ge²p² global foundation
governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

December 2024 :: Issue 72

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

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

Overall, we have elected to be inclusive in our content selection, including articles that may be controversial and warrant closer scrutiny. 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:

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

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

No new content was identified for the following established categories:

COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
GENERAL/OTHER
HUMANITARIAN CONTEXT
PRE-PRINT SERVERS [*all subject areas*]

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

This month we spotlight the new set of principles supporting ethical human genomic data collection and sharing released by the WHO in late November. In this normative guidance, WHO addresses eight principles [detailed below], many of which touch on consent either directly or indirectly. In particular, the first principle [3.1] presents a number of consent-related recommendations which we highlight here:

3.1. To affirm and value the rights of individuals and communities to make decisions

A commitment to affirm and value the rights and interests of individuals with capacity to make informed decisions about their human genome data throughout the data life cycle. In addition, a commitment to affirm the best interests of, and support for, individuals who do not have the capacity to make decisions for themselves.

The use of human genome data has implications beyond the individual, and the relevant views of family members and communities on collection, access to, use and sharing of these data should be taken into account throughout the data life cycle**.**

Recommendations: [selected]

:: Informed consent should be as specific and granular as possible in relation to the potential uses (including by for-profit entities and the potential to share the data to train artificial intelligence), benefits and harms possibly resulting from the use of human genome data, the infrastructure hosting the data (including location and access modalities), and this information must be tailored to respect social and cultural contexts.

:: The most appropriate informed consent model (e.g. specific, broad, tiered or dynamic informed consent) depends upon the individual/local context.
:: Informed consent should be supported by governance frameworks and processes, and individuals should be informed of such processes…
:: Individuals, families and communities should have access to clear, transparent, accessible, understandable and ongoing communication about their human genome data collection, access, use and sharing, for those who wish to receive that information. This ongoing communication should, where possible, continue throughout the data life cycle.
:: Individuals and their representative communities should be engaged in the governance and decision-making process regarding collection, access to, use and sharing of human genome data, including the development of appropriate informed consent models and processes.
:: Children, when sufficiently mature to understand what is involved in their participation, should be given the opportunity to affirm the informed consent previously given on their behalf or to withdraw their consent from that point onwards….

Below, we provide excerpts from the WHO media release and the full citation/overview of the guidance document.

WHO releases new principles for ethical human genomic data collection and sharing
20 November 2024
The World Health Organization (WHO) has issued a set of principles for the ethical collection, access, use and sharing of human genomic data. Created with guidance from the WHO Technical Advisory Group on Genomics (TAG-G) and other international experts, **these principles establish a global approach to help protect individual rights, promote equity and foster responsible collaboration in genomic research…**

"The potential of genomics to revolutionize health and disease understanding can only be realized if human genomic data are collected, accessed and shared responsibly," says Dr John Reeder, Director of WHO's Research for Health Department. "This document outlines globally applicable principles designed to guide ethical, legal and equitable use of human genome data, fostering public trust and protecting the rights of individuals and communities. It serves as a call to action, urging all stakeholders to adhere to these principles and ensure the benefits of genomic advancements are accessible to everyone."

The principles emphasize several core themes:
:: Informed consent and privacy are foundational, with clear guidelines to ensure that individuals understand and agree to how their genomic data will be used. WHO underscores the importance of transparency, requiring that data collection processes are openly communicated and safeguarded against misuse.
:: Another core focus is equity. The principles call for targeted efforts to address disparities in genomic research, especially in low- and middle-income countries (LMICs), and for ensuring that genomic research benefits populations in all their diversity. By prioritizing the inclusion of underrepresented groups, the guidelines aim to promote broader and fairer representation in genomic research and its applications.
:: Recognizing the **importance of international collaboration** through partnerships across borders and sectors, WHO encourages collaborative efforts between governments, academia and the private sector to maximize the positive impact of genomic research. Responsible data sharing, supported by robust governance structures, is essential for advancing global health while respecting privacy.
:: **WHO's principles also address capacity building in** regions with limited genomic infrastructure. By encouraging investment in local expertise and resources, the organization aims to close global disparities in research capacity, making genomic data practices more inclusive and sustainable.

The release of these principles represents a significant step forward in WHO's mission to promote ethical genomics practices. As the field continues to evolve, these guidelines offer a trusted framework to support genomic research that is equitable, transparent and respectful of individual rights.

Guidance for human genome data collection, access, use and sharing

WHO - Guidance [normative]
20 November 2024 :: 22 pages
Overview
The ethical, legal, and equitable sharing of human genomic data is critical to advancing global health research and ensuring fair access to the benefits of genomics. The WHO's new document outlines a comprehensive set of globally applicable principles designed to guide stakeholders in the responsible collection, use, and sharing of human genome data. This document serves as a key resource to navigate complex issues surrounding data governance, with the aim of fostering transparency, promoting equity, and safeguarding individual and collective rights. These principles are intended to support the implementation of best practices across diverse settings, thereby enhancing the global capacity for genomic research and its translation into health benefits for all.

Table of Contents [excerpt]
3. Principles for human genome collection, access, use and sharing
3.1 To affirm and value the rights of individuals and communities to make decisions
3.2 Social justice
3.3 Solidarity
3.4. Equitable access to and benefit from human genome data
3.5 Collaboration, cooperation and partnership
3.6. Stewardship of human genome data
3.7. Transparency
3.8. Accountability

Glossary [excerpt]
Benefit-sharing refers to **profit-sharing agreements,** equitable access to diagnostics, therapeutics and technology transfer, as well as capacity-building and -strengthening initiatives. What constitutes a benefit (and the nature of that benefit) is both subjective and context dependent
Human genome data include but is not limited to:
- DNA sequence(s) from the nuclear and mitochondrial genomes.
- Transcriptome (complete set of RNA transcripts).
- Proteome (complete set of proteins produced by an organism, from which the corresponding
- genetic sequences can be inferred)
- Methylome and other epigenetic modifications.

::::::
::::::

BIOMEDICAL RESEARCH

Consent-Related Outcomes in the Alteplase Compared to Tenecteplase Trial

Michel C. Shamy, Brian Dewar, Yan Deschaintre, Nishita Singh, Carol Kenney, Mohammed A. Almekhlafi, Ayoola Ademola, Brian H. Buck, Tolulope T. Sajobi, Luciana Catanese, Kayla D. Sage, Dar Dowlatshahi, Laura C. Gioia, Aleksander Tkach, Richard H. Swartz, Bijoy K. Menon
Neurology, 26 November 2024

Abstract
Background and Objectives
In recent years, researchers have sought to address the challenges of obtaining informed consent for participation in acute stroke trials. We studied outcomes related to the use of deferral of consent in the phase 3 Alteplase Compared to Tenecteplase (AcT) trial.
Methods
As part of our protocol, we captured methods of consent, participant withdrawals, door-to-randomization times, and door-to-needle times. Participants at 3 sites were invited to complete a survey of attitudes regarding consent for AcT and for acute stroke trials generally.
Results
The AcT trial enrolled 1,600 participants from 22 centers across Canada of whom 1,537 were enrolled through deferral of consent (96.0%) and 63 (4.0%) were enrolled by prospective verbal consent followed by written informed consent. Of those enrolled by deferral of consent, 95% (1,454/1,537) consented to ongoing participation. Door-to-randomization times were similar regardless of method of consent, with an overall median of 30 minutes (interquartile range [IQR] 22–42): 29 minutes (IQR 22–42) in the deferral of consent group vs 32 minutes (IQR 25–44) in the prospective consent group (p = 0.1602). Survey respondents overwhelming agreed or strongly agreed with the use of deferral of consent in AcT (86%) and in any acute stroke trial (76%).
Discussion
Deferral of consent was broadly acceptable to participants in the AcT trial as demonstrated by low rates of withdrawal and by survey results. Door-to-randomization times using deferral of consent in AcT were short, although a system of prospective verbal consent used at 1 center took only slightly longer. These results support the importance of innovation around consent for acute stroke trials.

Insights From the Development of a Dynamic Consent Platform for the Australians Together Health Initiative (ATHENA) Program: Interview and Survey Study

Eddy Xiong, Carissa Bonner, Amanda King, Zoltan Maxwell Bourne, Mark Morgan, Ximena Tolosa, Tony Stanton, Kim Greaves

JMIR Formative Research, 6 November 2024

Abstract
Background
Dynamic consent has the potential to address many of the issues facing traditional paper-based or electronic consent, including enrolling informed and engaged participants in the decision-making process. The Australians Together Health Initiative (ATHENA) program aims to connect participants across Queensland, Australia, with new research opportunities. At its core is dynamic consent, an interactive and participant-centric digital platform that enables users to view ongoing research activities, update consent preferences, and have ongoing engagement with researchers.
Objective
This study aimed to describe the development of the ATHENA dynamic consent platform within the framework of the ATHENA program, including how the platform was designed, its utilization by participants, and the insights gained.
Methods
One-on-one interviews were undertaken with consumers, followed by a workshop with health care staff to gain insights into the dynamic consent concept. Five problem statements were developed, and solutions were posed, from which a dynamic consent platform was constructed, tested, and used for implementation in a clinical trial. Potential users were randomly recruited from a pre-existing pool of 615 participants in the ATHENA program. Feedback on user platform experience was gained from a survey hosted on the platform.
Results

In the 13 consumer interviews undertaken, participants were positive about dynamic consent, valuing privacy, ease of use, and adequate communication. Motivators for registration were feedback on data usage and its broader community benefits. Problem statements were security, trust and governance, ease of use, communication, control, and need for a scalable platform. Using the newly constructed dynamic consent platform, 99 potential participants were selected, of whom 67 (68%) were successfully recontacted. Of these, 59 (88%) agreed to be sent the platform, 44 (74%) logged on (indicating use), and 22 (57%) registered for the clinical trial. Survey feedback was favorable, with an average positive rating of 78% across all questions, reflecting satisfaction with the clarity, brevity, and flexibility of the platform. Barriers to implementation included technological and health literacy.

