methods to recruit adolescents. However, there are additional challenges when using online methods with adolescents compared with offline methods. One of them is obtaining parental consent.

This article describes the challenges and alternatives to obtaining informed consent in online quantitative studies of adolescents with cancer and good practices. This may provide tools for researchers to define how they will obtain informed consent in online studies of adolescents with cancer and help lower barriers in research, encouraging more quantitative studies with this population.

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

Research Article

Maria Cristina Murano

Research Ethics, 29 March 2024

Open Access

Abstract

Over the last three quarters of a century, international guidelines and regulations have undergone significant changes in how children are problematised as participants in biomedical research. While early guidelines enacted children as vulnerable subjects with diminished autonomy and in need of special protection, beginning in the early 2000s, international regulatory frameworks defined the paediatric population as vulnerable due to unaddressed public health needs. More recently, ethical recommendations have promoted the active engagement of minors as research partners. In this paper, I adopt a post-structuralist approach to policy analysis to examine deep-seated assumptions and presuppositions underlying the changes in the problematisation of children as biomedical research participants over time. While biomedical research ethics focuses on the autonomy and vulnerability of minors, ethical guidelines are situated in specific sociocultural contexts, shaped, among other things, by contingent public health needs and changing conceptions of the value of research and science for society. In the process, I demonstrate the challenge of moving away from

an approach that in taking adults as the model overshadows the complexity of children's lived experiences as well as their personal, cultural, and social lives. The lack of acknowledgement of this complexity makes children vulnerable to epistemic injustice, which is particularly crucial to address in public involvement initiatives.

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CAPACITY TO CONSENT

It's a spiral staircase, not just two steps: An iterative approach to assessing patient capacity for medical decision-making

Marc Tunzi, Philip G. Day, David J. Satin
Patient Education and Counseling, October 2024
Abstract
The assessment of medical decision-making capacity as part of the process of clinical informed consent has been considered a bioethical housekeeping matter for decades. Yet in practice, the reality bears little resemblance to what is described in the medical literature and professed in medical education. Most literature on informed consent refers to medical decision-making capacity as a precondition to the consent process. That is, a clinician must first determine if a patient has capacity, and only then may the clinician engage with the patient for the rest of informed consent. The problem with this two-step approach is that it makes no sense in actual practice. We see the assessment of medical decision-making capacity within the process of informed consent as a spiral staircase, not just two steps, requiring clinicians to keep circling up and around, making progress, until they get to where they need to be: 1. Clinicians start with a general presumption of capacity for most adults, sometimes having a provisional appraisal of capacity based on prior patient contact. 2. Then, they begin performing informed consent for the current situation and intervention options. 3. Next, they must reassess capacity during this process. 4. After that, they continue with informed consent. 5. If capacity is not yet clear, they repeat 1–4.

Modifications to consent documentation with adults with communication disorders following brain injury: An exploratory study

Original Article
Jennifer Watermeyer, Chiara Aylward
Developing World Bioethics, 14 July 2024
Open Access
Abstract
Consent documentation for research studies is often inaccessible to people with neurogenic communication disorders following brain injury and there is limited literature on specific modifications for informed consent. This exploratory study aimed to identify effective strategies and modifications to consent processes for adults with brain injury. Using a fictitious research study, we developed a set of Participant Information Sheets (PISs) varying in complexity, presentation format, and communication modality. Evaluations were conducted with eight participants. Findings indicated diverse participant preferences for PIS modifications, suggesting simplified vocabulary, reduced text, carefully selected images, and an interactive presentation modality as helpful strategies. Building on previous literature, we present refined guidelines for consent modifications for adults with neurogenic communication disorder after brain injury. These guidelines can promote more appropriate inclusion of communicatively impaired populations in research and assist ethics committees and researchers in preparing modified consent documents.

Measuring Cognition in Clinical Trials in Parkinson's Disease, Dementia with Lewy Bodies, and Related Disorders

Roundtable Proceedings and Roadmap for Research

Shannon D. Donofry, Claire E. O'Hanlon

Rand, 8 July 2024

Excerpt

Emerging research suggests that Parkinson's disease (PD) and dementia with Lewy bodies (DLB) share underlying pathology and may represent a single, biologically defined disease spectrum. Cognitive changes are among the most worrisome symptoms for patients with PD, and are the core feature of DLB. While the cognitive changes experienced by individuals with PD and mild cognitive impairment share some clinical characteristics with patients who have undiagnosed or prodromal DLB, these changes are distinct from other types of dementias, such as Alzheimer's disease.

