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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

December 2023 :: Issue 60

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

In preparing this digest, we monitor a broad range of academic journals and utilize *Google Scholar* to search articles broadly capturing informed consent and 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 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:

Content Type/Subject Areas	Page
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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.

SPOTLIGHT ARTICLES

This month we are spotlighting **The Lived Experience of Pediatric Gene Therapy - A Scoping Review** by Kimberly et al. In this *Human Gene Therapy* article the authors assess empirical research examining the lived experience of both patients and caregivers participating in pediatric gene therapy trials. Their scoping review underscores a serious gap in the literature leading to an examination of narrative accounts from trial participants and their families, and areas where further research in necessary. The authors note that:

> [p. 4]
> "…When making a decision about whether to enroll a child in a GT clinical trial, caregivers must weigh factors such as: the inability for most treatments to be repeated or re-dosed; uncertainty around the durability, efficacy, and safety of an experimental treatment; risk of a child's disease progressing if they wait for an approved treatment or more safety data; and efficacy of existing approved alternative treatments… The confluence of these factors within a high-stakes decision-making framework creates a unique ethical context for pediatric rare disease patients and their parents and caregivers. The progressive nature of many of these diseases also adds a time constraint to participation…
>
> [p. 16]
> The field of pediatric GT research… has an important and timely opportunity to better understand how patients and their parents/caregivers choose whether or not to consider GT, and their lived experience of participating in clinical trials. Pediatric patients' own perspectives are almost completely absent from the literature, marking an important area for future research efforts. Such insights from further research will inform more patient- and family-centered clinical trial design and can help to ensure that clinical trial design and implementation reflect patients' and families' values, their priorities, and their goals for care. This scoping review lays a foundation for future research in this space."

The Lived Experience of Pediatric Gene Therapy - A Scoping Review

Laura Kimberly, Cara Hunt, Katherine Beaverson, Emma James, Alison Bateman-House, Richard McGowan, Jennifer DeSante-Bertkau

Human Gene Therapy, 15 November 2023

Abstract

Little is known about patients' and families' lived experience of participating in pediatric gene therapy (GT) clinical trials. Currently, pediatric GT research targets a broad range of indications—including rare and ultra-rare diseases—which vary in severity and in the availability of alternative therapies. Pediatric GT differs meaningfully from adult GT because the decision to participate involves a dyad of both the child and parent or caregiver/s. It is critical to understand patients' and caregivers' perceptions and experiences of the social, emotional, physical, and logistical burdens or benefits of participating in such trials, and how they weigh and prioritize these factors when deciding whether to participate. We conducted a scoping review of the current literature in this subject area with objectives to a) provide an overview of existing literature, b) identify gaps and areas for further research, and c) better understand the lived impact of pediatric GT research on patients and their parents/caregivers. , Four themes emerged, including 1) weighing risks and benefits 2) timing of GT trial participation 3) value of clear communication, and 4) potential impact on quality of life. Notably, our sample surfaced articles about how patients/parents/caregivers were thinking about GT – their understanding of its safety, efficacy, and risks – rather than accounts of their experiences, which was our initial intention. Nevertheless, our findings offer useful insights to improve the informed consent process and promote a more patient- and family-centered approach. Moreover, our findings can contribute to patient advocacy organizations' efforts to develop educational materials tailored to patients' and families' expressed informational needs and perspectives, and can inform more patient- and family-centered policies from GT clinical trial sponsors.

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BIOMEDICAL RESEARCH

Navigating Informed Consent Requirements and Expectations in Cluster Randomized Trials: Research Ethics Board Members' and Researchers' Views

Anita Ho, Soodabeh Joolaee, Michael McDonald, Don Grant, Michel M White, Holly Longstaff, Eirikur Palsson

Ethics of Human Research, November-December 2023

Abstract

Informed consent is a cornerstone of ethical human research. However, as cluster randomized trials (CRTs) are increasingly popular to evaluate health service interventions, especially as health systems aspire toward the learning health system, questions abound how research teams and research ethics boards (REBs) should navigate intertwining consent and data-use considerations. Methodological and ethical questions include who constitute the participants, whose and what types of consent are necessary, and how data from people who have not consented to participation should be managed to optimize the balance of trust in the research enterprise, respect for persons, the promotion of data integrity, and the pursuit of the public good in the research arena. In this paper, we report the findings and lessons learned from a qualitative study examining how researchers and REB members consider the ethical dimensions of when data can be collected and used in CRTs in the evolving research landscape.

Altered stakes: Identifying gaps in the informed consent process for psychedelic-assisted therapy trials

Tahlia R. Harrison

Journal of Psychedelic Studies, 20 November 2023

Abstract

Background and aims

Psychedelic-assisted therapy (P-AT) has been shown to reduce post-traumatic stress disorder (PTSD), depression, and anxiety symptoms, and is likely to be approved in the United States (US) in the coming years. However, concerns about participant safety in these early trials have surfaced, including allegations of sexual misconduct. This paper aims to illuminate how potential risks have been communicated to P-AT participants via informed consent documents and to suggest how existing policy might be modified given the unique risks involved in P-AT trials.

Methods

Publicly available informed consent forms (ICFs) were gathered by searching clinicaltrials.gov. Queries were applied to filter trials involving the use of a classical psychedelic (psilocybin, LSD) or psychedelic-adjacent substance (MDMA, ketamine) in tandem with psychotherapeutic intervention and those with a status of "completed," "recruiting," or "active."

Results

Nineteen ICFs met inclusion criteria and were reviewed to determine what risks, benefits, and safety protocols were communicated to participants in their respective trials. The primary finding from this review of ICFs from P-AT trials revealed that studies were in compliance with federal regulation. However, there were missing elements related to the vulnerability experienced while under the effects of psychedelics that warrant inclusion in future ICFs in P-AT trials.

Conclusion

Although the ICFs for P-AT trials examined in this study covered several important areas related to risk, benefits, safety, and accountability as required by federal regulations in the US, future research should consider ways to expand this content in order to assure that consent is truly informed prior to enrolling subjects.

Optimizing treatment expectations and decision making through informed consent for psychotherapy: A randomized controlled trial

Leonie Gerke, Franz Pauls, Sönke Ladwig, Sarah Liebherz, Klaus Michael Reininger, Levente Kriston, Manuel Trachsel, Martin Härter, Yvonne Nestoriuc

Journal of Consulting and Clinical Psychology, 16 November 2023

Abstract

Objective

The objective of this research was to determine the efficacy and safety of an optimized informed consent (OIC) consultation for psychotherapy.

Method

We performed a randomized controlled superiority online trial involving 2 weeks of treatment and 3 months of follow-up. One hundred twenty-two adults with mental disorders confirmed by structured interview currently neither in out- nor inpatient psychotherapy (mean age: 32, gender identity: 51.6% female, 1.6% diverse), were randomized. Participants received an information brochure about psychotherapy for self-study (treatment as usual [TAU]; n = 61) or TAU plus a one-session OIC utilizing expectation management, contextualization, framing, and shared decision making (n = 61). The primary outcome was treatment expectations at 2-week follow-up.

Results

At 2-week follow-up, participants receiving OIC showed more positive treatment expectations compared to those receiving TAU only (mean difference: 0.70, 95% CI [0.36, 1.04]) with a medium effect size (d = 0.73). Likewise, OIC positively influenced motivation (d = 0.74) and adherence intention (d = 0.46). OIC entailed large effects on reduction of decisional conflict (d = 0.91) and increase of knowledge (d = 0.93). Participants receiving OIC showed higher capacity to consent to treatment (d = 0.63) and higher satisfaction with received information (d = 1.34) compared to TAU. No statistically significant group differences resulted for expected adverse effects of psychotherapy. Results were maintained at 3-month follow-up. Data sets for n = 10 cases (8.2%) were missing (postassessment n = 4, 2-week n = 6, 3-month follow-up n = 8).

Conclusions

Explaining to patients how psychotherapy works via a short consultation was effective in strengthening treatment expectations and decision making in a nonharmful way. Further trials clarifying whether this effectively translates to better treatment outcomes are required. (PsycInfo Database Record (c) 2023 APA, all rights reserved).

Informed Consent among Clinical Trial Participants with Different Cancer Diagnoses

Research Article

Connie M. Ulrich, Sarah J. Ratcliffe, Camille J. Hochheimer, Qiuping Zhou, Liming Huang, Thomas Gordon, Kathleen Knafl, Therese Richmond, Marilyn M. Schapira, Victoria Miller, Jun J. Mao, Mary Naylor, Christine Grady

AJOB Empirical Bioethics, 3 November 2023

Abstract

Importance

Informed consent is essential to ethical, rigorous research and is important to recruitment and retention in cancer trials.

Objective

To examine cancer clinical trial (CCT) participants' perceptions of informed consent processes and variations in perceptions by cancer type.

