

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

May 2021

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” and “informed consent” in title and available text. After careful consideration, a selection of these results appear in the digest. 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, a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

Editor

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

Editor’s Note:

Posting of Informed Consent Content on Clinical Trials Registries was the latest webinar in the Center’s continuing series held on April 21st 2021. Foundation president David Curry opened the call with a short presentation followed by a panel discussion with Barbara Redman, Director of the Center for Informed Consent Integrity, and Jan Jaeger, Fellow of the GE2P2 Global Foundation. The discussion was focused on issues and opportunities around the posting of informed consent content [ICFs+] on clinical trial registries as a means to enhance transparency and strengthen consent in trials overall.

We organize content in each edition using subject categories to help readers navigate. We expect that these categories will evolve over time.

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No new content identified for the following established categories:

BIOBANKING

FREE PRIOR INFORMED CONSENT (FPIC)

HUMANITARIAN CONTEXT

POLICY GUIDANCE/PROGRAM ACTION

Please note that we maintain a glossary and an inventory of tools for assessment as well as standards and guidance documents on our [website](#).

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COVID-19

Nursing Home and Vaccination Consent: The Italian Perspective

Nunzia Cannovo, Roberto Scendonì, Marzia Maria Fede, Federico Siotto, Piergiorgio Fedeli, Mariano Cingolani
Vaccines, 24 April 2021; 4(429)

Open Access

Abstract

Since the beginning of the Covid-19 pandemic, many countries have begun vaccination campaigns, with different methods and timelines, with the goal of vaccinating over 75% of the population and thus achieving herd immunity. Initially it was necessary to identify the categories of citizens who should be the first to receive the vaccines, on the basis of scientific evidence. On the basis of this information, elderly residents in nursing homes and the staff who care for them should be the highest priority subjects for vaccination. In this context, obtaining informed consent to Covid-19 vaccination presents a considerable challenge, as the advanced age and frequent comorbidities of a significant number of the residents may mean that they are incapable of expressing consent themselves. The legislation of various Western nations substantially agrees on the general principle that those capable of judgement must be asked for their consent for healthcare services, and that even those with psychological weaknesses that limit their full ability to decide must be involved in these decision-making processes. The article can help systematize the processes to be implemented to protect the health of individuals as members of a close and fragile community.

Consent in covid: A researcher's dilemma

Review

Trends in Anaesthesia and Critical Care, 3 April 2021

Heena Garg, Puneet Khanna

Abstract

An informed consent is a vital component of health care and forms an important component of any research study. Informed consent is the process where a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. A proper consent is imperative to ensure safety of the patients. However, obtaining a consent in the hospital settings has become a matter of concern in the times of this coronavirus-19 (COVID-19) pandemic. This brief review describes the additional complexities added to the consent for research and the various modifications needed in view of this pandemic. The current consent proformas need to be modified and individualised to the patient ensuring

patient safety during research in the ongoing pandemic. We need to become more familiar with the technology and electronic tools as the acceptable alternative tools of communication in the current scenario. There is a need to incorporate a separate covid consent with due consideration to deferred consent, pre-emptive consent or waiver of a consent.

Global Ethical Considerations Regarding Mandatory Vaccination in Children

Julian Savulescu, Alberto Giubilini, Margie Danchin

The Journal of Pediatrics, 20 January 2021

Open Access

Abstract

Whether children should be vaccinated against coronavirus disease-2019 (COVID-19) (or other infectious diseases such as influenza) and whether some degree of coercion should be exercised by the state to ensure high uptake depends, among other things, on the safety and efficacy of the vaccine. For COVID-19, these factors are currently unknown for children, with unanswered questions also on children's role in the transmission of the virus, the extent to which the vaccine will decrease transmission, and the expected benefit (if any) to the child. Ultimately, deciding whether to recommend that children receive a novel vaccine for a disease that is not a major threat to them, or to mandate the vaccine, requires precise information on the risks, including disease severity and vaccine safety and effectiveness, a comparative evaluation of the alternatives, and the levels of coercion associated with each. However, the decision also requires balancing self-interest with duty to others, and liberty with usefulness. Separate to ensuring vaccine supply and access, we outline 3 requirements for mandatory vaccination from an ethical perspective: (1) whether the disease is a grave threat to the health of children and to public health, (2) positive comparative expected usefulness of mandatory vaccination, and (3) proportionate coercion. We also suggest that the case for mandatory vaccine in children may be strong in the case of influenza vaccination during the COVID-19 pandemic.

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BIOMEDICAL RESEARCH

Rethinking consent processes for research in emergency departments

Perspective

Joseph Miller, Stephen Guy Costa, David Alan Taylor, Paul Buntine

Emergency Medicine Australasia, 17 April 2021

Abstract

Emergency medicine researchers face the challenge of prioritising patients' immediate interests and maintaining hospital flow while attempting to collect clinical data. Even in low-risk scenarios, excessive consent processes can make it difficult to recruit patients while observing guidelines on efficient triage. We discuss a recent situation in which a six-page consent form appeared to deter clinicians from recruiting patients to a low-risk intervention. We then argue that there need be no conflict between the imperatives of patient wellbeing and clinical research. Apparent conflicts between treatment and research could be reduced through creative recruitment techniques: the adoption of an 'opt-out' approach; securing the budget for a dedicated research assistant; early consultation with the institution's human research ethics committee; and the use of a short, simple participant information and consent form with a QR code linking to a more detailed outline of the study.

Transparency of informed consent in pilot and feasibility studies is inadequate: a single-center quality assurance study

Research

Mohammed I.U. Khan, Lawrence Mbuagbaw, Matthew Holek, Faris Bdair, Zoha H. Durrani, Katie Mellor, Saskia Eddy, Sandra M. Eldridge, Claire L. Chan, Michael J. Campbell, Christine M. Bond, Sally Hopewell, Gillian A. Lancaster, Lehana Thabane

Pilot and Feasibility Studies, 16 April 2021; 7(96)

Open Access

Abstract

Background

Pilot and feasibility studies (PAFS) often have complex objectives aimed at assessing feasibility of conducting a larger study. These may not be clear to participants in pilot studies.

Methods

Here, we aimed to assess the transparency of informed consent in PAFS by investigating whether researchers communicate, through patient information leaflets and consent forms, key features of the studies. We collected this data from original versions of these documents submitted for ethics approval and the final approved documents for PAFS submitted to the Hamilton Integrated Research Ethics Board, Canada.

Results

One hundred eighty-four PAFS, submitted for ethics approval from 2004 to 2020, were included, and we found that of the approved consent documents which were provided to participants, 83.2% (153) stated the terms "pilot" or "feasibility" in their title, 12% (22) stated the definition of a pilot/feasibility study, 42.4% (78) of the studies stated their intent to assess feasibility, 19.6% (36) stated the specific feasibility objectives, 1.6% (3) stated the criteria for success of the pilot study, and 0.5% (1) stated all five of these criteria. After ethics review, a small increase in transparency occurred, ranging from 1.6 to 2.8% depending on the criteria. By extracting data from the protocols of the PAFS, we found that 73.9% (136) stated intent to assess feasibility, 71.2% (131) stated specific feasibility objectives, and 33.7% (62) stated criteria for success of the study to lead to a larger study.