To spur the adaptation of existing cognition-focused measures and the development of new ones to underlie clinical trial endpoints in PD and DLB, the PD/DLB Cognition Roundtable was held on January 10 and 11, 2024, in Washington, D.C. The roundtable brought together representatives from academia and industry, as well as with representatives of regulatory agencies, community partners, patient advocates, and research funders, to build consensus and collaborate on the outcome assessment and trial design methods that will support the development of new treatments for early or mild cognitive changes in disorders on the PD/DLB spectrum.

The authors of this document summarize the roundtable, discussing the state of the field for clinical trial design and cognition measures in PD and DLB, promising avenues of research, and perspectives of regulatory agencies…

Important legal principles of consent and mental capacity

Iwan Dowie

British Journal of Community Nursing, 4 July 2024

Abstract

Consent is an essential part of healthcare practice, allowing patients to make autonomous decisions. However, this changes when a patient has mental incapacity or is unable to make decisions for themselves for a duration of time. This month's Policy column looks at some of the key principles of the Mental Capacity Act 2005, and how this can be applied in community nursing practice.

Informed Consent and Surrogate Interference at the Initiation of Community-Based Palliative Care Services

John C. Stys

Palliative Medicine Reports, 22 April 2024

Open Access

Abstract

Community-based palliative care (CBPC) clinicians sometimes contend with an ethically charged scenario when they encounter patients for the first time: The patient’s spouse, or other loved one or caregiver, revokes the patient’s valid informed consent to initiate care. While surrogates are usually motivated by protective instincts, there are other situations where surrogates act out of self-interest. This article considers whether it is ever ethically justified for an adult to revoke another adult’s valid informed consent to initiate palliative care services. The article examines this scenario from three perspectives: the patient’s capacity to give or relinquish informed consent, the surrogate’s intent and use of substituted judgment or best interest, and the clinician’s duty to provide clinical care. This ethical analysis argues that CBPC clinicians have an

ethical responsibility to provide palliative care services for patients who have given valid informed consent for those services even when a surrogate acts as an interfering or oppositional force.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Qualitative Content and Discourse Analysis Comparing the Current Consent Systems for Deceased Organ Donation in Spain and England

Original Research

Kate Rees, Leah Mclaughlin, David Paredes-Zapata, Cathy Miller, Nicholas Mays, Jane Noyes

Transplant International, 4 July 2024

Abstract

England switched to an opt-out system of consent in 2020 aiming to increase the number of organs available. Spain also operates an opt-out system yet has almost twice the organ donations per million population compared with England. We aimed to identify both differences and similarities in the consent policies, documents and procedures in deceased donation between the two countries using comparative qualitative content and discourse analysis. Spain had simpler, locally tailored documents, the time taken for families to review and process information may be shorter, there were more pathways leading to organ donation in Spain, and more robust legal protections for the decisions individuals made in life. The language in the Spanish documents was one of support and reassurance. Documents in England by comparison appeared confusing, since additions were designed to protect the NHS against risk and made to previous document versions to reflect the law change rather than being entirely recast. If England's ambition is to achieve consent rates similar to Spain this analysis has highlighted opportunities that could strengthen the English system-by giving individuals' decisions recorded on the organ donor register legal weight, alongside unifying and simplifying consent policies and procedures to support families and healthcare professionals.

Self-Rated Competence of Ugandan Healthcare Workers to Obtain Informed Consent for Autopsy

Felix Bongomin, Winnie Kibone, Ritah Nantale, Robert Lukande, Ruth Bromley, Conrad Muzoora, Davidson H Hamer

American Journal of Tropical Medicine and Hygiene, 25 June 2024

Abstract

We examined the self-rated competence of Ugandan healthcare workers (HCWs) in obtaining informed consent for autopsies, considering the challenges of low autopsy acceptance rates globally. In September and October 2023, we conducted a nationwide cross-sectional study of HCWs, who provided informed consent to participate and completed an online, self-administered questionnaire. Participants' self-rated competence in obtaining informed consent for autopsy was assessed through Likert scale questions. Knowledge and practices were also assessed. All scores were converted to percentages, with scores ≥80% indicating higher competence. We enrolled 216 HCWs (including 145 [67.1%] doctors), with a mean age of 31.6 ± 7.2 years. Overall, 55.6% (n = 120) had ever assisted in obtaining consent for autopsy, 43.6% (n = 100) had ever obtained consent for autopsy themselves, and 13.4% (n = 29) had ever attended training on obtaining consent for autopsy. The mean competency score was 59.8 ± 17.0% (perfect score, 100%), with 29 (13.4%) participants demonstrating high competence. Healthcare workers with adequate knowledge had higher competence scores (odds ratio [OR]: 15.0, 95% CI: 6.17-36.58, P <0.001). Compared with nurses/midwives, doctors had 73% lower odds of having a high competence score (adjusted OR: 0.27, 95% CI: 0.08-0.94, P = 0.040). Fewer than one in five Ugandan HCWs demonstrated high self-rated competence or possessed adequate knowledge regarding informed consent for autopsies, and only a few had received specialized

training on how to obtain consent for an autopsy. Therefore, there is a pressing need for enhanced training and increased awareness among Ugandan HCWs in obtaining informed consent for autopsies.

