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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

November 2023 :: Issue 59

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* [search terms "consent", "informed consent", and "assent" in title and available text]. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic journal 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.

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

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

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT
POLICY/GUIDANCE/CODES/PROGRAM ACTION

Please note that while we strive to identify the primary subject area for the categorization of the monthly digest 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.

UPCOMING CALLS FOR PUBLIC CONSULTATION

We will selectively include calls for public consultation from multilateral agencies, governments, INGOs and other sources where there is a clear intersection with consent/assent. This might be obvious from the title of the draft guidance, regulations, etc., but more often, it will be a thematic area or topic – if properly addressed at all. If you would like to explore participation with our working group developing submissions for these calls, please contact us [david.r.curry@ge2p2global.org].

Call for input on the right to access and take part in scientific progress

Issued by Special Rapporteur in the field of cultural rights, UNHCHR
Deadline: 13 November 2023
Purpose: To inform the upcoming report of the Special Rapporteur to the Human Rights Council to be presented in March 2024
Key questions and types of input/comments sought via the questionnaire (Word):
English | Français | Español
[Excerpt]
…Participation in science

9. How is the right of every person to participate in scientific progress and in decisions concerning its direction understood and implemented? What are the challenges? How are lack of representativeness of marginalized groups and inequalities in participation addressed?
10 How is 'citizen science' (ordinary people doing science) understood in your country? Is it considered important, and what measures have been put in place to support it, particularly in terms of access to information and data, and participation in decision-making? What are the challenges? Please provide an example.
11. To what extent are indigenous sciences and alternative sciences acknowledged, supported and included in policy decision-making? How is the conversation ensured between science and other kinds of knowledge?

12. What are the limits to the right of every person to take part in scientific progress and in decisions concerning its direction and for which purposes? Please provide examples if any.

Request for Information (RFI): Inviting Comments and Suggestions on Opportunities and Challenges for the Collection, Use, and Sharing of Real-World Data (RWD) Including Electronic Health Records, for National Institutes of Health (NIH) Supported Biomedical and Behavioral Research

U.S. National Institutes of Health on 09/28/2023.

Responses must be received by December 14, 2023

Background

Researchers are increasingly using data collected in real-world settings to augment traditional research studies, as well as develop more effective treatments and interventions for patients. These "real-world data (RWD)", defined by the U.S. Food and Drug Administration, are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status. While these data hold tremendous promise for biomedical and behavioral research, they can be collected from a variety of sources through multiple mechanisms, creating challenges for researchers and questions for those whose data are being shared.

Importantly, NIH is committed to ensuring participant privacy and autonomy are protected in all NIH-supported research. As NIH establishes health-related research data platforms that include access to RWD, NIH continues to prioritize maximizing data access while upholding participant preferences regarding the collection and use of their data…

Information Requested

NIH is requesting public comment on the use of RWD for NIH-supported biomedical and behavioral research, including opportunities for leveraging the benefits of RWD and strategies for its responsible use. NIH also seeks to better understand community perspectives on the potential value and constraints—including scientific, administrative, legal, business, and bioethical—for the increased use of RWD in biomedical and behavioral research.

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SYMPOSIA/CONFERENCES

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

No new symposia/conferences identified.

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SPOTLIGHT ARTICLES

Generative AI – and LLMs [Large Language Models] which drive it – are receiving extensive (and appropriate) attention in the media, in regulatory contexts and in the academic literature. We feature here two articles which explore some of the intersections between generative AI and consent. The first, by Decker et al., explores how LLMs might be employed to potentially enhance ICF readability, improve articulation of risks, and "ease documentation burden for physicians." The second, by Litt et al., also explores improvements in readability through aggregating ICFs posted with oncology clinical trials registered on clinicaltrials.gov and then applying a generative AI tool generate more useful consent content. We anticipate a good deal more activity exploring how generative AI can contribute to consent content, effectiveness and integrity.

Large Language Model–Based Chatbot vs Surgeon-Generated Informed Consent Documentation for Common Procedures

Original Investigation Surgery

Hannah Decker, Karen Trang, Joel Ramirez, Alexis Colley, Logan Pierce, Melissa Coleman, Tasce Bongiovanni, Genevieve B. Melton, Elizabeth Wick

JAMA Network Open, 9 October 2023; 6(10)

Abstract

Importance

Informed consent is a critical component of patient care before invasive procedures, yet it is frequently inadequate. Electronic consent forms have the potential to facilitate patient comprehension if they provide information that is readable, accurate, and complete; it is not known if large language model (LLM)-based chatbots may improve informed consent documentation by generating accurate and complete information that is easily understood by patients.

Objective

To compare the readability, accuracy, and completeness of LLM-based chatbot- vs surgeon-generated information on the risks, benefits, and alternatives (RBAs) of common surgical procedures.

Design, Setting, and Participants

This cross-sectional study compared randomly selected surgeon-generated RBAs used in signed electronic consent forms at an academic referral center in San Francisco with LLM-based chatbot-generated (ChatGPT-3.5, OpenAI) RBAs for 6 surgical procedures (colectomy, coronary artery bypass graft, laparoscopic cholecystectomy, inguinal hernia repair, knee arthroplasty, and spinal fusion).

Main Outcomes and Measures

Readability was measured using previously validated scales (Flesh-Kincaid grade level, Gunning Fog index, the Simple Measure of Gobbledygook, and the Coleman-Liau index). Scores range from 0 to greater than 20 to indicate the years of education required to understand a text. Accuracy and completeness were assessed using a rubric developed with recommendations from LeapFrog, the Joint Commission, and the American College of Surgeons. Both composite and RBA subgroup scores were compared.

Results

The total sample consisted of 36 RBAs, with 1 RBA generated by the LLM-based chatbot and 5 RBAs generated by a surgeon for each of the 6 surgical procedures. The mean (SD) readability score for the LLM-based chatbot RBAs was 12.9 (2.0) vs 15.7 (4.0) for surgeon-generated RBAs ($P = .10$). The mean (SD) composite completeness and accuracy score was lower for surgeons' RBAs at 1.6 (0.5) than for LLM-based chatbot RBAs at 2.2 (0.4) ($P < .001$). The LLM-based chatbot scores were higher than the surgeon-generated scores for descriptions of the benefits of surgery (2.3 [0.7] vs 1.4 [0.7]; $P < .001$) and alternatives to surgery (2.7 [0.5] vs 1.4 [0.7]; $P < .001$). There was no significant difference in chatbot vs surgeon RBA scores for risks of surgery (1.7 [0.5] vs 1.7 [0.4]; $P = .38$).

Conclusions and Relevance

The findings of this cross-sectional study suggest that despite not being perfect, LLM-based chatbots have the potential to enhance informed consent documentation. If an LLM were embedded in electronic health

records in a manner compliant with the Health Insurance Portability and Accountability Act, it could be used to provide personalized risk information while easing documentation burden for physicians.

