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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

June 2022

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.

Each month we monitor *Google Scholar* for the 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 and guidance beyond the journal literature globally. 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 each edition using subject categories to help readers navigate. We expect that these categories will evolve over time. Active subject areas in this edition include:

No new content was identified for the following established categories:

BIOBANKING
CAPACITY TO CONSENT
COMPASSIONATE USE/EXPANDED ACCESS
GENOMIC MEDICINE/GENE EDITING

HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH

Please note that we maintain a glossary, an inventory of tools for assessment, as well as standards and guidance documents on our website.

POLICY GUIDANCE/PROGRAM ACTION

Emergency use of unproven clinical interventions outside clinical trials: ethical considerations

Technical Document
World Health Organisation, 12 April 2022
Open Access
Introduction
Outbreaks and other events that may become public health emergencies frequently face a lack of safe and effective therapeutic or preventive interventions, such as drugs specific to the pathogen or condition. WHO and its partners therefore established the "WHO R&D blueprint" in 2016 to stimulate research into diseases or conditions that pose the greatest public health risks because of their epidemic potential or for which there are no or insufficient countermeasures (31). In response to the ethical duty to conduct research during public health emergencies (17), rapid, rigorous, simple clinical trials or other types of research (32, 33) are essential to establish the safety and efficacy of unproven interventions – including "off label" interventions (9) – and to discard those that are unsafe or ineffective to avoid their use in health systems. When a PHEIC is declared, "it is critical that the global research effort is rapid, robust, conducted at scale and coordinated across multiple countries" (33)…

Summary of ethical criteria

10. Individual informed consent	A qualified ethics committee should determine that the informed consent of individuals or the appropriate, authorized representative is properly obtained.
11. Community engagement	A ministry of health or other relevant authority should establish appropriate policies for community engagement to prevent social practices that may threaten the validity of adequate consent, such as overstatement of evidence and potential benefits, understatement of risk and uncertainties, undue promotion of unproven interventions, undue influence on the public and the medical community or exploitation of vulnerability.

Commentary

10. Individual informed consent	A qualified ethics committee should determine that the informed consent of individuals or their appropriate authorized representative is properly obtained.

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COVID-19

Patient consent preferences on sharing personal health information during the COVID-19 pandemic: "the more informed we are, the more likely we are to help"

Research
Sarah Tosoni, Indu Voruganti, Katherine Lajkosz, Shahbano Mustafa, Anne Phillips, S. Joseph Kim, Rebecca K. S. Wong, Donald Willison, Carl Virtanen, Ann Heesters, Fei-Fei Liu

BMC Medical Ethics, 20 May 2022; 23(53)

Open Access

Abstract

Background

Rapid ethical access to personal health information (PHI) to support research is extremely important during pandemics, yet little is known regarding patient preferences for consent during such crises. This follow-up study sought to ascertain whether there were differences in consent preferences between pre-pandemic times compared to during Wave 1 of the COVID-19 global pandemic, and to better understand the reasons behind these preferences.

Methods

A total of 183 patients in the pandemic cohort completed the survey via email, and responses were compared to the distinct pre-pandemic cohort (n = 222); all were patients of a large Canadian cancer center. The survey covered (a) broad versus study-specific consent; (b) opt-in versus opt-out contact approach; (c) levels of comfort sharing with different recipients; (d) perceptions of commercialization; and (e) options to track use of information and be notified of results. Four focus groups (n = 12) were subsequently conducted to elucidate reasons motivating dominant preferences.

Results

Patients in the pandemic cohort were significantly more comfortable with sharing all information and biological samples (90% vs. 79%, p = 0.009), sharing information with the health care institution (97% vs. 83%, p < 0.001), sharing information with researchers at other hospitals (85% vs. 70%, p < 0.001), sharing PHI provincially (69% vs. 53%, p < 0.002), nationally (65% vs. 53%, p = 0.022) and internationally (48% vs. 39%, p = 0.024) compared to the pre-pandemic cohort. Discomfort with sharing information with commercial companies remained unchanged between the two cohorts (50% vs. 51% uncomfortable, p = 0.58). Significantly more pandemic cohort patients expressed a wish to track use of PHI (75% vs. 61%, p = 0.007), and to be notified of results (83% vs. 70%, p = 0.012). Thematic analysis uncovered that transparency was strongly desired on outside PHI use, particularly when commercialization was involved.

Conclusions

In pandemic times, patients were more comfortable sharing information with all parties, except with commercial entities, where levels of discomfort (~ 50%) remained unchanged. Focus groups identified that the ability to track and receive results of studies using one's PHI is an important way to reduce discomfort and increase trust. These findings meaningfully inform wider discussions on the use of personal health information for research during global crises.

Equipoise, standard of care and consent: responding to the authorisation of new COVID-19 treatments in randomised controlled trials

Current controversy

Soren Holm, Jonathan Lewis, Rafael Dal-Ré

Journal of Medical Ethics, 13 May 2022

Open Access

Abstract

In response to the COVID-19 pandemic, large-scale research and pharmaceutical regulatory processes have proceeded at a dramatically increased pace with new and effective, evidence-based COVID-19 interventions rapidly making their way into the clinic. However, the swift generation of high-quality evidence and the efficient processing of regulatory authorisation have given rise to more specific and complex versions of well known research ethics issues. In this paper, we identify three such issues by focusing on the authorization of molnupiravir, a novel antiviral medicine aimed at reducing the ability of SARS-CoV-2 to multiply in the body, for clinical use by the National Health Service in England and the concomitant testing of molnupiravir through the large-scale Platform Adaptive trial of Novel antivirals for early treatment of COVID-19 In the Community randomized control trial. By analysing the ways in which the authorisation and clinical use of molnupiravir complicate standard approaches to clinical equipoise, standard of care and participant consent in the

PANORAMIC randomised control trial, we will explain some ethical implications for clinical trials that aim to study the efficacy and safety of new COVID-19 and other therapeutics when conditional authorisation has already been granted and when such treatments have already been made available to patients by national health providers.

E-Consent – an innovative solution to maintain recruitment momentum in clinical trials during the COVID-19 pandemic

R Almeida-Magana, J. Grierson, H. Maroof, R. Clow, E. Dineen, T. Al-Hammouri, N. Muirhead, C. Brew-Graves, J. Kelly, G. Shaw

European Urology, 2022

Abstract

Introduction & Objectives

The NeuroSAFE PROOF trial is an ongoing randomized clinical trial evaluating the role of frozen section analysis during robot assisted radical prostatectomy for localized prostate cancer. In response to the COVID-19 crisis, recruitment was halted, and a remote e-Consent solution was designed. The aim of this is to describe the implementation, impact on recruitment rate and patient's experience using e-Consent.

Materials & Methods

To replace in person consent. An email-based PDF Auto-Archiver feature was created within the Research Electronic Data Capture (REDCap®) environment, following the structure and content of the already approved paper consent. Each question was included as a binary (yes/no) field. An electronic signature field allows the participant to sign the document using a mouse, stylus, or their finger. The signature is captured and appended as a PNG image with a timestamp. This allows research staff to review and electronically co-sign and lock the document. This new tool was approved by the Health Research Authority, Research Ethics Committee, Trial Management Group and Sponsor. Owing to the process collecting patient identifiable data, the platform resides within the REDCap service being hosted behind a Data Safe Haven, which conforms to National Health Service Data Security & Protection Toolkit, General Data Protection Regulation and ISO 27001 Information Security standards.