Conclusions

This study describes the successful development and testing of a dynamic consent platform that was well-accepted, with users recognizing its advantages over traditional methods of consent regarding flexibility, ease of communication, and participant satisfaction. This information may be useful to other researchers who plan to use dynamic consent in health care research.

Maximising the opportunities in lung cancer screening: uptake of consent to contact for research

T Patrick, SB Naidu, L Anandan, K Desai, V Marshman, P Robinson, S Patel, A Nair, R Thakrar, N Navani, JR Hurst, SM Janes, A Bhamani

BMJ Thorax, 3 November 2024

Abstract

Introduction

Low-Dose CT (LDCT) screening reduces lung cancer mortality. However, the benefits of Lung Cancer Screening (LCS) can be extended, for example, by offering individuals the opportunity to participate in research. We investigated the proportion and characteristics of individuals willing to be approached about research participation in our Targeted Lung Health Check programme.

Methods

In our programme, eligible individuals as assessed in an initial telephone questionnaire proceed to a face-to-face lung health check and LDCT. An additional question for eligible individuals ('Are you happy to be approached by a member of our research team about participating in research?') was introduced on 4th December 2023. All individuals subsequently completing a telephone questionnaire up to 20th May 2024 were included in this analysis.

Results

1708/3095 (55.2%) individuals consented to being approached about participating in research. Of these, 1068 (62.5%) were male, 746 (43.7%) were current smokers and 1380 (80.8%) were of white ethnicity. Multivariable binary logistic regression analysis (table 1) showed that the factors associated with an increased likelihood of agreeing to research contact were: personal cancer history (aOR 1.39 (95% confidence interval (CI) 1.15–1.69)) and exposure to asbestos (aOR 1.63 (95%CI 1.34–1.99)). Being Asian (aOR 0.56 (95%CI 0.44–0.72)), having fewer years of formal education (finished education aged 15 or less aOR 0.44 (95%CI 0.33–0.60)) and a self-reported medical history of COPD (aOR 0.83 (95%CI 0.69–0.99) were associated with a reduced likelihood of consenting to research contact.

Discussion

Increasing public participation in research is important and part of the current NHS Long Term Plan.1 The majority of individuals undergoing LCS consented to be approached about research. However, groups already underrepresented in research were less likely to consent. Future studies should focus on increased diversity in research, potential benefits of which include increased public trust, promotion of fairness and improved generalisability of research findings.

Design and implementation of community consultation for research conducted under exception from informed consent regulations for the PreVent and the PreVent 2 trials: Changes over time and during the COVID-19 pandemic

Research article

Tom Gugel, Karen Adams, Madelon Baranoski, N David Yanez, Michael Kampp, Tesheia Johnson, Ani Aydin, Elaine C Fajardo, Emily Sharp, Aartee Potnis, Chanel Johnson, Miriam M Treggiari

Clinical Trials, 27 April 2024

Abstract

Introduction

Emergency clinical research has played an important role in improving outcomes for acutely ill patients. This is due in part to regulatory measures that allow Exception From Informed Consent (EFIC) trials. The Food and Drug Administration (FDA) requires sponsor-investigators to engage in community consultation and public disclosure activities prior to initiating an Exception From Informed Consent trial. Various approaches to community consultation and public disclosure have been described and adapted to local contexts and Institutional Review Board (IRB) interpretations. The COVID-19 pandemic has precluded the ability to engage local communities through direct, in-person public venues, requiring research teams to find alternative ways to inform communities about emergency research.

Methods

The PreVent and PreVent 2 studies were two Exception From Informed Consent trials of emergency endotracheal intubation, conducted in one geographic location for the PreVent Study and in two geographic locations for the PreVent 2 Study. During the period of the two studies, there was a substantial shift in the methodological approach spanning across the periods before and after the pandemic from telephone, to in-person, to virtual settings.

Results

During the 10 years of implementation of Exception From Informed Consent activities for the two PreVent trials, there was overall favorable public support for the concept of Exception From Informed Consent trials and for the importance of emergency clinical research. Community concerns were few and also did not differ much by method of contact. Attendance was higher with the implementation of virtual technology to reach members of the community, and overall feedback was more positive compared with telephone contacts or in-person events. However, the proportion of survey responses received after completion of the remote, live event was substantially lower, with a greater proportion of respondents having higher education levels. This suggests less active engagement after completion of the synchronous activity and potentially higher selection bias among respondents. Importantly, we found that engagement with local community leaders was a key component to develop appropriate plans to connect with the public.

Conclusion

The PreVent experience illustrated operational advantages and disadvantages to community consultation conducted primarily by telephone, in-person events, or online activities. Approaches to enhance community acceptance included partnering with community leaders to optimize the communication strategies and trust building with the involvement of Institutional Review Board representatives during community meetings. Researchers might need to pivot from in-person planning to virtual techniques while maintaining the ability to engage with the public with two-way communication approaches. Due to less active engagement, and potential for selection bias in the responders, further research is needed to address the costs and benefits of virtual community consultation and public disclosure activities compared to in-person events.

::::::::::
::::::::::

SOCIAL SCIENCE RESEARCH

Scoping review and thematic analysis of informed consent in humanitarian emergencies

Research

Benjamin Thomson, S. Mehta, C. Robinson

BMC Medical Ethics, 20 November 2024

Open access

Abstract

Background

To identify and to summarize challenges related to the informed consent process for research completed during humanitarian emergencies.

Methods

Using relevant search terms, a search of 5 databases was completed, without language, date, or study type restriction. Studies were screened for inclusion, with eligible studies being those that were relevant to the informed consent process for research studies completed in humanitarian emergencies. A Grounded Theory Analysis was completed to identify themes and subthemes.

Results

Review identified 30 relevant studies. We identified 11 challenges (lack of trust, therapeutic misconception, reduced capacity, security and privacy concerns, harmful research, power differential, literacy, language/local and cultural context, researcher burden and re-evaluation of ongoing trials) and 7 strategies (engage local research communities, use alternative to standard written consent process, modify traditional process of research ethics board review, dynamic consent, training of research staff, mandating transparency of commercial interests, and mandating reporting of informed consent process in all publications) to confront the challenges. These challenges and strategies were unique to the informed consent process in research conducted during humanitarian emergencies.

Conclusions

This scoping review identified an evidence-based guide for researchers and research ethics boards to perform ethical informed consent procedures in humanitarian emergencies.

Emergency Verbal Consent for Intrapartum Research: A Grounded Theory Study

Research Article

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

BJOG: An International Journal of Obstetrics & Gynaecology, 7 November 2024

Open Access

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 postpartum haemorrhage (PPH).

Design

Grounded Theory.

Setting

Tertiary facility in North-West 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 one of the first studies 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 those discussing consent require adequate training.

::::::

::::::

ARTIFICIAL INTELLIGENCE

Enhancing patient understanding in obstetrics: The role of generative AI in simplifying informed consent for labor induction with oxytocin

Amos Grünebaum, Joachim Dudenhausen, Frank A. Chervenak

Journal of Perinatal Medicine, 30 October 2024

Abstract

Informed consent is a cornerstone of ethical medical practice, particularly in obstetrics where procedures like labor induction carry significant risks and require clear patient understanding. Despite legal mandates for patient materials to be accessible, many consent forms remain too complex, resulting in patient confusion and dissatisfaction. This study explores the use of Generative Artificial Intelligence (GAI) to simplify informed consent for labor induction with oxytocin, ensuring content is both medically accurate and comprehensible at an 8th-grade readability level. GAI-generated consent forms streamline the process, automatically tailoring content to meet readability standards while retaining essential details such as the procedure's nature, risks, benefits, and alternatives. Through iterative prompts and expert refinement, the AI produces clear, patient-friendly language that bridges the gap between medical jargon and patient comprehension. Flesch Reading Ease scores show improved readability, meeting recommended levels for health literacy. GAI has the potential to revolutionize healthcare communication by enhancing patient understanding, promoting shared decision-making, and improving satisfaction with the consent process. However, human oversight remains critical to ensure that AI-generated content adheres to legal and ethical standards. This case study demonstrates that GAI can be an effective tool in creating accessible, standardized, yet personalized consent documents, contributing to better-informed patients and potentially reducing malpractice claims.

Evaluating AI-Generated informed consent documents in oral surgery: A comparative study of ChatGPT-4, Bard gemini advanced, and human-written consents

Luigi Angelo Vaira, Jerome R. Lechien, Antonino Maniaci, Giuseppe Tanda, Vincenzo Abbate, Fabiana Allevi, Antonio Arena, Giada Anna Beltramini, Michela Bergonzani, Alessandro Remigio Bolzoni, Salvatore Crimi, Andrea Frosolini, Guido Gabriele, Fabio Maglitto, Miguel Mayo-Yáñez, Ludovica Orrù, Marzia Petrocelli, Resi Pucci, Alberto Maria Saibene, Stefania Troise, Giacomo De Riu

Journal of Cranio-Maxillofacial Surgery, 26 October 2024

Open Access

Abstract

This study evaluates the quality and readability of informed consent documents generated by AI platforms ChatGPT-4 and Bard Gemini Advanced compared to those written by a first-year oral surgery resident for

common oral surgery procedures. The evaluation, conducted by 18 experienced oral and maxillofacial surgeons, assessed consents for accuracy, completeness, readability, and overall quality.