Conclusion

The transparency of informed consent in PAFS is inadequate and needs to be specifically addressed by research ethics guidelines. Research ethics boards and researchers ought to be made aware and mindful of best practices of informed consent in the context of PAFS.

Under consent: participation of people with HIV in an Ebola vaccine trial in Canada

Research Article

Pierre-Marie David, Benjamin Mathiot, Oumy Thiongane & Janice E. Graham

BMC Medical Ethics, 9 April 2021; 22(42)

Open Access

Abstract

Background

Little is known about volunteers from Northern research settings who participate in vaccine trials of highly infectious diseases with no approved treatments. This article explores the motivations of HIV immunocompromised study participants in Canada who volunteered in a Phase II clinical trial that evaluated the safety and immunogenicity of an Ebola vaccine candidate.

Methods

Observation at the clinical study site and semi-structured interviews employing situational and discursive analysis were conducted with clinical trial participants and staff over one year. Interviews were recorded, transcribed and analysed using critical qualitative interpretivist thematic analytical techniques. Patterns were identified, clustered and sorted to generate distinct and comprehensive themes. We then reassembled events and contexts from the study participants' stories to develop two ideal portraits based on "composite characters" based on study participants features. These provide ethnographically rich details of participants' meaningful social worlds while protecting individual identities.

Results

Ten of the 14 clinical trial participants, and 3 study staff were interviewed. Participant demographics and socio-economic profiles expressed limited contextual diversity. Half were men who have sex with men, half were former injection drug users experiencing homelessness, one was female, none were racialized minorities and there were no people from HIV endemic countries. Fully 90% had previous involvement in other clinical studies. Their stories point to particular socio-economic situations that motivated their participation as clinical labor through trial participation.

Conclusions

Our findings support Fisher's argument of "structural coercion" in clinical trial recruitment of vulnerable individuals experiencing precarious living conditions. Clinical trials should provide more detail of the structural socio-economic conditions and healthcare needs which lie "under consent" of study participants. Going well beyond an overly convenient narrative of altruism, ethical deliberation frameworks need to sufficiently address the structural conditions of clinical trials. We offer concrete possibilities for this and acknowledge that further research and clinical data should be made available underlying study participant contexts with regards to recruitment and participation in resource poor settings, in both the South and the North.

Assessment of the Appropriateness of the i-CONSENT Guideline Recommendations for Improving Understanding of the Informed Consent Process in Clinical Studies

Fons-Martínez J, Ferrer-Albero C, Díez-Domingo J

Research Square, 5 April 2021

Abstract

Background

The H2020 i-CONSENT project has developed a set of guidelines that offer ethical recommendations and practical tools aimed at making the informed consent process in clinical studies more comprehensive, tailored, and inclusive. An analysis of the appropriateness of some of its novel recommendations was carried out by a group of experts representing different stakeholders.

Methods

An adaptation of the RAND/UCLA Appropriateness Method was used to assess the level of agreement on the recommendations among 14 representatives of different stakeholders, including patients, regulators, investigators, ethics experts, and the pharmaceutical industry. The process included two rounds of rating and a virtual meeting.

Results

Fifty-three recommendations were evaluated. After the first round, 34 recommendations were judged appropriate; 19 were judged uncertain; and none was judged inappropriate. After the second round, 9 uncertain changed to appropriate. All recommendations rated medians of 6.5-9 on a 1-9 scale (1 = extremely inappropriate, 5 = uncertain, 9 = extremely appropriate). The sections "General recommendations" and "Gender perspective during the consent process for clinical studies" showed the highest uncertainty rating. The four keys to improving the understanding of the ICP in clinical studies are to: (1) consider consent a two-way continuous interaction that begins at the first contact with the potential participant and continues until the end of the study; (2) improve investigators' communication skills; (3) co-create the information; and (4) use a layered approach, including information to compensate for the potential participant's possible lack of health literacy and a glossary of terms.

Conclusions

The RAND/UCLA method has demonstrated validity for assessing the appropriateness of recommendations in ethical guidelines. The recommendations of the i-CONSENT guidelines were mostly judged appropriate by all stakeholders involved in the informed consent process.

Framing a Consent Form to Improve Consent Understanding and Determine How This Affects Willingness to Participate in HIV Cure Research: An Experimental Survey Study

Research Article

John A. Saucedo, Karine Dubé, Brandon Brown, Ashley E. Pérez, Catherine E. Rivas, David Evans, Celia B. Fisher

Journal of Empirical Research on Human Research Ethics, 14 December 2020

Abstract

HIV cure research carries serious risks and negligible benefits. We investigated how participants understand these risks and what influences their willingness to participate. Through internet-based and in-person convenience sampling, 86 HIV+ participants completed an experimental survey. Participants were randomized to read a standard consent form describing a hypothetical HIV cure study or one adapted using Fuzzy Trace Theory—a decision-making model to facilitate complex information processing. We measured consent understanding and cognitive (e.g., safe/harmful) and affective (e.g., concerning, satisfying) evaluations of HIV cure research. Participants who read the adapted consent form had improved consent understanding, but only positive affective evaluations were associated with a willingness to participate. Consent processes can use decision-making theories to facilitate comprehension of study information.

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SOCIAL SCIENCE RESEARCH

Is the Language of Informed Consent Templates for Dental Treatment Patient Friendly?

Viktorii Kostenko, Olena Bieliaieva, Iryna Solohor

Eurasian Conference on Language & Social Sciences, 2-3 February 2021; Gjakova, Kosovo pp 324-328

Abstract

The patient's voluntary informed consent for medical intervention has been known as an integral part of the modern system of moral, ethical and legal regulation of healthcare provision. Grammar complexity of formal language and terminology differences between healthcare providers and patients may cause communication problems and adversely affect patient access to health information, leading to poor satisfaction for both parties. There have been few reports clarifying the selection of the language means in order to facilitate patients' complete and unhindered understanding of the information in informed consent template for dental treatment and to influence them in making the right decision. The aim of the study is to investigate grammar characteristics (sentence structure, voice, the tense and aspect of finite verb phrases) and to analyze the findings from functional perspective and communicative purposes. This empirical research of qualitative descriptive type was based on the corpus of 50 informed consent templates for dental treatment used by the USA healthcare settings authorized to provide oral and dental services. Critical discourse analysis is a main analytic technique employed in the study. The main idea behind the informed consent is that individuals having obtained a sufficient amount of special information and clearly understood it should be able to make their own knowledgeable and voluntary decisions concerning the exposure to potentially dangerous dental procedures. Text structuring, headings, metatextual devices in the templates demonstrate doctor's responsibility for understanding text by the patients, i.e. the respectful and careful attitude to the clients. The average length of the texts and the average length of the sentences are also taken into account, whereas the documents are designed within the patient-centred approach and in patient-friendly manner. Though the texts of informed consent templates are relatively short, they abound in composite sentences: the complex sentences make up 69.3 %, the complex-compound sentences make up to 7.14%. Simple sentences, 21.5%, rank the second position. Composite sentences as well as numerous simple sentences with extended homogenous parts are exploited in the informed consent templates in order to minimize misunderstanding in the interpretation medical information, but, on the other hand, they can to interfere with quick and complete comprehension of the dependency relations among the ideas expressed in the

sentences. Sentences in the active voice exceed those in passive voice that makes the text more readable and understandable.