Results

Before recruitment suspension, the trial was recruiting an average of 9 patients per month, with an increasing trend. (Figure 1) After e- Consent implementation in June 2020, 63 new patients (4/month) have been enrolled despite a second lockdown, none of whom would have been recruited using the old methods given restrictions on face-to-face consultations. Patients have given positive feedback on the use of the platform. The use of this pathway eliminates the need to travel and, therefore, the resultant cost and potential risk of infection, while allowing patients to read and understand information in their own time before providing consent. (Figure Presented)

Conclusions

Guidelines for e-Consent implementation are currently lacking. We present the first description of its use for prostate cancer research. This innovation was critical to resume recruitment for the NeuroSAFE PROOF trial and will be essential for planning future research.

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BIOMEDICAL RESEARCH

Ethical Justification for Deferral of Consent in the AcT Trial for Acute Ischemic Stroke

Research Article

Hannah Faris, Brian Dewar, Dar Dowlatshahi, Alnar Ramji, Carol Kenney, Stacey Page, Brian Buck, Michael D. Hill, Shelagh B. Coutts, Mohammed Almekhlafi, Tolulope Sajobi, Nishita Singh, Arshia Sehgal, Richard H. Swartz, Bijoy K. Menon, Michel Shamy

Stroke, 23 May 2022

Abstract

The AcT trial (Alteplase Compared to Tenecteplase) compares alteplase or tenecteplase for patients with acute ischemic stroke. All eligible patients are enrolled by deferral of consent. Although the use of deferral of consent in the AcT trial meets the requirements of Canadian policy, we sought to provide a more explicit and rigorous approach to the justification of deferral of consent organized around 3 questions. Ultimately, the approach we outline here could become the foundation for a general justification for deferral of consent.

Should informed consent and information related to patient recruitment in clinical trials be available to the reader of scientific articles? A case study in dentistry

Research Article

Clovis Mariano Faggion Jr

Accountability in Research, 16 May 2022

Abstract

Ethical aspects in research should be transparently reported. This study aimed to investigate whether informed consent and information related to patient recruitment in clinical studies are well-reported in the scientific literature. Randomized clinical trials (RCTs) on root coverage procedures published between November 2016 to November 2021 were selected from the PubMed database. Items/questions were used to guide the extraction of data related to patient recruitment, with a focus on the detailed report of informed consent used to clarify the research to the patient. Data were extracted from the published article and the respective research protocol published in a public registry. Information related to potential selective outcome reporting (SOR) was also extracted. 187 documents were initially screened and 74 reports of RCTs were included. No informed consent was published in the article. Only one research protocol provided a link to the informed consent. Deviations from reporting in the research protocol and published article were found, suggesting SOR. Informed consent and information related to patient recruitment in RCTs on root covering procedures are severely underreported. The present findings may stimulate further discussion and debate on the need for making this information publicly available.

Patient and Proxy Recall After Providing Written or Oral Informed Consent to Participate in an Interventional Trial

Research Letter Ethics

Angela Huttner, Elodie von Dach, Virginie Prendki, Stephan Harbarth, Laurent Kaiser

JAMA Network Open, 13 May 2022; 5(5)

Abstract

Introduction

Patients' understanding and recall after granting written consent for trial participation are known to be suboptimal.1 A 2006 study among 44 hospitalized patients providing written consent to an interventional trial found that only 68% remembered the purpose of the trial 10 days later; one-fifth had no recollection of having consented to any study.2 Recall by patients granting oral consent, and by the healthy proxies granting written consent for patients without capacity, is underreported. We compared recall rates after 30 days for participation in a randomized clinical trial (RCT) among patients with capacity who had given written or oral consent and for proxies of patients without capacity who had given written consent.

Methods

The RCT and this nested cohort study were approved by the Geneva Cantonal Ethics Commission. All participants or their proxies provided informed consent. This study is reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline. This nested

prospective cohort study included all patients with capacity and all proxies of patients without capacity participating at a single site (Geneva University Hospital, Switzerland) of a multicenter RCT by von Dach et al3 comparing antibiotic durations for gram-negative bacteremia in adults hospitalized between 2017 and 2019. In line with Swiss law, consent could be granted in writing by the patient, orally with a witness's signature (for patients who were illiterate or physically unable to sign), or in writing by the proxy of a patient without capacity. Our primary outcome was the 30-day recall rate for RCT participation among patients providing written or oral consent and proxies providing written consent. On day 30, patients and proxies were contacted for the RCT's first clinical follow-up. They were asked whether they remembered (1) that they were (or their dependent was) participating in the RCT, (2) that they had granted consent, (3) the RCT's purpose, and (4) potential risks. Data were analyzed in Stata statistical software version 16.0 (StataCorp). Comparisons were performed with Fisher exact test; associations were 2-sided with P = .05 considered significant. Univariate logistic regression was used to assess factors potentially associated with recall. Data were analyzed from November 1 to 30, 2021.

Results

The Geneva site enrolled 240 patients in the RCT. Consent was granted in writing by 167 patients (69%), orally by 16 patients (7%), and in writing by the proxies of 57 patients (24%) without capacity. At 30 days, data were available for 231 patients (96%): 4 patients (2%) had died, 3 patients (1%) had been otherwise lost to follow-up, and 2 patients (1%) were not asked the nested study's questions. Median (IQR) patient age was 83 (74-89) years; 157 patients (65%) were women (Table 1). All proxies were next of kin. The time spent presenting the study and whether participants and proxies asked questions are detailed in Table 1. A total of 111 of 161 patients providing written consent (69%), 9 of 14 patients providing oral consent (64%), and 36 of 56 proxies (64%) remembered that they or their loved ones were participating in a trial. Furthermore, 60 patients providing written consent (37%), 5 patients providing oral consent (36%), and 21 proxies (37%) recalled granting consent; 40 patients providing written consent (25%), 5 patients providing oral consent (36%), and 20 proxies (36%) remembered the purpose of the trial. Few remembered the trial's potential risks (Table 1). In linear and univariate regression models, neither the time spent with patients or proxies, whether they had questions, nor consent modality was associated with improved recall (Table 2).

Discussion

This cohort study among hospitalized patients, most of whom were elderly and all of whom had been acutely ill and hospitalized in the days prior, found that most patients had poor recall of their written consent to participate in an interventional trial (63%), a finding consistent with earlier studies.1,2 Yet recall after oral consent was no worse (64%), suggesting that the act of signing a document was not associated with improved retention or understanding. Perhaps most strikingly, recall by proxies, presumably healthy, providing written consent for their loved ones was as poor as that of patients who were seriously ill (63%). This study is limited by the impossibility of randomizing candidates or proxies to oral or written consent and by the small number of patients granting oral consent. The ability of patients—deemed competent by their physicians—to grant truly informed consent has long been in question.4,5 The ability of their proxies, physically healthy but emotionally stressed, to do the same requires further exploration. While these results require confirmation in larger studies, the act of signing consent, as opposed to granting it orally, was not associated with later recall or understanding.