ChatGPT-4 consistently outperformed both Bard and human-written consents. ChatGPT-4 consents had a median accuracy score of 4 [IQR 4-4], compared to Bard's 3 [IQR 3–4] and human's 4 [IQR 3–4]. Completeness scores were higher for ChatGPT-4 (4 [IQR 4–5]) than Bard (3 [IQR 3–4]) and human (4 [IQR 3–4]). Readability was also superior for ChatGPT-4, with a median score of 4 [IQR 4–5] compared to Bard and human consents, both at 4 [IQR 4-4] and 4 [IQR 3–4], respectively. The Gunning Fog Index for ChatGPT-4 was 17.2 [IQR 16.5–18.2], better than Bard's 23.1 [IQR 20.5–24.7] and the human consents' 20 [IQR 19.2–20.9].

Overall, ChatGPT-4's consents received the highest quality ratings, underscoring AI's potential in enhancing patient communication and the informed consent process. The study suggests AI can reduce misinformation risks and improve patient understanding, but continuous evaluation, oversight, and patient feedback integration are crucial to ensure the effectiveness and appropriateness of AI-generated content in clinical practice.

::::::
::::::

TECHNOLOGY/OTHER MEDIATION

Impact of Informative Videos on Proxy Consent by Parents for Pediatric Surgery: A Randomized Controlled Trial

Original Article

Shreyas Dudhani, Bindey Kumar, Amit Kumar Sinha, Amit Kumar, Rashi Rashi, Gaurav Shandilya

Journal of Indian Association of Pediatric Surgeons, November–December 2024; 29(6) pp 573-578

Abstract

Background

Consent is never truly exercised in children as parents act as their proxy and often do not understand the advantages, disadvantages, risks, and benefits of the procedure. Their high anxiety state is mirrored in the child, leading to slower recovery. Hence, this study was designed to understand if an intervention can impact the effect of consent on parents' anxiety, satisfaction, and knowledge.

Methodology

A two-arm, parallel design, randomized controlled trial was conducted from March 2020 to March 2022 to analyze the effect of an educational video in comparison to an informational leaflet in parents giving proxy consents for various listed pediatric surgical procedures.

Results

Parents in the video group had a higher mean knowledge score (6.97 vs. 6.77, P = 0.40), comparable satisfaction scores (27.45 vs. 27.58, P = 0.88), and statistically insignificant difference between anxiety scores. We noted highest score of satisfaction (28.5/40) in the parents educated up to High School level or less. Knowledge scores were lowest in pelvic-ureteric junction obstruction (5.1/10) patients.

Conclusions

Our study done over a period of 2 years included a variety of diagnoses, and the videos and information leaflets were self-designed. It showed comparable anxiety, knowledge, or satisfaction in parents. Studies with more participants would be needed to take this research forward.

Comprehensive consent in urology using decision aids, leaflets, videos and newer technologies: empowering patient choice and shared decision-making

Review article

Carlotta Nedbal, Nithesh Naik, Niall Davis, Sanjeev Madaan, Theodoros Tokas, Giovanni Cacciamani, Eugenio Ventimiglia, Robert M. Geraghty, Dmitry Enikeev, Bhaskar K. Somani

Therapeutic Advances in Urology, 23 November 2024

Open access

Abstract

In this paper, we explore the usage of decision aids, patient information leaflets (PILs), videos, social media and modern technology to empower patients and enable shared decision-making (SDM). It explores the role of enhanced consent processes in urology. A re-evaluation of the conventional consent process is required towards more patient-centred care and SDM, which prioritises patient education and understanding of their medical conditions and treatment pathways. The use of decision aids, such as multimedia resources and PILs, is crucial in enhancing patients' understanding, level of satisfaction, quality of life and healthcare utilisation. New tools are opening exciting possibilities for patient education and information distribution, such as Chat Generative Pre-Trained Transformer (ChatGPT). The effectiveness of ChatGPT in comparison to well-established PILs is still up for debate, despite the fact that it makes information easily accessible. Improving patients' involvement, understanding and engagement in SDM procedures relies heavily on decision aids, PILs and current technological integration. Patients and healthcare practitioners should work together in accordance with the principles of SDM, which include considering patients' values, backgrounds, priorities and preferences when making treatment decisions. The emphasis on patient-centred care has prompted a re-evaluation of traditional consent processes in urology, with more emphasis on the shared decision-making process. Several informative aids are currently available as reported in the literature, ranging from 3D models, multimedia presentations and virtual reality (VR) devices. While the costs of these tools might be substantial, the advantages of adopting such informative resources are unmistakable. Social media and platforms such as patient–physician blogs are increasingly popular sources of medical information. Urologists should embrace these platforms to enhance patient engagement and the quality of information provided. Despite recent progress, there remains significant room for improvement in patient education and engagement which is achievable via concerted efforts of a wider medical community.

Short-Form Video Informed Consent Compared With Written Consent for Adolescents and Young Adults: Randomized Experiment

Aliyyat Afolabi, Elaine Cheung, Joanne Chen Lyu, Pamela M Ling

JMIR Formative Research, 22 November 2024

Abstract

Background

Adolescents and young adults have the highest prevalence of e-cigarette use ("vaping"), but they are difficult to enroll in health research studies. Previous studies have found that video consent can improve comprehension and make informed consent procedures more accessible, but the videos in previous studies are much longer than videos on contemporary social media platforms that are popular among young people.

Objective

This study aimed to examine the effectiveness of a short-form (90-second) video consent compared with a standard written consent for a vaping cessation study for adolescents and young adults.

Methods

We conducted a web-based experiment with 435 adolescents and young adults (aged 13-24 years) recruited by a web-based survey research provider. Each participant was randomly assigned to view either a short-form video consent or a written consent form describing a behavioral study of a social media–based vaping cessation program. Participants completed a postexposure survey measuring three outcomes: (1) comprehension of the consent information, (2) satisfaction with the consent process, and (3) willingness to participate in the described study. Independent sample 2-tailed t tests and chi-square tests were conducted to compare the outcomes between the 2 groups.

Results

In total, 435 cases comprised the final analytic sample (video: n=215, 49.4%; written: n=220, 50.6%). There was no significant difference in characteristics between the 2 groups (all P>.05). Participants who watched the short-form video completed the consent review and postconsent survey process in less time (average 4.5 minutes) than those in the written consent group (5.1 minutes). A total of 83.2% (179/215) of the participants in the video consent condition reported satisfaction with the overall consent process compared with 76.3% (168/220) in the written consent condition (P=.047). There was no difference in the ability to complete consent unassisted and satisfaction with the amount of time between study conditions. There was no difference in the composite measure of overall comprehension, although in individual measures, participants who watched the short-form video consent performed better in 4 measures of comprehension about risk, privacy, and procedures, while participants who read the written document consent had better comprehension of 2 measures of study procedures. There was no difference between the groups in willingness to participate in the described study.

Conclusions

Short-form informed consent videos had similar comprehension and satisfaction with the consent procedure among adolescents and young adults. Short-form informed consent videos may be a feasible and acceptable alternative to the standard written consent process, although video and written consent forms have different strengths with respect to comprehension. Because they match how young people consume media, short-form videos may be particularly well suited for adolescents and young adults participating in research.

Virtual reality for patient informed consent in skull base tumors and intracranial vascular pathologies: A pilot study

Research

Emilia Westarp, Attill Saemann, Marek Zelechovski, Balazs Faludi, Philippe Cattin, Jehuda Soleman, Raphael Guzman

Acta Neurochirurgica, 15 November 2024

Open Access

Abstract

Purpose

With the growing demand for shared decision-making and patient-centered care, optimal informed consent (IC) has gained relevance. Virtual reality (VR) has seen significant technological advancements, and its medical applications currently include surgical planning and medical education. This pilot study investigates the feasibility of VR-enhanced informed consent (VR-IC) in neurosurgery to improve preoperative IC and patient satisfaction.

Methods

We included patients aged 18 to 75 years who were scheduled for skull base meningioma or brain aneurysm surgery between May and December 2023. Exclusion criteria were visual/auditory impairments and severe cognitive/psychiatric disorders. Patients received standard IC followed by VR-IC using patient-specific VR models of their pathology. After an initial demonstration by the surgeon, the patients used the VR station independently. A questionnaire with 18 questions on a 5-point Likert scale assessed the subjective impression of VR-IC.

Results

Ten patients participated in the study, with six (60%) undergoing aneurysm clipping and four (40%) undergoing skull base meningioma resection. The mean age of the participants was 58 years (± 15, range 27 to 75 years), with four female patients (40%). Patients overall rated the VR-informed consent (VR-IC) positively with a mean of 4.22 (± 0.84). There was a better understanding of their pathology (mean 4.30 ± 0.92) and the planned procedure (mean 3.95 ± 1.04). Trust in the surgeon was rated with a mean of 3.47 (± 0.94). Only minimal side effects from the VR experience including dizziness or discomfort were noted (mean 4.60 ± 0.22). None of the participants dropped out of the study.

Conclusion

VR-enhanced informed consent is feasible and improves patient understanding and satisfaction without significant side effects. These findings will guide the planning of a randomized controlled trial to validate the benefits of VR-IC in neurosurgery further.

Demonstrating the Electronic Consent Process for Emergency Surgical Patients

David Fellows, Giles Bond-Smith

Cureus, 25 October 2024

Abstract

Introduction

Patient consent for surgery is a vital part of the surgical pathway from both a patient safety and medicolegal point of view. Improvement in documenting the full consent process in the electronic patient record (EPR), alongside the standard completion of the paper consent form in a surgical emergency unit (SEU), to comply with the Montgomery ruling of informed consent, has become of paramount importance. The aim of this project was to improve the documentation of the full consent process by creating an electronic template that was easy for the consenting clinician to use and provided a robust record of the bespoke consent process for the individual patient.

Methods

In July 2020, clinicians in the SEU were asked to begin documenting the patient's consent process in the EPR. The number of documented electronic consent processes (ECPs) of patients who underwent emergency general surgery during a two-week period was then captured between October and November 2020. The second cycle involved creating a single consent template, allowing the ECP to be easily documented in one template for all the common emergency surgery operations. All clinicians who were responsible for surgical consenting were asked to use the electronic template as part of the consent process. The rate of electronic consent was recorded over a second two-week period, six months later, in May 2021.