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GENOMIC MEDICINE/GENE EDITING

Views on genomic research result delivery methods and informed consent: a review

Danya F Vears , Joel T Minion, Stephanie J Roberts, James Cummings, Mavis Machirori & Madeleine J Murtagh

Personalized Medicine, 6 April 2021; 18(3)

Abstract

There has been little discussion of the way genomic research results should be returned and how to obtain informed consent for this. We systematically searched the empirical literature, identifying 63 articles exploring stakeholder perspectives on processes for obtaining informed consent about return of results and/or result delivery. Participants, patients and members of the public generally felt they should choose which results are returned to them and how, ranging from direct (face-to-face, telephone) to indirect (letters, emails, web-based delivery) communication. Professionals identified inadequacies in result delivery processes in the research context. Our findings have important implications for ensuring participants are supported in deciding which results they wish to receive or, if no choice is offered, preparing them for potential research outcomes.

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HEALTH DATA

To consent, or not to consent? The publicness effect on citizens' willingness to grant access to personal data in the face of a health crisis

Nicola Belle, Paola Cantarelli, R. Paul Battaglio

Journal of European Public Policy, 16 April 2021

Abstract

This study contributes to the nascent behavioral governance scholarship by experimentally testing whether individuals' likelihood of lifting their privacy rights in the face of a health crisis varies based on the public versus private nature of the entity accessing their personal data and the length of time during which records can be used. We run an online, randomized control trial with 1,500 citizens representative of the Italian general adult population. Results show a significant increase in subjects' willingness to grant access to personal records when the entity analyzing data is public rather than private. Further, the propensity to consenting is higher when access to personal data is granted for a limited rather than an unlimited period of time. We discuss how these patterns of results change remarkably across geographic areas within the country.

Informed consent for linking survey and social media data

Johannes Breuer, Tarek Al Baghal, Luke Sloan, Libby Bishop, Dimitra Kondyli, Apostolos Linardis

IASSIST Quarterly, 2021; 45(1) pp 1-27

Open Access

Abstract

Linking social media data with survey data is a way to combine the unique strengths and address

some of the respective limitations of these two data types. As such, linked data can be quite disclosive and potentially sensitive, it is important that researchers obtain informed consent from the individuals whose data are being linked. When formulating appropriate informed consent, there are several things that researchers need to take into account. Besides legal and ethical questions, key considerations are the differences between platforms and data types. Depending on what type of social media data is collected, how the data are collected, and from which platform(s), different points need to be addressed in the informed consent. In this paper, we present three case studies in which survey data were linked with data from 1) Twitter, 2) Facebook, and 3) LinkedIn and discuss how the specific features of the platforms and data collection methods were covered in the informed consent. We compare the key attributes of these platforms that are relevant for the formulation of informed consent and also discuss scenarios of social media data collection and linking in which obtaining informed consent is not necessary. By presenting the specific case studies as well as general considerations, this paper is meant to provide guidance on informed consent for linked survey and social media data for both researchers and archivists working with this type of data.

Rethinking Informed Consent in the Context of Big Data

Anna Bruvere, Victor Lovic

Cambirdge Journal of Science & Policy, 2021; 2(2)

Open Access

Abstract

A widely accepted method for addressing digital privacy concerns is the use of informed consent: asking users to agree to privacy policies and consent to the use of their personal data. This approach has come under strain with the emergence of “big data” in which large datasets are collected and analysed. This paper argues that since individuals do not understand or even read the privacy policies they agree to, informed consent ultimately fails to protect privacy. Following the work of Solon Barocas and Helen Nissenbaum, this paper proposes an updated definition of informed consent and argues that the responsibility of protecting privacy should be shifted from individuals to organisations.

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TECHNOLOGY/OTHER MEDIATION

073: Improving Consent with a Visual Tool for Communicating Surgical Risks

SJ Tingle, JK Ramsingh, RD Bliss, PP Truran

British Journal of Surgery, 27 April 2021; Volume 108(Supplement 1)

Abstract

Introduction

Patients must understand the risks of a procedure to provide valid consent. Guidance from the General Medical Council and Royal College of Surgeons of England highlights that surgeons need to communicate risks in a way that patients can understand, and both institutions specifically mention the use of written information. We aimed to improve communication of surgical risks to patients undergoing thyroid surgery.

Method

Over 3 months, all patients undergoing thyroid surgery in a tertiary referral centre were included (n=51). Participants were given a 10 point questionnaire after the consent process. Each question had 4 options (very common, common, uncommon and rare) and tested participant understanding of surgical risks. Our intervention was a single page annotated graphic, which used a traffic-light system to explain surgical risks.

Result

When consented prior to our intervention (n=28), patient understanding of the magnitude of surgical risks was poor; median questionnaire score was 4.5 out of 10, and for some questions <15% of participants selected the correct answer. Following introduction of our surgical risk tool (n=23) median overall participant score increased from 4.5 (range 2-7) to 8.0 (4-10) out of 10 (P<0.0001; Mann-Whitney U test).

Conclusion

Patients must understand the risks of an operation, and the magnitude of those risks, in order to provide valid consent. Addition of a visual surgical risk tool enabled us to increase patient understanding of surgical risks, improving the consent process. This has implications not just for thyroid surgery, but for any procedure requiring consent.

Take-home message

Clear communication of surgical risks is essential to obtain valid consent. The use of a visual surgical risk tool increases patient understanding of risks, and therefore improves the consent process.

Randomized comparison of two interventions to enhance understanding during the informed consent process for research

Research Article

Holly A Taylor, Daphne Washington, Nae-Yuh Wang, Hiten Patel, Daniel Ford, Nancy E Kass, Joseph

Clinical Trials, 23 April 2021

Abstract

Background/Aims

Many investigators have tested interventions to improve research participant understanding of information shared during the informed consent process, using a variety of methods and with mixed results. A valid criticism of most consent research is that studies are often conducted in simulated research settings rather than ongoing clinical studies. The present study rigorously tested two simple and easily adoptable strategies for presenting key consent information to participants eligible to enroll in six actual clinical trials (i.e. six parent studies).