Translating informed consent in Scottish maternity services: Perspectives from providers and researchers of both maternity care and translation/interpreting services

Jenny Patterson, Sebnem Susam-Saraeva

Language and Health, 22 June 2024

Abstract / Description of output

Background

Failing to meet the communication and information needs of childbearing women leaves them unable to provide true informed consent. Lack of control or lack of involvement in decision making contribute to birth trauma. For those with Limited English Proficiency (LEP) receiving information requires use of interpreters often hindered within pressurised maternity services and urgent situations. Women with LEP are often of ethnicities at risk of poorer maternity outcomes and from cultures where maternity service practices differ from Scottish maternity services.

Question

How do maternity care professionals (MCPs) and translation & interpreting (T&I) providers experience their role around informed consent when caring for women with LEP in Scotland; what do they identify as barriers or facilitators?

Methods

Data were collected using qualitative methodology through online focus groups and interactive workshops including a mix of MCPs and T&I providers. Recruitment used a snowball approach via word of mouth and email. Focus groups were audio recorded and transcribed verbatim, workshops were audio-visually recorded and closely examined. Data were analysed using Framework analysis.

Results

Four themes emerged from the study: 1) Limited resources; 2) Inter-professional concerns; 3) Cultural heritage; and 4) Power.

Discussion

Limited resources affect women, MCPs and interpreting services. A lack of cultural awareness and power differentials create pressure for everyone within the process.

Conclusion

LEP increases complexity around informed consent. Challenges are multifaceted compounded by lack of time and resources alongside power differentials. Trust, respect and continuity are key facilitators.

Evolution of Organ Donation Consent, Retrospective Data on Potential Organ Donors

Petru Cotraua, Marcel Negraub, Viviana Hodosana, Adriana Vladua, Cristian Marius Dainab, Dorel Dulaua, Lucia Georgeta Dainab, Carmen Pantis

Journal of Clinical Medicine, 18 June 2024; 19(2) pp 292-297

Abstract

Introduction and aim

Identifying the best practices to obtain consent for organ donation involves several strategies. This retrospective analysis of the activity in the field of organ donation identifies the most critical impediments, of which the refusal of families to donate is one of the most frequently encountered. Our main aim was to determine the factors that negatively influence the activity of organ and tissue donations from brain dead donors and to summarize the total number of potential and actual deceased donors, their yearly characteristics, and the organ and tissue donation types performed.

Materials and methods

A retrospective descriptive study, covering data from 1 January 2014 to 31 December 2023, was conducted in the intensive care unit of the Emergency Clinical County Hospital of Bihor, a recognized facility engaged in organ donation and transplantation from Romania. All potential and actual deceased donors were included in our research.

Results

During a period of 10 years, between 2014 and 2023, of the 488 potential and actual deceased donors, 355 (72.7%) were potential donors and 133 (27.3%) actual deceased donors.

*Con*clusions

From 2014 to 2023, a significant percentage [15.28% (133)] of the total number of actual deceased organ donors registered at the national level (870) were identified by us in the Emergency Clinical County Hospital of Bihor.

Evaluating Egg Donor Recruitment Strategies in Czech ART Clinics: A Critical Analysis of Informed Consent and Ethical Considerations

Anna De Bayas Sanchez, Jitka Fialová, Hana Konečná, Francisco Güell

Czech Sociological Review, 2024; 60(3) pp 321-346

Abstract

There is a high demand for egg donors in the Czech Republic, driven by international couples' interest in assisted reproductive procedures due to affordable treatment, no waiting list, and an extended age limit for recipients up to 49 years. For a population of 10.5 million, the country has 48 reproductive clinics. This study aims to evaluate Czech egg donor recruitment campaigns through the lens of free, informed, and specific consent requirements. A quantitative-qualitative analysis of recruitment strategies from 29 unique clinic websites in Czechia was conducted, with 12 sites specifically designed for marketing purposes. The analysis was based on 14 criteria. Of the 29 clinic websites, only three did not indicate compensation amounts, ranging from 800 to 1400 EUR. Thirteen clinics did not provide information on risks associated with oocyte donation, with one falsely stating no risks exist. Twenty-two websites used emotionally evocative quotes and images. Thirteen clinics did not disclose time commitments, and one provided misleading information. Seventeen clinics omitted conditions for donor refusal and the number of allowable donations. Eighteen clinics did not offer post-donation referrals. Conversely, 15 clinics highlighted psychological benefits, and 23 emphasized health benefits. None fully complied with international guidelines on oocyte donation. Analysed websites lack sufficient information for responsible egg donation decisions. The emphasis on compensation, benefits, and suggestive graphics creates an image of safe, community-oriented donation, potentially leading to inadequate understanding of health risks and commodification of the female body.