Results

From the first cycle, 78 patients were identified as undergoing emergency surgery, of which 13% (N=10) had an electronic entry regarding the consent process fully documented and personalised to the patient. From the second cycle, 64 patients were identified. The rate of documented ECPs increased to 77% (N=49).

Conclusion

This project has successfully improved the electronic demonstration of a consent process, bespoke to the individual, in accordance with the Montgomery ruling, by implementing an easy-to-use template on EPR. This is a significant step towards full digital consent in the future.

A Randomized Controlled Trial of Video-Assisted Electronic Consent vs. Standard Consent for Percutaneous Kidney Biopsy (eConsent Bx)

Pedro Henrique Franca Gois, Vera Y. Miao, Rebecca Saunderson, Marina Wainstein, Kylie-Ann Mallitt, Shaun Patrick Chandler, Belinda Elford, Rebecca Hudson, Julia Jefferis, Helen Healy, Ann Bonner,

Journal of the American Society of Nephrology, October 2024

Abstract

Background

Video-assisted electronic consent (eConsent) enhances understanding, reduces anxiety, and boosts satisfaction in medical procedures. Yet, its impact on percutaneous kidney biopsies (PKB) remains unexplored. We aimed to assess patient-reported benefits of eConsent versus conventional consent for PKB.

Methods

In a single-center, open-label, RCT, consecutive patients undergoing PKB were randomized (1:1) to either video-assisted eConsent (intervention) or conventional consent (control). The intervention group accessed an online platform featuring an 8-minute explanatory animation before providing eConsent, while the control group was consented by clinicians and signed a paper form. The primary outcome was questionnaire-based

patient comprehension, with secondary outcomes including patient-reported experience (KidneyPREM), anxiety, and satisfaction with consent.
Results
Median participant age was 52 years (IQR [34-65]), 30.7% had ≤ year 12 education and 69.3% post-secondary qualifications. Baseline characteristics were similar between groups. PKB comprehension was significantly higher in the intervention group compared to control (3 more questions correct/9; p<0.001), regardless of education level. Moreover, the intervention group demonstrated better understanding of critical information related to pre- and post-PKB care and when to seek medical attention for complications. There were no statistically significant differences in KidneyPREM, anxiety, or satisfaction between groups.
Conclusion
Video-assisted eConsent enhances PKB comprehension without affecting KidneyPREM, anxiety or satisfaction. These benefits extend to patients with lower education levels. Its implementation could standardize and streamline consent processes in PKB, with potential application in other nephrology domains.

::::::
::::::

HEALTH DATA/DATA

Patient and practice characteristics related to patient's consent for health data exchange

J J Keuper, K Hek, LHD van Tuyl, R S Batenburg, R A Verheij
European Journal of Public Health, 28 October 2024
Abstract
Background
Sharing patient health data electronically between healthcare providers can prevent medical errors and improve patient safety. In the Netherlands, exchange of health information is facilitated on a national level and is only allowed with patient consent. Consequently, it is important to know which factors are related to this patient consent.
Methods
Routine electronic health records data from up to 10% of Dutch general practices (sourced from the Nivel Primary Care Database) were utilized, covering the period from 2016 to 2020. We examined whether patient consent for health data exchange varied depending on patient and practice characteristics, which are expected to have a relationship with granting consent for health data exchange. Therefore, multilevel analysis was performed.
Results
The percentage of patients granting consent ranged between 40%-50% in the period 2016 to 2019, while this was 97% in 2020, due to the governmental corona opt-in regulation. Significant disparities were observed across several of the included patient and practice characteristics in relation to patient consent for all the years examined. In most years, patient consent provision varied by gender, age, socioeconomic position, location, and healthcare use. Practice characteristics showed notable differences in patient consent across information systems, patient volumes, and practice types over all years examined.
Conclusions
We observed significant variations in patient consent for health data exchange, both among the included patient (need) and practice characteristics. These differences may stem from unequal exposure to opportunities to grant consent, differences in risk of inadequate communication between healthcare providers, levels of health literacy, and practice resources. These factors should be taken into account by policymakers when further implementing and upscaling the national health data exchange system.

Parental Confirmation of a Child's Consent to Data Processing

Paulina Klisowska

Adam Mickiewicz University Law Journal, 2024; pp 49–59

Open Access

Abstract

This article attempts to define the conditions for consenting to the processing of children's personal data under the GDPR. The article focuses on analysing the data protection law, regarding to the most important problem, that at present, consent to data processing involves at most a few clicks or nudges, making it difficult to speak of any real control of data controllers over whether consent to the processing of a child's personal data has been lawfully given or confirmed by an authorized person. It's not hard to see that the young age of users, along with limited awareness of data protection and the risks associated with its use, makes this topic extremely relevant and worth addressing.

Editor's note: Adam Mickiewicz University is based in Poznań, Poland.

::::::
::::::

BIOBANKING

Enabling Demonstrated Consent for Biobanking with Blockchain and Generative AI

Caspar Barnes, Mateo Riobo Aboy, Timo Minssen, Jemima Winifred Allen, Brian D. Earp, Julian Savulescu

The American Journal of Bioethics, 5 November 2024

Abstract

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

::::::
::::::

GENOMIC MEDICINE/GENE EDITING

Precision medicine and Friedreich ataxia: promoting equity, beneficence, and informed consent for novel gene therapies

International Journal for Equity in Health, 8 November 2024

Faith A. A. Kwa, Evie Kendal

Open Access

Abstract

Friedreich Ataxia (FA) is an incurable neurodegenerative disease with systemic consequences affecting vital organs including those of the central and peripheral nervous systems. This article will use FA as an example to explore some of the practical and ethical issues emerging in precision medicine for rare diseases. It will first describe the existing management strategies available for FA patients, before considering the potential

impact of gene therapy trials on the prevention and treatment of disease symptoms. Finally, ethical considerations will be discussed, including equity of access and managing resource allocation dilemmas; balancing benefits, burdens and harms; and gaining informed consent for novel treatments.

::::::
::::::

YOUNG PERSONS

Ethical issues in vaccine trial participation by adolescents: qualitative insights on family decision making from a human papillomavirus vaccine trial in Tanzania

Lucy Frost, Ms Tusajigwe Erio, Hilary Whitworth, Ms Graca Marwerwe, Richard Hayes, Kathy Baisley, Silvia de SanJosé, Deborah Watson-Jones, Kirstin Mitchell

BMC Medical Ethics, 20 November 2024

Open access

Abstract

Background

Research in children is essential for them to benefit from the outcomes of research but involvement must be weighed against potential harms. In many countries and circumstances, medical research legally requires parental consent until the age of 18 years, with poorly defined recommendations for assent prior to this. However, there is little research exploring how these decisions are made by families and the ethical implications of this.

Aim

To explore key ethical debates in decision-making for participation of children and adolescents in a human papillomavirus (HPV) vaccine trial.

Methods

Semi-structured interviews were undertaken with Tanzanian girls (aged 9–16 years) who had participated in an HPV vaccine trial (n = 13), their parents or guardians (n = 12), and girls together with their parents (in paired parent-child interviews) (n = 6). The interviews were analysed using thematic analysis. Interview data came from a qualitative acceptability study undertaken as part of the Dose Reduction Immunobridging and Safety Study of Two Human Papillomavirus (HPV) Vaccines in Tanzanian Girls (DoRIS) trial.

Results

Girls and parents desired collaborative decision-making, with parents ultimately making the decision to consent. However, girls wanted a larger part in decision-making. Decisions to consent involved many people, including extended social networks, the trial team, media outlets and healthcare professionals and this resulted in conflicts to be negotiated. Deciding where to place trust was central in participants and parents considering decisions to consent and overcoming rumours about trial involvement.

Conclusions

Existing models of decision-making help to understand dynamics between parents, adolescents and researchers but neglect the important wider social impacts and the fundamental nature of trust. Children's roles in discussions can be evaluated using the principles of consent: autonomy, freedom and information. Concepts such as relational autonomy help to explain mechanisms families use to negotiate complex consent decisions. Whilst interviewees supported the maintenance of legal parental consent, researchers must design consent processes centring the child to ensure that whole family decision-making processes are supported.

Tools for effective patient education to manage outcome expectations in paediatric facial reanimation: a systematic review

Systematic Review

Dimitris Reissis, Cédric Zubler, Edel de Buitleir, Sam Brown, Jonathan Leckenby, Adriaan Grobbelaar
Plastic and Aesthetic Research, 30 October 2024
Open Access
Abstract
Aim
Informed consent for paediatric facial reanimation requires effective patient/parent education and involvement in a shared decision-making (SDM) process to help set their expectations and understanding from the outset. No article in the current literature has systematically reviewed the available tools for facilitating effective patient/parent education and the validity of informed consent in the context of paediatric facial reanimation.
Methods
A systematic literature review was undertaken, following the Preferred Reporting Items of Systematic Reviews and Meta-analyses (PRISMA) 2020 guidelines. MEDLINE via PubMed, Embase and Cochrane Library were searched and the results screened and reviewed in accordance with pre-defined inclusion and exclusion criteria.
Results
The initial search yielded 478 articles, of which only 4 fulfilled the study's inclusion criteria. One cohort study evaluated qualitative feedback from patients and their relatives participating in a family education and support day for paediatric facial palsy, while another article from the same group reviewed the readability of online education resources. The remaining two articles represented educational reviews focusing on treatment and patient education based on expert opinion without providing original outcome data.
Conclusion
There is a paucity of evidence regarding patient/parent education to support the informed consent process for children undergoing paediatric facial reanimation. There remains a need for further resources and platforms to be developed that may support children and their parents in engaging in a SDM process, setting appropriate expectations, and providing valid informed consent for their surgery.