Methods

In collaboration with the study team from each parent study, we developed two consent interventions: a fact sheet and an interview-style video. The content of each of the intervention was based on the information shared in the consent form approved for each parent study. Participants were randomized to the standard consent process, or to one of the two interventions. Once exposed to the assigned consent mode, participants were asked to complete an assessment of understanding. The study was powered to determine whether those exposed to the fact sheet or video performed better on the consent assessment compared to those exposed to the standard consent. We also assessed participant satisfaction with the consent process.

Results

A total of 284 participants were randomized to one of the three consent arms. Assessments of understanding were completed with a total of 273 participants from July 2017 to April 2019. Participants exposed to the video had better understanding scores compared to those exposed to the standard consent form process (p value = 0.020). Participants were more satisfied with the video when compared to the standard consent. Participants who received the fact sheet did not achieve higher overall understanding or satisfaction scores when compared to the standard consent process.

Conclusion

This randomized study of two novel consent interventions across six different clinical trials demonstrated a statistically significant difference in participant understanding based on overall scores among those exposed to the video intervention compared to those exposed to the standard consent.

Multimedia for Delivering Participant Informed Consent in Cardiovascular Trials

Niamh Chapman, Rebekah Mcwhirter, Matthew Armstrong, Ricardo Fonseca, Julie Campbell, Mark Nelson, Martin Schultz, James Sharman

Journal of Hypertension, April 2021; 39 pp e217-e218

Open Access

Abstract

Objective

Obtaining informed consent is a cornerstone requirement of conducting ethical research. Traditional paper-based consent is often excessively lengthy, legalistic in character, and may fail to achieve desired participant understanding of study requirements. Multimedia tools including video and audio may be a useful alternative. This study aimed to determine the efficacy, usability and acceptability of stand-alone multimedia delivery of participant consent relating to a cardiovascular trial.

Design and method

A total of 298 participants (63 ± 8 years; 51% female) were randomised to delivery of cardiovascular research study information and signed consent via multimedia (intervention; n = 146) compared with standard paper-based approach (control; n = 152) in a clinical research setting. Intervention was free of research staff and included short audio-visual explanations, with computer-based finger-signed consent. Efficacy, usability and acceptability were assessed by questionnaire.

Results

All participants successfully completed allocated interventions. Efficacy parameters were significantly higher among intervention participants, including better understanding of study requirements compared with controls (P < 0.05 all). Intervention participants were also significantly more likely to engage with the study information and spend more time on the consent process and study questionnaire (P = 0.038 and P = 0.007, respectively). Both groups reported similar levels of acceptability of the consent process, although more control participants reported that the study information was too long (24% versus 14%; P = 0.020).

Conclusions

A standalone multimedia consent process is effective for achieving participant understanding and obtaining consent on cardiovascular research in a clinical research setting free of research staff. Thus, multimedia represents a viable method to reduce the burden on researchers, meet participant needs, and achieve informed consent in clinical cardiovascular research.

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CAPACITY TO CONSENT

Assessment of capacity to give informed consent for medical assistance in dying: a qualitative study of clinicians' experience

Ellen Wiebe, Michaela Kelly, Thomas McMorro, Sabrina Tremblay-Huet, Mirna Hennawy *Abstract*

Canadian Medical Association Journal, 13 April 2021;9(2) pp E358-E363

Open Access

Abstract

Background

Under the Canadian Criminal Code, medical assistance in dying (MAiD) requires that patients give informed consent and that their ability to consent is assessed by 2 clinicians. In this study, we intended to understand how Canadian clinicians assessed capacity in people requesting MAiD.

Methods

This qualitative study used interviews conducted between August 2019 and February 2020, by phone, video and email, to explore how clinicians assessed capacity in people requesting MAiD, what challenges they had encountered and what tools they used. The participants were recruited from provider mailing listserves of the Canadian Association of MAiD Assessors and Providers and Aide médicale à mourir. Interviews were audio-recorded and transcribed verbatim. The research team met to review transcripts and explore themes as they emerged in an iterative manner. We used abductive reasoning for thematic analysis and coding, and continued to discuss until we reached consensus.

Results

The 20 participants worked in 5 of 10 provinces across Canada, represented different specialties and had experience assessing a total of 2410 patients requesting MAiD. The main theme was that, for most assessments, the participants used the conversation about how the patient had come to choose MAiD to get the information they needed. When the participants used formal capacity assessment tools, this was mostly for meticulous documentation, and they rarely asked for psychiatric consults. The participants described how they approached assessing cases of nonverbal patients and other challenging cases, using techniques such as ensuring a quiet environment and adequate hearing aids, and using questions requiring only "yes" or "no" as an answer.

Interpretation

The participants were comfortable doing MAiD assessments and used their clinical judgment and experience to assess capacity in ways similar to other clinical practices. The findings of this study suggest that experienced MAiD assessors do not routinely require formal capacity assessments or tools to assess capacity in patients requesting MAiD.

Impact of Age on Consent in a Geriatric Orthopaedic Trauma Patient Population

Research Article

Madeline M. McGovern, Michael F. McTague, Erin Stevens, Juan Carlos Nunez Medina, Esteban Franco-Garcia, Marilyn Heng

Geriatric Orthopedic Surgery & Rehabilitation, 30 March 2021

Open Access

Abstract

Introduction

Persistent misconceptions of frailty and dementia in geriatric patients impact physician-patient communication and leave patients vulnerable to disempowerment. Physicians may inappropriately focus the discussion of treatment options to health care proxies instead of patients. Our study explores the consenting process in a decision-making capable orthogeriatric trauma patient population to determine if there is a relationship between increased patient age and surgical consent by health care proxy.

Methods

Patients aged 65 and older who underwent operative orthopaedic fracture fixation between 1 of 2 Level 1 Trauma Centers were retrospectively reviewed. Decision-making capable status was defined as an absence of patient history of cognitive impairment and a negative patient pre-surgical Confusion Assessment Method (CAM) and Mini-Cog Assessment screen. Provider of surgical consent was the main outcome and was determined by signature on the consent form.

Results

510 patients were included, and 276 (54.1%) patients were deemed capable of consent. In 27 (9.8%) of 276 decision-capable patients, physicians obtained consent from health care proxies. 20 of these 27 patients (74.1%) were 80 years of age or older. However, in patients aged 70 to 79, only 7 health care proxies provided consent. ($p = 0.07$). For every unit increase in age, the log odds of proxy consent increased by .0008 ($p < 0.001$). Age ($p < 0.001$), income level ($p = 0.03$), and physical presence of proxy at consult ($p < 0.001$) were factors associated with significantly increased utilization of health care proxy provided consent. Language other than English was a significant predictor of proxy-provided consent ($p = 0.035$). 48 (22%) decision-making incapable patients provided their own surgical consent.