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RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT

Editor's Note:

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

More broadly, we recognize that this literature raises critically important issues around consent integrity. Our Center for Informed Consent Integrity is actively developing a position on this matter, mindful of core

guidance in research involving human participants overall, and selected instruments such as the Universal Declaration on Bioethics and Human Rights [2005] which notes:

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

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

A qualitative study on informed consent decision-making at two tertiary hospitals in Uganda: Experiences of patients undergoing emergency surgery and their next of kin

Research Article

Olivia Kituuka, Erisa Sabakaki Mwaka, Ian Guyton Munabi, Moses Galukande, Nelson Sewankambo

SAGE Open Medicine, 22 June 2024

Open Access

Abstract

Background

In emergency situations, patients and their next of kin must make complex medical and ethical decisions in a quick and timely way.

Objectives

To describe the decision-making process during informed consent for emergency surgery among patients and the next of kin of patients who have undergone emergency surgery.

Methods

Consecutive sampling of 39 participants and in-depth semi-structured interviews were conducted at two tertiary teaching hospitals in Uganda. There were 22 patients and 17 next of kin of patients who had undergone emergency surgery within 24–72 h. Responses about decision-making were coded into themes using the social constructivist theory and phenomenological approach

Results

There were four emergent themes; decision-makers, people consulted, documentation of the consent and factors influencing decision-making. Most patients and next of kin made decisions on their own and documented the consent for themselves. Other family members and doctors were consulted during the decision-making process. Decision-making was influenced by reassurance of good outcomes of surgery and disclosure by the doctors.

Conclusion

Decisions were made collaboratively with the patient at the center but with input of health personnel, the next of kin and other family members. A communitarian approach combined with shared decision-making between the doctor and the patient and next of kin with adequate discussion and disclosure of information in simple language would improve decision-making for patients and their next of kin.

Communities and Informed Consent in Medical Research in Africa

Book Chapter

Yaw A. Frimpong-Mansoh

An African Research Ethics Reader, 2024 [Brill]

Abstract

This chapter seeks to clarify the imperative role of community in the complex process of obtaining informed consent in clinical research in African societies. Although the communal character of African ethics and cultures have been much discussed in recent research ethics scholarship, there is still a lack of clarity on the role and justification of community members in the complex process of obtaining informed consent in

medical research. The Western liberal individualistic system of ethics is seen as antithetical to the African communal system. The Western system seems concerned that the communal system encourages intrusive paternalism and infringement upon the autonomous rights of the individual. It is argued here however that community involvement in clinical research in Africa is nothing but another justified level of institutional protection comparable to the roles of REC s in efforts to safeguard against exploitative and abusive unethical practices.

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RIGHTS/LEGAL/LEGISLATIVE

Informed consent and the duty to warn: More than the mere provision of information

Rajesh Gounder
Journal of Law and Medicine, 1 June 2024
Abstract
Before providing any form of medical treatment, medical practitioners are generally required to discharge their duty to warn. It is argued in this article that the duty to warn, at least as it relates to frail and elderly patients, requires the principles of shared decision-making to be adopted. Doing so will ensure a comprehensive biopsychosocial understanding of the patient and assist in identifying material risks that May not be readily apparent. Such risks include risks that threaten the patient's values, preferences, treatment aims and long-term outcomes. Once such risks are identified, in discharging the duty to warn, they should be contextualised in a manner that makes clear how that risk will manifest in that particular patient. These risks should then also be synthesised within the context of their other medical issues and longer-term interests. Finally, it is suggested that the traditional consent process may need restructuring.

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

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

Presumed Consent To High-Risk Medical Actions In Emergencies: Perspective Of Law Number 17 Of 2023

Irsyam Risdawati

Law Synergy Conference (LSC), 2024

Abstract

Patients must provide informed consent before medical procedures are carried out in ordinary situations, but this does not apply in emergency situations and presumed consent is used instead. Doctors are often faced with situations that require high-risk medical procedures for emergency patients. The concept of presumed consent for this action is not recognized under Law Number 17 of 2023 concerning Health. The aim of the research is to analyze the role of presumed consent in the perspective of this law for high-risk medical procedures in emergency cases emergency. This research uses a normative juridical legal research type, namely library legal research, with a statutory approach and a conceptual approach. The results of the analysis show that presumed consent for high-risk medical procedures in emergency situations is not clearly regulated in Law Number 17 of 2023. However, doctors can still rely on several other articles in this law, including Article 293 paragraph (10) which emphasizes the best interests of patients, Article 275 paragraph (1) which requires doctors to provide assistance in emergency cases, and Article 273 paragraph (1) which provides legal protection to doctors who act according to standards. Apart from that, Article 275 paragraph (1) also exempts doctors from claims for compensation in emergency cases, providing legal security for doctors to act quickly to save the patient's life without any doubt.