Prescribing contraceptives to minors without parental knowledge and consent

M Peled-Raz, O Goldstick
European Journal of Public Health, 28 October 2024
Abstract
Background
Sexually active adolescents may seek oral contraceptives without parental consent, posing challenges due to minors' confidentiality and consent regulations. This is especially the case under the un-nuanced Israeli legal scheme regarding adolescents' care.
Methods
Israeli OBGYNs were contacted through mailing lists and social media groups and asked to fill an online questionnaire regarding their experience and protocols concerning prescription of contraceptives to minors. They were also asked about their comprehension of the relevant legal obligations, the importance they ascribe to different ethical interests and considerations, as well as their training.
Results
Of the 177 responding gynecologists, 75% consulted minors about contraceptives during the past year, most of them without any training on providing care to adolescents. More than a third of respondents believed that parental involvement wasn't legally required, while only 8% thought it mandatory for all minors under the age of 18. Most (75%) would 'almost always' prescribe contraceptives without parental knowledge upon request, while 20% never would. No correlation was found between respondents' practices and their perception of the legal obligations. Participants agreed that the risk to the health of the minor due to having sex without contraceptives is of utmost importance. Those willing to prescribe gave greater weight to minor's autonomy consideration, while those who do not prescribe were more concerned with the acts legal

ramifications. The majority set the age of 15 as the threshold for consistently prescribing contraceptives to minors without parental involvement.
Conclusions
Access to contraceptives for mature minors without parental involvement is vital. There is great need for education and training for healthcare providers on providing medical treatment to adolescents, as well as for the development of policies and guidelines, addressing adolescents' health disparities.

::::::
::::::

CAPACITY TO CONSENT

The ethical inadequacy of uninformed surrogate consent: advancing respect for persons in clinical research

Robert R. Harrison
Theoretical Medicine and Bioethics, 10 November 2024
Abstract
In clinical research, decision-making capacity is often equated with unspecified conceptions of autonomy, and autonomy is often equated with personhood. On this view, the loss of decision-making capacity is seen as a loss of autonomy, and the loss of autonomy subsumes a loss of personhood. An ethical concern arises at the intersection of those philosophical considerations with the legal considerations in informed consent. Because persons with inadequate decision-making capacity cannot provide legally effective consent, enrollment in research can occur only if a surrogate gives permission on the person's behalf. Federal regulations and resulting institutional policies allow permission from surrogates empowered under state law to consent to medical treatment procedures, typically in a hierarchy of legislatively prioritized relationships lacking regard for what the surrogate actually knows about the current research-related values and preferences of the potential subject. As a result, the research enterprise often countenances reliance on surrogates who have no relational or informational basis for an enrollment decision that aligns with the values and preferences of the subject. Arguing from the perspective that losing decision-making capacity does not alter the moral status of persons, and that respect for persons rather than respect for autonomy is the central ethical obligation, I assess the ethical implications of allowing persons with no knowledge of the values and preferences of the potential subject to make enrollment decisions, concluding that reliance on uninformed surrogates is not an ethically defensible approach to enrolling subjects in clinical research.

Electroconvulsive therapy and informed consent: navigating clinical efficacy and patient rights

Conference Presentation
Anghel Claudia
Beyond borders: united for mental health 2024; Chişinău, Moldova, 10-13 October 2024
Abstract
Electroconvulsive Therapy (ECT) remains a highly effective treatment for severe mental health disorders, such as treatment-resistant schizophrenia and major depressive disorder. However, its use raises important ethical and legal concerns, particularly regarding informed consent. Balancing the clinical efficacy of ECT with patients' rights to make informed decisions about their treatment is a complex challenge for mental health professionals. Informed consent is crucial, requiring that patients fully understand the potential benefits, risks, and side effects of ECT before agreeing to the procedure. Mental health care providers must ensure that patients are not only informed about the short- and long-term effects of ECT but also supported in their decisionmaking process. This includes addressing any cognitive impairments or mental health symptoms that may impact their capacity to give informed consent. Additionally, legal guardians or family members may be

involved in the consent process, especially when patients are unable to provide it themselves. Ultimately, navigating the delicate balance between ensuring the clinical success of ECT and respecting patient autonomy is essential for ethical practice. Continued research into improving patient education and consent processes can help to understand the efficacy of ECT and the rights of them receiving this treatment.

Anosognosia in Alzheimer's Disease: Clinical Psychology and Medico-Legal Issues. Informed Consent in Healthcare

Tomasello Letters, Miriana Ranno, Claudia Pitrone

New Medical Innovations and Research, 28 March 2024

Abstract

Insight or deficit awareness have been used interchangeably to refer the lack of knowledge or recognition of one's deficit. Our aim was to investigate whether this lack could influence Alzheimer's disease patients' ability to understand and do.

Disease awareness is a phenomenon that in recent years is obtaining an increasing interest in a clinical and research point of view. It has important implications on patient care and management. The present study is aimed to contribute to the comprehension of disturbing awareness in patients with Alzheimer disease, and provided a starting point on a complex disease linked to medical and psychological scopes but also involve Bioethics and Law.

Informed consent and decision-making skills

Informed consent is a fundamental prerequisite of every medical act and the autonomy of a patient, in the fullness of his ability to decide on treatments and possible therapeutic treatments. Presupposition of informed consent, beyond the information (well given and well understood) and freedom (absence of conditioning factors or at least awareness of their presence), is the ability to decide. The ability to decide on medical treatment is inherent in the legal concept of capacity to act (Art. 2 of the CC). The definition, proposed by Wong et al. (1999) (10), provides an indication of the relationships between the ability of the individual and the society around him: "capacity is what distinguishes a person, who is able to make a decision and whose choice must be respected, regardless of the reasonableness of the choice, by a person for whom decisions must be made by others". There are cases where a person may no longer be able to manage his or her current account but may be able to give his or her consent to simple medical treatment. The ability to decide must be presumed, until proven otherwise. Dementia is, therefore, a risk factor for incapacity, but it does not inevitably involve it. The ability (or inability) is always relative to a certain task. For example, a person may be able to make a decision for simple medical treatment but not be able to discern complex alternatives with different risk/benefit profiles…

::::::
::::::

CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Evaluating the Informed Consent Process: Insights from Post-Operative Experiences in Pharmaceutical Care

Research Article

Muhammad Ajmal, Arslan Wajid, Zahra Rafique, Ahsan Sikandar Khan, Abdul Rehman Saddiq, Muhammad Sulaiman, Muhammad Aqeel Sultan, Usman Wajid

History of Medicine, 30 September 2024

Abstract

Background

An informed consent must be obtained legally and ethically before invasive or high-risk therapeutic procedures are performed. It is defined as the "process of communication between a patients and healthcare professionals that leads in the patient's permission or agreement to undergo any specific medical procedure.
Aim
To investigate informed consent's practices and determine whether the persons who have signed for surgical treatments have a sufficient understanding about the process of informed consent.
Methodology
It was a descriptive cross-sectional study that was conducted at the Rehman Medical Institute (RMI) Peshawar. Using Simple Random Probability Sampling Technique; a sample of 108 surgical patients was recruited. Data was collected using closed ended interview schedule. The validity of the redesigned instrument was evaluated by a panel of specialists, including a research supervisor and surgical practitioners. To analyze data a descriptive statistic will be used. The computer's software, Statistical Package for Social Science (SPSS version 20) will be used for data analysis and interpretation.
Result
The sample size was 108 patients, with a 100% response rate. A total of 108 patients (89 male and 19 female) were randomly selected for post-operative interviews. Out of 108 patients, all the patients gave and signed the pre-operative informed consent process form on their own. Only 21 (19.44%) patients already knew about the informed consent process because they had almost a bachelor's degree education. Only 31 patients (28.70%) read and fully understood the surgical informed consent process form. And 106 (98.14%) had their consent taken by a young doctor rather than the surgeon who would be doing the surgery.
Conclusion
Our study revealed that quality of informed consent process is limited at RMI Hayatabad Peshawar, due to surgeons making little or no attempt to educate their patients on this subject and the informed consent form is only available in English, with no verified translation into the patient's mother tongue.

Assessing the Process of Written Informed Consent for Surgical Procedures among Inpatients: A Cross-sectional Study from a Tertiary Care Teaching Hospital in Southern India

P. V. Dinesh, Imaad Mohammed Ismail, Kahkashan Azeez
Journal of Clinical & Diagnostic Research, 2024
Abstract
Introduction
Informed Consent (IC) is a decision-making process wherein patients are provided with all necessary information regarding treatment to make an uncoerced, educated choice. There are gaps in the implementation of the IC process that need to be identified and addressed.
Aim
To estimate the proportion of patients/surrogates who read, understood, and signed the IC form before undergoing surgical procedures; to identify the different healthcare team members involved in explaining the IC form; to evaluate the extent to which different components of the IC form were explained to patients/surrogates; and to determine the influence of the IC form on surgical decision-making, and the overall satisfaction with the IC process.
Materials and Methods
This cross-sectional study was conducted at a tertiary care hospital in the Dakshina Kannada District of Southern India from April 2020 to March 2021. It included 100 adult patients admitted to the postsurgical wards of general surgery, orthopaedics, obstetrics and gynaecology, otorhinolaryngology, and ophthalmology. Ethical clearance was obtained from the Institutional Ethics Committee. The parameters studied included socio-demographic variables, administration of the IC form, details on the person explaining the IC form along with its content, and the influence of the IC form on decision making, as well as overall satisfaction with the IC process. Data were collected using a predesigned questionnaire and analysed using descriptive statistics in Statistical Package for the Social Sciences (SPSS) version 27.0. Categorical variables

were presented as frequencies and proportions, whereas continuous variables were presented as means and standard deviations.