Design and Setting and Participants

Cross-sectional survey from mixed-methods study at National Cancer Institute–designated Northeast comprehensive cancer center. Open-ended and forced-choice items addressed: (1) enrollment and informed consent experiences and (2) decision-making processes, including risk-benefit assessment. Eligibility: CCT participant with gastro-intestinal or genitourinary, hematologic-lymphatic malignancies, lung cancer, and breast or gynecological cancer (N = 334).

Main Outcome Measures

Percentages satisfied with consent process and information provided; and assessing participation's perceptions of risks/benefits. Multivariable logistic or ordinal regression examined differences by cancer type.

Results

Most patient-participants felt well informed by the consent process (more than 90% overall and by cancer type) and. most (87.4%) reported that the consent form provided all the information they wanted, although nearly half (44.8%) reported that they read the form somewhat carefully or less. More than half (57.9%) said that talking to research staff (i.e., the consent process) had a greater impact on participation decisions than reading the consent form (2.1%). A third (31.1%) were very sure of joining in research studies before the informed consent process (almost half of lung cancer patients did—47.1%). Most patients personally assessed the risks and benefits before consenting. However, trust in physicians played an important role in the decision to enroll in CCT.

Conclusions and Relevance

Cancer patients rely less on written features of the informed consent process than on information obtained from the research staff and their own physicians. Research should focus on information and communication

strategies that support informed consent from referring physicians, researchers, and others to improve patient risk-benefit assessment and decision-making.

Effects of same-day consent vs delayed consent on the recruitment and retention of trial participants—an observational SWAT

Methodology

M. Elfghi, F. Jordan, S. Sultan, W. Tawfick

Trials, 25 October 2023

Open access

Abstract

Background and aim

The recruitment process in a randomized trial can be challenging. Poor recruitment can have a negative impact on the allocated budget and estimated completion date of the study and may result in an underpowered study. We aimed to perform a Study Within A Trial (SWAT) to evaluate the impact of same-day consent or delayed consent on recruitment and retention in the host trial.

Methods

This SWAT is designed as a prospective cohort design. The host trial was a randomized controlled trial evaluating the effectiveness of an intensive lifestyle modification programme in participants with peripheral arterial disease. Researchers screened the participants for inclusion and exclusion criteria. Informed consents were obtained from the participants who were willing to participate in the study on a standardized consent form. Participants were given the option to consent on the same day or to delay their consent. Following the consent, the participants were allocated to two groups (same-day consent vs. delayed consent) based on pre-determined criteria for SWAT. One hundred sixteen participants were consented to take part in the host trial. Seventy-five participants were randomized to the host trial. The primary outcome was the proportion of participants who withdrew consent at the recruitment phase. Secondary outcomes were reasons for consent withdrawal and dropout, attrition rate, and adherence with the host trial intervention.

Results

There was a significantly lower consent-withdrawal rate in same-day consent (17.4%, n = 8/46), compared to the delayed consent group (47.1%, n = 33/70), p = 0.001. There was a significantly lower dropout rate in participants randomized following same-day consent (10.5%, n = 4/38), compared to those randomized after delayed consent (29.7%, n = 11/37), p = 0.038. Transport was the main reason mentioned for consent withdrawal and dropout. In participants randomized to the host trial intervention arm, there was a significant difference in adherence (percentage of the 12-week programme completed) between same-day consent (96.7% ± 4.9) and delayed consent participants (86.4% ± 11.2), p = 0.003, as well as number of weeks completed (mean difference = − 1.547, 95% confidence intervals (− 2.237 to − 0.85)), p = 0.02.

Conclusion

This SWAT found evidence that participants who gave consent on the same day seemed to have better adherence and fewer-withdrawal and dropout rates.

Editor's note: A SWAT is a "study within a trial".

A Systems Approach to Improving Clinical Trial Informed Consent Forms in Lung Cancer Clinical Trials

Conference Paper

B. King-Kallimanis, T. Chihuri, A. Ferris, U. BasuRoy

Precision Language In Thoracic Oncology, 11 September 2023

Abstract

Introduction

The informed consent form (ICF) literature is filled with ideas about how to aid potential trial participants in making informed choices. Yet, ICFs continue to grow in length with increased trial complexity and remain dense documents. In our review of lung cancer ICFs presented at WCLC 2022, we reported that these ICFs did not meet the regulatory requirement of being written at an 8th grade reading level. Building on that work we explored, from a systems perspective, the barriers to implementing a patient-centric addendum summarizing key information to the ICF.

Methods

We solicited key stakeholder feedback in three stages to understand barriers and facilitators to creating an addendum. Three stages of work are described. 1. Industry roundtable; Presentation of our earlier work to eight companies followed by a discussion of potential barriers to implementing an addendum. 2. One-on-one research stakeholder interviews; 15 interviews including IRB chairs, legal/compliance advisors, regulators, bioethicists, research nurses and principal investigators. Each interview explored the stakeholder's role in developing/using ICFs, information selection, and improving the ICF. 3. Patient/Caregiver online survey; open to patients and caregivers living with lung cancer. Participants were asked to read 13 regulatory requirements for ICFs and rank the six most important to them, and provide their preferences regarding the presentation of information.

Results

Industry stakeholders generally supported an addendum to the ICF. However, they raised concerns regarding how "key information" would be selected and not be perceived as "cherry picking". This concern was raised because of internal efforts of attendees when creating summaries to accompany the ICF for their own trials. In the research stakeholder one-on-one interviews, participants involved in developing ICF language expressed a desire for a standardized form. There was no agreement on the creation of an addendum; some participants argued it is yet another document for review while others supported its creation. One participant succinctly described the addendum as analogous to the patient leaflet for prescribed medications. Surveyed patients and caregivers indicated a strong preference for information to be presented in bullet format (67%). Most participants ranked, as their first preference, the requirement of being told "What will happen during the study" (Figure).

Conclusions

Previous studies identifying methods to help with comprehension of ICFs have gone mostly ignored. By taking a systems approach through leveraging key stakeholder feedback to learn of hidden barriers, we want to ensure patients are making an informed choice to participate in clinical trials.

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SOCIAL SCIENCE RESEARCH

Proactively tailoring implementation: the case of shared decision-making for lung cancer screening across the VA New England Healthcare Network

Research

Abigail N. Herbst, Megan B. McCullough, Renda Soylemez Wiener, Anna M. Barker, Elizabeth M. Maguire, Gemmae M. Fix

BMC Health Services Research, 22 November 2023

Open Access

Abstract

Background

Shared Decision-Making to discuss how the benefits and harms of lung cancer screening align with patient values is required by the US Centers for Medicare and Medicaid and recommended by multiple organizations. Barriers at organizational, clinician, clinical encounter, and patient levels prevent SDM from meeting quality standards in routine practice. We developed an implementation plan, using the socio-

ecological model, for Shared Decision-Making for lung cancer screening for the Department of Veterans Affairs (VA) New England Healthcare System. Because understanding the local context is critical to implementation success, we sought to proactively tailor our original implementation plan to address barriers to achieving guideline-concordant lung cancer screening.

Methods

We conducted a formative evaluation using an ethnographic approach to proactively identify barriers to Shared Decision-Making and tailor our implementation plan. Data consisted of qualitative interviews with leadership and clinicians from seven VA New England medical centers, regional meeting notes, and Shared Decision-Making scripts and documents used by providers. Tailoring was guided by the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS).

Results

We tailored the original implementation plan to address barriers we identified at the organizational, clinician, clinical encounter, and patient levels. Overall, we removed two implementation strategies, added five strategies, and modified the content of two strategies. For example, at the clinician level, we learned that past personal and clinical experiences predisposed clinicians to focus on the benefits of lung cancer screening. To address this barrier, we modified the content of our original implementation strategy *Make Training Dynamic* to prompt providers to self-reflect about their screening beliefs and values, encouraging them to discuss both the benefits and potential harms of lung cancer screening.

Conclusions

Formative evaluations can be used to proactively tailor implementation strategies to fit local contexts. We tailored our implementation plan to address unique barriers we identified, with the goal of improving implementation success. The FRAME-IS aided our team in thoughtfully addressing and modifying our original implementation plan. Others seeking to maximize the effectiveness of complex interventions may consider using a similar approach.

Developing a person-centred care environment aiming to enhance the autonomy of nursing home residents with physical impairments, a descriptive study

Research

Jolande van Loon, Meriam Janssen, Bienke Janssen, Ietje de Rooij, Katrien Luijkx

BMC Geriatrics, 15 November 2023

Open Access

Abstract

Background

Enhancing autonomy is important within the context of the care environment in nursing homes. A nursing home is a place for older adults with physical impairments, who need assistance, to live and where staff work who help them to exercise autonomy. Previous research shows that older adults and staff are influenced by the care environment to apply autonomy-enhancing activities. Therefore, organisational policies regarding the care environment seem promising for enhancing autonomy. The aim is to gain a deeper insight into the development and implementation of organisational policies aimed to enhance the autonomy of older adults with physical impairments.