Improving clinical trial consent form readability through artificial intelligence

Conference Presentation – ASCO Quality Care Symposium 2023

Henry Kazunaru Litt, Emma Greenstreet Akman, Dame Idossa, Narjust Florez, Ana I. Velazquez Manana

JCO Oncology Practice - Health Care Access, Equity, and Disparities, 26 October 2023; 18(11)suppl

Abstract

Background

High literacy levels are needed to understand oncology clinical trial (CT) informed consent forms (ICF), which represents a barrier to enrollment of older adults and diverse populations. ChatGPT-4 is an artificial intelligence chatbot that responds to user prompts and can summarize large amounts of text. We tested whether ChatGPT-4 could simplify CT information from ICFs.

Methods

On May 22, 2023, we searched clinicaltrials.gov for interventional, therapeutic, NIH-funded, CTs involving adults with the 14 most prevalent cancer types. Only CTs with available study protocols that were currently recruiting, “enrolling by invitation”, and “active not recruiting” were included. Trials that were diagnostic, preventative, or supportive were excluded. Publicly available ICFs from the resulting CTs were downloaded and analyzed. Using the ChatGPT-4 plugin askyourpdf.com, we asked ChatGPT-4 to review each ICF and answer 8 questions recommended by the NCCN for patients considering a CT in a 6th grade literacy level. Our prompt included the following 8 questions: “1) What are the treatments used in the clinical trial? 2) Has the treatment been used for other types of cancer? 3) What are the risks and benefits of this treatment? 4) What side effects should I expect and how will they be managed? 5) How long will I be in the clinical trial? 6) Will I be able to get other treatment if this doesn’t work? 7) How will you know if the treatment is working? 8) Will the clinical trial cost me anything?” Reading level (readability) was assessed for both the ICFs and ChatGPT-4’s question responses using the validated Flesch-Kincaid (FK), Gunning Fog (GF), and SMOG indices using the online Readable App. Data was summarized with descriptive statistics and t-test was used to compare text reading levels between ICFs and ChatGPT-4’s answers.

Results

Our search yielded 83 therapeutic oncology CTs, of which 70 had publicly available ICFs. ChatGPT-4 successfully analyzed 66 of the 70 ICFs (94.3%). The mean text reading levels of its answers were 6.2 (95% CI: 5.9-6.5), 8.6 (95% CI: 8.2-8.9), and 9.2 (95% CI: 8.9-9.4) based on FK, GF, and SMOG indices, respectively. Of 70 ICFs, 54 (77.1%) contained text that could be evaluated for readability analysis and were included in the analysis. The mean text reading levels was 7.9 (95% CI: 7.7-8.1), 9.3 (95% CI: 9.1-9.6), and 10.5 (95% CI: 10.2-10.8) based on FK, GF, and SMOG indices, respectively. ChatGPT-4’s text responses had a significantly lower reading level compared to ICFs text for all three readability indices (FK: $p<0.01$, GF: $p=0.02$, SMOG: $p<0.01$).

Conclusions

ChatGPT-4 presented key information from oncology CT ICFs at a 6th to 9th grade reading level, which was significantly lower than the original ICFs. While further studies are needed to assess ChatGPT-4’s accuracy, this study shows its potential as tool for improving patients’ understanding of oncology CTs.

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BIOMEDICAL RESEARCH

uConsent: Addressing the gap in measuring understanding of informed consent in clinical research

Richard F. Ittenbach, J. William Gaynor, Jenny M. Dorich, Nancy B. Burnham, Guixia Huang, Madisen T. Harvey, Jeremy J. Corsmo

Clinical and Translational Science, 12 October 2023

Abstract

The purpose of this study was to establish the technical merit, feasibility, and generalizability of a new measure of understanding of informed consent for use with clinical research participants. A total of 109 teens/young adults at a large, pediatric medical center completed the consenting process of a hypothetical biobanking study. Data were analyzed using a combination of classical and modern theory analytic methods to produce a final set of 19 items referred to as the uConsent scale. A requirement of the scale was that each item mapped directly onto one or more of the Basic Elements of Informed Consent from the 2018 Final Rule. Descriptive statistics were computed for each item as well as the scale as a whole. Partial credit (Rasch) logistic modeling was then used to generate difficulty/endorsability estimates for each item. The final, 19-item uConsent scale was derived using inferential methods to yield a set of items that ranged across difficulty levels (−3.02 to 3.10 logits) with a range of point- measure correlations (0.12 to 0.50), within- range item- and model- fit statistics, varying item types mapped to both Bloom's Taxonomy of Learning and required regulatory components of the 2018 Final Rule. Median coverage rate for the uConsent scale was 95% for the 25 randomly selected studies from ClinicalTrials.gov. The uConsent scale may be used as an effective measure of informed consent when measuring and documenting participant understanding in clinical research studies today.

Risk to Research Non-Participants: Ethical Dimensions of Protecting Bystanders in Xenotransplantation Clinical Trials

Conference Presentation - IPITA-IXA-CTRMA 2023 Joint Congress Abstracts

Daniel Hurst, Luz Padilla, Daniel Rodger, Tamar Schiff, David KC Cooper

Transplantation, October 2023

Abstract

Introduction

Ethical issues regarding clinical xenotransplantation have been described for decades with most of the issues centering on animal welfare, the risks posed to the recipient, and the potential public health risks. Much less attention has been given to thinking through ethical issues for those who may care for xenograft recipients (e.g., caregivers, family members), especially when the recipient returns home. These caregivers or bystanders, due to their close interaction with the xenotransplantation recipient, face potential exposure to a xenozoonotic disease, with implications regarding informed consent for that risk, and whether or not such bystanders should be regularly monitored for infection, as is proposed for recipients.

Methods

This presentation raises concerns for the risks to bystanders in xenotransplantation which we believe have not been adequately addressed in the literature to date. We will propose several options for how bystanders should be informed of, and consented for, the risks of close contact with a xenotransplant recipient. The benefits and pitfalls of each potential option are explored.

Results

We conclude that only the xenograft recipient needs to provide their informed consent to the xenotransplantation and agree to lifelong (or long-term) monitoring. As no legal enforcement mechanism currently exists for requiring recipients to be monitored without evidence of infectious disease, such monitoring could only be strongly encouraged and agreed to at the point of xenotransplantation, but not required. In addition, we argue that the xenograft recipient, prior to xenotransplantation, should provide a list of members of the same household/close contacts for record keeping and future possible contact tracing. We propose at a minimum that all members listed should be provided with an information sheet or assent form that contains the basic elements of the informed consent form but does not require a signature or other declaration of agreement. This approach seeks to balance ethical concerns, namely the potential risks posed to bystanders and how strong a duty this creates to protect them and support their right to choose how or if they continue to interact with the potential xenograft recipient, with the recipient's reasonable right to patient privacy.

Conclusion

This presentation discusses a significant concern related to xenotransplantation, made increasingly pressing by the possibility of forthcoming clinical trials. By the end of the presentation, the audience will better understand the bystander risk, differing modes of mitigating that risk, and why it is important to foster dialogue and develop policy on this issue.