Results

All participants received the IC form; however, only 21% read, understood, and signed it. The explanation of the IC form was given to 59% of the patients, with only 15% of these explanations provided by the treating surgeon. The components of the IC form, such as the surgical procedure and its benefits, were explained to the majority of the patients; however, the risks of the surgical procedure and alternative options were explained to only 53% and 7% of patients, respectively. The IC form had a minor influence on surgical decision-making for 61% of patients, and 43% expressed satisfaction with the IC process.

Conclusion

The study revealed that the implementation of IC was inadequate. Surgeons should provide and explain the IC form well in advance, allowing time for patients to read, understand, and clarify their doubts. Hospital Ethics Committees need to enforce strict adherence to IC guidelines to ensure informed decision-making.

Consent for organ donation: a case study in the light of bioethics

Health Sciences

Kelly C.B. Gomes, Mary R.G. Esperandio, José E. De Siqueira, José R. Goldim

The Annals of the Brazilian Academy of Sciences, 2024

Abstract

Fewer donations are being made in Brazil to meet the growing organ demand. Organ donation in Brazil reached an average of 53% consent. However, hospitals in Paraná have reached a level of 94.2%. What reasons could be given for these levels? Accordingly, this study aimed to understand the causes involved in decision-making to donate organs. The methodology used was qualitative based on a case study. Data was collected at a hospital in Toledo, a city in Paraná, through documentary research and semi-structured interviews with two distinct groups: professionals responsible for the family approach to donation and five families consenting to donation. The search for data was restricted to the period between 2015 and 2023. Data analysis used Bardin's content analysis. The results were organized into four categories in the first group, and two categories in the second group, suggesting that aspects linked to bioethical references present in the interview, such as beneficence and autonomy, contribute to the emergence of high rates of family consent for organ donation in the hospital studied. It is recommended for future research to test successful interview models to reverse the current organ donation rates in Brazil.

Thematic category	Sense core
Approach strategies	Humanized approach to the family
	Promotion of attitudes based on virtue ethics
Valuing the autonomy of the family in the decision-making process	Interview with no time limit, with freedom of thought and based on family consensus
	Decision-making autonomy based on the possibility of conscious and responsible choice and not on obligation
Clear communication on the brain death protocol	Clarification on standardization of the national protocol and feedback from families
	Clarification of care information until the donor's death
Internal cohesion of the team and credibility of the family in the work of the care team	Aligned team in the organ donation process
	Guarantee of the technical training of the professional team

Four categories from the first group as mentioned in the abstract

Thematic category	Sense core
Desire to perform an act of kindness	Emergence of a feeling of empathy
	Emergence of an Attitude of Compassion
Confidence in the team	Feeling of welcome on the part of the team
	Clarification of the process by the team

Two categories from the second group as mentioned in the abstract

::::::
::::::

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].

Clinicians' experiences of obtaining informed consent for research and treatment: a nested qualitative study from Pakistan

Research
Rakhshi Memon, Muqaddas Asif, Bushra Ali Shah, Tayyeba Kiran, Ameer B Khoso, Sehrish Tofique, Jahanara Miah, Ayesha Ahmad, Imran Chaudhry, Nasim Chaudhry, Nusrat Husain, Sarah J L Edwards
BMC Medical Ethics, 15 November 2024
Open access
Abstract
Background
Informed consent is considered to be the standard method for respecting the autonomy of individual participants in research and practices and is thought to be based on several conditions: (1) providing information on the purpose of the research or a specific treatment, what it will entail, (2) the participants being mentally competent to understand the information and weigh it in the balance, and (3) the participants to be free from coercion. While there are studies of informed consent in other countries, especially Low and Middle Income Countries (LMICs), this study explored the experiences of clinicians regarding the process of

obtaining informed consent to participate in a Randomised Controlled Trial (RCT) in particular and treatment in general in healthcare settings, both general and mental health, specifically focusing on the tension between individualistic concept of autonomy and collectivist values in cultures such as Pakistan.
Methods
Qualitative interviews with 20 clinicians from healthcare settings in Pakistan who also served as recruiters in a suicide prevention RCT in Pakistan. The interviews were guided by semi-structured topic guide. All interviews were audio-recorded and transcribed verbatim.
Results
The interviews revealed that shared decision making was more morally important than individual autonomy, the role of the family played a dominant part in the consent-taking procedure, the decision of the elder and/or family patriarch took prominence, and that clinician-researchers encountered significant challenges in consent process in Pakistan, while recruiting patients into the trial as well as during routine treatment processes in healthcare settings. Four distinct themes emerged which were (1) Family deciding for patients, (2) Benefits of involving family in consent process, (3) Gender disparity in consent process, (4) Challenges experienced by clinician-researchers during consent process in Pakistan.
Conclusions
The concept of consent is generally considered important in many cultures, however, there are two strands of understanding. There seems to be consensus that participant agreement is necessary to protect the participant but with regards to autonomy there are significant cultural differences whether it is the right for autonomy of the individual (individualistic concept) or family, community, or expert authority in other cultures. In Pakistan clinician-researchers sometimes preferred one approach and sometimes the other as they appreciated the interests of the patient to be.

The Ubuntu Way: Ensuring Ethical AI Integration in Health Research

Review
Brenda Odero, David Nderitu, Gabrielle Samuel
Wellcome Open Research, 28 October 2024
Open Access
Abstract
The integration of artificial intelligence (AI) in health research has grown rapidly, particularly in African nations, which have also been developing data protection laws and AI strategies. However, the ethical frameworks governing AI use in health research are often based on Western philosophies, focusing on individualism, and may not fully address the unique challenges and cultural contexts of African communities. This paper advocates for the incorporation of African philosophies, specifically Ubuntu, into AI health research ethics frameworks to better align with African values and contexts.

This study explores the concept of Ubuntu, a philosophy that emphasises communalism, interconnectedness, and collective well-being, and its application to AI health research ethics. By analysing existing global AI ethics frameworks and contrasting them with the Ubuntu philosophy, a new ethics framework is proposed that integrates these perspectives. The framework is designed to address ethical challenges at individual, community, national, and environmental levels, with a particular focus on the African context.

The proposed framework highlights four key principles derived from Ubuntu: communalism and openness, harmony and support, research prioritisation and community empowerment, and community-oriented decision-making. These principles are aligned with global ethical standards such as justice, beneficence, transparency, and accountability but are adapted to reflect the communal and relational values inherent in Ubuntu. The framework aims to ensure that AI-driven health research benefits communities equitably, respects local contexts and promotes long-term sustainability.

Integrating Ubuntu into AI health research ethics can address the limitations of current frameworks that emphasise individualism. This approach not only aligns with African values but also offers a model that could

be applied more broadly to enhance the ethical governance of AI in health research worldwide. By prioritising communal well-being, inclusivity, and environmental stewardship, the proposed framework has the potential to foster more responsible and contextually relevant AI health research practices in Africa.

::::::
::::::

RIGHTS/LEGAL/LEGISLATIVE

Protocol and Statistical Analysis Plan for a Comparative Interrupted Time Series Evaluation of the Impact of Deemed Consent for Organ Donation Legislative Reform in Nova Scotia, Canada

Organ Donation and Procurement

Matthew J. Weiss, Kristina Krmpotic, Stephen Beed, Sonny Dhanani, Jade Dirk, David Hartell, Cynthia Isenor, Nick Lahaie, Scott T. Leatherdale, Kara Matheson, Karthik Tennankore, Gail Tomblin-Murphy, Amanda Vinson, Hans Vorster, Caroline King

Transplantation Direct, December 2024

Abstract

The Canadian province of Nova Scotia recently became the first North American jurisdiction to implement deemed consent for deceased organ donation as part of a comprehensive legislative reform of their donation and transplantation system. This study will examine the performance metrics and effectiveness of this policy in comparison with other Canadian provinces via a natural experiment evaluation. We will use a cross-sectional controlled interrupted time series quasi-experimental design. Our primary outcome will be consent for deceased donation as confirmed at the time of eligibility (prior registered intent to donate will be noted but not be considered positive unless affirmed at the time of eligibility). Secondary outcomes will include identification and referral of patients who are potential donors, rates of family override of previously registered intent to donate, and donation and transplantation rates per million population. Data will be collected from potential donor audits in Nova Scotia and 3 control provinces (provinces in Canada without deemed consent policies). Study outcomes will be compared in Nova Scotia relative to control provinces in the 3 y before and 3 y after the implementation of legislative reform. These provinces were selected as having systems resembling those of Nova Scotia but without deemed consent.Using controlled interrupted time series methodology compared with other Canadian provinces with otherwise similar systems, we aim to isolate the impact of the deemed consent aspect of legislative reform in Nova Scotia using a robust natural experiment evaluation design as much as possible. Careful selection of outcome measures will allow donation and transplantation stakeholders to properly evaluate if similar reforms should be considered in their jurisdictions.