Methods

A qualitative descriptive design was chosen, using two methods. A document study was conducted on the policies, plans and proceedings in two care organisations. Moreover, interviews were conducted with 17 stakeholders involved in the policies, such as managers and members of the client council. The fragments of the 137 documents and 17 verbatim transcripts were coded and deductively categorised into the seven aspects (i.e., power-sharing, supportive organisational systems, appropriate skill mix, potential for innovation and risk-taking, the physical environment, effective staff relationships and shared decision-making systems) of the key domain care environment, as defined in the person-centred practice (PCP) framework developed by McCormack and McCance.

Results

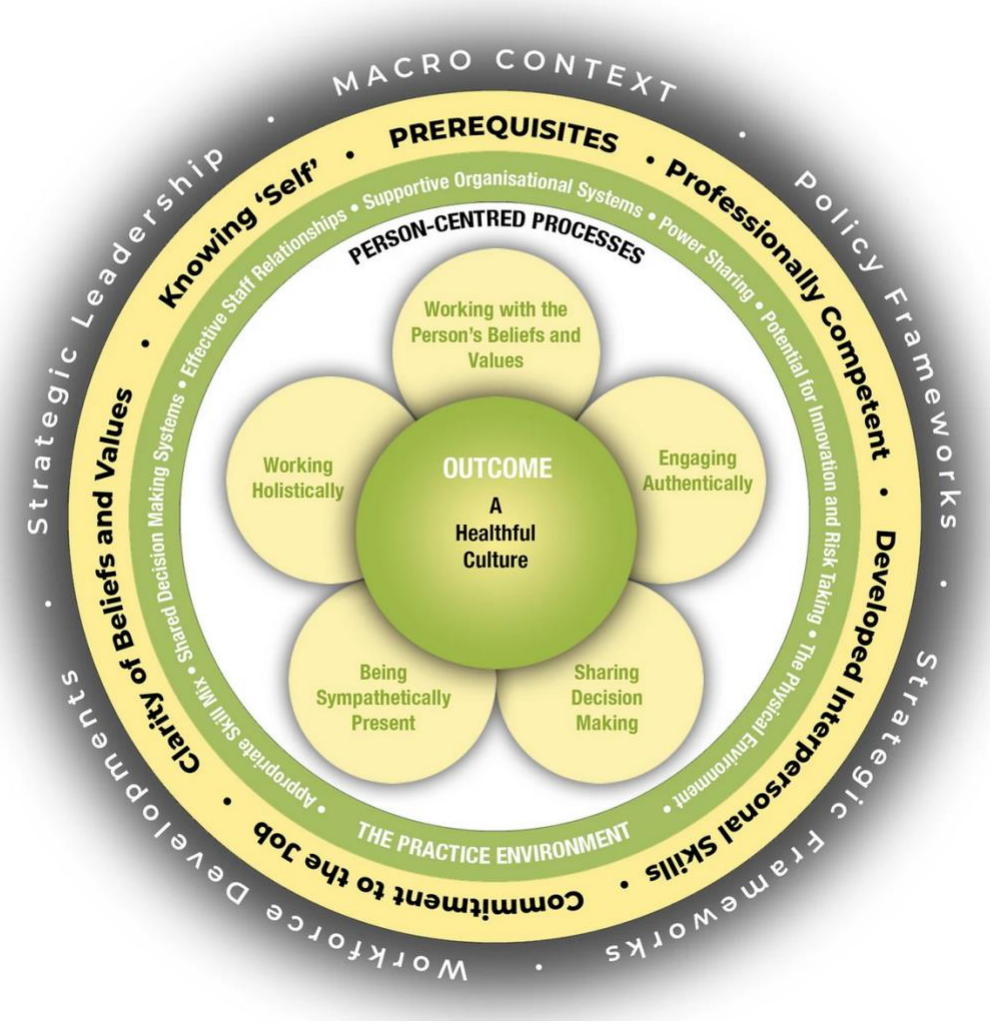
The aspect of power-sharing was used the most in the policies of the two participating organisations. The organisations expected much from the implementation of indirect interventions, such as access to the electronic care plan for residents and the development of staff towards self-managing teams. Less attention was paid to interventions in the physical environment, such as the interior of the building and privacy, and the collaboration processes between staff.

Conclusions

The PCP framework poses that all aspects of the key domain care environment are important to develop a person-centred practice. This is not yet the case in practice and the authors therefore recommend using all seven aspects of the care environment in a balanced combination with the other key domains of the PCP framework to achieve person-centred practice and as a result the enhancement of the autonomy of nursing home residents with physical impairments.

Fig. 1

From: Developing a person-centred care environment aiming to enhance the autonomy of nursing home residents with physical impairments, a descriptive study



Person-centred Practice framework. Retrieved from The Centre for Person-centred Research practice (CPCPR) of Queen Margaret University Edinburgh. Reused with permission from McCormack & McCance

Protecting Personhood: A Classic Grounded Theory

Research Article

Amélia Didier, Alvita Nathaniel, Helen Scott, Susanne Look, Lazare Benaroyo, Maya Zumstein-Shaha

Qualitative Health Research, 5 September 2023

Open Access

Abstract

The importance of perceiving and considering patients as healthcare partners has been increasingly promoted. Healthcare systems around the world are now highly interested in patient engagement, participation, collaboration, and partnership. Healthcare professionals are advised that patients, as autonomous beings, should be active in and responsible for a portion of their own care. The study presented here focused on patients' perceptions of interprofessional collaboration. It was conducted using the classic grounded theory methodology. The theory of protecting personhood emerged as the core concept of hospitalized patients, cared for by interprofessional healthcare teams. This theory encapsulates the process hospitalized patients go through to find balance in their sense of self, oscillating between personhood and patienthood in the unfamiliar hospital environment. The process consists of four stages: the stage of introspection, during which hospitalized patients become aware of their self as a person and as a patient; the stage of preservation, when patients find a balance between the sense of personhood and patienthood; the stage of rupture, wherein patients experience an imbalance between their sense of personhood and patienthood; and the stage of reconciliation, in which personhood is restored. The theory of protecting personhood offers insights into a better understanding of hospitalized patients' experiences and strategies, revealing the importance of relationships, and the driving force of empowerment. This study is about patients' perspectives of interprofessional healthcare teams. A grounded theory process allowed the emergence of patients' concerns and expectations, leading to a substantive theory grounded in the patients' data.

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GENOMIC MEDICINE/GENE EDITING

Ambivalence and regret in genome sequencing

Editorial

Alisdair McNeill

European Journal of Human Genetics, 21 November 2023

Excerpt

…Consent conversations relating to genome sequencing for children are recognised as being potentially problematic. Given the vast number of potential outcomes of genome sequencing (e.g. no diagnosis, incidental finding), it has been disputed if 'informed' consent can be achieved. A qualitative study of medical geneticists views on consent for genome sequencing in paediatrics provides useful insights. One view was that truly informed consent for genome sequencing in paediatrics is not possible. The need for more genetics professionals and better information resources for families was recognised. A further issue around informed consent in genetics is around that of reuse of genetic information and data in research projects…

Consumer Genetics: What About Informed Consent?

Research Article

Matt Artz, Doug Henry, Carolina Severiche Mena

Human Organization, 17 November 2023; 82(4) pp 394–404

Abstract

With the dramatic rise in Direct-to-Consumer Genetics has come increasing concern for the potential abuse of consumer health data, often presumed confidential. Companies exchange and monetize their customers' DNA in a competitive marketplace, obtaining consent through complex legal contracts that consumers must sign. However, drawing on ethnographic data, we show that this consent is rarely "informed." Particular concerns include lack of contractual knowledge, misunderstanding of the potential benefits and risks, privacy, and low genetic literacy.

> *Editor's note: Human Organization is the Journal of the Society for Applied Anthropology, "*founded in 1941 to promote the investigation of the principles of human behavior and the application of these principles to contemporary issues and problems..

Uncertain futures and unsolicited findings in pediatric genomic sequencing: guidelines for return of results in cases of developmental delay

Research

BMC Medical Ethics, 11 November 2023

Candice Cornelis, Wybo Dondorp, Ineke Bolt, Guido de Wert, Marieke van Summeren, Eva Brilstra, Nine Knoers, Annelien L. Bredenoord

Open Access

Abstract

Background

Massively parallel sequencing techniques, such as whole exome sequencing (WES) and whole genome sequencing (WGS), may reveal unsolicited findings (UFs) unrelated to the diagnostic aim. Such techniques are frequently used for diagnostic purposes in pediatric cases of developmental delay (DD). Yet policy guidelines for informed consent and return of UFs are not well equipped to address specific moral challenges that may arise in these children's situations.