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HEALTH DATA

Emergency department patients' attitudes towards the use of data in their clinical record for research without their consent

Brief Report

Chase Schultz-Swarthfigure, Anne-Maree Kelly, Deborah Zion

Journal of Medical Ethics, 18 May 2022

Abstract
Background
Health research often uses health information, a subcategory of personal information, collected during clinical encounters. Conditions under which such health information can be used for the secondary purpose of research are set out in state, national and international law. In Australia, consent is required or the relevant conditions for a waiver of consent must be met and approved by a human research ethics committee (HREC). Consent for use of health information for research is rarely sought at an emergency department (ED) presentation. Research often occurs after the index visit and gaining consent can be difficult. Waiver of consent provisions are frequently used, but acceptability of this approach to patients is unclear.
Objective
To identify ED patients' knowledge and attitudes towards the use of health information for research, consent preferences and acceptability of waiver of consent.
Methods
An online, anonymous survey of adult patients attending two large EDs in Melbourne, Australia.
Results
103 patients completed the survey. We found that 52% were unaware that health information might be used for research. A majority (77%) felt that HREC approval for use of health information without consent was acceptable. However, 36% would prefer to be contacted regarding consent.
Conclusion
These findings suggest a lack of awareness that health information can be used for research and that waiver of consent is acceptable, but not necessarily preferred, in most of the ED patient population. Efforts to increase awareness and provide opportunities to express preferences about health information use for research are needed.

Patient-centered cross-enterprise document sharing and dynamic consent framework using consortium blockchain and ciphertext-policy attribute-based encryption

Research Article
Liang Zhang, Haibin Kan, Honglan Huang
Proceedings of the 19th ACM International Conference on Computing Frontiers, 17 May 2022; pp 58–66
Abstract
Patient-centered healthcare data sharing and data usage consent are gaining popularity. Cross-enterprise document sharing (XDS) is the crucial system of sharing personalized healthcare data. Furthermore, dynamic consent is vital to the XDS system, because it respects people's autonomy and achieves recognition of data sovereignty. Because of its transparency, blockchain is a powerful system for managing storage and computing without a trusted third party. Besides, ciphertext-policy attribute-based encryption (CP-ABE) extends public-key encryption by implying access control policies in ciphertexts, making it suitable for protecting the privacy of individual healthcare data in versatile cases. Particularly, we use hospital name, "date" and "department" as attribute strings in the access control policies. Consequently, based on consortium blockchain and CP-ABE, we propose a patient-centered XDS and a dynamic consent framework. Compared with previous related literature, we make the proposed framework consistent with current practices and achieve favorable criteria, such as data confidentiality, data recoverability and time-aware ciphertext. Further, we conduct comprehensive experiments to show the feasibility and practicality.

A Consent Tool for Secondary Use of Biomedical Data

Simon Adams, Gausegan Uthayathas, Murat Sariyar
Studies in Health Technology and Informatics, 16 May 2022; 292 pp 107-110
Abstract

To pursue scientific goals with patient data usually requires informed consent from the data subjects. Such a consent constitutes a contract between the research institute and the patient. Several issues must be included in the consent to be valid, for example, how the data is processed and stored as well as specifics of the research questions for which the data is going to be used. Here, we describe the development and the implementation of a user-friendly IT solution that supports the process-oriented obtainment of consents. Current solutions often focus only on the benefits for the researcher. Our solution intends to add value to all participants and to reduce paperwork to a minimum. The consent Tool was evaluated by a usability test using the UEQ Method (User Experience Questionnaire) and received positive feedback - both efficiency and originality were rated above the average UEQ-Benchmark. Nevertheless, the lack of compatibility with the technical infrastructure of the hospital was a significant shortcoming. Hence, although there is a general interest in digitized solutions in the healthcare sector, there are still many hurdles to implement them and roll them out.

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YOUNG PERSONS

Health-related confidentiality and consent among minors: Data on adult perspectives from Belgium and The Netherlands

David De Coninck, Koen Matthijs. Peter de Winter, Jaan Toelen
Data in Brief, June 2022; 42
Open access
Abstract
The data presented in this article provide one of the first large-scale insights on adult preferences for confidentiality and consent with regards to medical decision-making for minors. We collected data on these preferences through 12 hypothetical scenario's that were presented, for which each participant had to indicate if they would (not) follow the minor's preferences. Data regarding family communication, relationship quality, and sociodemographic characteristics were also collected. The data were collected through an online survey in September and October 2020, which yielded responses from 1000 Belgian and 1000 Dutch participants between 35 and 55 years of age. We selected this age range because it increased the chances that they had a child near the age of the fictional minor in the hypothetical cases. These data can be of interest for family researchers and/or health workers who want to explore adults' perceptions regarding confidentiality and consent among minors.

Getting parental consent when treating children

Feature
Rupert Hoppenbrouwers
BDJ Team, 20 May 2022; 9 pp 20–21
Excerpt
When treating young children, it may be necessary to get the authority of someone with parental responsibility. With complex family relationships however, it might not be clear to dental professionals who has parental responsibility, and this can create a dilemma. Here we explain the principles and procedures around parental responsibility when treating younger children…

Editor's note: BDJ Team is a product of the British Dental Association.

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TECHNOLOGY/OTHER MEDIATION

Implementation of Surgical Education Video to Burn Patients Before the Informed Consent Process

Theses and Dissertations

Brian Piatkowski

Doctor of Nursing Practice, 28 May 2022

Open Access

Abstract

Purpose

Before the initiation of this evidence-based Doctor of Nursing Practice (DNP) project, a systematic review of literature set forth by other researchers regarding the informed consent process was done. The literature showed patient satisfaction scores increased, while anxiety decreased regarding surgical procedures after using a multimedia educational tool. The first goal of the project was to determine any gaps in knowledge of the burn surgical patient population. The second goal of the project was to determine gaps in knowledge and comfort levels with providers obtaining informed consent. The third goal was to determine the efficacy of implementing a surgical education video for patients and providers.

Background

The informed consent process is a daily task for providers with a surgical patient population. In the burn population, informed consent is often presented by an intern or resident physician. Consent is comprised of surgical debridement with a multitude of options for coverage of their wounds. The current state of practice is a verbal overview of all the possible procedures that may be done to the patient's wound(s). Patients often verbalize feeling overwhelmed with the amount of information on the consent and often have questions related to their procedure just before the brief of the operative case.

Methods

An educational video was developed that detailed the surgical procedure and the potential burn wound coverings. A 3-question survey was given to patients who have already been through the informed consent process. Survey metrics examined knowledge of consent when signed, the satisfaction of verbal explanation, and if a video would increase understanding. The video was given to the same patients to watch. After the video was viewed, those patients were then again surveyed. Providers were also given a 3-question survey before viewing the video. Survey metrics examined comfort of consent, knowledge of procedures, and if the video would increase patient understanding of consent topics. The providers were then surveyed after watching the video.

Results

Initial post-implementation data shows that patients and providers have increased comfort and knowledge in the informed consent process. Patients show an 80% increase in understanding of consent, a 72% increase in satisfaction with video vs verbal overview, and a 97% increase in satisfaction with material viewed. Provider data shows a 65% increase in the comfort of consent, a 64% increase in knowledge of procedures, and a 97% increase that the video will help patients understand their consent. This shows that this evidence-based project is an improvement from the current standard of practice.