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SOCIAL SCIENCE RESEARCH

Encouraging greater empowerment for adolescents in consent procedures in social science research and policy projects

Oddrun Samdal, Isabelle Budin-Ljøsne, Ellen Haug, Trond Helland, Lina Kjostarova-Unkovska, Claire Bouillon, Christian Bröer, Maria Corell, Alina Cosma, Dorothy Currie, Charli Eriksson, Rosemarie Felder-Puig, Tania Gaspar, Curt Hagquist, Janetta Harbron, Atle Jaastad, Colette Norena Kelly, Cécile Knai, Dorota Kleszczewska, Bjarte Birkeland Kysnes, Nanna Lien, Aleksandra Luszczynska, Gerben Moerman, Concepción Moreno-Maldonado, Saoirse NicGabhainn, Iveta Pudule, Jelena Gudelj Rakic, Ana Rito, Alfred Mestad Rønnestad, Madeleine Ulstein, Harry Rutter, Knut-Inge Klepp

Obesity Reviews, September 2023

Open Access

Abstract

The United Nations Convention on the Rights of the Child emphasizes the importance of allowing children and adolescents to influence decisions that are important to them following their age and maturity. This paper explores the principles, practices, and implications around using parental versus child/adolescent consent when participating in social science research and policy development. Experiences from two studies are presented: The Confronting Obesity: Co-creating policy with youth (CO-CREATE) and the Health Behaviour in School-aged Children (HBSC) study, a World Health Organization (WHO) Collaborative Cross-National study. Although parental consent may be an important gatekeeper for protecting children and adolescents from potentially harmful research participation, it may also be considered an obstacle to the empowerment of children and adolescents in case they want to share their views and experiences directly. This paper argues that evaluation of possible harm should be left to ethics committees and that, if no harm related to the research participation processes is identified and the project has a clear perspective on collaborating with the target group, adolescents from the age of 12 years should be granted the legal capacity to give consent to participate in the research project. Collaboration with adolescents in the development of the research project is encouraged.

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GENOMIC MEDICINE/GENE EDITING

'It's a nightmare': informed consent in paediatric genome-wide sequencing. A qualitative expert interview study from Germany and Switzerland

Johanna Eichinger, Bettina Zimmermann, Bernice Elger, Stuart McLennan, Isabel Filges, Insa Koné

European Journal of Human Genetics, 29 September 2023

Open Access

Abstract

The use of genome-wide sequencing (GWS) in paediatrics has added complexity to informed consent (IC) and pretest counselling because of the vast number and interpretation of potential findings, and their implications. However, empirical data from continental Europe on these issues remains limited. This study therefore aimed to explore the experiences and views of medical geneticists working with children in Germany and Switzerland regarding the challenges of obtaining valid IC in paediatric GWS. Qualitative interviews with 20 medical geneticists were analysed employing reflexive thematic analysis. In the interviews, many medical geneticists questioned the validity of parents' IC due to the enormous amount of relevant information given and the variety and complexity of the possible test outcomes. Key barriers identified included familial implications, administrative challenges and struggles with non-directiveness. Medical geneticists' suggestions for improvement included increasing the number of genetics professionals and better information material, which is crucial as GWS becomes a diagnostic standard in the early care pathways of children. An adjustment of aspirations from still existing ideal of traditional fully IC to appropriate IC seems to be needed. Such a more realistic and ethically sound adaptation of the requirements for IC can lead to better 'informedness' and improve the validity of the consent. This might also help reduce the moral distress for the medical geneticists involved.

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HEALTH DATA/DATA

The Social Contract for Health and Wellness Data Sharing Needs a Trusted Standardized Consent

Brief Report

Stefanie Brückner, Toralf Kirsten, Peter Schwarz, Fabienne Cotte, Michael Tsesis, Stephen Gilbert

Mayo Clinic Proceedings: Digital Health, December 2023; 1(4) pp 527-533

Open Access

Abstract

The rise of health and wellness applications has led to a new category of citizen-generated health data, which are collected through sensors and user inputs. As more parameters are measured over longer time periods, these data will gradually become more important for disease prediction, care, and research than classical clinic-generated health data. Policymakers now recognize the potential of both data types in initiatives such as the European Health Data Space, which aims to enable data sharing for patient care and research at scale. Although it could be argued that clinic-generated data come from public-funded health systems and should therefore be sharable, after depersonalization, for public service, this argument extends poorly to data from wearables and applications. We propose a new approach for standardized health consent, both broad and dynamic, to overcome consent fatigue and engage citizens in data sharing.

Specific measures for data-intensive health research without consent: a systematic review of soft law instruments and academic literature

Review Article

Julie-Anne R. Smit, Menno Mostert, Rieke van der Graaf, Diederick E. Grobbee, Johannes J. M. van Delden

European Journal of Human Genetics, 17 October 2023

Open Access

Abstract

It is a common misunderstanding of current European data protection law that when consent is not being used as lawful basis, the processing of personal data is prohibited. Article 9(2)(j) of the European General Data Protection Regulation (GDPR) permits Member States to establish a legal basis in national law that allows for the processing of personal data for scientific research purposes without consent. However, the

European legislator has formulated this “research exemption” as an opening clause, rendering the GDPR not specific as to what measures exactly are required to comply with the research exemption. This may have significant implications for both the protection of personal data and the advancement of data-intensive health research. We performed a systematic review of relevant soft law instruments and academic literature to identify what measures are mentioned in those documents. Our analysis resulted in the identification of four overarching themes of suggested measures: organizational measures; technical measures; oversight and review mechanisms; and public engagement and participation. Some of the suggested measures do not substantially contribute to the clarification of the GDPR’s “suitable and specific measures” requirement because they remain vague or broad in nature and encompass all types of data processing. However, the themes oversight and review mechanisms and public engagement and participation provide valuable insights which can be put to practice. Nevertheless, further clarification of the measures and safeguards that should be installed when invoking the research exemption remains necessary.

Toward Consent in Molecular HIV Surveillance? Perspectives of Critical Stakeholders

Research Article

Stephen Molldrem, Anthony K J Smith, Vishnu Subrahmanyam

AJOB Empirical Bioethics, 28 September 2023

Abstract

Background

The emergence of molecular HIV surveillance (MHS) and cluster detection and response (CDR) programs as key features of the United States (US) HIV strategy since 2018 has caused major controversies. HIV surveillance programs that re-use individuals’ routinely collected clinical HIV data do not require consent on the basis that the public benefit of these programs outweighs individuals’ rights to opt out. However, criticisms of MHS/CDR have questioned whether expanded uses of HIV genetic sequence data for prevention reach beyond traditional public health ethics frameworks. This study aimed to explore views on consent within MHS/CDR among critical stakeholders.

Methods

In 2021 we interviewed 26 US HIV stakeholders who identified as being critical or concerned about the rollout of MHS/CDR. Stakeholders included participants belonging to networks of people living with HIV, other advocates, academics, and public health professionals. This analysis focused on identifying the range of positions among critical and concerned stakeholders on consent affordances, opt-outs, how to best inform people living with HIV about how data about them are used in public health programs, and related ethical issues.

Results

Participants were broadly supportive of introducing some forms of consent into MHS/CDR. However, they differed on the specifics of implementing consent. While some participants did not support introducing consent affordances, all supported the idea that people living with HIV should be informed about how HIV surveillance and prevention is conducted and how individuals’ data are used.