Editor's note: Law 17 of 2023 is part of the Indonesian Health Transformation Plan.

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MEDICAL/SURGICAL

Do Interns Learn On-The-Job How to Obtain Proper Informed Consent for Surgical Procedures?

Original Reports

Michael Lamb, John M. Woodward, Brian Quaranto, Bobbie Ann Adair White, Linda M. Harris, James K. Lukan, Jeffrey Brewer, Steven D. Schwaitzberg, Clairice A. Cooper

Journal of Surgical Education, 17 July 2024

Abstract

Objective

Obtaining surgical informed consent (SIC) is a critical skill most residents are expected to learn "on-the-job." This study sought to quantify the effect of 1 year of clinical experience on performance obtaining SIC in the absence of formal informed consent education.

Design

In this case-control cohort study, PGY1 and PGY2 surgical residents in an academic program were surveyed regarding their experiences and confidence in obtaining SIC; then assessed obtaining informed consent for a right hemicolectomy from a standardized patient.

Setting

Single academic general surgery residency program in Buffalo, NY.

Participants

Ten PGY1 and eight PGY2 general surgery residents were included in the study, after excluding residents with additional years of training.

Results

PGY2 residents had significantly more experience obtaining SIC compared to PGY1 residents (median response: ">50" vs "between 6 and 15," p = 0.001), however there was no difference in self-reported confidence in ability obtaining SIC (mean 3.2/5 in PGY1 vs 3.4/5 in PGY2, p = 0.61), self-reported knowledge of SIC (mean 3.1/5 in PGY1 vs 3.6/5 in PGY2, p = 0.15), performance on a test regarding SIC (mean score

9.0/20, SD 3.9 for PGY1 vs mean score 9.6/20, SD 3.5, t = 0.387, p = 0.739) or performance during a standardized patient interview (mean 11.2/20, SD 2.78 for PGY1 vs mean 11.4/20, SD 1.51 for PGY2, p = 0.87). In the interviews all residents addressed general risks (bleeding/infection), however both groups performed worse in addressing procedure-specific risks including anastomotic leak as risk for hemicolectomy.
Conclusions
A year of clinical training between PGY1 to PGY2 did not improve performance in obtaining surgical informed consent when lacking formal education, despite self-confidence in their ability. A curriculum covering the content, delivery and assessment of informed consent should be initiated for residents upon arrival to surgical training.

Improving Clinical Communication: a qualitative study on the Informed Consent

Isabel García-Izquierdo, Begoña Bellés-Fortuño
Revista De Lingüística Y Lenguas Aplicadas, 8 July 2024
Abstract
In the context of the Patient-Centred Care paradigm (Epstein et al., 2005; Suojanen et al., 2012) and the shift toward the psychobiological model (Dean & Street, 2015; Muñoz & García-Izquierdo, 2020), there is a growing demand for the patient to be an active agent in the management of their health. Clinical communication should be conveyed accurately and empathetically (Bellés Fortuño & García-Izquierdo, forthcoming), especially in complex legal genres such as the Informed Consent (IC). The research carried out by the Gentt research group up-to-date has revealed that there is no specific monitoring with the use of IC protocols in clinical practice. In this paper, we present the results of a qualitative pilot study with a group of practitioners from the Valencian Community (Spain). A focus group was conducted where the articulation of communication with patients was analyzed. The study tries to define the practical insights of using the IC to draw conclusions that can improve clinical communication. Results show that MPs generally consider that the IC process needs improvement, especially when considering closeness with patients to enhance communication.

Reviewing past and present consent practices in unplanned obstetric interventions: an eye towards the future