Evaluation

Implementation of a standardized audio/video teaching method for burn surgical patients is an effective way to increase patient and provider satisfaction regarding the informed consent process. This tool can easily be modified with practice changes for sustainability. Implementing this educational tool is a cost-effective and simple way to educate burn patients before their surgical procedures. There is an overall improvement in patient satisfaction and increased satisfaction in the providers who obtain the consent.

Participant comprehension and perspectives regarding the convenience, security, and satisfaction with teleconsent compared to in-person consent: A parallel-group pilot study among Danish citizens

Anne Nyholm Gaarskjær, Meg Duroux, Rasmus Hogreffe

Contemporary Clinical Trials Communications, 27 May 2022

Abstract

Background

Teleconsent via video conferencing enables decentralized trials with remote consent and has the additional benefit of allowing a real-time reaction to potential misunderstandings. However, participant acceptance of and satisfaction with teleconsent versus in-person consent processes are unknown.

Methods

We conducted a parallel-group pilot study to evaluate participant comprehension and perspectives regarding the convenience, security, and satisfaction with teleconsent compared to in-person consent among Danish citizens for a hypothetical research study.

Results

There were no statistically significant differences in perceptions of security or satisfaction between teleconsent and in-person consent arms. However, participants viewed teleconsent as more convenient than in-person consent, as no transportation was needed and the process was less time-consuming. Recruitment was also faster in the teleconsent arm, and more people dropped out of the in-person arm, citing difficulties with transportation and time.

Conclusion

Decentralized clinical trials have been demonstrated to increase recruitment and enrollment rates, improve trial efficiency, and decrease dropout rates and trial delays. We add to this literature by suggesting that patients perceive teleconsent as similar to in-person consent, suggesting this is a feasible and acceptable substitution for in-person consent in multisite, decentralized trials. Future work should include patient perspectives from a larger, more diverse group of participants.

Video-assisted informed consent in a clinical trial of resuscitation of extremely preterm infants: Lessons learned

Namrita Jain Odackal, Catherine Grace Caruso, Melissa Klitzman, Mónica Rincón, Bobbi Byrne, Jameel Justin Winter, Gina Petroni, Karen D Fairchild, Jamie B Warren

American Journal of Perinatology, 26 May 2022

Abstract

Objective

Obtaining informed consent for clinical trials is challenging in acute clinical settings. For the VentFirst randomized clinical trial (assisting ventilation during delayed cord clamping for infants <29 weeks' gestation), we created an informational video that sites could choose to use to supplement the standard in-person verbal and written consent. Using a post-consent survey, we sought to describe the impact of the video on subject recruitment, satisfaction with the consent process, and knowledge about the study.

Study design

Descriptive survey-based sub-study.

Results

Of the sites participating in the VentFirst trial that obtained IRB approval to allow use of the video to supplement the standard informed consent process, three elected to participate in the survey substudy. From February 2018 to January 2021, 82 women at these three sites were offered the video and completed the post-consent survey. Overall, 73 of these 82 women (89%) consented to participate in the primary study, 78 (95%) indicated the study was explained to them very well or extremely well, and the range of correct answers on 5 knowledge questions about the study was 63%-98%. Forty-six (56%) of the 82 women offered the video chose to watch it. There were no major differences in study participation, satisfaction with the consent process, or knowledge about the study between the women who chose to watch or not watch the video.

Conclusion

Watching an optional video to supplement the standard informed consent process did not have a major impact on outcomes in this small sub-study. The ways in which audiovisual tools might modify the traditional informed consent process deserve further study.

Improving comprehension, recall and attention using multimedia-informed assent among pediatric oncology patients: A comparative randomized controlled trial

Psychosocial and Supportive Care: Research Article

Passara Wongthai, Apichat Photia, Chanchai Traivaree, Chalinee Monsereenusorn, Nawachai Lertvivatpong, Khemika Khemakanok Sudnawa, Piya Rujkijyanont

Pediatric Blood & Cancer, 25 May 2022

Abstract

Background

Assent should be obtained in all children involved in research in keeping with their level of maturity. Traditional assent forms contain too much information and are difficult to read. The study aimed to identify an effective tool to enhance children's comprehension during the assent process and focused on those with cancer who are likely more engaged in research involving greater than minimal risk.

Methods

In all, 116 children with cancer were randomized to receive either a paper-based assent document or a multimedia-based assent document. Open-ended and multiple-choice questions were used to assess comprehension and recall. Time spent on the documents and children's behavior during the assent process was recorded to determine their attention and satisfaction.

Results

Children randomized to a multimedia-based assent document achieved significant higher comprehension and recall assessment scores (p-values <.001). The high score achievement significantly correlated with the child's age with adjusted odds ratio (OR) of 1.90 (p-value <.001; 95% confidence interval [CI]: 1.35–2.66) for comprehension assessment and 1.59 (p-value .001; 95% CI: 1.20–2.12) for recall assessment. Children randomized to a multimedia-based assent document had significant longer time spent on the document (p-value .001) with less numbers of inattention (p-value <.001) and expressed more signs of enjoyment during the assent process (p-values <.001).

Conclusion

Multimedia-based assent document successfully enhanced comprehension, recall, and attention with more satisfaction compared with a traditional paper-based document among children with cancer. This approach may be considered as an alternative format for children engaging in research involving greater than minimal risk.

Context, Prioritization, and Unexpectedness: Factors Influencing User Attitudes About Infographic and Comic Consent

Xengie Doan, Annika Selzer, Arianna Rossi, Wilhelmina Maria Botes, Gabriele Lenzini

WWW '22 Companion, 25-29 April 2022; Lyon, France [Virtual Event]

Open Access

Abstract

Being asked to agree to data disclosure is a ubiquitous experience in digital services - yet it is rare to encounter a well-designed consent experience. Considering the momentum for a European data space where personal information easily flows across organizations, sectors, and nations, solving the thorny issue of "how to get consent right" cannot be postponed any further. In this paper, we describe the first findings from a study based on 24 semi-structured interviews investigating participants' expectations and opinions toward a consent form redesigned as a comic and an infographic in a data-sharing scenario. We found that time, information prioritization, tone, and audience fit are crucial when individuals are invited to disclose their information and the infographic is a better fit in biomedical scenarios.

Effective Communication of Personalized Risks and Patient Preferences During Surgical Informed Consent Using Data Visualization: Qualitative Semistructured Interview Study With Patients After Surgery

Undina Gisladottir, Drashko Nakikj, Rashi Jhunjhunwala, Jasmine Panton, Gabriel Brat, Nils Gehlenborg

JMIR Hum Factors, 1 April 2022; 9(2)

Abstract

Background

There is no consensus on which risks to communicate to a prospective surgical patient during informed consent or how. Complicating the process, patient preferences may diverge from clinical assumptions and are often not considered for discussion. Such discrepancies can lead to confusion and resentment, raising the potential for legal action. To overcome these issues, we propose a visual consent tool that incorporates patient preferences and communicates personalized risks to patients using data visualization. We used this platform to identify key effective visual elements to communicate personalized surgical risks.

Objective

Our main focus is to understand how to best communicate personalized risks using data visualization. To contextualize patient responses to the main question, we examine how patients perceive risks before surgery (research question 1), how suitably the visual consent tool is able to present personalized surgical risks (research question 2), how well our visualizations convey those personalized surgical risks (research question 3), and how the visual consent tool could improve the informed consent process and how it can be used (research question 4).