Discussion

The positive linear association between age and health care proxy provided consent in cognitively intact geriatric orthopaedic patients indicates that increased patient age impacts the consenting process. Increased physician vigilance and adoption of institutional consenting guidelines can reinforce appropriate respect of geriatric patients' consenting capacity.

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YOUNG PERSONS

Consent, refusal of care, and shared decision-making for pediatric patients in emergency settings

Morrison SN, Sigman L

Pediatric Emergency Medicine Practice, 2 May 2021, 18(5) pp 1-20

Abstract

Involving patients or their surrogate decision-makers in their care is an important element of modern medical practice. General consent, informed consent, treatment refusal, and shared decision-making are concepts that are used regularly but can be more complex in pediatric emergency settings. This issue summarizes these concepts and provides case examples that may be encountered. It explains the essential elements of informed consent, the distinction between the informed consent process and the document, how to approach treatment refusal, and approaches to involving patients and their surrogates in shared decision-making. Special circumstances include treatment for sexual and mental health conditions, emancipated minors, mature minors, and situations when custody is unclear. Implementation of these concepts can increase patient satisfaction, resolve conflict, and reduce risk.

[The consent of adolescents in an outpatient setting].

Desmarets-Malik V

Soins Psychiatrie, 23 March 2021; 42(333) pp 23-25

Abstract

The part-time therapeutic reception center (CATTP) presented in this article has modified its organization in order to retain the adolescents who attend it. Clinical work on indications and the implementation of a reception protocol mobilized the team in view of admissions. The CATTP, in its current functioning, brings together the adolescent and his family, in search of a double consent.

Editor's note: This is a French language publication

Social Media Terms and Conditions and Informed Consent From Children: Ethical Analysis

Christophe Olivier Schneble, Maddalena Favaretto, Bernice Simonne Elger, David Martin Shaw

JMIR Pediatrics and Parenting, 22 April 2021; 4(2)

Open Access

Abstract

Background

Terms and conditions define the relationship between social media companies and users. However, these legal agreements are long and written in a complex language. It remains questionable whether users understand the terms and conditions and are aware of the consequences of joining such a network. With children from a young age interacting with social media, companies are acquiring large amounts of data, resulting in longitudinal data sets that most researchers can only dream of. The use of social media by children is highly relevant to their mental and physical health for 2 reasons: their health can be adversely affected by social media and their data can be used to conduct health research.

Objective

The aim of this paper is to offer an ethical analysis of how the most common social media apps and services inform users and obtain their consent regarding privacy and other issues and to discuss how lessons from research ethics can lead to trusted partnerships between users and social media companies. Our paper focuses on children, who represent a sensitive group among users of social media platforms.

Methods

A thematic analysis of the terms and conditions of the 20 most popular social media platforms and the 2 predominant mobile phone ecosystems (Android and iOS) was conducted. The results of this analysis served as the basis for scoring these platforms.

Results

The analysis showed that most platforms comply with the age requirements issued by legislators. However, the consent process during sign-up was not taken seriously. Terms and conditions are often too long and difficult to understand, especially for younger users. The same applies to age verification, which is not realized proactively but instead relies on other users who report underaged users.

Conclusions

This study reveals that social media networks are still lacking in many respects regarding the adequate protection of children. Consent procedures are flawed because they are too complex, and in some cases, children can create social media accounts without sufficient age verification or parental oversight. Adopting measures based on key ethical principles will safeguard the health and well-being of children. This could mean standardizing the registration process in accordance with modern research ethics procedures: give users the key facts that they need in a format that can be read easily and quickly, rather than forcing them to wade through chapters of legal language that they cannot understand. Improving these processes would help safeguard the mental health of children and other social media users.

Implementing new consent procedures for schools-based human papillomavirus vaccination: a qualitative study

Research

Suzanne Audrey, Karen Evans, Michelle Farr, Joanne Ferrie, Julie Yates, Marion Roderick, Harriet Fisher
British Journal of Child Health, 10 April 2021; 2(2)

Abstract

Background

The requirement for written parental consent for school-based human papillomavirus vaccination programme in England can act as a barrier to uptake for some young women, with the potential to exacerbate health inequities.

Aims

To consider the practicalities and implications of implementing new consent procedures, including parental telephone consent and adolescent self-consent, in two local authority areas in the southwest of England.

Methods

Digitally recorded, semi-structured interviews were conducted with 53 participants, including immunisation nurses, school staff, young people, and parents. All interviews were fully transcribed and thematic analysis was undertaken.

Results

Parental telephone consent was welcomed by the immunisation nurses, parents, and young women in the study. Adolescent self-consent was rare. Greater understanding of the barriers to uptake outside of mainstream school-based sessions is needed to further address inequalities in uptake.

Conclusions

The new procedures generally worked well but some important barriers to vaccination uptake remain.

Primary caregivers' experience with the informed consent process in the paediatric emergency department: An interview-based qualitative study

Adonis Wazir, Ibrahim Sandokji, Morten Greaves, Rasha D Sawaya
Paediatrics & Child Health, 3 April 2021

Abstract

Objective

This study aims to understand primary caregivers' (PCG) experience with the informed consent (IC) process.

Methods

We conducted in-depth interviews with PCGs of paediatric patients who underwent a procedure requiring IC in the paediatric emergency department (PED) of a tertiary care paediatric centre in the USA, between January and March 2013 and between September 2013 and January 2014. We triangulated the qualitative findings from the PCG interviews with Likert-scale responses from the PCGs and with results from surveyed physicians.

Results

We included 14 PCG–physician dyads. Our results show that PCGs understand the importance of the IC process. They appreciated the calm demeanor of providers, and the clarity of their wording. PCGs felt that IC can add to the stress, and that it could be made simpler and timelier. PCGs also had varying extents of retention of the information provided.

Conclusion

This exploratory study suggests an overall positive IC experience of the PCGs while highlighting areas for improvement including a more thorough discussion of alternatives, a better assessment of knowledge transmission and retention by the PCG, and recognition of the PCG’s discomfort during decision making in a stressful environment.

Forms to capture child consent to surgical procedures: Time to focus on function rather than form

A Strode, C Badul

South African Journal of Bioethics and Law, April 2021; 14(1)

Open Access

Abstract

It is uncontroversial that no form of treatment, including a surgical operation, can be undertaken without the consent of the patient/proxy. The Children’s Act deals expressly with consent to ‘surgical operations’ on children. Section 12 creates a framework based on the principles of child participation and protection. Nevertheless, obtaining consent from children remains complex: firstly, children are legal minors and have limited capacity to act independently. Secondly, there may be risks or longer-term consequences of surgery that distinguish it from medical treatment. Third, a child’s capacity to understand risks is not static: it evolves with age, and limited tools exist to access capacity. Fourth, there are at least three parties to the consent procedure – the child, the parent/guardian and the medical practitioner, all of whom may have different interests. Fifth, in some instances there is the added complication of child parents who need to provide consent for their own child. This article aims to provide guidance to surgeons and other medical practitioners performing surgery on children. It does this through setting out the legal norms relating to child consent to an operation. It critically examines the pro forma consent forms (forms 34 and 35) found in the regulations issued in terms of the Children’s Act that are to be used to document the consent process, and identifies key gaps and weaknesses. It concludes with recommendations for the adaptation of these forms through the use of a checklist to ensure that all the requirements for valid consent are documented, protecting children and medical practitioners.