Discussion

In previous empirical studies conducted by our research group, we found that it is sometimes uncertain how children with a DD will develop and whether they could come to possess capacities for autonomous decision-making in the future. Parents sometimes felt this brought them into a Catch-22 like situation when confronted with choices about UFs before undergoing WES in trio-analysis (both the parents' and child's DNA are sequenced). An important reason for choosing to consent to WES was to gain more insight into how their child might develop. However, to make responsible choices about receiving or declining knowledge of UFs, some idea of their child's future development of autonomous capacities is needed. This undesirable Catch-22 situation was created by the specific policy configuration in which parents were required to make choices about UFs before being sequencing (trio-analysis). We argue that this finding is relevant for reconfiguring current policies for return of UFs for WES/WGS and propose guidelines that encompass two features. First, the informed consent process ought to be staged. Second, differing guidelines are required for withholding/disclosing a UF in cases of DD appropriate to the level of confidence there is about the child's future developmental of autonomous capacities.

Conclusion

When combined with a dynamic consent procedure, these two features of our guidelines could help overcome significant moral challenges that present themselves in the situations of children undergoing genomic sequencing for clarifying a DD.

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HEALTH DATA/DATA

Preferences for onward health data use in the electronic age among maternity patients and providers in South Africa: a qualitative study

LeFevre A, Welte O, Moopelo K, Tiffin N, Mothoagae G, Ncube N, Gwiji N, Shogole M, Slogrove AL, Moshani N, Boulle A, Goudge J, Griffiths F, Fairlie L, Mehta U, Scott K, Pillay N

Sexual and Reproductive Health Matters, 20 November 2023; 31(4)

Abstract

Despite the expanding digitisation of individual health data, informed consent for the collection and use of health data is seldom explicitly sought in public sector clinics in South Africa. This study aims to identify perceptions of informed consent practices for health data capture, access, and use in Gauteng and the Western Cape provinces of South Africa. Data collection from September to December 2021 included in-depth interviews with healthcare providers (n = 12) and women (n = 62) attending maternity services. Study findings suggest that most patients were not aware that their data were being used for purposes beyond the individualised provision of medical care. Understanding the concept of anonymised use of electronic health data was at times challenging for patients who understood their data in the limited context of paper-based folders and booklets. When asked about preferences for electronic data, patients overwhelmingly were in favour of digitisation. They viewed electronic access to their health data as facilitating rapid and continuous access to health information. Patients were additionally asked about preferences, including delivery of health information, onward health data use, and recontacting. Understanding of these use cases varied and was often challenging to convey to participants who understood their health data in the context of information inputted into their paper folders. Future systems need to be established to collect informed consent for onward health data use. In light of perceived ties to the care received, these systems need to ensure that patient preferences do not impede the content nor quality of care received.

Enhancing the reuse of health data for research purposes: laws and regulations as pillars of trust

R Verheij, E B Van Veen

European Journal of Public Health, 24 October 2023

Abstract

Background

Routinely recorded health data are increasingly used for research purposes and indispensable to stimulating appropriate and sustainable health care. In many countries access to data has proven to be a challenge. Trust by researchers, organisations and the general public is key, and adherence to the rule of law is one of the key elements determining that trust. We investigated the laws and regulations regarding the reuse of health data and how they work out practically for researchers.

Methods

Our study focuses on France, Finland, Denmark, Germany, England and The Netherlands. We investigated consent mechanisms, the possibilities of record linkage, and how the sharing of data for research purposes was organised, with a combination of desk research and interviews with researchers in these countries.

Results

All countries investigated except England are subject to the General Data Protection Regulation. However, explicit consent is the default in Germany and the Netherlands, while other countries maintain an opt-out system or even a system of neither consent nor opt-out. A central data access authority is in place in all countries investigated except Germany and the Netherlands. The nature and level of detail of data varies widely.

Conclusions

GDPR does not dictate a specific modality for the reuse of data. In terms of the reuse of health data, Germany and the Netherlands are lagging. The Netherlands seems to be the only country with continuing discussions about consent modalities. A broader societal debate about the balance between trust and the reuse of health data is needed, also against the background of a European Health Data Space. In the

Netherlands, widespread government distrust is one of the challenges. Options to counteract this distrust will be discussed.

Blockchain Based Dynamic Consent Management Systems for Enhancing Quality of Life for People with Disabilities

Conference Paper

Muhammad Irfan Khalid, Mansoor Ahmed

IEEE International Smart Cities Conference, September 2023

Abstract

This research investigates the potential impact of dynamic consent management systems (DCMSs) on individuals with disabilities (PwDs). An extensive literature review found a lack of discussion regarding using advanced tools like blockchains to give PwDs control over their data in smart cities. Our study aims to fill this gap by demonstrating how blockchain-based DCMSs can improve the quality of life (QoL) for people with disabilities. We present a conceptual model that showcases the feasibility of using dynamic consent management systems to enhance the quality of life (QoL) for people with disabilities. This model emphasizes the importance of managing consent choices during their participation in research or data sharing with third parties. Using blockchain-based DCMSs, PwDs can securely exercise their data rights, maintaining privacy while enabling researchers to conduct their work. Existing works in dynamic consent management systems utilizing blockchain technology focus on security and privacy but do not address the unique needs of PwDs or their QoL. Our proposed model illustrates how blockchain-based DCMSs can positively impact people with disabilities's quality of life. We advocate for adopting advanced tools and techniques to fully implement these models, ensuring tailored solutions for PwDs' specific requirements.

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CAPACITY TO CONSENT

Reproductive psychiatric advance directives: promoting autonomy for perinatal people with serious mental illness diagnoses

Original Article

Emily C. Dossett, Sonja L. Castañeda-Cudney, Michelle T. Nguyen, Melisa Olgun, Jennifer Wang, Keris Jän Myrick, Laurie Hallmark, Elyn R. Saks

Archives of Women's Mental Health, 10 November 2023

Open Access

Abstract

People with serious mental illness (SMI) diagnoses who become pregnant are particularly vulnerable to symptom recurrence and resulting potential lack of decision-making capacity (Taylor et al. J Psychiatr Res 104:100-107, 2018; Bagadia et al. Int J Soc Psychiatry 66:792-798, 2020). In these situations, prenatal and behavioral health providers have little legally viable guidance on what medical and/or psychiatric care the patient desires (Aneja and Arora Indian J Med Ethics V:133-139, 2020). We created a “Reproductive Psychiatric Advance Directive (PAD),” grounded in Reproductive Justice principles, that promotes patient autonomy by proactively articulating perinatal medical and psychiatric care preferences. We conducted a medical and legal literature review using two sets of terms related to (1) PADs and (2) reproductive health. We convened an expert working group of legal, medical, psychiatric, peer, and advocacy leaders and community-based organizations to develop a Reproductive PAD. Our literature review yielded no results about Reproductive PADs. We created de novo a Reproductive PAD template with sections on medical and psychiatric history, informed consent for critical medical and psychiatric care, family planning and custody

preferences, and optional sections on abortion and on electroconvulsive therapy. The Reproductive PAD provides a possible legal mechanism for people of childbearing age with SMI diagnoses to articulate their medical and psychiatric care choices around reproduction and pregnancy. Future research should evaluate the Reproductive PAD as an effective tool for protecting patient autonomy during pregnancy and postpartum and guiding medical and psychiatric providers.

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YOUNG PERSONS

Childhood vaccine refusal and what to do about it: a systematic review of the ethical literature

Kerrie Wiley, Maria Christou-Ergos, Chris Degeling, Rosalind McDougall, Penelope Robinson, Katie Attwell, Catherine Helps, Shevaun Drislane, Stacy M Carter

Research

BMC Medical Ethics, 8 November 2023

Open Access

Abstract

Background

Parental refusal of routine childhood vaccination remains an ethically contested area. This systematic review sought to explore and characterise the normative arguments made about parental refusal of routine vaccination, with the aim of providing researchers, practitioners, and policymakers with a synthesis of current normative literature.

Methods

Nine databases covering health and ethics research were searched, and 121 publications identified for the period Jan 1998 to Mar 2022. For articles, source journals were categorised according to Australian Standard Field of Research codes, and normative content was analysed using a framework analytical approach.

Results

Most of the articles were published in biomedical journals (34%), bioethics journals (21%), and journals that carry both classifications (20%). Two central questions dominated the literature: (1) Whether vaccine refusal is justifiable (which we labelled 'refusal arguments'); and (2) Whether strategies for dealing with those who reject vaccines are justifiable ('response arguments'). Refusal arguments relied on principlism, religious frameworks, the rights and obligations of parents, the rights of children, the medico-legal best interests of the child standard, and the potential to cause harm to others. Response arguments were broadly divided into arguments about policy, arguments about how individual physicians should practice regarding vaccine rejectors, and both legal precedents and ethical arguments for vaccinating children against a parent's will. Policy arguments considered the normative significance of coercion, non-medical or conscientious objections, and possible reciprocal social efforts to offset vaccine refusal. Individual physician practice arguments covered nudging and coercive practices, patient dismissal, and the ethical and professional obligations of physicians. Most of the legal precedents discussed were from the American setting, with some from the United Kingdom.