Subgroup differences in public attitudes, preferences and self-reported behaviour related to deceased organ donation before and after the introduction of the 'soft' opt-out consent system in England: mixed-methods study

Research

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

BMC Health Services Research, 21 November 2024

Open access

Abstract

Background

In the UK, over 7,000 people are on the waiting list for an organ transplant and there are inequalities in need, access and waiting time for organs, with notable differences between minority ethnic groups. In May 2020,

England changed the law and introduced a 'soft' opt-out system of consent to organ donation with a view to increase consent rates. We aimed to learn more about the impact of the law change on attitudes and views likely to be relevant to consent to deceased organ donation between different population subgroups.
Methods
Mixed-methods design involving latent class analysis of data from twelve repeated cross-sectional surveys undertaken from 2015 to 2021 (n = 19,011); analysis of the law change survey dataset collected quarterly from 2018 to 2022 (n = 45,439); and interviews with purposively selected members of the public (n = 30) with a focus on minority perspectives.
Results
Support for the principle of deceased organ donation remained high and stable in the general population (80%) but was 20% lower among ethnic minorities. From 2018 to 2022, an average of 58% of the general population was aware of the law change; this was lower among minority ethnic groups (31%). We identified four population subgroups (supportive donors (24% of the population); unengaged donors (22%); uncommitted donors (46%); and unsupportive donors (9%)). Interview themes included the challenges of discussing organ donation decisions, balancing autonomy with respecting family relationships, targeted misinformation, frustrations at the lack of consensus between community leaders, limited understanding of what happens during the end-of-life care leading to organ donation, and how this aligns with cultural values and preferences.
Conclusion
Implementation of the law change has not been associated to date with any change in public attitudes and preferences likely to influence consent overall or in minority ethnic groups in England. Uncommitted donors may benefit from encouragement to express their organ donation decision, and unengaged donors from attempts to address mis/information, confusion, and uncertainty. Interventions to raise the consent rate need to take account of the significant role of the family as well as wider community influences on attitudes, preferences and decision-making, particularly among certain minority (ethnic) groups.

A review of consent policies in Dermatological Surgery in the United Kingdom and the impact of leaner pathways and teledermatology on consent

Aparna Potluru, Daniel Sokol, Aaron Wernham
Clinical and Experimental Dermatology, 21 November 2024
Abstract

Obtaining valid consent is an ethical and legal requirement in clinical practice, ensuring patients are adequately informed about their treatments. Recent updates in consent policies, including GMC guidance, the Patterson inquiry report, and key legal rulings like Montgomery, emphasise a shift towards patient-centred care and the importance of a comprehensive patient-clinician dialogue. Budget constraints and increasing NHS demand have led to the adoption of digital solutions and streamlined pathways, such as teledermatology and direct booking to surgery, potentially compromising the consent process.

This review examines the current state of informed consent in UK dermatology, particularly in light of the Montgomery ruling, which requires clinicians to ensure patients are aware of all material risks and alternatives associated with their treatments. The two-stage consent process, involving consent at two distinct points, is advocated to allow patients adequate time for reflection and decision-making. However, challenges remain in pathways like one-stop clinics and direct booking for surgery, where limited face-to-face interaction and time constraints can undermine the quality of informed consent.

To mitigate these issues, integrating multimedia tools and standardised procedure-specific consent forms can enhance patient comprehension and satisfaction. These tools ensure consistent and clear communication of risks, benefits, and alternatives, maintaining robust informed consent amidst evolving healthcare delivery models. Sustaining a thorough and individualised dialogue throughout the patient care journey is essential for upholding patient autonomy and shared decision-making in dermatological surgery.

Unproven stem cell therapies: an evaluation of patients' capacity to give informed consent

Research Article

Laura Langford, Patrick Foong

Griffith Law Review, 30 October 2024

Abstract

Capitalising on the hype surrounding regenerative medicine, there are clinics worldwide marketing unproven stem cell-based therapies to patients. Some patients have travelled overseas to access treatments they believe are safe and effective. This practice, known as stem cell tourism, could result in adverse effects in some patients. This paper seeks to examine how the industry could threaten the validity of the patient's informed consent. The vulnerable groups include adults, minors and incompetent patients. Since patients are exposed to exaggerated claims and inaccurate information, this article argues that each cohort may not truly consent to such therapies. While each group hopes to obtain a miracle cure, the reality is that these purported medical treatments may not enable patients to give their informed consent, which thereby inhibits good decision-making. Accordingly, states could restrict patients' access to unproven stem cell-based therapies to control the problem. This paper illustrates how the regulatory framework in countries such as Australia and the United States (U.S.) has allowed the industry to thrive. Recommendations on how states can take a restrictive stance against this complex phenomenon are proposed.

Exploring the Foundations of Informed Consent, Legal Capacity, Privacy, and Dignity in Medical Law and me

Parvina Ismayilova

Juridical Sciences and Education, July 2024; 75(75) pp 136-151

Abstract

This article presents a comparative study exploring the foundations of informed consent, legal capacity, privacy, and dignity in medical law across different jurisdictions. The concept of informed consent is fundamental to medical practice and is rooted in the principle of patient autonomy. Legal capacity, on the other hand, refers to an individual's ability to make decisions about their own healthcare and is often closely linked to informed consent. Privacy and dignity are also crucial aspects of medical law, protecting the rights and autonomy of patients. Through a comparative analysis of laws and regulations in various countries, this study examines the legal frameworks surrounding informed consent, legal capacity, privacy, and dignity in medical practice. The research aims to identify common principles and differences in the implementation of these concepts, addressing potential challenges and areas for improvement. By shedding light on the foundations of informed consent, legal capacity, privacy, and dignity in medical law, this study contributes to a better understanding of the rights and responsibilities of patients and healthcare professionals. The findings may inform future developments in medical law and practice, promoting ethical and respectful treatment of patients and upholding their rights to autonomy and dignity.

Editor's note: This is an Azerbaijani language publication.

::::::
::::::

MEDICAL/SURGICAL

Ethical Concerns Regarding the Timing of Written Consent

Sean C. Wightman, Victoria Yin, Jacob S. Hershenhouse, Tsehay B. Abebe, Li Ding, Scott M. Atay, Takashi Harano, Anthony W. Kim, John N. Pagteilan, Abhineet Uppal, Baddr A. Shakhsheer

The Journal of Clinical Ethics, Winter 2024; 35(4)

Abstract
Objective
Thorough informed consent requires decision-making capacity, adequate information, lack of coercion, and an appropriate environment. Consent obtained in the preoperative area is hurried, limiting the quality of informed consent and the opportunity for patient reflection, characteristics inconsistent with patient-centered practice. The incidence of obtaining consent immediately prior to surgery is unknown.
Methods
Consecutive patients undergoing surgery at a single center between 1 June 2021 and 14 June 2021 were identified. Time between consent signature and operating room arrival time was measured. Three surgeons reviewed cases and categorized them as major or not major operations.
Results
78.7 percent (199/253) of patients arriving to the preoperative area the day of surgery signed written consent that day. 99.6 percent (248/249) of anesthesia consents were signed the day of surgery. Spanish as a primary language corelated significantly with consent signing on the day of surgery ($p = .04$). Race and distance traveled for surgery were not significantly associated with consent signing in the preoperative area. 79.3 percent (157/198) had consent signed within 90 minutes of arrival to the operating room. Among major outpatient cases, 77.8 percent (182/234) had consent signing in the preoperative area.
Conclusions
This demonstrates routine consent signing in the hurried preoperative setting, suggesting a potential source for improved informed consent. Additionally, language-based consenting disparities, specifically in Spanish, offer opportunity for improvement. The majority of consents were signed the day of surgery, in the preoperative area, and within 90 minutes prior to operating room start time. This offers an opportunity for improved patient-centered care.

Informed consent in assisted reproductive technology: Implications for pediatric clinicians

Mary E Graham, Shannon Blee, Rebecca D Pentz, Emily Roebuck, Alexander H Hoon Jr, Mara Black
Developmental Medicine & Child Neurology, 17 November 2024

Abstract
After conceiving through assisted reproductive technologies (ART), parents may present to their pediatrician with concerns related to their child's neurodevelopment, including whether their child's health may be related to their use of ART. Pediatricians may be unfamiliar with the ART process and what the families endured up to this point, resulting in difficulty counseling parents through these discussions. Before presentation to the pediatrician, parents have undergone extensive evaluation with reproductive endocrinologists. During counseling, the reproductive endocrinologist provides information on maternal and childhood risks associated with ART. However, in this rapidly evolving field, providing comprehensive, patient-centered, informed consent is increasingly complex and counseling patients properly can be challenging. When parents have gone through the proper informed consent process, and when the pediatrician has an understanding of what this process entails, care of the child can be optimized. In this review, we discuss the complexities of the prenatal informed consent process that parents navigate before presenting to pediatricians. We emphasize the importance of these discussions and highlight ethical principles, as well as emotional, medical, legal, and financial stressors that parents face during ART, with the belief that this understanding will improve the care that pediatricians subsequently provide.

Consent to advanced imaging in antenatal pulmonary embolism diagnostics: Prevalence, outcomes of nonconsent and opportunities to mitigate delayed diagnosis risk

David R Vinson, Madeline J Somers, Edward Qiao, Aidan R Campbell, Grace V Heringer, Cole J Florio, Lara Zekar, Cydney E Middleton, Sara T Woldemariam, Nachiketa Gupta, Luke S Poth, Mary E Reed, Nareg H Roubinian, Ali S Raja, Jeffrey D Sperling

Academic Emergency Medicine, 17 November 2024

Abstract

Background

Nonconsent to pulmonary vascular (or advanced) imaging for suspected pulmonary embolism (PE) in pregnancy can delay diagnosis and treatment, increasing risk of adverse outcomes. We sought to understand factors associated with consent and understand outcomes after nonconsent.

Methods

This retrospective cohort study was undertaken across 21 community hospitals from October 1, 2021, through March 31, 2023. We included gravid patients undergoing diagnostics for suspected PE who were recommended advanced imaging. The primary outcome was verbal consent to advanced imaging. Diagnostic settings were non-obstetric (99% emergency departments [EDs]) and obstetrics (labor and delivery and outpatient clinics). Using quasi-Poisson regression, we calculated adjusted relative risks (aRRs) of consenting with 95% confidence intervals (CIs). We also reported symptom resolution and delayed imaging at follow-up and 90-day PE outcomes.