Conclusions

MHS/CDR has caused sustained controversy. Among critical stakeholders, consent is generally desirable but contested, although the right for people living with HIV to be informed was centrally supported. In an era of big data-driven public health interventions and routine uses of HIV genetic sequence data in surveillance and prevention, CDC and other agencies should revisit public health ethics frameworks and consider the possibility of consent processes.

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CAPACITY TO CONSENT

Informed consent practices for acute stroke therapy: principles, challenges and emerging opportunities

Review

Amir Mbonde, Michael J. Young, Adam A. Dmytriw, Quentin J. Moyer, Joshua A. Hirsch, Thabele M. Leslie-Mazwi, Natalia S. Rost, Aman B. Patel, Robert W. Regenhardt

Journal of Neurology, 10 October 2023

Abstract

Importance

Informed consent (IC) plays a crucial yet underexplored role in acute stroke treatment, particularly in the context of intravenous thrombolysis (IVT) and endovascular thrombectomy (EVT). This narrative review examines data on current IC practices in acute ischemic stroke management, specifically for patients treated with IVT or EVT, with the aim of identifying areas for improvement and strategies to enhance the IC process.

Observations

IC practices for IVT vary significantly among hospitals and physicians with the frequency of always requiring consent ranging from 21 to 37%. Factors influencing IC for IVT include patient decision-making capacity, standard of care, time sensitive nature of treatments, legal and moral obligations, risk of complications, physician age and speciality, treatment delays, and hospital size. Consent requirements tend to be stricter for patients presenting within the 3–4.5-h window. The content and style of information shared as part of the IC process revealed discrepancies in the disclosure of stroke diagnosis, IVT mechanism, benefits, and risks. Research on IC practices for EVT is scarce, highlighting a concerning gap in the available evidence base.

Conclusions and relevance

This review underscores the significant variability and knowledge gaps in IC for EVT and IVT. Challenges related to decision-making capacity assessment and the absence of standardised guidance substantially contributes to these gaps. Future initiatives should focus on simplifying information delivery to patients, developing formal tools for assessing capacity, standardising ethical frameworks to guide physicians when patients lack capacity and harmonizing IC standards across sites. The ultimate goal is to enhance IC practices and uphold patient autonomy, while ensuring timely treatment initiation.

[Proposal for participation in intensive care and emergency medicine studies for patients unable to give informed consent (Cologne Model)]

Kochanek M, Grass G, Böll B, Eichenauer DA , Shimabukuro-Vornhagen A , Hallek M, Zander T, Mertens J, Voltz R

Medizinische Klinik, Intensivmedizin und Notfallmedizin, 29 September 2023

Abstract

When conducting clinical trials in intensive care and emergency medicine, physicians, ethics committees, and legal experts have differing views regarding the inclusion of patients who are incapable of giving consent. These different views on the participation of patients who are not capable of giving consent also complicate how clinical trials are prepared and conducted. Based on the results of a literature search, a consensus model (Cologne Model) was developed by physicians performing clinical research, ethics committees, and lawyers in order to provide patients, those scientifically responsible for the study, ethics committees, and probate (guardianship) judges with a maximum of patient safety and legal certainty, while simultaneously enabling scientific research.

Editor’s note: This is a German language publication.

Developing a dementia friendly approach to consent in dementia research

Michelle Pyer, Alison Ward

Aging and Mental Health, 11 September 2023

Abstract

Objectives

This paper explores the process of gaining consent from the perspectives of people living with dementia, their relatives/carers, and service providers. This is developed based on new primary qualitative research and addresses a gap in critical reflection on the practice and ethical process of research consent.

Methods

A qualitative approach was used to conduct this research through the implementation of four focus groups run with people living with dementia (n=12), two focus groups with family members (n=6), two focus groups with service staff (n=5).

Results

Data was analysed thematically, to identify two core themes: consent as a journey and the flexible consent approach. These identified concerns with autonomy, decision making and placing people living with dementia at the centre of the consent process. The journey of consent emerged as central to supporting participation and enhancing the consent process.

Conclusion

The paper presents new evidence about the lived experience of research consent in the field of dementia, presenting the process of collecting consent in research as a flexible process that is best supported through a growing knowledge of participants and participation sites.

Capacity Assessment in Emergency Surgery

Selwyn O. Rogers, Darren S. Bryan

Journal of Clinical Ethics, Fall 2023; 34(3) pp 270-272

Abstract

Informed consent is a necessary component of the ethical practice of surgery. Ideally, consent is performed in a setting conducive to a robust patient-provider conversation, with careful consideration of risks, benefits, and outcomes. For patients with medical or surgical emergencies, navigating the consent process can be complicated and requires both careful and expedited assessment of decision-making capacity. We present a recent case in which a patient in need of emergency care refused intervention, requiring urgent capacity assessment and a modification to usual care.

Why we have duties of autonomy towards marginal agents

Book Chapter

Anna Hirsch

Theoretical Medicine and Bioethics, 12 May 2023 [Springer]

Open Access

Abstract

Patients are usually granted autonomy rights, including the right to consent to or refuse treatment. These rights are commonly attributed to patients if they fulfil certain conditions. For example, a patient must sufficiently understand the information given to them before making a treatment decision. On the one hand, there is a large group of patients who meet these conditions. On the other hand, there is a group that clearly does not meet these conditions, including comatose patients or patients in the late stages of Alzheimer's disease. Then there is a group of patients who fall into the range in between. At the lower end of this range are so-called 'marginal agents,' which include young children and patients in the middle stages of Alzheimer's disease. They also do not meet the typical requirements for autonomy, which is why they are usually granted fewer autonomy rights. However, some of them are capable of 'pre-forms' of autonomy that express what is important to them. These pre-forms differ from mere desires and reflect the identification/authenticity condition of autonomy. They have something in common with autonomous attitudes, choices, and actions – namely, they express the value of autonomy. As I will argue, autonomy is a value worthy of protection and promotion – even in its non-reflexive forms. Against this background, it becomes clear why we have autonomy duties, more precisely positive, autonomy-enabling duties, towards marginal agents and why we should give them as much attention as autonomy duties towards competent patients.

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YOUNG PERSONS

Parental views on prospective consent: experience from a pilot neonatal randomized control trial

Original Research

Hannah Skelton, Patricia Viola, Traci-Anne Goyen, Pranav Jani

Frontiers in Pediatrics, November 2023

Abstract

Objective

To explore parental perceptions of the consenting process and understanding of the study in a pilot Randomized Controlled Trial wherein extremely premature infants (<29 weeks' gestation) were recruited either antenatally or by 4-hours of age. We prospectively interviewed parents who had consented, declined consent and missed eligible infants in the Positioning Preterm Infants for Neuroprotection (PIN) study, a low-risk intervention study. Structured interview questions explored the process and acceptability of the consenting approach by the parents and their knowledge of the study. Additional comments made by the parents were transcribed verbatim.