Methods

We designed a visual consent tool to meet the objectives of our study. To calculate and list personalized surgical risks, we used the American College of Surgeons risk calculator. We created multiple visualization mock-ups using visual elements previously determined to be well-received for risk communication. Semistructured interviews were conducted with patients after surgery, and each of the mock-ups was presented and evaluated independently and in the context of our visual consent tool design. The interviews were transcribed, and thematic analysis was performed to identify major themes. We also applied a quantitative approach to the analysis to assess the prevalence of different perceptions of the visualizations presented in our tool.

Results

In total, 20 patients were interviewed, with a median age of 59 (range 29-87) years. Thematic analysis revealed factors that influenced the perception of risk (the surgical procedure, the cognitive capacity of the patient, and the timing of consent; research question 1); factors that influenced the perceived value of risk visualizations (preference for rare event communication, preference for risk visualization, and usefulness of comparison with the average; research question 3); and perceived usefulness and use cases of the visual consent tool (research questions 2 and 4). Most importantly, we found that patients preferred the visual consent tool to current text-based documents and had no unified preferences for risk visualization. Furthermore, our findings suggest that patient concerns were not often represented in existing risk calculators.

Conclusions

We identified key elements that influence effective visual risk communication in the perioperative setting and pointed out the limitations of the existing calculators in addressing patient concerns. Patient preference is highly variable and should influence choices regarding risk presentation and visualization.

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RIGHTS/LEGAL/LEGISLATIVE

Impact of Informed Consent and Education on Care Engagement After Opioid Initiation in the Veterans Health Administration

Tigran Avoundjian, Lara Troszak, Jennifer Cohen, Mary Beth Foglia, Jodie Trafton, Amanda Midboe

Journal of Pain Research, 25 May 2022; 15 pp 1553-1562

Abstract

Objective

To ensure all patients receiving long-term opioid therapy (LTOT) understand the risks, benefits and treatment alternatives, the Veterans Health Administration (VHA) released a national policy in 2014 to standardize a signature informed consent (SIC) process. We evaluated the impact of this policy on medical follow-up after LTOT initiation, a guideline recommended practice.

Methods

Using VHA administrative data, we identified patients initiating LTOT between May 2013 and May 2016. We used an interrupted time series design to compare the monthly rates of medical follow-up within 30 days and primary care visits within 3 months after LTOT initiation across three periods: 12 months before the policy (Year 1); 12 months after policy release (Year 2); and 12– 24 months after policy release, when the SIC process was mandatory (Year 3).

Results

Among the 409,895 patients who experienced 758,416 LTOT initiations, medical follow-up within 30 days and primary care engagement within 3 months increased by 4% between Year 1 and Year 3. Compared to Year 1, patients in Year 3 were 1.12 times more likely to have any medical follow-up (95% CI: 1.10, 1.13) and 1.13 times more likely to have a primary care visit (95% CI: 1.12, 1.15). Facilities with a greater proportion of patients receiving SIC had increased medical follow-up (RR: 1.04, 95% CI: 1.01, 1.07) and primary care engagement (RR: 1.06, 95% CI: 1.03, 1.10).

Conclusion

The VHA's SIC policy is associated with increased medical follow-up among patients initiating LTOT, which may result in improved patient safety and has implications for other healthcare settings.

The Conceptual Legal Structure of The Patient's Right to Informed Consent

Noelia Martínez-Doallo

European Journal of Health Law, 12 May 2022

Abstract

Informed consent has been inconsistently conceptualised as a right, an immunity or even a power in the hands of the patient, which leaves its legal definition as partially indefinite. From the norms of the CHRB, a legal theory stance and the proposals of celebrated authors — namely, W.N. Hohfeld, H. Kelsen and R. Alexy, I will provide a steady conceptual structure for the subjective legal positions of the parties involved in the healthcare relationship regarding informed consent.

Informed Consent in Pringsewu Regional General Hospital: Legal Evidence Perspective

Samino Samino, Agung Aji Perdana, Selamet Kuntoro

Jounral Ilmu Kesehatan, 2022; 7(1)

Abstract

Quality health care is the right of every patient and his family. One of the indicators of quality services is the fulfillment of informed consent in accordance with the laws and regulations. Preliminary studies of several informed consent documents at Pringsewu Hospital found that all of them were not filled out completely. This study aims to analyze informed consent documents from the perspective of legal evidence.The study was conducted at Pringsewu Hospital in July 2021. The research method used a qualitative descriptive analysis approach, with 75 informed consent documents and two informants. How to collect data by reviewing the informed consent document that has been filled in at the hospital medical record installation, by checking the completeness of filling out the informed consent document for the five most types of

actions, and in-depth interviews with the responsible leadership.The results showed that 75 informed consent documents were reviewed, none of which were filled out completely. The five most important indicators were not filled in completely, consecutively: name and signature of witness II, name and signature of witness I, gender of the patient, and gender of the giver of consent. To improve the completeness of filling out documents, the hospital will provide education to doctors, nurses, and administrative staff, as well as strict supervision. It was concluded that incomplete informed consent documents, as legal evidence, were low quality. The hospital leaders should conduct socialization to doctors, nurses and administrative staff regarding the importance of filling out the medical treatment approval form properly and completely.

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FREE PRIOR INFORMED CONSENT (FPIC)

The Extraction Industry in Latin America and the Protection of Indigenous Land and Natural Resource Rights: From Consultation Toward Free, Prior, and Informed Consent

Kylah Staley

Hastings Law Journal, May 2022; 73(4)

Open Access

Abstract

Resource extraction and exploitation threaten the survival of Indigenous and tribal peoples, who are amongst the most marginalized communities in the world. This is both a human rights issue and an environmental issue. There are around 300 million people that make up Indigenous communities worldwide, the majority of whom live in forests. Furthermore, Indigenous customary lands contain 80% of the world's biodiversity. Traditionally, Indigenous communities have been stewards of their lands, where they regard the land as means for their own physical, spiritual, and cultural survival rather than a commodity to be exploited. The only protection Indigenous Peoples have against resource extraction in international law, under the Indigenous and Tribal Peoples (ILO) Convention 169, is the right to consultation and participation. Effectively, Indigenous communities have limited decision-making power in this context. This narrow protection of Indigenous Peoples' lands and natural resources under ILO Convention 169 is inadequate and informed by a colonial past. For there to be adequate protections of Indigenous Peoples' land and resource rights, Indigenous Peoples must hold actual decision-making power, not just participatory power. Free, prior, and informed consent (FPIC) is the principle and right that is critical to safeguarding Indigenous lands and resources as it is grounded in the foundational right of self-determination. Thus, I argue operationalizing FPIC would provide a comprehensive protection of Indigenous rights by ensuring that affected Indigenous communities (1) design the procedures for obtaining their consent (2) retain negotiating power and (3) actually agree to proposed projects.