Shared decision-making between paediatric haematologists, children with sickle cell disease and their parents: an exploratory study

Ricardo Wijngaarde, Mijra Koning, Karin Fijnvandraat, Dirk Ubbink

European Journal of Pediatrics, 31 October 2023

Open access

Abstract

Children with sickle cell disease (SCD) face various healthcare choices to be made during the disease process that may impact their lives. Shared decision-making (SDM) could improve their health outcomes. We assessed if, and to what extent, paediatricians engage children with SCD and/or their parents in the decision-making process. In this observational cross-sectional study, paediatric SCD patients and their parents visiting the outpatient paediatrics clinic of a university hospital participated in a SDM baseline measurement. Two evaluators independently and objectively analysed the level of patient involvement in decision-making from the audio-recordings of the consultations using the OPTION-5 instrument, a 0–20-point scale from which scores are usually expressed as a percentage of ideal SDM. The level of SDM, as perceived by patients, parents and paediatricians, was appreciated using the SDM-Q-9 and SDM-Q-Doc questionnaires, respectively. Scores could range from 0% (no SDM) to 100% (exemplary SDM). Twenty-four consultations in which a decision needed to be made about SCD treatment were audiotaped and analysed; six were from each paediatrician. The group consisted of 17 male and 7 female patients from various cultural backgrounds between 2 and 17 years old, with a mean age of 9.4 years (SD 4.2). Median OPTION-5 scores were 25.0% [IQR] 20.0–40.0%; range 0–55%). Median SDM-Q-9 and SDM-Q-Doc scores were 56.7% (IQR 39.4–88.9%) and 68.9% (IQR 57.8–77.8%), respectively.

Conclusion

Although subjective scores of SDM were fair, the objectively scored level of SDM among children suffering from SCD leaves room for improvement. This may be realized by increasing knowledge about the benefits of SDM, child-centred SDM interventions and SDM-training for paediatricians that takes into account the complexity of intercultural challenges and risk communication between stakeholders.

Ethical Considerations for Engaging Children and Adolescents Living with HIV in Research in African Countries: A Systematic Review

Emma Gillette, Winstone Nyandiko, Ashley Chory, Michael Scanlon, Josephine Aluoch, Nandini Choudhury, Daniel Lagat, Celestine Ashimosi, Whitney Biegon, Dennis Munyoro, Janet Lidweye, Jack Nyagaya, Ilene Wilets, Allison DeLong, Rami Kantor, Rachel Vreeman, Violet Naanyu

Journal of Empirical Research on Human Research Ethics, 23 October 2023

Abstract

Research engaging children and adolescents living with HIV (CALWH) is critical for youth-friendly services and HIV care, and researchers need to ensure that such engagement is ethical. We conducted a systematic review to identify key ethical considerations for the engagement of CALWH in research. The review focused on primary research articles conducted in African countries that examined ethical issues in CALWH engaged in research. Ten studies met the inclusion criteria; the following seven key domains were extracted: 1) justifications for engaging CALWH in research; 2) community involvement; 3) informed consent/assent; 4) caregiver involvement; 5) perceptions of benefits; 6) perception of the risks of involvement; and 7) confidentiality. These domains can inform the ethical engagement of CALWH in research.

Ethical and Legal Nuances in Child and Adolescent Mental Health

Book Chapter

Pratibha Gehlawat, Tanu Gupta

Handbook of Research on Child and Adolescent Psychology Practices and Interventions, 2023 [IGI Global]

Abstract

Child and adolescent psychiatry are mainly concerned with the diagnosis and treatment of mental disorders in child and adolescent populations. The children are vulnerable and their ability to understand matters related to their well-being is restricted. Common ethical issues in children and adolescents include assent, consent, autonomy, confidentiality, justice, and equity. The chapter discusses ethical issues as well as the difficulties faced in following ethics. The chapter outlines the summary of the existing laws pertaining to

children and adolescents in India including the basic rights and criminal responsibility. The laws related to child and adolescent mental health are discussed in detail. The provisions related to treatment of minors under Mental Health Care Act, 2017 is discussed along with the critical appraisal. Critical appraisal of other relevant laws/Acts allied to children and adolescent mental health is discussed. The need for formal training of all mental health professionals regarding the laws and acts of the land is also highlighted.

Young Children as Co-Researchers: Authentic Partnership in an Early Childhood Context

Book Chapter

Catherine Kelly, Fionnuala Waldron, Thérèse Dooley

Pushing the Boundaries of Human Rights Education, 2023 [Routledge]

Abstract

Under Article 12 of the United Nations Convention on the Rights of the Child (UNCRC), children have the right to express their views freely and to have those views given due consideration in accordance with their age and maturity; this right also applies in the context of research. Premised on changing conceptions of children and childhoods and on the impact of Article 12 of the UNCRC, the active participation of children in research has become standard practice for researchers whose work is focused on children's lives and the complex nature of such practice is well-documented. However, age remains a limiting factor and less attention has been given to the idea of very young children as co-researchers and to the methodological and ethical tensions that might ensue from such an approach. Guided by a children's rights framework, this chapter examines the idea of engaging with young children (5–6 years) as co-researchers in a classroom context. Ultimately, the chapter argues that, while the idea of children as co-researchers in the context of early childhood education is a challenging one, through the use of innovative approaches which prioritise children's participation, perceived barriers relating to age and maturity can be substantially overcome, resulting in research findings that are grounded in children's perspectives and experiences.

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TECHNOLOGY/OTHER MEDIATION

Digital and paper consent errors

Rohin Wong, Mohammad Iqbal Hussain, Simon Toh, Christopher Rao, Edward R St John

British Journal of Surgery, 8 November 2023

Excerpt

Over 300 million patients undergo an operation globally each year. The content (risks, benefits, alternatives) discussed with the patient is important to enable them to make the correct informed decision about their treatment options. The consent form is used to document the informed consent process. However, current consent practice and documentation are variable, and permit human errors of recall, incomplete form filling, and illegible handwriting, which can lead to inadequate shared decision-making, misunderstanding, complaints, and litigation. Expenditure on litigation owing to an inadequate consent process has increased across multiple healthcare systems. For example in England, UK, the number of claims and total annual spend related to failure to warn dealt with by NHS Resolution was 128 cases and €28 125 911 in 2011 versus 248 and €91 729 270 in 2021.

Digital consent has been proposed as a solution to address the challenges associated with standard paper-based consent because it improves shared decision-making and enables a bespoke informed consent process. It also facilitates the transition to paperless electronic health records, which is an increasing requirement of many global healthcare providers.

Previous systematic reviews have demonstrated that patient comprehension and satisfaction are improved by digital compared with paper-based consent. However, there has not been any synthesized evidence evaluating the impact of digital consent on error rates and standardization of informed consent. These factors were explored in the present analysis by comparing the error rates of standard paper-based and digital consent…

Evaluation of an audio-visual informed consent procedure in a diagnostic tuberculosis trial

Luis Gómez Paciello, Floryn Schippers, Ana Aguiar, Cecile Magis

European Respiratory Journal, January 2023

Abstract

Background

In line with the End Tuberculosis (TB) Strategy of the World Health Organization a diagnostic study, PriNose NCT0440732, has started in Paraguayan prisons. Due to high illiteracy among persons deprived of liberty (PDL) and low educational attainment, an audio-visual message was developed and incorporated in the informed consent (IC) procedure. The aim of this study is evaluating the experience and thoughts on the IC procedure in a vulnerable population from multiple viewpoints.

Objectives

1. Evaluation of the participants' thoughts and experience on the IC procedure. 2. Evaluation of the user experience of the IC procedure.

Methods

Inclusion strategy: convenience sampling by face-to-face request, directly after completion of the IC procedure of the PriNose study. Separate written ICs were obtained. Semi-structured interview guides with 11 integrated true/false questions and Likert scales were used for in depth face-to-face interviews with respectively the PDL and the volunteers, lasting on average 22 minutes. Cyclic thematic inductive analysis with open and axial coding of data in ATLAS.ti v.22 followed.

Results

A total of 22 PDL and 4 volunteers, (Males; mean age: 31.8 years (Sd: 11.8)), were included from penitentiary institution 'Emboscada'. Preliminary data analysis presented 3 main themes: improving disease knowledge, importance of selfcare in relation to health and level of information comprehension. Final analysis and interpretation will follow soon.

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CULTURAL/COUNTRY CONTEXT

A Conduit for a Culturally Competent Consent: Medical Interpreters' Perspectives on Surgical Informed Consent Discussions

Original Study

Benjamin G. Allar, Cristina Ponce, James Wallace, Gezzer Ortega, Amanda J. Reich, Shari Gold-Gomez, Sidhu P. Gangadharan, Tara S. Kent

Annals of Surgery, 22 November 2023

Abstract

Objective

To understand medical interpreter's perspectives on surgical informed consent discussions and provide feedback for surgeons on improving these conversations.