Results

Sixty-two parents participated in the interviews, of those 41 had provided their consent, 8 declined consent and 13 were parents of missed eligible infants. Overall, most parents reported they understood the study well before providing their consent and approaching them for consenting did not create a burden for them. A verbal explanation of the study by the study team, especially by the medical practitioners, was viewed as beneficial. It was suggested that the 4-hour period for obtaining postnatal consent may be too short. A deferred consent with a follow-up opportunity for obtaining informed consent could be a suitable alternative. Parents found the consenting process acceptable and that they had sufficient understanding of the study to provide an informed consent. Deferred consent should be explored for future, low-risk intervention studies as an alternative to prospective consent where infants need to be recruited in the immediate neonatal period.

The ethics of informed consent for infants born to adolescents: A case study from Malaysia

Research Article

Jeffrey Soon-Yit Lee, Benjamin Wei-Liang Ng, Mohammad Firdaus bin Abdul Aziz

Clinical Ethics, 17 October 2023

Abstract

Adolescent pregnancy results from the complex interaction between various internal and external vulnerabilities. These vulnerabilities persist after the infant's birth when the adolescent becomes a parent. Adolescent parents are unfairly stereotyped as unmotivated and incompetent. Some legislations prohibit adolescents from giving consent on the grounds of incompetency. Despite being different, “competency” is frequently used interchangeably with “capacity”; thus, incompetent individuals are often mistaken to lack capacity. Consequently, legally incompetent adolescents who became parents are frequently disregarded during their infant's decision-making process. This article discusses the distinction between the competence and capacity of adolescent parents, the various vulnerabilities that contribute to an adolescent's incompetency, and advocates respect for the adolescent's capacity in making decisions for her infant. We propose a workflow for obtaining informed consent for infants born to adolescents ethically guided by the respect for individuals principle while staying within the country's legal framework.

Engaging with hard-to-reach children and parents using a creative methodology

Kylie Poppe, Angela Abela

Qualitative Research, 12 October 2023

Abstract

This paper delves into the creative methodology adopted whilst engaging in a research study with five families whose young children (aged between 8 and 10 years old) were excluded from school due to social, emotional and mental health difficulties. The complex needs surrounding these families often lead to them being labelled as hard-to-reach and therefore challenging to engage in research. This paper will explore these challenges, the ethical dilemmas that emerged, the constant observation throughout, the reflexivity and flexibility required by the researchers and the relationships forged. Using various creative methods as part of the Mosaic approach both the children and their parents were able to play a part in the meaning-making process throughout the research journey. The culmination of the research study took place in the format of a multi-family group session which provided a safe space for an intergenerational encounter allowing for the children’s and parent's authentic voices to continue to be heard.

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TECHNOLOGY/OTHER MEDIATION

Evaluation of Informed Consent with Teach-Back and Audio Assistance to Improve Willingness to Participate in a Clinical Trial Among Underrepresented Minorities: A Randomized Pilot Trial

Research article

Brenda Jamerson, Barry Shuster

Journal of Empirical Research on Human Research Ethics, 12 October 2023

Abstract

The informed consent form (ICF) is intended to assure that subject participation in research studies is informed and voluntary. Yet, there is ample evidence that many subjects do not adequately understand the concepts and language in a clinical trial ICF, which may undermine their willingness to participate in a clinical trial. In a randomized setting, we compared a standard read-only ICF to an audio-assisted ICF with or without teach-back. We found that audio-assisted ICFs significantly improved willingness to participate in a mock clinical trial among our sample of primarily African-American participants.

Efficacy of informed consent process using educational videos for skin biopsy procedures

Dichitchai Mettarikanon, Tawanwongsri, Pitchaya Jaruvijitrattana, Sasipaka Sindhusen, Surinnart Charoenchitt, Patsaraporn Manunyanon

Contemporary Educational Technology, 26 September 2023; 15(4)

Open Access

Abstract

The informed consent process is integral to medical procedures, including skin biopsies, which are the definitive method for diagnosing challenging skin lesions. Educational videos are recognized for effective delivery of information for informed consent. This study aimed to evaluate the efficacy of an informed consent process using educational videos to improve patient understanding and reduce preprocedural anxiety. This multicenter, randomized controlled study was conducted during December 2021-June 2023. Participants were randomly assigned to either the video or verbal group in a 1:1 ratio. They completed knowledge and anxiety questionnaires before and after biopsy. The final analysis included 54 participants (verbal group: n=28; video group: n=26) with a mean age of 51.9 years (standard deviation [SD] 18.1), and a balanced gender distribution. Post-intervention knowledge scores (median 10.0; IQR 8.0-10.0) significantly increased compared to pre-intervention scores (median 6.0; IQR 4.0-9.0), p<0.001. Post-intervention Spielberger state-trait anxiety inventory (STAI) scores (median 5.0; interquartile range, IQR 5.0-6.0) significantly decreased compared to pre-intervention scores (median 7.0; IQR 5.0-10.0), p<0.001. Knowledge scores increased more in the video group (median, 2.5; IQR 1.0-5.0) than in the verbal group (median, 1.5; IQR 0.0-4.0), p=0.217. There was no significant difference in STAI score changes between the video group (median 1.0, IQR 0.0-4.0) and the verbal group (median 1.0, IQR 0.0-3.0), p=0.824. Despite statistical insignificance, educational videos exhibited greater effectiveness in enhancing comprehension and demonstrated comparable efficacy in reducing anxiety compared to conventional intervention.

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CULTURAL/COUNTRY CONTEXT

Surgical Consent in the Pediatric Age Group: Parental Perceptions Toward Legal Aspects of Informed Consent

Original Article
Madani Essa
Saudi Journal of Medicine & Medical Sciences, October–December 2023; 11(4) pp 326-331
Abstract
Background

The perceptions of parents/legal guardians may drive their decisions on providing informed consent for minors. Currently, no study from Saudi Arabia has assessed the perceptions of parents/legal guardians toward informed consent for pediatric surgical procedures.

Objective

To determine parents' perception and understanding of pediatric informed consent for surgeries from Saudi Arabia and determining their level of participation in the decision-making process of the treatment modality.

Methods

This observational cross-sectional study was conducted among parents from the Jazan region of Saudi Arabia with at least one child aged ≤ 12 years. Three aspects of surgical informed consent were evaluated: parents' awareness, attitude, and understanding of informed consent and its legal issues; the knowledge they sought during informed consent discussions; and parents' opinions about their respective roles in the decision-making process for the treatment.

Results

A total of 366 responses were included in this study. More than 95% of the participants agreed that informed consent was necessary; however, 94.7% felt that regardless of their beliefs, they had to sign the form. Surprisingly, the majority (61%) believed that any relative can sign the consent form on behalf of the parents/legal guardian. Most respondents believe that pre-operative procedures (80.8%), the cost (93.9%), and the reason for the procedure and its alternatives (87.2%) should be discussed when informed consent is being sought. About 76.5% of the participants wanted to know all the information regarding the procedure; of these, 48.3% responded that they would play a role in deciding the eventual treatment modality.

Conclusion

The findings of this study indicate the need to increase knowledge regarding surgical informed consent among parents in the Jazan region of Saudi Arabia.