Principle of Free, Prior and Informed Consent as a Resolution of Land Conflicts Between Oil Palm Plantation Companies and Indigenous Peoples in Kampar Regency

Rahmad Hendra, Firdaus Firdaus, Samariadi Samariadi

Advances in Social Science, Education and Humanities Research, 2021; 659

Open Access

Abstract

The research was conducted in Bencah Kelubi Village and Subarak Village. In both villages there are oil palm plantation companies. In Subarak Village, oil palm plantation investors implement the principle of free, prior and informed consent (FPIC) at the beginning before the start of investment, while in Bencah Kelubi Village the oil palm plantation companies that make investments do not follow the FPIC principle. The writing

method used by the author is descriptive analysis with a qualitative research pattern. The author found that FCPIC is significantly reduces the conflict between oil palm plantation companies and indigenous peoples.

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CULTURAL/COUNTRY CONTEXT

Ethical obligation and legal requirements: On informed consent practices in Bangladesh

Original Article

Sonia Mannan, Jobair Alam, K. M. Ashbarul Bari, S. M. A. A. Mamun, Rehnuma Mehzabin Orin

Developing World Bioethics, 19 May 2022

Abstract

Informed consent to medical intervention is fundamental in both ethics and law. But in practice it is often not taken seriously in developing countries. This paper provides an appraisal of informed consent practices in Bangladesh. Following a review of the ethical and legal principles of informed consent, it assesses the degree to which doctors adhere to it in Bangladesh. Based on findings of non-compliance, it then investigates the reasons for such non-compliance through an appraisal of informed consent practices in Bangladesh and provides recommendations aimed at improving such practices. The significance of this paper lies in unveiling the interdependence between the ethical and legal traits of informed consent and their ramifications on strengthening the patient-oriented approach of duty to care.

Understanding of Critical Elements of Informed Consent in Genomic Research: A Case of a Paediatric HIV-TB Research Project in Uganda

Research Article

Francis Anyaka Amayoa, Frederick Nelson Nakwagala, John Barugahare, Ian Guyton Munabi, Erisa Sabakaki Mwaka

Journal of Empirical Research on Human Research Ethics, 12 May 2022

Abstract

Several studies have reported inadequate comprehension of informed consent for genomic research. This study aimed to assess research participants' understanding of critical elements of informed consent for genomic research. A cross-sectional survey involving 123 parents/caregivers of children participating in a paediatric genomic TB/HIV study was conducted. Only 47.2% of the participants had adequate understanding of consent information. The mean objective (actual) and subjective (perceived) understanding scores were 78.7% and 91.7% respectively. Participants adequately understood most elements of consent however, some elements were poorly understood including foreseeable risks, protection of confidentiality and compensation for research related injury. Overall there was inadequate comprehension of critical elements of informed consent and there was dissonance between actual and perceived comprehension of informed consent.

Awareness of Knowledge, Attitude and Practices of Medical Students and Surgical Trainees Regarding Surgical Informed Consent: A Cross-sectional Multicentric Study from Northern India

Nishtha Singh, Sudhir Kumar Jain, Tariq Hameed, Kanwal Preet Kochhar, Param Jit, Chandra Bhushan Singh

Asian Journal of Medicine and Health, 22 March 2022; 20(3) pp 25-31

Open Access

Abstract

Background

Informed Consent is the cornerstone of modern medical and surgical care. All patients have the right to be involved in decisions about their treatment and care. Obtaining SIC (surgical informed consent) is an

important and essential skill that one must acquire in medical training, yet many residents receive very little formal education.

Methods

Multiple choice questionnaire designed and after pretesting circulated on Google formsTM having questions pertaining to knowledge, attitude and practice. Total 463 responses obtained and appropriate statistical tests applied in Microsoft Excel and StataSE.

Result

Knowledge-score remained constant for medical students and trainees, Attitude-score (18.59 to 18.93) and Practice-score (2.30 to 3.62) statistically significant increase in score with clinical exposure was noted. Gender wise difference were in A-score, females scored higher 18.87 and males scored 18.49. For trainee doctors unlike P scores, K and A scores did not increase with experience.

Discussion

Early intervention in undergraduate years and continuous upskilling is the need tobridge the hiatus of doctor-patient relationship. This necessitates scenario and role play based teaching, student teaching patient based learning regarding the SIC.

Conclusion

There is a Knowledge attitude practice gap present not only in undergraduate students but postgraduates residents regarding SIC, for which the current curriculum and the ongoing practical training is insufficient to bridge. Indian curriculum must make amendments to bridge it.

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MEDICAL/SURGICAL

Evolution of Investigating Informed Assent Discussions about CPR in Seriously Ill Patients

Renee D. Stapleton, Dee W. Ford, Katherine R. Sterba, Nandita R. Nadig, Steven Ades, Anthony L. Back, Shannon S. Carson, Katharine L. Cheung, Janet Ely, Erin K. Kross, Robert C. Macauley, Jennifer M. Maguire, Theodore W. Marcy, Jennifer J. McEntee, Prema R. Menon, Amanda Overstreet, Christine S. Ritchie, Blair Wendlandt, Sara S. Ardren, Michael Balassone, Stephanie Burns, Summer Choudhury, Sandra Diehl, Ellen McCown, Elizabeth L. Nielsen, Sudiptho R. Paul, Colleen Rice, Katherine K. Taylor, Ruth A. Engelberg

Journal of Pain and Symptom Management, June 2022; 63(6) e621-e632

Abstract

Context

Outcomes after cardiopulmonary resuscitation (CPR) remain poor. We have spent 10 years investigating an “informed assent” (IA) approach to discussing CPR with chronically ill patients/families. IA is a discussion framework whereby patients extremely unlikely to benefit from CPR are informed that unless they disagree, CPR will not be performed because it will not help achieve their goals, thus removing the burden of decision-making from the patient/family, while they retain an opportunity to disagree.

Objectives

Determine the acceptability and efficacy of IA discussions about CPR with older chronically ill patients/families.

Methods

This multi-site research occurred in three stages. Stage I determined acceptability of the intervention through focus groups of patients with advanced COPD or malignancy, family members, and physicians. Stage II was an ambulatory pilot randomized controlled trial (RCT) of the IA discussion. Stage III is an ongoing phase 2 RCT of IA versus attention control in in patients with advanced chronic illness.

Results

Our qualitative work found the IA approach was acceptable to most patients, families, and physicians. The pilot RCT demonstrated feasibility and showed an increase in participants in the intervention group changing from “full code” to “do not resuscitate” within two weeks after the intervention. However, Stages I and II

found that IA is best suited to inpatients. Our phase 2 RCT in older hospitalized seriously ill patients is ongoing; results are pending.
Conclusions
IA is a feasible and reasonable approach to CPR discussions in selected patient populations.

Consent in Interventional Radiology—How Can We Make It Better?

Review Article
Tia Forsman, Sara Silberstein, Eric J. Keller
Canadian Association of Radiologists Journal, 25 May 2022
Abstract
Informed consent is an important part of the clinician-patient relationship. However, studies suggest consent practices tend to be limited in consistency and completeness. This may be particularly challenging for interventional radiology given more limited public awareness and the often fast-paced, dynamic nature of our practices. This article reviews these challenges as well as ideal consent practices and potential approaches to improve consent in interventional radiology.