Summary Background Data

Informed consent is a critical component of patient-centered surgical decision-making. For patients with limited English proficiency (LEP), this conversation may be less thorough, even with a medical interpreter, leaving patients with an inadequate understanding of their diagnosis or treatment options.

Methods

A semi-structured interview guide was developed with input from interpreters and a qualitative research expert. We purposively sampled medical interpreters representing multiple languages until thematic saturation was achieved. Participants discussed their experience with the surgical consent discussion and process. Interview transcripts were analyzed using emergent thematic analysis.

Results

Among 22 interpreters, there were ten languages represented and an average experience of 15 years (range 4-40 y). Four major themes were identified. First, interpreters consistently described their roles as patient advocates and cultural brokers. Second, interpreters reported unique patient attributes that influence the discussion, often based on patients' cultural values/expectations, anticipated decisional autonomy, and family support. Third, interpreters emphasized the importance of surgeons demonstrating compassion and patience, using simple terminology, conversing around the consent, providing context about the form/process, and initiating a pre-encounter discussion. Finally, interpreters suggested reducing legal terminology on consent forms and translation into other languages.

Conclusions

Experienced interpreters highlighted multiple factors associated with effective and culturally tailored informed consent discussions. Surgeons should recognize interpreters' critical and complex roles, be cognizant of cultural variations among patients with LEP, and improve interpersonal and communication skills to facilitate effective understanding.

A Survey on Applying Ethics of Informed Consent Among Egyptian Surgeons

Original Article

Omneya Ibrahim Mohamed, Rasha Ismail Khedr, Hend Mostafa Ali, Saffa Abdelaziz Mohamed Abdelaziz

Mansoura Journal of Forensic Medicine & Clinical Toxicology, 21 November 2023

Abstract

Surgical informed consent (SIC) is a fundamental part of safe clinical practice. SIC is an outcome of a proper informative process between surgeons and patients. The current study aimed to assess SIC-related practices among Egyptian surgeons. A self-administered questionnaire was formulated upon review of available literature and surgeons were invited to submit their responses electronically. 97 Egyptian surgeons participated in the study. Participants less than 40 years old represented 85.6% and 91.8% had less than 20 years' experience. Most surgeons (83.6%) had postgraduate qualifications, 38.1% were consultants. Upon analysis of responses, it was found that 73.2% of the surgeons didn't consider non-obtaining valid SIC an error. Regarding SIC practices, it was found that 82.5% of surgeons informed patients of all the possible risks, 75.3% of participants emphasized expected surgical outcomes and 70.1% ensured that patients understood the relevant information. 63.9% of surgeons explained the drawbacks of the procedure's refusal. Also, 63.9% of surgeons documented SIC elements. Alternative treatment strategies were provided by 62.9% of participants. Regarding scoring of these six SIC practices, the median score was 5. Male surgeons had significantly higher median scores compared to females (p=0.003). Higher scores were observed among those less than 40 years old, consultants and those with doctorate degrees. The study concluded that a high percentage of participating surgeons didn't appreciate the relationship between non-obtaining valid SIC and malpractice. However, the participants' practices of SIC elements were generally good. Current results highlighted need to raise surgeons' awareness of ideal SIC practices.

Editor's note: Mansoura Journal of Forensic Medicine & Clinical Toxicology is published by the Department of Forensic Medicine and Clinical Toxicology, Faculty of Medicine, Mansoura University, Egypt.

Knowledge, attitude, and practice regarding informed consent among dental professionals in Madina City, Saudi Arabia: A cross-sectional study

Original Article

Hussein Koura, Ahmad A. Al-Fraidi, Wasseem Abdulhameed Alzemei

Journal of Orthodontic Science, November 2023; 12(1)

Abstract

Aim

The aim of this study was to assess the knowledge, attitude, and practice (KAP) of dental professionals regarding informed consent (IC) in Madina City.

Methods

A descriptive cross-sectional design using a self-administered questionnaire was conducted. The questionnaire was tested for validity and reliability before it was distributed using Google Forms through WhatsApp among a sample of 299 dental professionals working in Madina City. IBM Statistical Package for Social Sciences (SPSS) version 26 was used for analysis.

Results

Two-hundred ninety-nine responses were collected. Sixty percent scored less than the group average regarding knowledge, and 52% scored less than the group average regarding attitude. Regarding practice, 57% scored below the group average. Saudi dentists and those who work in the Ministry of Health (MOH) had better knowledge scores than other tested groups. Dentists working in the MOH had better attitude and practice scores than those who work in the private sector. Regarding attitude and practice, consultants achieved better scores than registrars and general dentists. More than 90% indicated that the main reason for obtaining an IC is to protect themselves from legal actions.

Conclusion

The KAP of surveyed dental professionals in Madina is suboptimal and needs improvement.

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RIGHTS/LEGAL/LEGISLATIVE

Early experiences of deemed consent legislation for organ donation in Nova Scotia: a qualitative study

Reports of Original Investigations

Robin Urquhart, Jessica Vickery, Cynthia Kendell, Jade Dirk, Stephen Beed

Canadian Journal of Anesthesia, 20 November 2023

Abstract

Purpose

In 2021, Nova Scotia, Canada, became the first jurisdiction in North America to adopt a deemed consent organ donation system under its revised Human Organ and Tissue Donation Act. This study sought to understand the early experiences of program staff and clinicians involved in implementing this legislation.

Methods

We conducted semistructured interviews with members of the provincial organ donation program and intensive care unit and emergency department clinicians (n = 14). Two investigators coded transcripts of interviews, then categorized the coded data into themes.

Results

We identified four key themes: 1) legislation has limited impact on daily practice; 2) legislation does not address existing barriers; 3) legislation aids conversations with donor families; and 4) legislation should provide more autonomy to patients and families, not less.

Conclusion
Deemed consent legislation had limited impact on clinician's day-to-day practices, because of lack of infrastructure changes and infrequent donation opportunities. Nevertheless, participants felt the introduction of deemed consent in Nova Scotia eased conversations between families of potential donors and clinicians. These findings should be used to inform ongoing implementation of deemed consent and be considered by those contemplating similar legislative changes.

Our "WMA Declaration of Helsinki": Opinions and Proposals from Patient and Public for Research Ethics

Book Chapter
Chieko Kurihara, Keiko Inoue, Hiroto Kai, Katsura Suzuki, Haruko Saeki, Yoshikazu Funabashi, Noriko Kishi, Akemi Kuge, Toshie Murakami, Yoshiko Saito, Eiko Uchida, Naoki Tsutsumi, Kyoko Imamura
Ethical Innovation for Global Health, November 2023 [Springer]
Abstract

The Declaration of Helsinki (DoH) was first issued in 1964 by the World Medical Association (WMA), addressed to physicians, and was amended nine times with the latest version being adopted in 2013. While it has been incorporated into research regulations in many countries and is well known to most researchers, most patients and the public see its title for the first time when they are requested to participate in medical research. We therefore formed a group composed mainly of patients and the public together with experts having perspectives of patients and the public. Our activity was intended to enhance our understanding of the DoH and to have it explained in our own language. In this way, patients and the public would be able to better comprehend its scope and contents.

This chapter is resulting from about 2 years of our monthly web-meetings, during COVID-19 pandemic. We found some discussion points not included in the current version of the DoH, such as the value of research aimed at Sustainable Development Goals (SDGs), patient and public involvement, multidisciplinary collaboration, shared decision-making founded on informed consent, patient-oriented research, diversity and fairness of research ethics committees, assuring the rights of those considered to be "vulnerable populations," broad informed consent, dynamic consent, and social contract.

We hope that this chapter will contribute to the future revision of the DoH, as well as stimulate discussion for the international research ethics norms being under development, and that can be agreed to uniformly by all relevant stakeholders.

The British Transplantation Society guidelines on ethics, law and consent in relation to deceased donors after circulatory death

Review article
Greg Moorlock, Ellie Asgari, Chris Callaghan, Heather Draper, Peter Dupont, Patty Gilbert, David Nasralla, Peter Veitch, Chris Watson, Stephen O'Neill
Transplantation Reviews, 26 October 2023
Highlights

- UK nations have moved to deemed consent organ donation systems.
- 'Overall benefit' should be the guiding principle for decisions about end-of-life care in relation to organ donation.
- The patient's wishes, especially strength of those wishes, play a significant role in determining what is of overall benefit.

Abstract

The British Transplantation Society (BTS) 'Guideline on transplantation from deceased donors after circulatory death' has recently been updated and this manuscript summarises the relevant recommendations from chapters specifically related to law, ethics, donor consent and informing the recipient.