Family-based consent and motivation for familial organ donation in Bangladesh: An empirical exploration

Original Article

Sanwar Siraj

Developing World Bioethics, 19 October 2023

Abstract

The government of Bangladesh approved the human organ transplantation law in 1999 and updated it in 2018. This legislation approved both living-related donor and posthumous organ transplantation. The law only allows family members to legally donate organs to their relatives. The main focus of this study was to explore how Bangladeshis make donation decisions on familial organs for transplantation. My ethnographic fieldwork with forty participants (physicians and nurses, a healthcare administrator, organ donors, recipients, and their relatives) disclosed that the organ donation decision was family-based. An assessment of the relationship between religion, culture, and biomedicine leads to the conclusion that deciding on donating organs to relatives is primarily family-based and is perceived to be steeped in Islamic ethical principles and religious cultural tradition. The family-based consent and motivation for donor-recipient pair organ transplantation strengthen an altruistic environment for the family and act as the moral and legal authority that ensures ethical healthcare outcomes for Bangladeshis.

Examining the adequacy of preoperative informed consent in a developing country: Challenges in the era of surgical specialisation

Ede O, Obadaseraye OR, Anichi I, Mbaeze C, Udemezue CO, Basil-Nwachuku C, Madu KA, Iyidobi EC, Anyaehie UE, Nwadinigwe CU, Ngwangwa C, Adetula UE

Developing World Bioethics, 9 October 2023

Abstract

Preoperative informed consent is a legal and ethical requirement that ensures patients understand a procedure, its associated risks and benefits, alternative treatment options, and potential complications to make an informed decision about their care. This cross-sectional study evaluated the informed consent process for major orthopaedic surgeries at a tertiary hospital in Nigeria. A self-administered questionnaire was used to collect data from 120 adult participants. Results showed that many patients do not read the consent form before signing it, and surgeons do not adequately explain the alternatives to surgery, potential risks, and available anaesthetic options. Higher-educated patients are more likely to read the consent form. Surgeons performed well in explaining the nature of the condition and prognosis, the procedure's potential benefits, and answering patients' questions. The study emphasises the need to improve the informed consent process to ensure patients understand and can make rational decisions about their healthcare.

Effects of the Informed Health Choices secondary school intervention: A prospective meta-analysis

Faith Chesire, Michael Mugisha, Ronald Ssenyonga, Christopher J. Rose, Allen Nsangi, Margaret Kaseje, Nelson K. Sewankambo, Matt Oxman, Sarah E. Rosenbaum, Jenny Moberg, Astrid Dahlgren, Simon Lewin, Andrew D. Oxman

Journal of Evidence-Based Medicine, 21 September 2023

Abstract

Aim

The aim of this prospective meta-analysis was to synthesize the results of three cluster-randomized trials of an intervention designed to teach lower-secondary school students (age 14–16) to think critically about health choices.

Methods

We conducted the trials in Kenya, Rwanda, and Uganda. The intervention included a 2- to 3-day teacher training workshop, digital resources, and ten 40-min lessons. The lessons focused on nine key concepts. We did not intervene in control schools. The primary outcome was a passing score on a test (≥9 of 18 multiple-choice questions answered correctly). We performed random effects meta-analyses to estimate the overall adjusted odds ratios. Secondary outcomes included effects of the intervention on teachers.

Results

Altogether, 244 schools (11,344 students) took part in the three trials. The overall adjusted odds ratio was 5.5 (95% CI: 3.0–10.2; $p < 0.0001$) in favor of the intervention (high certainty evidence). This corresponds to 33% (95% CI: 25–40%) more students in the intervention schools passing the test. Overall, 3397 (58%) of 5846 students in intervention schools had a passing score. The overall adjusted odds ratio for teachers was 13.7(95% CI: 4.6–40.4; $p < 0.0001$), corresponding to 32% (95% CI: 6%–57%) more teachers in the intervention schools passing the test (moderate certainty evidence). Overall, 118 (97%) of 122 teachers in intervention schools had a passing score.

Conclusions

The intervention led to a large improvement in the ability of students and teachers to think critically about health choices, but 42% of students in the intervention schools did not achieve a passing score.

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RIGHTS/LEGAL/LEGISLATIVE

Informed Consent and Medicolegal Aspects

Book Chapter

Bernardo Hontanilla, Andrés Ros Magallón

Post-maternity Body Changes, 20 October 2023 [Springer]

Abstract

It is not seldom in our trade that one must face litigation, be it against oneself or when testifying for or against something a colleague has done in their practice. Having a working knowledge of the regulations that permeate the doctor-patient relationship is paramount to building a successful practice and reducing the risks associated with patient care.

This is especially relevant in the field of aesthetic surgery, where a patient is not seeking a treatment that is essentially curative, but one to look like a younger version of themselves or improve their appearance. Often due to the aggressive marketing performed by some surgeons or reality TV, such a patient can present with unrealistic expectations or without even knowing the risks surgery entails, which becomes even more harmful when a third party can be affected by the results of the surgery as it is the case when treating a post-maternity patient.

The aims of this chapter are to provide a basic knowledge of the different kinds of regulations that specifically affect our trade, to bring forward the possible pitfalls when treating a post-maternity patient, and to emphasize the importance of the informed consent both to reduce risk and to improve the doctor-patient relationship.

[The presumed consent legislation - A success factor or a disruptive factor for tissue donation? A qualitative study based on multidisciplinary interviews with experts]

Kirchner K, Lauerer M, Nagel E

The Journal of Evidence and Quality in Health Care, 6 October 2023
Abstract
Introduction
Tissue transplantation can improve the quality of life of patients in a very wide range of applications. In 2021, around 900 people in Germany agreed to donate organs after death - the number of tissue donors was significantly higher. Nevertheless, there is a shortage of organs and tissues in Germany. In order to counteract this, the introduction of a presumed consent legislation has been discussed time and again. However, the debates focused on possible positive effects for organ donation, whereas potential consequences for tissue donation have so far not been considered in the political discourse or in research. Using an exploratory approach, this paper aims to contribute to closing this research gap: Multidisciplinary interviews with experts were conducted to investigate whether the presumed consent legislation is a key success factor for increasing the number of tissue donors in Germany and which other approaches might be promising.

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

Opt-out, mandated choice and informed consent

Ben Saunders
Bioethics, 4 October 2023
Abstract
A number of authors criticise opt-out (or 'deemed consent') systems for failing to secure valid consent to organ donation. Further, several suggest that mandated choice offers a more ethical alternative. This article responds to criticisms that opt-out does not secure informed consent. If we assume current (low) levels of public awareness, then the explicit consent secured under mandated choice will not be informed either. Conversely, a mandated choice policy might be justifiable if accompanied by a significant public education campaign. However, if this entitles us to assume that members of the public are informed, then an opt-out system would also be justified in the same circumstances. The alleged advantages of mandated choice seem to rest on an unfair comparison, between mandated choice with a public education campaign and an opt-out system without one. While it may be that some countries with opt-out systems should do more to inform their publics, I see no reason to assume that this cannot be done. Indeed, advocates of mandated choice seem committed to thinking it possible to raise awareness. If opt-out systems adopt the same methods, such as writing to every individual, this should also address concerns about whether consent is informed.