Development of Shared Decision-Making Training Module for Patients Facing Preference-Sensitive Decisions regarding Major Surgical Procedures

Poster Abstracts
Ryan Gainer, Greg Hirsch, Elias Hirsch
International Journal of Integrated Care, 16 May 2022
Abstract
Introduction
Studies of surgical decision making demonstrate poor decisional quality, especially patient comprehension and expression of preferences. Shared decision making (SDM), a formalized approach wherein patients are educated about risks, benefits to treatment options, and supported to share personal preferences, has been shown to improve comprehension, reduce decisional conflict, and better align patient expectations with outcome, however multiple systematic reviews have demonstrated almost no sustained uptake of this approach in surgery. The goal of this study is to implement SDM with relevant training aimed at the surgical team with a pre-post design that measures effectiveness through Option-5 scoring of informed-consent interactions.
Aims Objectives Theory or Methods
Five focus groups with patients (n=2) and health care providers (HCPs) (n=3) were carried out to determine barriers and facilitators of SDM and learning preferences for HCPs. Common barriers and facilitators identified in focus groups using thematic analysis were used to develop communication and logistical strategies included in the training. HCP learning preferences identified informed format and presentation style of the training to improve participant engagement. Informed consent discussions were audio recorded and analyzed using Option-5 methodology which comprises a 5 item measure of SDM used to assess the extent to which clinicians involve patients in the decision making process.
Highlights or Results or Key Findings
Common barriers to SDM identified in thematic analysis included; lack of time during surgeon patient interaction; authoritative imbalance between patients and clinicians; and deficits in patient comprehension. HCPs expressed preferences regarding presentation style and format specifically; synchronous short events with relevant examples. Pre-intervention OPTION-5 scoring (n=40) demonstrated low decisional quality (average score 27/100) with almost no perceptible elicitation or incorporation of patient preferences during consent discussions. Following the training of cardiac surgeons and multidisciplinary team members, 62 more informed consent discussions will be audio-recorded and evaluated using the OPTION-5 scoring metric.

OPTION-5 scores before and after training will be compared by item and total score to determine change in informed consent discussion quality.

Conclusions

Informed consent in surgery is lacking in SDM approaches. Barriers have been identified and SDM training has been developed with a team based approach in mind. Effectiveness of the training intervention on the improvement of surgical consent discussion quality will be measured using OPTION-5 and if successful broader implementation will

Implications for applicability/transferability sustainability and limitations

Successful implementation of SDM training showing measurable improvement in cardiac surgery informed consent discussion quality will substantiate the implementation of SDM training modules specified for other surgical disciplines as well as subsequent evaluation of long term sustainability of the effects of SDM training.

Barriers to Informed Consent in Interventional Radiology: A Pilot Study

Sara Silberstein, Eric J.Keller

Journal of Radiology Nursing, 9 May 2022

Abstract

Background

Informed consent is a central part of the relationships between patients and interventional radiology teams, but consent practices are variable and limited.

Purpose

This study explored consent practices among clinicians and staff in an academic IR department to identify barriers to informed consent.

Methods

Systematic interviews were conducted with 17 clinicians and staff about their roles in obtaining informed consent, perceptions of what informed consent and capacity determinations entail, and barriers to patients' understanding of IR procedures.

Findings

Results revealed four key barriers to adequate informed consent: limited procedural experience/knowledge by the consenting clinician, unclear division of responsibilities, inconsistent approaches to assessing capacity and surrogate decision making, and wide variation in patients' baseline understandings.

Discussion

This variation seemed to stem from a lack of shared understanding about consent processes and responsibilities, highlighting an important area for quality improvement in IR that would benefit from a larger multipractice investigation of consent practices.

Poor compliance documenting informed consent in trauma patients with distal radius fractures compared to elective total knee arthroplasty

Scott M Bolam, Leigh Munro, Mark Wright

Royal Australasian College of Surgeons, 4 May 2022

Open Access

Abstract

Background

The purpose of this study was (1) to evaluate the adequacy of informed consent documentation in the trauma setting for distal radius fracture surgery compared with the elective setting for total knee arthroplasty (TKA) at a large public hospital and (2) to explore the relevant guidelines in New Zealand relating to consent documentation.

Methods

Consecutive adult patients (≥16 years) undergoing operations for distal radius fractures and elective TKA over a 12-month period in a single-centre were retrospectively identified. All medical records were reviewed for the risks and complications recorded. The consent form was analysed using the Flesch Reading Ease Score (FRES) and the Simple Measure of Gobbledygook (SMOG) index readability scores.

Results

A total of 133 patients undergoing 134 operations for 135 distal radius fractures and 239 patients undergoing 247 TKA were included. Specific risks of surgery were recorded significantly less frequently for distal radius fractures than TKA (43.3% versus 78.5%, $P < 0.001$). Significantly fewer risks were recorded in the trauma setting compared to the elective (2.35 ± 2.98 versus 4.95 ± 3.33, $P < 0.001$). The readability of the consent form was 40.5 using the FRES and 10.9 using the SMOG index, indicating a university undergraduate level of reading.

Conclusions

This study has shown poor compliance in documenting risks of surgery during the informed consent process in an acute trauma setting compared to elective arthroplasty. Institutions must prioritize improving documentation of informed consent for orthopaedic trauma patients to ensure a patient-centred approach to healthcare.

A Systematic Review on Improving the Family Experience After Consent for Deceased Organ Donation

Review Article

Sonja Bjelland, Krista Jones

Progress in Transplantation, 2 May 2022

Abstract

Introduction

The demand for transplanted organs outweighs the supply and intensifies the need to improve care for donor families. Studies have shown inadequate care by hospital staff can increase posttraumatic stress disorder and complicated grief in these families but putting solutions into practice remains slow.

Objective

This systematic review identified factors that relieve or contribute to distress for deceased organ donor families in the time since the decision to donate. Additionally, it provides insights into potential improvements at public health, educational, and health system levels to address these deficiencies.

Methods

Search terms included organ don*, famil* or relati*, family-centered, grief, and experience*. The search covered original research articles, published in English, from 2014 to July 2021.

Results

Four key themes emerged among the studies. (a) Understanding factors that affect the emotional aftermath can help staff prevent posttraumatic stress disorder and complicated grief. (b) Improving communication by hospital staff includes: avoiding medical jargon, providing adequate audio and visual explanations, and understanding that the next of kin is struggling to comprehend the tragedy and the information they are being told. (c) End-of-life care such as memory making, bringing in palliative care resources, and parting ceremonies can assist with familial coping as well as staff interactions. (d) Families want more support in the months and years after the donation decision.

Discussion

Changes at multiple levels can improve the quality of care for families whose relative gave the gift of life, but more research and translation into practice are needed.

Consent: risk assessment, risk communication and shared decision making

Jayne M. Sewell, Catherine Rimmer

Surgery (Oxford), 30 April 2022

Abstract

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

An Ethical Defense of a Mandated Choice Consent Procedure for Deceased Organ Donation

Original Paper

Xavier Symons, Billy Poulden

Asian Bioethics Review, 29 April 2022

Open Access

Abstract

Organ transplant shortages are ubiquitous in healthcare systems around the world. In response, several commentators have argued for the adoption of an opt-out policy for organ transplantation, whereby individuals would by default be registered as organ donors unless they informed authorities of their desire to opt-out. This may potentially lead to an increase in donation rates. An opt-out system, however, presumes consent even when it is evident that a significant minority are resistant to organ donation. In this article, we defend a mandated choice framework for consent to deceased organ donation. A mandated choice framework, coupled with good public education, would likely increase donation rates. More importantly, however, a mandated choice framework would respect the autonomous preferences of people who do not wish to donate. We focus in particular on the Australian healthcare context, and consider how a mandated choice system could function as an ethical means to increase the organ donation rate in Australia. We make the novel proposal that all individuals who vote at an Australian federal election be required to state their organ donation preferences when voting.