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MEDICAL/SURGICAL

Informed consent or empowered collaboration

Book Chapter
Samuel J. Knapp, Randy Fingerhut
Practical ethics for psychologists: A positive approach; 2024, [American Psychological Association]
Abstract
Informed consent is the legal and ethical obligation to give information to patients or research participants before they initiate assessment, treatment, or participation in a study. Informed consent procedures reflect respect for patient autonomy. Psychologists should respect the autonomy of their patients except for very narrow circumstances, such as when patients are incapable of giving consent or the lives of individuals are at stake. This chapter discusses these exceptions. It reviews basic information about informed consent and special issues that may arise in couples, family, or group therapy or in supervised services. It describes some ways that psychotherapists can embed respect for patient autonomy beyond the traditional informed consent process. It also covers the desirability of obtaining assent to promote greater participation from individuals who are not legally capable of giving informed consent. In addition, the chapter considers options when patients appear unable to participate in decisions about treatment.

The illusion of explanatory depth in patient consent

Correspondence
George Rarichan, Stephen Bacchi, Aashray Gupta, Weng Onn Chan
Eye, 22 November 2023
Excerpt
Ullrich et al. highlight the importance of informed consent discussions with patients, especially when considering vitreoretinal surgeries and eye removal procedures, where the risk of sympathetic ophthalmia may be a material consideration. Consent with respect to sympathetic ophthalmia can be a vital topic which can be further elucidated with patients through understanding of the concept of the "illusion of explanatory depth".

The illusion of explanatory depth refers to the tendency of individuals to overestimate their understanding of complex concepts, which has important implications for the informed consent process, especially in intricate medical contexts like vitreoretinal surgery and the risk of developing sympathetic ophthalmia. Informed consent is a fundamental ethical principle, especially entailing patients' entitlement to a thorough comprehension of the potential risks and benefits of a procedure. Understanding how this cognitive bias may influence both patients and doctors may enrich the consent process. For example, this bias may mean that patients feel they have a greater understanding of a procedure and risks, than they truly do. Similarly, a doctor may feel they have a greater understanding of the circumstances and priority of a patient than is the case…

Not just for surgeons: A qualitative exploration of the surgical consent process

Therese M. Gardiner, Sharon Latimer, Jayne Hewitt, Brigid M. Gillespie
Collegian, 22 November 2023

Open Access

Abstract

Background

Obtaining consent for surgery is a legal requirement and a professional practice standard, but little is known about how nurses and other healthcare professionals (HCPs) engage with this process.

Aim

To describe operating room (OR) HCPs' perceptions of consent processes for adult patients undergoing planned surgery at one health service.

Methods

A qualitative exploratory design and purposive maximum variation sampling relative to age, discipline, experience, and role, were used to ensure broad perspectives were gathered. Semi-structured interviews with 17 OR HCPs were conducted between April and May 2021.

Findings

Thematic analysis identified three themes: the HCPs' role in verifying consent goes beyond the World Health Organization's Surgical Safety Checklist, effective communication is crucial for obtaining and verifying consent, and day-of-surgery delays and errors are multi-factorial.

Discussion

Production pressures in surgery can compromise consent processes, undermine communication, and impact patient safety in the OR.

Conclusion

HCPs verify more items than the World Health Organization Surgical Safety Checklist, suggesting the checklist may not go far enough when verifying consent in surgery.

Engaging Women in Decisions About Their Heart Health

Chapter

Krystina B. Lewis, Faria Ahmed, Sandra Lauck, Sandra Carroll, Dawn Stacey

Biology of Women's Heart Health, 19 November 2023 [Springer]

Abstract

Women living with cardiovascular disease face many health decisions throughout their journey. Most women want more information and greater involvement in decision-making about their health in partnership with their clinicians. Yet, facing these decisions can lead to a sense of personal uncertainty about the best course of action. The individualized and intentional communication offered by a shared decision-making approach is particularly important for women with cardiovascular disease, given the limited availability of scientific data about women regarding the risks and benefits for screening and treatment options, making the elicitation and incorporation of personal preferences and values in their decision-making critical. Further, sex and gender considerations are important in shared decision-making particularly as they are associated with various decision-making styles, communication styles, and values and preferences which can influence an individual's preferred option. In this chapter, we begin by providing a definition of shared decision-making and discuss the evidence related to women's involvement in health decisions, particularly for cardiovascular conditions. We present the evidence supporting interventions to facilitate shared decision-making in clinical practice such as patient decision aids, decision coaching and question prompt lists. Finally, we present considerations for shared decision-making implementation in clinical practice. Throughout, we highlight opportunities for meaningful patient engagement amidst the challenges of shared decision-making to achieve true patient-centered care for women living with cardiovascular disease.

Perioperative visual loss and consent for adult spine surgery: a national survey of the practice amongst spine surgeons and anaesthetists

Research Article

Marina Pitsika, Vasiliki-Maria Paschou, Rachel Pollard, Justin J. Nissen
British Journal of Neurosurgery, 9 November 2023
Abstract
Background
Perioperative Visual Loss (POVL) is a devastating complication for patients undergoing spine surgery. Consent process for POVL amongst spine surgeons and anaesthetist remains variable. The aim of this study is to evaluate their practice and views about it.
Methods
Two similar questionnaires were distributed to members of the Society of British Neurological Surgeons (SBNS), British Association of Spine Surgeons (BASS), and Neuroanaesthsia and Critical Care Society (NACCS).
Results
A total of 271 responses were received (SBNS/BASS n = 149, NACCS n = 122). Fewer surgeons considered POVL as a material risk for patients compared to the anaesthetists (57.7 versus 79.7%). Outpatient/pre-assessment clinics were considered as the optimal setting for discussing POVL by the majority of the clinicians (81.2 and 93.4%). POVL should be discussed by both specialists according to 75% of the anaesthetists. Estimated incidence of POVL was considered to be higher by the anaesthetists (0.03–0.2% by 63% of the anaesthetist versus 0.0001–0.004% by 57% of the surgeons). Twenty-three surgeons and 10 anaesthetists had a patient who suffered from POVL, which led to a change of practice in most of them. This questionnaire will lead to a change in practice/consent to 18.1% of the surgeons and 23.5% of the anaesthetists.
Conclusions
Most of the surgeons and anaesthetist feel that POVL is a material risk that ideally needs to be firstly discussed before the day of surgery, by both specialties. However, a significant number of clinicians have an opposite view. A national guidance from respective societies should encourage POVL to be discussed routinely.

Challenge of achieving truly individualised informed consent in therapeutic endoscopy

Original Research
Philip Berry, Sreelakshmi Kotha
Frontline Gastroenterology, 8 November 2023
Abstract
Objective
Guidance covering informed consent in endoscopy has been refined in the UK following the obstetric case of Nadine Montgomery, and in light of updated General Medical Council guidance. All risks likely to be material to the patient must be explored, as well as alternatives to the procedure. Despite this, departments and endoscopists still struggle to meet the current standards. In this article, we explore the challenges encountered in achieving individualised consent in therapeutic endoscopy through real-life scenarios.
Methods
Five realistic therapeutic endoscopy (hepatobiliary) scenarios are described, followed by presentation of possible or ideal approaches, with references related to existing literature in this field.
Results
The vignettes allow consideration of how to approach difficult consent challenges, including anxiety and information overload, urgency during acute illness, failure to disclose the risk of death, the role of trainees and intraprocedural distress under conscious sedation.
Conclusions
The authors conclude that a high degree of transparency is required while obtaining consent for therapeutic endoscopy accompanied by full documentation, involvement of relatives in nearly all cases, and clarity around the presence of trainees who may handle the scope. A greater focus on upskilling trainees in the consent process for therapeutic endoscopy is required.

A Scoping Review of Adverse Outcomes Associated With Cardiac Resynchronization Therapy Device Implantation: Implications for Informed Consent

John Mancini, Aanand Naik, Parag Goyal

Circulation, 6 November 2023

Abstract

Background/Objectives

Cardiac Resynchronization Therapy (CRT) is a treatment option for many adults with heart failure with reduced ejection fraction (HFrEF). While the benefits of CRT are well-established, the downstream implications of adverse events are not well-characterized. We sought to better understand the ramifications of CRT-related adverse events on length of hospital stay (LOS) and mortality—information relevant for patients and clinicians to make informed decisions about pursuing CRT.

Design

Scoping Review

Methods

We conducted an initial PubMed search using terms including “Congestive Heart Failure” or “Heart Failure” and "Cardiac resynchronization" or "Cardiac re-synchronization" or "Biventricular pacing.” We reviewed resulting articles that were written in English, studied CRT devices, and outlined adverse events related to CRT device placement. We separately searched PubMed for additional articles outlining individual adverse events identified using search terms “event name,” “mortality,” and “hospital stay.” We read articles and summarized data regarding the impact of reported adverse events on hospital LOS and mortality.