Results

Imaging was recommended for 405 outpatients: median age was 30.5 years; 50% were in the third trimester. Evaluation was more common in non-obstetric (83%) than obstetric settings (17%). Overall, 314 (78%) agreed to imaging and 91 (22%) declined imaging. Consenting was more prevalent in obstetric settings compared with non-obstetric settings: 99% versus 73% ($p < 0.001$). When adjusted for demographic and clinical variables, including pretest probability, only obstetric setting was independently associated with consenting: aRR 1.26 (95% CI 1.09-1.44). Seventy-nine (87%) patients declining imaging had 30-day follow-up. Eight of 12 who reported persistent or worsening symptoms on follow-up were again recommended advanced imaging and consented. Imaging was negative. None who initially declined imaging were diagnosed with PE or died within 90 days.

Conclusions

One in five gravid patients suspected of PE declined advanced imaging, more commonly in non-obstetric (principally ED) settings than obstetric settings. Patients symptomatic on follow-up responded favorably to subsequent imaging recommendations without 90-day outcomes. Improving the communication and documentation of informed consent and securing close follow-up for non-consenters may mitigate risks of missed and delayed PE diagnosis.

Editor's note: Academic Emergency Medicine is the official journal of the Society for Academic Emergency Medicine.

Clinical staff attitudes towards opt-out consent for blood-borne virus screening in emergency departments in England

Esther G Blakey, Cassandra E L Fairhead, Alison J Rodger, Fiona M Burns, Lucie Ralph, David R Chadwick

HIV Medicine, 13 November 2024

Abstract

Objective

Opt-out screening for blood-borne viruses (BBVs) in emergency departments (EDs) has been established in areas with a high prevalence of HIV diagnoses in England. This multi-site study explored the attitudes of healthcare workers (HCWs) towards BBV screening in EDs post-implementation.

Design

This was a cross-sectional electronic survey of HCWs.

Methods

Between November 2023 and February 2024, HCWs across 33 EDs in England participating in opt-out BBV screening were invited to complete a survey about the feasibility and acceptability of screening, including the opt-out consent process. Factors independently associated with acceptability of opt-out screening were identified using multivariable logistic regression. Free-text responses were analysed thematically.

Results

Responses from 610 HCWs in 19 EDs were provided: 50.4% were nurses, 43.1% doctors, and 6.5% other healthcare professionals. Acceptability of the screening programme and opt-out consent was high (90.3% and 77.7%, respectively), with some variation between EDs. Acceptability of opt-out consent was greater among doctors than among other HCWs, and among HCWs who proactively discussed screening further with patients who opted out. However, 50.8% of HCWs felt that patients should be verbally reminded at blood draw, and 44.3% of HCWs wanted more training in discussing opt-out screening with patients. Free-text answers suggested changes to test-ordering systems, including simple integration of tick boxes to document whether patients opted out and to block repeated testing.

Conclusions

There was substantial support from ED HCWs for routine opt-out ED BBV screening, including opt-out consent. Key areas suggested for improvement included changes to test-ordering systems and additional training for HCWs. Frequent preference for verbal reminders at the point of blood draw suggests continued HIV testing exceptionalism.

Improving the Consent Process for Superficial Abscesses Through Pre-printed Consent Forms

Sima Patel, Ceri Gillett

Cureus, 11 November 2024; 16(11)

Abstract

Introduction

Informed consent is essential to ensure that patients are appropriately educated about proposed procedures, including associated risks and potential benefits, to make a valid decision. Incision and drainage of an abscess is a common procedure performed by various healthcare professionals. Inconsistent practices in the consent process can lead to misunderstandings among the patient and have financial and legal complications for both the clinician and the hospital. This study aims to improve the consent process for the incision and drainage of a superficial abscess via the implementation of pre-printed consent forms.

Method

We conducted a retrospective, single-centre study to evaluate existing consent forms, found in patients' notes, for the incision and drainage of superficial abscesses. The goal was to assess these forms for standardisation, ultimately developing a pre-printed consent form suitable for use by a diverse range of healthcare professionals.

Results

This study revealed significant inconsistencies in consent documentation. While 20 out of 22 (91%) consent forms included infection as a documented risk, only 11 out of 22 (50%) mentioned COVID-19 as a potential risk. The study found that 22 of our 22 (100%) consent forms were documented in black ink. Providing patients with copies of the consent forms can enhance their understanding by allowing them to review the information at home. Eight out of 22 (36%) patients were offered a copy, and 13 out of 22 consent forms (59%) were noted to have abbreviations, both of which may limit understanding and comprehension of the procedure. After implementing a pre-printed consent form, 14 clinicians surveyed (100%) reported that the forms were effective, with 12 out of 14 (86%) indicating they would use these pre-printed forms in their future practice.

Conclusion

The identified variations and inconsistencies in the consent process prompted the creation of a standardised pre-printed consent form. Feedback on this form has been positive, indicating its potential to transform the

consent process. The sample size was small, so early results are positive; however, further ongoing work would be required to draw a more definitive conclusion.

Interventions and strategies for enhancing the consent process in neurosurgery. A systematic review of the literature

Review Article

Ashraf Elmahdi, David Smith

British Journal of Neurosurgery, 3 November 2024

Abstract

Background

The informed consent process in neurosurgery aims to support patient autonomy and provide comprehensive information for decision-making. However, gaps in communication and understanding between patients and surgeons persist, that need to be addressed. This systematic review examined the interventions and strategies which to enhance the process of consent in neurosurgery.

Methods

A comprehensive search of databases and relevant sources to identify relevant studies for inclusion. Systematic review of prospective and retrospective studies that assess the effect of interventions which improve the consent process. Data collection and analysis involved independent reviewers assessing eligibility, study quality, and risk of bias. Findings from the included studies were used to write the review.

Main results

The reviewed identified seven studies notably revealed an educational and interactive consent process involving strategies like booklets, videos, multiple interviews, and interactive websites showed improvements in patient knowledge. Recall of risks decreased over time, and factors like age, education, and timing of consent influenced recall.

Authors' conclusions

To maximise informed consent, neurosurgeons should consider various strategies. Tailoring communication-based on patient's health literacy and treatment knowledge, involving their support system, and using a bullet-point consent form is essential. Utilising multiple modalities like verbal, static, and dynamic visuals improve information retention. Creative and memorable visual aids enhance comprehension. Allowing time for questions and team approach is superior.

Informed consent in gynecological oncology: a JAGO/NOGGO survey on real-world practices in daily clinical routine

M. G. Biersack, L. L. Volmer, C. Geißler, J. Fromme, S. Fröhlich, K. Pietzner, J. Sehouli, M. H. Beck

Archives of Gynecology and Obstetrics, 1 November 2024

Open Access

Abstract

Purpose

Informed consent is a quintessential element of contemporary medicine, reflecting the fundamental right of patients to participate in decision-making regarding their health. Despite its critical importance, there is a lack of data on real-world practices regarding patient informed consent in the context of modern, high-pressure medical environments.

Methods

We conducted a multinational multicentric survey from February 24, 2022, to September 14, 2022, investigating the practices and challenges surrounding informed consent in hospitals across Germany, Austria, and Switzerland with the use of a specifically developed questionnaire.

Results

Drawing on over 200 responses from gynecologists, the survey shows a critical need for structured training in conducting informed consent discussions with over 80% of participants expressing interest in courses addressing this aspect. Notably, a considerable portion of the physicians (59.9%) reported conducting discussions on procedures they had never personally witnessed. Significant disparities between types of hospitals and professional groups were observed in the frequency of informed consent discussions, with limitations arising from factors such as time constraints, language barriers, and insufficient resources for patient education. Moreover, the psychological burden experienced by physicians after informed-consent discussions underscores the need for systemic changes to alleviate concerns regarding patient safety, legal repercussions, and patient satisfaction.

Conclusion

This study serves as a call to action, emphasizing the need of enhancing resources and support for medical professionals to uphold the principles of empathic and comprehensive patient information and shared decision-making.

Bariatric Surgery: Informed Consent Resource

Rachel Stefaniuk, Sophie Lalonde-Bester, Jackie Liu, Asia Luna Patlis, Marisa Langton

Medical Students for Size Inclusivity, October 2024

Introduction

This resource was created by Medical Students for Size Inclusivity (MSSI), an international community of medical students dedicated to addressing weight bias in medicine. We have seen many patients undergo bariatric surgery aimed at promoting weight loss, and remain concerned that patients may receive misleading or insufficient information from their healthcare providers before undergoing these operations. While MSSI does not believe weight & BMI are accurate measures of health, or that weight loss improves health outcomes, we also champion patient autonomy. Weight discrimination permeates so many aspects of society, and the physical and mental harm it directly causes larger bodied people is immeasurable and far reaching. Our goal is to give patients desiring to undergo bariatric surgery to lose weight a more comprehensive understanding of bariatric surgeries, so they can make the most informed decisions about their care. Knowing what alternatives are available is part of full informed consent, so we also include evidence-based options for improving health that do not require weight loss.

Responsibility of the radiologist in the management of contrast media: Informed consent and other controversies

P. Rodríguez Carnero, C. Sebastià Cerqueda, L. Oleaga Zufiria

Radiology, October 2024

Abstract

Radiological contrast media play an essential role in radiology departments by facilitating more precise and detailed images. It is important to note that for radiologists the use of these contrast agents implies several legal responsibilities and ethical considerations towards patients. This related article will explore the main issues related to responsibility and complication management for radiologists, referring physicians and other professionals, as well as issues around informed consent, contraindications for their use and the benefit-risk balance assessed when deciding if a contrast-enhanced test should be carried out. In addition, we will address the crucial role of the radiologist in effective communication with patients and in obtaining informed consent. This research relates to Spanish legislation in the context of medical practice.

::::::

::::::

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.

::::::
::::::

NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

Guidance for human genome data collection, access, use and sharing

Normative Guidance
WHO, 20 November 2024
[see Spotlight treatment above]

::::::
::::::

SYMPOSIA/CONFERENCES/WEBINARS

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

No new relevant events identified.

# # # #

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

# # # #