Original Research
Morganne Wilbourne, Hand, Sophie McAllister, Louise Print-Lyons, Meena Bhatia
Journal of Medical Ethics, 26 June 2024
Abstract
Many first-time mothers (primiparous) within UK National Health Service (NHS) settings require an obstetric intervention to deliver their babies safely. While the antepartum period allows time for conversations about consent for planned interventions, such as elective caesarean section, current practice is that, in emergencies, consent is addressed in the moments before the intervention takes place. This paper explores whether there are limitations on the validity of consent offered in time-pressured and emotionally charged circumstances, specifically concerning emergency obstetric interventions. Using the legal framework of the Mental Capacity Act, Montgomery v. Lanarkshire Health Board (2015) and McCulloch v Forth Valley Health Board (2023), we argue that while women have the capacity to consent during labour, their autonomy is best supported by providing more information about instrumental delivery (ID) during the antepartum period. This conclusion is supported by some national guidelines, including those developed by the Royal College of Obstetricians and Gynaecologists, but not all. Further, we examine the extent to which these principles are upheld in modern-day practice. Data suggest there is relatively little antepartum information provision regarding ID within NHS settings, and that primiparous women do not report a thorough understanding of ID before labour. Based on these results, and bearing in mind the pressures under which NHS obstetric services

currently operate, we recommend further research into patient and clinician perceptions of the consent process for ID. Pending these results, we discuss possible modes of information delivery in future practice.

Antenatal reproductive screening for pregnant people including preconception: Provides the best reproductive opportunity for informed consent, quality, and safety

R. Douglas Wilson

Best Practice & Research Clinical Obstetrics & Gynaecology, 25 June 2024

Abstract

Introduction

This antenatal screening review will include reproductive screening evidence and approaches for pre-conception and post-conception, using first to third trimester screening opportunities.

Methods

Focused antenatal screening peer-reviewed publications were evaluated and summarized.

Results

Evidenced-based reproductive antenatal screening elements should be offered and discussed, with the pregnancy planning or pregnant person, during Preconception (genetic carrier screening for reproductive partners, personal and family (including reproductive partner) history review for increased genetic and pregnancy morbidity risks); First Trimester (fetal dating with ultrasound; fetal aneuploidy screening plus consideration for expanded fetal morbidity criteria, if appropriate; pregnant person preeclampsia screening; early fetal anatomy screening; early fetal cardiac screening); Second Trimester for standard fetal anatomy screening (18–22 weeks) including cardiac; pregnant person placental and cord pathology screening; pregnant person preterm birth screening with cervical length measurement); Third Trimester (fetal growth surveillance; continued preterm birth risk surveillance).

Conclusion

Antenatal reproductive screening has multiple elements, is complex, is time-consuming, and requires the use of pre- and post-testing counselling for most screening elements. The use of preconception and trimesters 'one to three' requires clear patient understanding and buy-in. Informed consent and knowledge transfer is a main goal for antenatal reproductive screening approaches.

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GENERAL/OTHER

[Broad informed consent or partial informed consent]

Y M Zhao

Zhonghua Yi Xue Za Zhi, 9 July 2024

Abstract

The establishment of clinical research resource platforms, including research databases and bio-sample library, is an important development in the field of clinical research. The international academic community proposes broad informed consent to regulate the ethical management of the issue. However, the broad informed consent fails to capture the main features of incomplete informed consent and authorization, misleads researchers and managers and leads to miss ethical management for clinical research projects. Therefore, the author proposes a named partial informed consent to improve ethical management for clinical research projects. Partial informed consent separates ethical management for establishing clinical research resource platforms and clinical research projects. After reviewing the legal and ethical foundation of clinical research ethics management, the author discussed the similarities and differences between project management and task management in the two informed consent solutions, the basis for approval of exempted informed consent signatures by the ethics committee, issues to be noted in the ethics

management of multi-center research at the task level, and explained the substantive differences between broad informed consent and partial informed consent.

Editor's note: This a Chinese language publication.

Informed proxy consent for ancient DNA research

Comment

Victoria E. Gibbon, Jessica C. Thompson, Sianne Alves

Communications Biology, 4 July 2024

Open Access

Abstract

We argue for implementation of informed proxy or relational autonomy consent in human aDNA research, where the deceased may be represented by living people the research affects. Embracing the underlying principles and process of informed proxy consent has the potential to transform research by (1) enriching outcomes by learning from and collaborating with interested and affected persons; (2) empowering people potentially impacted by research to stipulate evidence for information flow; (3) guarding researchers against actual or perceived violations by providing a common set of guidelines; and (4) highlighting the essential nature of long-term consultation and community partnerships to research outcome success.

Clarifying the ethical landscape of psychedelic-assisted psychotherapy

Research Article

Christopher Kochevar

Philosophical Psychology, 27 June 2024

Abstract

This paper attempts to integrate ongoing conversations about the nature and ethics of psychedelic-assisted psychotherapy (PAP) in order to clarify some outstanding ethical questions. First, I address a debate about whether informed consent is possible for "transformative" therapies like PAP, and I conclude that reasonable approaches to informed consent should not be considered especially difficult for PAP. Next, I argue that a focus on potential barriers to information about PAP has obscured a more central risk for the therapy – that posed by a PAP patient's radical susceptibility to environmental influence, or what I call epistemic vulnerability. After expanding on this concept, I conclude that warnings about epistemic vulnerability should be a part of informed consent to PAP in all cases. Finally, I discuss more broadly the complexities of informed consent in PAP, drawing on analogous concerns for regular psychotherapy that may be addressed by a "process view" of consent. I propose that a "nondirective" approach to PAP may be more ethically supportable than other approaches, in part because of the theoretical benefit to patients from managing their own experience, prioritizing the potential for autonomous transformation.