Results

Our search identified 18 full length articles with relevant data. The most common adverse events included device implant failure/non-response, lead dislodgment, coronary sinus dissection, and pocket hematoma. The LOS and mortality rates of each event are shown in Table 1. Of note, LOS for implantation in the ambulatory setting is up to 1 day; LOS for uncomplicated implantation during hospitalization is 4.6 days. Implantation during hospitalization with complication is mean 13.6 days.

Conclusion

While absolute risks for adverse events associated with CRT implantation are low, several have important implications on hospital LOS and mortality. These findings warrant inclusion in discussion regarding the risks of CRT when clinicians and patients engage in informed decision making related to CRT.

Developing an International Framework for Informed Consent in Plastic Surgery: A Focus on Cosmetic Breast Augmentation

Rodney D. Cooter, Louise A. Brightman, Anand Deva, Robert X. Murphy, Jr, Mikko Larsen, Ahmed Khashaba

Plastic & Reconstructive Surgery-Global Open, November 2023

Abstract

Background

Informed consent is a fundamental pillar of patient rights and is an essential part of good clinical practice. In 2019, the International Confederation of Plastic Surgery Societies launched a survey to collect feedback on informed consent practices, with an aim to develop an international guideline for cosmetic surgery

Methods

A 15-question survey was sent to delegates of the International Confederation of Plastic Surgery Societies for dissemination to their national society members. The survey comprised a range of quantitative and qualitative questions. Descriptive and thematic analysis was performed.

Results

There were 364 respondents. Over half of the respondents reported no local informed consent policy, whereas others noted national society, specialist college, or government policies. The majority of respondents believed that the performing surgeon should be responsible for obtaining informed consent with at least two face-to-face consultations. Most respondents agreed with a cooling-off period (duration based on procedure type and use of high-risk devices). Regarding cosmetic breast augmentation, the majority of respondents felt that the performing surgeon should be responsible for postoperative management, including cases that occur as part of surgical tourism. Some respondents incorporate financial consent as part of their informed consent practice. Most supported the development of an international informed consent guideline.

Conclusions

Informed consent should result from face-to-face consultations with the performing surgeon. There should be a minimum cooling-off period. Postoperative surveillance should be available in all settings. The findings of this survey will help inform an international standardized informed consent guideline for cosmetic surgery.

Consent to testing for brain death

Original research

Barry Lyons, Mary Donnelly

Journal of Medical Ethics, 25 October 2023

Abstract

Canada has recently published a new Clinical Practice Guideline on the diagnosis and management of brain death. It states that consent is not necessary to carry out the interventions required to make the diagnosis. A supporting article not only sets out the arguments for this but also contends that 'UK laws similarly carve out an exception, excusing clinicians from a prima facie duty to get consent'. This is supplemented by the claim that recent court decisions in the UK similarly confirm that consent is not required, referencing two judgements in Battersbee. We disagree with the authors' interpretation of the law on consent in the UK and argue that there is nothing in Battersbee to support the conclusion that consent to testing is not necessary. Where there is a disagreement about testing for brain death in the UK, court authorisation is required.

Birthing Consent: Supporting Shared Decision Making and Informed Consent in Labour and Childbirth

Book Chapter

Laura Pascoe

Consent: Gender, Power and Subjectivity, 2023 [Routledge]

Abstract

Labour and childbirth are vulnerable yet powerful experiences for birth givers. In an ideal world, women and other birth givers are active and informed participants in their care and their consent is sought throughout labour, birth, and postpartum by their health providers. Due to competing interests and the medicalization of childbirth, however, many birth givers are unprepared for the choices they may face or are unaware that the decisions presented to them are theirs to make. Highlighting the perspectives of midwives and doulas who take a normal and physiologic approach to birth, this chapter explores why informed consent in labour and childbirth is so important, what gets in the way of informed consent, and concrete strategies to best facilitate informed consent. In particular, this chapter examines how health providers and doulas can facilitate informed consent to ensure that no matter what the birth experience, birth givers feel respected, cared for, and heard.

Informed consent in surgical practice with patients' experiences: A cross-sectional study

Seda Kumru, Pakize Yiğit, Meryem Demirtaş, Hüseyin Fındık

Patient Experience Journal, 2023; 10(3) pp 42-48

Abstract

This study aims to evaluate patients' experiences and perspectives regarding informed consent in surgical practice. Data for this cross-sectional study were collected from 276 patients using a questionnaire developed by Falagas et al. Descriptive statistics were employed for all questions. Statistical tests such as the Mann-Whitney U test, Kruskal-Wallis test, and Spearman's rank correlation analysis were performed, and Cohen's effect sizes were reported. IBM SPSS 23.0 was used for all analyses, and $p<0.05$ was considered statistically significant. A high score on both The Delivered Information Index and The Patient-Physician Index represents a positive informed consent process. Among the participants, 65.2% indicated that they understood all parts of the consent form. Of all patients, 92.8% reported that information about the specific surgical procedure was provided by physicians. However, 47.5% of the patients reported that they did not feel comfortable with their surgeons. The mean score of the Delivered Information Index was 5.63 (2.38). The mean patient-physician relationship score was 14.38 (3.31). There was a moderate positive correlation between the delivered information index and the patient-physician relationship ($r=0.50$; $p<0.001$). In addition, there was a moderate positive correlation between the delivered information index and the time spent on the informed consent process, as well as between the patient-physician relationship and the time spent on the informed consent process ($r=0.52$; $r=0.40$, respectively). The study emphasized the lack of communication between patients and physicians, the limitation of information on treatment risks, adverse effects, and alternative treatment options.

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GENERAL/OTHER

Public health measures and the rise of incidental surveillance: Considerations about private informational power and accountability

Original Paper

B. A. Kamphorst, A. Henschke

Ethics and Information Technology, 16 November 2023

Open Access

Abstract

The public health measures implemented in response to the COVID-19 pandemic have resulted in a substantially increased shared reliance on private infrastructure and digital services in areas such as healthcare, education, retail, and the workplace. This development has (i) granted a number of private actors significant (informational) power, and (ii) given rise to a range of digital surveillance practices incidental to the pandemic itself. In this paper, we reflect on these secondary consequences of the pandemic and observe that, even though collateral data disclosure and additional activity monitoring appears to have been generally socially accepted as inevitable consequences of the pandemic, part and parcel of a larger conglomeration of emergency compromises, these increased surveillance practices were not directly justified by appeals to solidarity and public health in the same way that the instigating public health measures were. Based on this observation, and given the increased reliance on private actors for maintaining the digital space, we argue that governments have a duty to (i) seek and ensure that there are justifications for collateral data disclosure and activity monitoring by private actors in the context of (future) public health emergencies like the COVID-19 pandemic, and (ii) regulate and provide accountability mechanisms for and oversight over these private surveillance practices on par with governmental essential services that engage in surveillance activities.

Consent as Mechanism to Preserve Information Privacy: Its Origin, Evolution, and Current Relevance

Conference paper

Marietjie Botes

International Workshop on Security and Trust Management, STM 2023, 30 October 2023

Abstract

Informed consent and the requirements to obtain ethical-legal sound consent has a long and rich history that originated with the medical treatment of patients and then evolved into its application in the field of biomedical research. The same concepts and principles of consent has been adopted to be applied in the digital sphere. However, upon closer scrutiny it is clear why this principle, that originated for the protection of a person's bodily integrity cannot be adequately applied in the digital sphere to protect people's personal data. To the contrary it transpired that the ethical-legal requirements of consent has been made futile in the context of digital consent receipts by erroneously comparing and applying this concept to transactions receipts and commercial contracts. This paper investigates this evolution of biomedical consent to digital consent and analyze the difference between the concept of consent as it developed for biomedical application and compare that with the current application of consent in the digital sphere.

Consent: Legacies, Representations, and Frameworks for the Future

Book

Sophie Franklin, Hannah Piercy, Arya Thampuran, Rebecca White

Routledge, 2023

Abstract

Consent: Legacies, Representations, and Frameworks for the Future examines the conceptualisation of 'consent' across various historical periods, cultures, and disciplines to offer an expansive, pluralistic vision for future articulations of consent as it circulates throughout contemporary life in sexual encounters, medical contexts, and media representations.

This volume is distinctive in its diverse conceptual scope and commitment to cross-disciplinary dialogue, accommodating perspectives on consent that are contextually sensitive and culturally diverse. The chapters examine a range of topics, from socio-cultural engagements with consent in Latin American music, feminist movements in Pakistan, and BDSM in Poland, to theoretical and pedagogical ones exploring alternative possibilities for framing and understanding consent through intersectional approaches and institutional curricula.

Consent: Legacies, Representations, and Frameworks for the Future is of value to researchers, practitioners, undergraduate and postgraduate students, and general readers interested in histories, representations, and future possibilities of consent in its many manifestations.

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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].

No new relevant calls for public consultation identified.

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SYMPOSIA/CONFERENCES

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

No new symposia/conferences identified.

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