Patient Experience of Informed Consent for Diagnostic Coronary Angiogram and Follow-On Treatments: A Research Brief

Diane L. Carroll, Howard T Blanchard, Felicity Astin

Journal British Journal of Cardiac Nursing, 25 April 2022

Abstract

Background/Aims

Coronary angiography requires a complex informed consent process, a legal and ethical requirement before treatment, which may allow percutaneous coronary intervention (PCI) to be completed as a continuation of a coronary angiography. Patients are routinely consented for both interventions, but over a quarter will only receive diagnostic angiogram. Therefore, the specific aim of this study is to describe patients' demography, views and understanding of the informed consent process, in patients who gave informed consent for coronary angiography and same setting PCI but were found to be ineligible for same setting PCI.

Methods

A descriptive cross sectional survey design was used to explore these patients' views. Participants completed a 36-item survey on the day after diagnostic coronary angiography.

Results
Data was collected from a convenience sample of 62 subjects, 73% male, 68% college educated, 40% working with a mean age of 68.4 (11.4) years. Women reported; greater difficulty in recalling treatment information (p<.03) found discussions about alternative treatments more confusing (p<.02), and the disclosure of comprehensive risk information a deterrent to consent 2 for treatment (p<.02), when compared to men. Higher levels of education were associated with greater preference for information and involvement in treatment decisions (p<.002).
Conclusions
Patients who participate in an informed consent for diagnostic coronary angiography with, or without, a same-setting PCI need clear comprehensive information on alternatives. Recognizing patient's need for information is an opportunity for nursing to provide individualized explanation and reinforcement of the information provided during informed consent

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GENERAL/OTHER

Information Provision for Informed Consent Procedures in Psychological Research under the GDPR: A Practical Guide

Dara Hallinan, Franziska Boehm, Annika Külpmann, Malte Elson
The Society for the Improvement of Psychological Science; GDPR and Consent Forms in Psychological Research, 18 May 2022
Open Access
Abstract
Psychological research often involves the collection and processing of personal data from human research participants, and there is a norm that informed consent should be obtained before such research can go ahead. The European General Data Protection Regulation (GDPR) applies, in principle, to psychological research. It elaborates a range of conditions concerning the forms of information which should be communicated to research participants whenever personal data are collected from them, in order that they might be considered to be 'informed'. There is reason to believe, however, that the information required by the GDPR may not always be provided in consent materials. This may – at least in part – be due to the fact that psychological researchers are not aware of the exact requirements. This tutorial thus aims to provide general practical guidance to psychological researchers allowing them to understand which forms of information must be provided to research subjects in consent materials according to the GDPR.

Without their Consent: Handling Legacy Collections and Anatomy Teaching Specimens Acquired without Informed Consent

Pamela L. Geller
Federation of American Societies for Experimental Biology, 13 May 2022; 36(1)
Open Access
Abstract
Legacy collections have proven invaluable for teaching students about anatomy and standard methods. It is safe to presume, however, that ancient and historic decedents never consented to their inclusion in collections or use as pedagogical tools. A utilitarian position—that the use of these human remains serves a higher scientific purpose—becomes even harder to justify when educators acknowledge the historic necropolitical projects and suffering that underpinned the formation of legacy collections. How then to proceed scholastically with such affective and politically charged human remains?

As a complex case study, I consider the Samuel G. Morton Crania Collection. To instruct the medical students who populated his anatomy classes, the Philadelphia physician amassed over 900 crania from 1830 to 1851. After Morton's death, the Academy of Natural Sciences purchased the collection, where it was all but forgotten. Almost a century later, in 1966, it came under the stewardship of the Penn Museum, its pedagogical purpose resurrected. While Stephen Jay Gould drew attention to the scientific racism of Morton's research, it was not until the passage of the Native American Graves Protection and Repatriation Act of 1990 that ethical deliberations began in earnest. Here I continue these trains of thought with a discussion of the Afro-Cuban crania in the Morton Collection.

Morton acquired these decedents from his Cuban colleague Dr. José Rodriguez Cisneros in 1840. The latter designated them "negros bozales," an indicator of their enslaved status and African origins; additional information about tribe and country was not provided. In summer 2020, in the wake of the murder of George Floyd and the racial justice protests his death catalyzed, these skulls erupted into the public consciousness. There were calls to "Return Them All." I regard this response as well intentioned but also reactionary and unnuanced. To determine if sustained use is viable where consent is inadequate, for this case and more generally, I bring to the fore two concepts: the agentive corpse and ontological insecurity. Both concepts require educators and researchers to culturally contextualize human remains, as well as attend to the dynamic meanings attached to them—by past communities and their living descendants. With this knowledge in hand, I make some tentative recommendations about the fate of these controversial and highly sensitive human remains.

'If we don't have consent, we need to have beneficence': Requiring beneficence in nonconsensual neurocorrection

Emma Dore-Horgan

Bioethics, 8 April 2022

Abstract

Neurointerventions—interventions that cause direct physical, chemical or biological effects on the brain—are sometimes administered to criminal offenders for the purpose of reducing their recidivism risk and promoting their rehabilitation more generally. Ethical debate on this practice (henceforth called 'neurocorrection') has focused on the issue of consent, with some authors defending a consent requirement in neurocorrection and others rejecting this. In this paper, I align with the view that consent might not always be necessary for permissible neurocorrective use, but introduce a qualification I argue ought to inform our ethical and legal analysis of neurocorrection if we are to administer neurocorrectives nonconsensually. I maintain our use of nonconsensual neurocorrection should be constrained by a beneficence requirement—that it should be limited to neurocorrectives that can be expected to benefit those required to undergo them; and my argument is that a beneficence requirement is necessary in order to safeguard against offender abuse. I highlight how we afford a heightened protective role to beneficence in other instances of biomedical intervention where consent is absent or in doubt; and I argue a beneficence requirement is also necessary in the correctional context because alternative candidate protections would provide insufficiently strong safeguards on their own. I then consider whether requiring beneficence in nonconsensual neurocorrection would (a) be incompatible with penal theory, (b) be objectionably paternalistic, or (c) foreclose many fruitful avenues of crime control. I argue in each case that it would not.

Is true informed consent achievable?

Miya Matz

MacEwan University Student eJournal, 6 May 2022; 6(1)

Abstract

Imagine you have just found out that a loved one, such as a parent, sibling, or close friend, suffers from a rare and deadly genetic disorder. There are currently no successful mainstream treatments for this disorder. However, the doctor mentions a highly experimental treatment that would involve removing bone marrow

from a healthy donor once a month for a full year and could potentially cause permanent damage to them. It turns out that you are a match. How would you make your decision regarding treatment? Most individuals would suggest leaving it to the doctor's discretion, but because it is your body, it is ultimately your choice. You attempt to do further research on the internet but end up confused and frustrated. How will you ultimately decide as to whether you should give informed consent for the procedure?

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