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PRE-PRINT SERVERS

Emergency verbal consent for intrapartum research: a grounded theory study to explore its acceptability in a clinical trial of a novel device to treat postpartum haemorrhage

Bedwell C, Wendy Taylor, Caroline Cunningham, Andrew D Weeks, Dame Tina Lavender

Advance, 16 July 2024

Abstract

Objective

To understand the experiences of women, birth partners and health professionals of verbal followed by retrospective written consent in a prospective cohort study of a device to manage post-partum haemorrhage (PPH).
Design
Grounded Theory.
Setting
Tertiary facility in the North-West of England, UK.
Sample
We used purposive and theoretical sampling to recruit 51 participants; 12 women, 12 birth partners, 16 obstetricians and 11 midwives.
Methods
Semi-structured interviews were conducted, using a topic guide for focus, until data saturation was achieved. Data were analysed using framework analysis technique.
Results
Most women wanted sufficient information to make a decision at the time of the event, rather than in advance, and preferred not to be overwhelmed with detail. A key factor in making the decision to participate was a positive and trusting relationship with the attending obstetrician. Obtaining consent for research in emergencies was viewed by obstetricians as requiring a different approach and more challenging than consent for standard procedures in an emergency.
Conclusions
This is the first study to explore verbal followed by retrospective written consent processes with women, clinicians and observers. This was acceptable to all, however information needs to be appropriate, and consenters require adequate training.

Online unsupervised performance-based cognitive testing: a feasible and reliable approach to scalable cognitive phenotyping of Parkinson's patients

Nasri Balit, Sophie Sun, Yilin Zhang, Madeleine Sharp
MedRxiv, 5 July 2024
Abstract
Introduction
A better understanding of the heterogeneity in the cognitive and mood symptoms of Parkinson's disease will require research conducted in large samples of patients. Fully online and remote research assessments present interesting opportunities for scaling up research but the feasibility and reliability of remote and fully unsupervised performance-based cognitive testing in individuals with Parkinson's disease is unknown. This study aims to establish the feasibility and reliability of this testing modality in Parkinson's patients.
Methods
Sixty-seven Parkinson's patients and 36 older adults completed two sessions of an at-home, online battery of five cognitive tasks and three self-report questionnaires. Feasibility was established by examining completion rates and data quality. Test-retest reliability was evaluated using the Intraclass Correlation Coefficient (ICC (2,1)).
Results
Overall completion rates and data quality were high with few participant exclusions across tasks. With regards to test-retest reliability, intraclass correlation coefficients were quite variable across measures extracted from a task as well as across tasks, but at least one standard measure from each task achieved moderate to good reliability levels. Self-report questionnaires achieved a higher test-retest reliability than cognitive tasks. Feasibility and reliability were similar between Parkinson's patients and older adults.
Conclusion

These results demonstrate that remote and unsupervised testing is a feasible and reliable method of measuring cognition and mood in Parkinson's patients that achieves levels of test-retest reliability that are comparable to those reported for standard in-person testing.

Designing Value-Centered Consent Interfaces: A Mixed-Methods Approach to Support Patient Values in Data-Sharing Decisions

David Leimstädtner, Peter Sörries, Claudia Müller-Birn

arXiv, 4 July 2024

Abstract

In the digital health domain, ethical data collection practices are crucial for ensuring the availability of quality datasets that drive medical advancement. Data donation, allowing patients to share their clinical data for secondary research use, presents a promising resource for such datasets. Yet, current consent interfaces mediating data-sharing decisions are found to favor data-collectors' values by leveraging cognitive biases in data-subjects towards higher data-sharing rates. Seeking to establish patient-centered data collection practices in digital health, we investigate the design of consent interfaces that support end-users in making valuecongruent health data-sharing decisions. Focusing our research efforts on the situated context of health data donation at the psychosomatic unit of a German university hospital, we demonstrate how a human-centered design can ground technology within the perspective of a vulnerable group. We employed an exploratory sequential mixed-method approach consisting of five phases: (1) Participatory workshops explore patient values, informing the (2) design of a proposed Value-Centered Consent Interface. A (3) online experiment demonstrates our interface element's effect, increasing value-congruence in data-sharing decisions. Our proposed consent interface design is then adapted to the research context through a (4) co-creation workshop with subject experts and (5) a user evaluation with patients. Our work contributes to recent discourse in CSCW concerning ethical implications of new data practices within their socio-technological context by exploring patient values on medical data sharing, introducing a novel consent interface leveraging reflection to support value-congruent decision-making, and providing a situated evaluation of the proposed consent interface with patients.