‘Informed consent’ in consensual child welfare: some reflections on its controversial nature

Rosi Enroos, Johanna Korpinen, Tarja Pösö

European Journal of Social Work, 28 March 2021

Open Access

Abstract

The article examines the nature of consent in the context of Finnish care order decision-making as described by social workers, parents and young people, all personally involved in care order decision-making, albeit in different roles: on the one hand, an authority asking for the view about a child removal, and on the other, a party expressing a view which has huge legal, social and moral implications for their family relations. Based on qualitative data, the analysis examines two criteria for informed consent: adequate information and

freedom from undue influence. The findings highlight the messy and blurred nature of consent that is found in other fields of practice as well. There are, however, some distinctive features relevant to consensual services in child welfare which need to be further elaborated. In particular, family relationality shapes the nature of consent through intra-familial power and emotions, differently for parents and children. Critical awareness of the nature of consent is also important for an understanding of service-user participation and self-determination.

Informed Consent From Children

Tim Moore

Sage Research Methods, 17 September 2019

Abstract

Children’s informed consent in participatory research is an essential component to ethical research practice. Although there has been significant attention from researchers about the importance of seeking children’s informed consent prior to their participation in data collection, some commentators see consent as an ongoing process rather than a hurdle to be overcome prior to data collection. After discussing the participation of children in research, this entry presents five steps that may help researchers consider how to embed informed consent in research activities as well as examples to show how researchers can assist children to understand, indicate, utilize, and reflect on their consent.

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RIGHTS/LEGAL/LEGISLATIVE

Beyond Montgomery – decision making, consent and the GMC

Anastasia Georgiou, Helen Bolton

Obstetrics, Gynaecology & Reproductive Medicine, 17 April 2021

Abstract

In November 2020 the General Medical Council (GMC) updated its guidance on decision making and consent. This new document reflects significant legal and ethical developments that have occurred in recent years. It is helpful to understand the context from which this guidance has arisen, and imperative to understand the implications it will have on clinical practice. As such, this article will (i) outline the evolution of consent (ii) briefly explain the landmark case of Montgomery and (iii) highlight the key updates in the GMC's 2020 guidance.

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COMPASSIONATE USE/EXPANDED ACCESS

Changing FDA Approval Standards: Ethical Implications for Patient Consent

Viewpoint

Jonathan J. Darrow, Sanket S. Dhruva, Rita F. Redberg

Journal of General Internal Medicine, 8 April 2021

Open Access

Excerpt

The pace of new drug and medical device introductions has accelerated in recent years. In 2018, 59 novel drugs were approved in the USA, the most since 1996. A rising proportion of drugs and devices qualify for one of the US Food and Drug Administration’s (FDA) expedited programs, which allow approval based on less

rigorous clinical trials. Expanded access and emergency use authorization allow access to products—such as remdesivir (Veklury) and COVID-19 vaccines—even before they are approved.

The growing array of products made available with limited evidence poses important challenges for patients and physicians. Ethical principles require that patients consent to treatment after being informed of the benefits and harms of each alternative. In routine practice, however, the consent process is often truncated, with limited presentation of alternatives, risks, and outcome data. As regulatory processes have evolved, the consent process—already criticized by some as inadequate—has changed little. We review the evolution of drug and device evidence requirements and consider the implications for informed consent...

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CULTURAL/COUNTRY CONTEXT

Knowledge and practices of seeking informed consent for medical examinations and procedures by health workers in the Democratic Republic of Congo

Doudou Nzaumvila, Patrick Ntotolo, Indiran Govender, Philip Iukanu, JD Landu Niati, Didier Sanduku, Tombo Bongongo

African Journals Online, 16 April 2021; 21(1)

Open Access

Abstract

Background

Informed consent (IC) is linked to the ethical principle of respecting patient autonomy, respect for human rights and ethical practice, while in many countries it is a standard procedure. Anecdotally, it should be noted that in the Democratic Republic of Congo (DRC) in many instances ICs are not obtained systematically. To date, no research appears to have been conducted on this matter. This study aimed to assess the knowledge and practice of obtaining IC from patients among health care providers (HCP) in the DRC.

Methods

This was a cross-sectional study, with a convenient sampling of 422 participants. Data from the questions were collected on an imported Microsoft Excel spreadsheet for review at INSTAT.TM The authors set IC's accurate knowledge and practice at 80% or higher. The Fisher Exact test was used to compare categorical association results, and a p-value < 0.05 was considered statistically significant.

Results

Results showed that giving information in detail to patients on their medical condition was associated with formal training on medical ethics and IC (p: 0.0028; OR: 1.894; CI: 1.246 to 2.881), which was also associated with answering the patient's questions in detail (p: 0.0035; OR: 1.852; CI: 1.236 to 2.774). About 127(30.09 %) of participants scored 80% or higher. Extracurricular training was associated with withholding information from patients, up to 27 times more than other factors (p< 0.0001; OR: 27.042; CI: 13.628 to 53.657). when it comes to get IC, HCP with many years of practice scored better than others, in one of the question the odd ratio was closer to 7 (p< 0.0001; OR: 6.713; CI: 4.352 to 10.356). Only 47(11.14%) of the participants scored 80% or more of the questions about practice of IC.

Conclusion

For a variety of reasons, knowledge and practice of IC among HCPs was very low. A common programme for the country as part of formal training might lead to an improvement. In addition, patients' education on IC should be displayed in waiting areas at all medical centres.

Validation of the factors influencing family consent for organ donation in the UK

Original Article

R. M. K. Curtis A. R. Manara S. Madden C. Brown S. Duncalf D. Harvey A. Tridente D. Gardiner
Anaesthesia, 16 April 2021

Summary

Between 2013 and 2019, there was an increase in the consent rate for organ donation in the UK from 61% to 67%, but this remains lower than many European countries. Data on all family approaches (16,896) for donation in UK intensive care units or emergency departments between April 2014 and March 2019 were extracted from the referral records and the national potential donor audit held by NHS Blood and Transplant. Complete data were available for 15,465 approaches. Consent for donation after brain death was significantly higher than for donation after circulatory death, 70% (4260/6060) vs. 60% (5645/9405), (OR 1.58, 95%CI 1.47–1.69). Patient ethnicity, religious beliefs, sex and socio-economic status, and knowledge of a patient's donation decision were strongly associated with consent ($p < 0.001$). These factors should be addressed by medium- to long-term strategies to increase community interventions, encouraging family discussions regarding donation decisions and increasing registration on the organ donor register. The most readily modifiable factor was the involvement of an organ donation specialist nurse at all stages leading up to the approach and the approach itself. If no organ donation specialist nurse was present, the consent rates were significantly lower for donation after brain death (OR 0.31, 95%CI 0.23–0.42) and donation after cardiac death (OR 0.26, 95%CI 0.22–0.31) compared with if a collaborative approach was employed. Other modifiable factors that significantly improved consent rates included less than six relatives present during the formal approach; the time from intensive care unit admission to the approach (less for donation after brain death, more for donation after cardiac death); family not witnessing neurological death tests; and the relationship of the primary consentor to the patient. These modifiable factors should be taken into consideration when planning the best bespoke approach to an individual family to discuss the option of organ donation as an end-of-life care choice for the patient.