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MEDICAL/SURGICAL

Informed Consent for Spine Procedures: Best Practice Guideline from the American Society of Pain and Neuroscience (ASPN)

Timothy Deer, Ankur A Patel, Dawood Sayed, Ashley Bailey-Classen, Ashley Comer, Benjamin Gill, Kiran Patel, Alaa Abd-Elsayed, Natalie Strand, Jonathan M Hagedorn, Zohra Hussaini, Nasir Khatri, Ryan Budwany, Melissa Murphy, Dan Nguyen, Vwaire Orhurhu, Morteza Rabii, Douglas Beall, Stephen Hochschuler, Michael E Schatman, Timothy Lubenow, Richard Guyer, Ahmed M Raslan
Journal of Pain Research, 24 October 2023; pp 3559-3568
Open Access
Abstract
Introduction
The evolution of treatment options for painful spinal disorders in diverse settings has produced a variety of approaches to patient care among clinicians from multiple professional backgrounds. The American Society

of Pain and Neuroscience (ASPN) Best Practice group identified a need for a multidisciplinary guideline regarding appropriate and effective informed consent processes for spine procedures.

Objective

The ASPN Informed Consent Guideline was developed to provide clinicians with a comprehensive evaluation of patient consent practices during the treatment of spine pathology.

Methods

After a needs assessment, ASPN determined that best practice regarding proper informed consent for spinal procedures was needed and a process of selecting faculty was developed based on expertise, diversity, and knowledge of the subject matter. A comprehensive literature search was conducted and when appropriate, evidence grading was performed. Recommendations were based on evidence when available, and when limited, based on consensus opinion.

Results

Following a comprehensive review and analysis of the available evidence, the ASPN Informed Consent Guideline group rated the literature to assist with specification of best practice regarding patient consent during the management of spine disorders.

Conclusion

Careful attention to informed consent is critical in achieving an optimal outcome and properly educating patients. This process involves a discussion of risks, advantages, and alternatives to treatment. As the field of interventional pain and spine continues to grow, it is imperative that clinicians effectively educate patients and obtain comprehensive informed consent for invasive procedures. This consent should be tailored to the patient's specific needs to ensure an essential recognition of patient autonomy and reasonable expectations of treatment.

FIGO best practice guidance in surgical consent

Special Article

E. Goknur Topcu, Phil McClenahan, Koketso Pule, Hajra Khattak, S. Eda Karsli, Marijo Cukelj, Akaninyene E. Ubom, Esraa Algurjia, Kubra Ozpinar, Yotin Ramon Perez, Rashid Bunu, Leopoldo S. Sanabria, Francisco J. R. Portilla, Elizabete Pumpure, Priyankur Roy, Paul Fogarty

International Journal of Gynecology & Obstetrics, 14 October 2023

Abstract

Obtaining medical consent preoperatively is one of the key steps in preparing for surgery, and is an important step in informed decision making with the patient. According to good medical practice guidelines, doctors are required to have the knowledge and skills to treat patients as well as inform them, respect their wishes, and establish trust between themselves and their patients. Valid consent includes elements of competence, disclosure, understanding, and voluntariness. Documentation of these elements is also very important. The International Federation of Gynecology and Obstetrics (FIGO) Education Communication and Advocacy Consortium (ECAC) has realized that the quality of consent varies considerably across the world and has developed simple guidelines regarding consent and procedure-specific checklists for the most common obstetric and gynecological procedures.

Knee'd To Know Basis: Informed Consent in Total Hip and Knee Arthroplasty

Commentary

Kevin C. Chang, Benjamin Hershfeld, Peter B. White, Randy M. Cohn, Michael A. Mont, Adam Bitterman

The Journal of Arthroplasty, 9 October 2023

Abstract

Informed consent is the process by which a medical provider explains the benefits, risks, and alternatives to a proposed medical intervention. It is a crucial part of maintaining patient autonomy and is particularly important in the context of elective surgical procedures, such as joint arthroplasty. The goal of this article is to review the topic of informed consent in the context of total joint arthroplasty. In this review, we discuss informed consent in general, considerations for informed consent in general arthroplasty procedures, and special twelve considerations for both hip and knee arthroplasty.

Pathways to informed choices: The impact of freedom of choice and two-sided messages on psychological reactance and vaccination intentions among individuals who express concerns

Author links open overlay panelToni Claessens, Simone Krouwer, Heidi Vandebosch, Karolien Poels

Vaccine, 6 October 2023; 41(42) pp 6272-6280

Abstract

Background

Reducing the spread of infectious diseases through vaccination faces the challenge of vaccine hesitancy: referring to questions, concerns and doubts arising when making a vaccine-related decision. A motivational state often arising within people exposed to health messages supporting informed decision making is psychological reactance, functioning as a driver to behavior opposed to the one recommended through the health message. Hence, there is a pressing need for communication strategies effective in counteracting reactance to health messages.

Methods

This study tested two communication strategies that can potentially reduce psychological reactance and ameliorate evaluations of the message and subsequent behavioral vaccination intentions in the context of COVID-19. These were: (1) explicitly reminding individuals of their freedom of choice (to either accept or refuse the vaccine) and (2) providing a two-sided message, including, apart from evidence-based information on the necessity of vaccines, a set of concerns, and questions (about the vaccines) which are refuted immediately. A total of 234 participants who indicated having concerns about the COVID-19 vaccine participated in a 2 (freedom of choice: no choice vs. choice) × 2 (message sidedness: one-sided vs. two-sided) between-subjects online experiment where they received an informational brochure about COVID-19 vaccination.

Results

The results show that emphasizing freedom of choice significantly increased perceived credibility of the message, perceived information utility, and ultimately, vaccination intentions. A decrease in psychological reactance mediated these effects. Message sidedness did only show a significant direct effect on perceived information utility. No interaction effect was found.

Conclusion

These findings indicate the importance of freedom of choice in reducing psychological reactance, which in its turn can lead to an increase of positive message evaluations and vaccination intentions among individuals who express concerns. The opportunities of message sidedness as an efficacious vaccination communication strategy should be further investigated.

Informed choice and routinization of the second-trimester anomaly scan: a national cohort study in the Netherlands

Research

Eline E.R. Lust, Kim Bronsgeest, Lidewij Henneman, Neeltje Crombag, Caterina M. Bilardo, Elsbeth H. van Vliet-Lachotzki, Robert-Jan H. Galjaard, Esther Sikkel, Monique C. Haak & Mireille N. Bekker

BMC Pregnancy and Childbirth, 26 September 2023; 23(694)

Open Access

Abstract

Background

Since 2007 all pregnant women in the Netherlands are offered the second-trimester anomaly scan (SAS) in a nationwide prenatal screening program. This study aims to assess the level of informed choice of women opting for the SAS and to evaluate the presence of routinization 16 years after its implementation. It further explores decisional conflict and women's decision making.

Methods

This prospective national survey study consisted of an online questionnaire which was completed after prenatal counseling and before undergoing the SAS. Informed choice was measured by the adapted multidimensional measure of informed choice (MMIC) and was defined in case women were classified as value-consistent, if their decision for the SAS was deliberated and made with sufficient knowledge.