Consent Considerations for Generation and Sharing of Genomic Data

Review

Charles D. Warden

Preprints.org, 25 June 2024

Abstract

It is important to consider both requirements and limitations for the generation and sharing of genomic data. For example, human genomic sequence data should typically not be deposited publicly without the appropriate "explicit consent" to do so. This includes genetic identifying data that may exist within raw reads for bulk RNA Sequencing (RNA-Seq) data and genomic data from cell lines that are available to purchase. At the same time, data sharing is important for re-analysis and reproducibility/replication in the scientific community. A review of known rules and guidelines for genomic data sharing is provided. This includes specific rules for NIH-funded data for controlled access deposit of HeLa cell line data, including bulk RNASeq data. The ability to create "partial" Gene Expression Omnibus (GEO) public deposits with only processed data is described, with search criteria that can identify many "partial" GEO deposits for a variety of data types where reads were not made public for patient privacy concerns. However, it is the opinion of the author that this should be considered a short-term solution, and additional considerations and action should be carried out for genomic data generated in future experiments. Information about how to learn more about what is known for consent for cell line samples is also briefly provided, along with search results for genomic data from widely available cell lines that is deposited in controlled access databases. Finally, it should be made

clear that this article presents some amount of opinion. Additionally, open feedback for this preprint is encouraged to further enhance knowledge and communication.

Informed Consent Practices Among Emergency Staff for Patients Undergoing Emergency Surgery in the Emergency Surgical Units of Two Tertiary Teaching Hospitals in Uganda: A Qualitative Study

Research Article

Olivia Kituuka, Ian Munabi, Moses Galukande, Adelline Twimukye, Erisa Mwaka

BMC Medical Ethics, 25 June 2024

Abstract

Background

Staff in low resourced emergency units of a low-income country face the challenge of obtaining informed consent for incapacitated patients or their next of kin in a time-constrained situation often in an overcrowded environment. Therefore, we aimed to establish the informed consent practices for emergency surgical care among healthcare professional at two emergency surgical units at two tertiary teaching hospitals in Uganda.

Methods

In October 2022 – February 2023we conducted key informant interviews in Uganda and purposively selected 16 staff in surgical emergency units at two tertiary teaching hospitals and directly observed the informed consent practices. Data was managed and analyzed inductively using NVivo version 12.

Results

Six themes emerged from key informant interviews including knowledge and perspectives no informed consent; processes, procedures, and practices regarding informed consent; communication strategies for informed consent; ethical considerations; benefits of informed consent during surgery; and challenges to emergency informed consent. Staff had adequate knowledge about informed consent but faced several challenges during the consent process due to lack of guiding institutional policies. Overall, the informed consent process was inadequate at both institutions with greeting of patients, disclosure of risks and assessment of understanding poorly done. Consent was conducted in a noisy environment at both institutions and there was no privacy in the public hospital.

Conclusion

Although knowledge about consent practices by emergency staff at both institutions was good, in practice there was inadequate disclosure of risks, inadequate knowledge about the surgical procedure, risks, and benefits. Emergency staff identified the need for procedure specific consent documents which capture the information that is given to the patient and guiding policies on consent for incapacitated patients who have no surrogates.

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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

The protection of mental privacy in the area of neuroscience - Societal, legal and ethical challenges

European Parliament, 24 July 2024

Excerpt

Advances in (neuro)technological development have led to an increase in the use and accessibility of neurotechnologies (NT), allowing brain activity to be recorded, analysed and manipulated by neurotechnological devices. While they were originally used only for clinical purposes, they are becoming more and more attractive for healthy populations willing to enhance their cognitive or physical abilities. Consumer-grade devices can be acquired and used by lay persons without supervision in work, education and entertainment environments.

This state of affairs raises a multitude of open questions and the possibility of threats to data security and privacy, as well as neuropsychological, ethical and societal implications. As a result, the Neurorights Foundation (NRF) was formed in 2017 to investigate and discuss these questions and make them visible to the public. This study addresses the NRF's claims and suggestions and evaluates the need for their proposed 'neurorights'. Disciplinary evaluations of the issues at stake are followed by recommendations and policy options.

> *Editor's Note: This study explores a range of "neurorights" and the arguments underlying their normative status, including ideas around a right to mental privacy, a right to personal identity, right to free will, and a right to "equal access to mental augmentation." Consent is referenced 27 times in the document.*

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SYMPOSIA/CONFERENCES

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

No new symposia/conferences identified.

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