Obstacles to Obtaining Informed Consent from the Perspective of Transplant Coordinators: A Qualitative Study

Research Article

Alireza Shamsaeefar, Nasrin Motazedian, Fatemeh Rahmanian, Saman Nikeghbalian, Seyed Ali Malek-Hosseini

Hepatitis Monthly, 5 April 2021; 21(2)

Abstract

Background

The lack of consent to donate body organs leads to an increase in the death rate of patients on the waiting list for transplantation. Unwillingness of families is known as the main obstacle to organ donation, and the media has an essential role in motivating organ donation.

Objectives

This study aimed to explore obstacles to obtaining consent for organ donation from transplant coordinators' perspective throughout Iran.

Methods

In this qualitative study, 13 in-depth semi-structured face-to-face interviews were conducted with transplant coordinators from November 2018 to March 2019. The participants were investigated using a purposive sampling method. The participants' age and work experience ranged between 32 - 49 years and 6 - 25 years, respectively. Open-ended questions were asked from the participants in a private room. An experienced interviewer explained the study's objectives to the coordinators, and each interview lasted on average 50 minutes. The interview scripts were analyzed using a content analysis method.

Results

The findings highlighted the difficulty of obtaining consent from brain-dead patients' families. The obstacles could be internal or external. External determinants were healthcare providers' lack of empathy, inadequate consultation from doctors outside the hospital, media content, and uninformed comments from relatives. Internal determinants were hoping for recovery, denial, and disagreement among family members.

Conclusions

The healthcare team should have a better connection with families to obtain organ donation consent from them. Therefore, a training program must be developed for the treatment team so that they show more supportive behavior and improve quality of care in hospitals before and after brain death.

Health workers' perspectives on informed consent for caesarean section in Southern Malawi

Wouter Bakker, Siem Zethof, Felix Nansongole, Kelvin Kilowe, Jos van Roosmalen, Thomas van den Akker
Research Article

BMC Medical Ethics, 29 March 2021; 22(33)

Open Access

Abstract

Objective

Informed consent is a prerequisite for caesarean section, the commonest surgical procedure in low- and middle-income settings, but not always acquired to an appropriate extent. Exploring perceptions of health care workers may aid in improving clinical practice around informed consent. We aim to explore health workers' beliefs and experiences related to principles and practice of informed consent.

Methods

Qualitative study conducted between January and June 2018 in a rural 150-bed mission hospital in Southern Malawi. Clinical observations, semi-structured interviews and a focus group discussion were used to collect data. Participants were 22 clinical officers, nurse-midwives and midwifery students involved in maternity care. Data were analysed to identify themes and construct an analytical framework.

Results

Definition and purpose of informed consent revolved around providing information, respecting women's autonomy and achieving legal protection. Due to fear of blame and litigation, health workers preferred written consent. Written consent requires active participation by the consenting individual and was perceived to transfer liability to that person. A woman's refusal to provide written informed consent may pose a dilemma for the health worker between doing good and respecting autonomy. To prevent such refusal, health workers said to only partially disclose surgical risks in order to minimize women's anxiety. Commonly perceived barriers to obtain a fully informed consent were labour pains, language barriers, women's lack of education and their dependency on others to make decisions.

Conclusions

Health workers are familiar with the principles around informed consent and aware of its advantages, but fear of blame and litigation, partial disclosure of risks and barriers to communication hamper the process of obtaining informed consent. Findings can be used to develop interventions to improve the informed consent process.

Multicomponent Informed Consent with Marshallese Participants

Research Article

Rachel S. Purvis, Britni L. Ayers, Cari A. Bogulski, Kyle F. Kaminicki, Lauren K. Haggard-Duff, Lynda A. Riklon, Anita Iban, Rotha Mejbon-Samuel, Rumina Lakmis, Sheldon Riklon, Joseph W. Thompson, Pearl A. McElfish
Journal of Empirical Research on Human Research Ethics, 29 March 2021

Abstract

Pacific Islanders are the second fastest-growing population in the United States; however, Pacific Islanders, and Marshallese specifically, are underrepresented in health research. A community-based participatory research (CBPR) approach was used to engage Marshallese stakeholders and build an academic-community research collaborative to conduct health disparities research. Our CBPR partnership pilot tested a multicomponent consent process that provides participants the option to control the use of their data. Consent forms used concise plain language to describe study information, including participant requirements, risks, and personal health information protections, and were available in both English and Marshallese. This study demonstrates that when provided a multicomponent consent, the vast majority of

consenting study participants (89.6%) agreed to all additional options, and only five (10.4%) provided consent for some but not all options. Our description of the development and implementation of a multicomponent consent using a CBPR approach adds a specific example of community engagement and may be informative for other indigenous populations.

Informed Consent for Mobile Phone Health Surveys in Colombia: A Qualitative Study

Research Article

Mariana Rodriguez-Patarroyo, Angelica Torres-Quintero, Andres I. Vecino-Ortiz, Kristina Hallez, Aixa Natalia Franco-Rodriguez, Eduardo A. Rueda Barrera, Stephanie Puerto, Dustin G. Gibson, Alain Labrique, George W. Pariyo, Joseph Ali

Journal of Empirical Research on Human Research Ethics, 25 September 2020

Abstract

Public health surveys deployed through automated mobile phone calls raise a set of ethical challenges, including succinctly communicating information necessary to obtain respondent informed consent. This study aimed to capture the perspectives of key stakeholders, both experts and community members, on consent processes and preferences for participation in automated mobile phone surveys (MPS) of non-communicable disease risk factors in Colombia. We conducted semi-structured interviews with ethics and digital health experts and focus group discussions with community representatives. There was meaningful disagreement within both groups regarding the necessity of consent, when the purpose of a survey is to contribute to the formulation of public policies. Respondents who favored consent emphasized that consent communications ought to promote understanding and voluntariness, and implicitly suggested that information disclosure conform to a reasonable person standard. Given the automated and unsolicited nature of the phone calls and concerns regarding fraud, trust building was emphasized as important, especially for national MPS deployment. Community sensitization campaigns that provide relevant contextual information (such as the name of the administering institution) were thought to support trust-building. Additional ways to achieve the goals of consent while building trust in automated MPS for disease surveillance should be evaluated in order to inform ethical and effective practice.