Results

A total of 894/1167 (76.6%) women completed the questionnaire. Overall, 54.8% made an informed choice, 89.6% had good knowledge, 59.8% had deliberated their choice and 92.7% held a positive attitude towards the SAS. Women with low educational attainment ($p=0.004$) or respondents of non-Western descent ($p=0.038$) were less likely to make an informed choice. Decisional conflict was low, with a significantly lower decisional conflict score in women that made an informed choice ($p<0.001$). Most respondents (97.9%) did not perceive pressure to undergo the SAS.

Conclusions

Our study showed a relatively low rate of informed choice for the SAS, due to absence of deliberation. Therefore, some routinization seem to be present in the Netherlands. However, most women had sufficient knowledge, did not perceive pressure and experienced low decisional conflict.

Navigating Informed Consent and Patient Safety in Surgery: Lessons for Medical Students and Junior Trainees

August A. Culbert, Alejandro Bribriesco, Michael S. O'Connor, Eric Kodish

The Journal of Clinical Ethics, Fall 2023; 34(4)

Abstract

In the operating room, patient safety is of paramount importance. Medical students and junior trainees, despite their primary role as students, may play active roles in assessing patient safety and reporting suspected errors. Active consent is one layer of patient safety that is continuously assessed by several team members. This article examines an instance where patient consent may have been violated. Through the lens of trainee and senior perspectives, we discuss the ethical principles at stake and provide recommendations for medical student and junior trainee involvement in patient care when an error is suspected.

Midshaft clavicle fractures treatment: proposal of informed consent for a shared-treatment decision

Remo Goderecci, Stefano Di Filippantonio, Norman Ciprietti, Alessio Ciuffoletti

Lo Scalpello, August 2023

Abstract

Fractures of clavicle frequently occur in young active patients and the middle-third of the shaft is the most involved segment. Traditionally mid-shaft clavicle fractures have been treated mainly non-operatively. The literature of the first decade of the 2000s strongly supported a routine indication of surgical treatment for the fracture of this segment, resulting in a clear change of attitude compared to previous years. However, most recent systematic reviews demonstrated an uncertain superiority of surgery over conservative treatment in the acute management of these fractures. In fact, both types of treatment can result in complications that need to be balanced for the individual patient in order to determine the best indication; in addition, increasing attention is being given to the patient's involvement in the decision-making process for the therapeutic choice, which also influences final treatment satisfaction. Herein, we propose an informed consent that is clearly understandable to the patient in which all the points relating to the two types of treatment (conservative vs surgical) are discussed: from a review of the literature, we report the factors and relative percentages that can influence the final result. We believe that this document can be a useful tool in

the clinic for an informed and shared choice of treatment with the patient suffering from a fracture of the middle third of the clavicle, potentially influencing surgical practice from a legal point of view.

Editor's note: Lo Scalpello is published by the Italian Journal of Orthopaedics and Traumatology.

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GENERAL/OTHER

Green bioethics, patient autonomy, and informed consent in health care

Original Research

David B Resnik, Jonathan Pugh

Journal of Medical Ethics, 13 October 2023

Abstract

Green bioethics is an area of research and scholarship that examines the impact of health care practices and policies on the environment and emphasizes environmental values, such as ecological sustainability and stewardship. Some green bioethicists have argued that health care providers should inform patients about the environmental impacts of treatments and advocate for options that minimize adverse impacts. While disclosure of information pertaining to the environmental impacts of treatments could facilitate autonomous decision-making and strengthen the patient-provider relationship in situations where patients have clearly expressed environmental concerns, it may have the opposite effect in other situations if it serves to make patients feel like they are being judged or manipulated. We argue, therefore, that there is not a generalizable duty to disclose environmental impact information to all patients during the consent process. Providers who practice green bioethics should focus on advocating for system-level changes in health care financing, organization, and delivery and use discretion when bringing up environmental concerns in their encounters with patients.

Animal products in neurosurgery – navigating informed consent

Review Article

Patrick Donnelly, Rui Soares, Andy Eynon, Paul Grundy, Andrew Durnford

British Journal of Neurosurgery, 21 September 2023

Abstract

Informed consent is an ethical and legal requirement integral to modern surgical practice. Clinicians have a duty to consider, disclose and discuss risks and concerns relevant to an individual patient. With medical advances there are now a significant number of animal-derived products and adjuncts available for use in modern neurosurgical practice, which may be relevant when consenting patients for specific procedures if such products are used. This paper highlights commonly used products in neurosurgery that contain animal-derived constituents with the aim of facilitating an informed discussion between the neurosurgeon and patient. We have reviewed the commonly used products in the centres of the authors and their commercial equivalents. The product information is taken from the manufacturer's instructions or the Federal Drug Administration documents regarding the product. Animal products commonly available to neurosurgeons can be broadly categorised into haemostatic agents, dural substitutes, dural sealants and bone cements. Many products contain a variety of animal (or human) derived products. In order to ensure informed consent and shared decision making, it is important to establish any relevant patient beliefs or views regarding the use of animal-derived products. Given the wide availability and use of neurosurgical adjuncts containing human or animal derived products, coupled with the heterogeneity within ethnic, religious, and social groups, each patient must be approached individually to ensure patient-specific concerns are identified and alternatives offered when appropriate.

Stop agonising over informed consent when researchers use crowdsourcing platforms to conduct survey research

Jonathan Lewis, Vilius Dranseika, Søren Holm

Clinical Ethics, 2023; 18(4)

Abstract

Research ethics committees and institutional review boards spend considerable time developing, scrutinising, and revising specific consent processes and materials for survey-based studies conducted on crowdsourcing and online recruitment platforms such as MTurk and Prolific. However, there is evidence to suggest that many users of ICT services do not read the information provided as part of the consent process and they habitually provide or refuse their consent without adequate reflection. In principle, these practices call into question the validity of their consent. In this paper we argue that although the ‘no read problem’ and the routinisation of consent may apply to research participants’ consent practices for studies on crowdsourcing platforms, this is not a serious problem. Furthermore, given that the informational requirements for informed consent in these contexts are minimal, we argue that these participants are, nevertheless, sufficiently informed to give valid consent. We conclude that research ethics committees and institutional review boards should only agonise over the precise details of the informed consent process and materials in those rare cases where appreciable risks to research participants need to be managed.

Consent

Book Chapter

Elizabeth Groeneveld, Carrie Rentschler

Rethinking Women's and Gender Studies, 2023 [Routledge]

Abstract

This chapter examines liberal, affirmative, and critical consent frameworks that inform constructions of this term, after a review of the circulation of consent as a keyword in Women's and Gender Studies (WGS). Feminist theory starts from the premise that social relationships are, by-and-large, unequal, critiquing liberal models of consent precisely for their failures to address power. Many feminists have critiqued the liberal model of consent for its failures to address structural conditions of oppression along the axes of gender, race, class, age, and ability, all of which shape the very conditions. The focus of the affirmative consent model on the negotiation of mutual pleasure and the setting of limits in sexual situations—an ideal many of us do invest in—when codified into law may serve the criminal justice system more than anyone else. In contrast to affirmative consent, critical, ethical, and trauma-informed consent practice reveals power as something that is both always present and something that can be negotiated in relationship.

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

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