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MEDICAL/SURGICAL

The use of bovine pericardial patches in vascular surgery: where do we draw the line in obtaining informed consent?

Stacie Hodge, Nicholas Greaves, David Murray

Annals of Vascular Surgery, 24 April 2021

Abstract

With advances in modern medicine there has been unprecedented growth in biological materials derived from either porcine or bovine products. Absolute or relative restrictions of the dietary consumption of bovine or porcine products among different religious groups are relatively well documented. However, there are no clear guidelines about the non-dietary use of animal products for patients with particular secular or religious beliefs. For a patient undergoing a carotid endarterectomy, induction with propofol, administration of heparin at the time of vessel clamping, use of a bovine pericardial patch for angioplasty, covering the wound with a hydrocolloid dressing and post-operative aspirin administration exposes the patient to animal products at every stage, from the moment they walk through the door. A number of articles have advocated obtaining informed consent when using animal products in healthcare but where should the line be drawn? In particular, should we consent for the use of bovine pericardium in vascular surgery? This paper reviews the evidence available and discusses our current standpoint from both a legal and ethical aspect.

Do we achieve the Montgomery standard for consent in orthopaedic surgery?

Xenia N Tonge, Henry Crouch-Smith, Vijay Bhalai, William D Harrison

British Journal of Hospital Medicine, 21 April 2021

Abstract

Aims/Background

The Montgomery v Lanarkshire Health Board (2015) case set a precedent that has driven the modernisation of consenting practice. Failure to demonstrate informed consent is a common source of litigation. This quality improvement project aimed to provide pragmatic guidance for surgeons on consent and to improve the patient experience during decision making.

Methods

Elective orthopaedic patients were assessed and the quality of documented consent was recorded. Data were collected over two discrete cycles, with cycle 1 used as a baseline in practice. The following criteria were reviewed: grade of consenting clinician, alternative treatment options, description of specific risks, place and timing of consent and whether the patient received written information or a copied clinic letter. Cycle 1 results were presented to clinicians; a teaching session was provided for clinicians on the standard of consent expected and implementation of a change in practice was established with a re-audit in cycle 2.

Results

There were 111 patients included in cycle 1, and 96 patients in cycle 2. Consent was undertaken mostly by consultants (54%). Specific patient risks were documented in 50% of patients in cycle 1 and 60% in cycle 2. Risks associated with a specific procedure were documented in 42% in cycle 1 and 76% in cycle 2, alternative options in 48% (cycle 1) and 66% (cycle 2). A total of 14% of patients in cycle 1 and 8% in cycle 2 had documented written information provision. Copied letters to patients was only seen in 12% of all cycles. Documentation from dedicated consenting clinics outperformed standard clinics.

Conclusions

Highlighting poor documentation habits and refining departmental education can lead to improvements in practice. The use of consenting clinics should be considered and clinicians should individually reflect on how to address their own shortcomings. Other units should strongly consider a similar audit. This article provides stepwise advice to improve consent and specifics from which to audit.

Informed consent in interventional radiology – are we doing enough?

Akash Prashar, Saqib Butt, Davide Giuseppe Castiglione, Nadeem Shaida

British Journal of Radiology, 21 April 2021

Abstract

Objectives

Obtaining informed consent is a mandatory part of modern clinical practice. The aim of this study was to identify how often complications relating to Interventional Radiology (IR) procedures were discussed with the patient prior to the procedure.

Methods

A retrospective analysis of 100 patients who experienced a complication related to an IR procedure was performed. The patient's procedure consent form was examined to identify whether the complication they experienced had been discussed as a possible risk. Other parts of the consent form relating to need for blood transfusion and the need for further procedures were also examined.

Results

39% of patients who experienced a complication did not have the complication documented as a potential risk on the consent form. 14% of patients required a blood transfusion but were not consented for this. 42% of patients required a further procedure or operation but were not warned of this.

Conclusion

The model of gaining informed consent on the day of procedure is no longer valid. Better education and the use of clinics, patient information sheets and other resources is essential.

Pre-Abortion Informed Consent Through Telemedicine vs. in Person: Differences in Patient Demographics and Visit Satisfaction

Original Article

Shelly Kaller, Sara Daniel, Sarah Raifman, M. Antonia Biggs, Daniel Grossman

Women's Health Issues, 5 April 2021

Abstract

Purpose

Utah law requires patients to have a face-to-face "informed consent" visit at least 72 hours prior to abortion. Planned Parenthood Association of Utah (PPAU) offers this visit via telemedicine as an alternative to an in-person visit, which can require burdensome travel. This novel study identifies factors associated with using telemedicine for informed consent, patients' reasons for using it, and experiences with it, compared to in-person informed consent.

Methods

In 2017 and 2018, patients 18 years and older seeking abortion at PPAU completed a self-administered online survey about their experiences with the informed consent visit. We used linear and logistic regression models to compare participants' demographic characteristics by informed consent visit type, and descriptive statistics to describe reasons for using each visit type and experiences with the visit. Multivariable logistic regression models examined associations between visit type and satisfaction.

Results

Responses from 166 telemedicine patients and 217 in-person informed consent patients indicate that telemedicine participants would have had to travel significantly further than in-person participants traveled to attend the visit at the clinic (mean of 65 miles versus 21 miles, $p < .001$). In multivariable analyses, telemedicine participants had higher odds of being "very satisfied" with the visit (aOR, 2.89; 95% CI: 1.93–4.32) and "very comfortable" asking questions during the visit (aOR, 3.76; 95% CI: 2.58–5.49), compared to participants who attended in-person visits.

Conclusions

Telemedicine offers a convenient, acceptable option for mandated pre-abortion informed consent visits and reduces the burden of additional travel and associated barriers for some patients, particularly those who live further away from clinics.

[In search of open minds and shared consent - Information, treatment options and postoperative care from the patient's perspective]

Ganz-Blättler U

Therapeutische Umschau. Revue Therapeutique, 1 April 2021; 78(3) pp 149-157

Abstract

This paper addresses knowledge gaps which are prone to handicap the ongoing communication process between medical / care personnel and patients of breast cancer, due to everyday routine and presumed lack of time. The respective qualitative studies do point to divergent expectations with regards to medical consultations and indicate that patients' satisfaction with therapeutic measures, which were decided in advance, might be improved. Three exemplary aspects of doctor-patient communication are then looked at closer: first the variety of treatment options offered, second the risk of expressing unconscious bias regarding patients' physical appearance and identity, and third the increasingly acknowledged desire of breast cancer patients to consult (... additionally, not alternatively) with other patients that are, or were previously affected by breast cancer and confronted with the decisions this condition entails.

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

Informed consent: What risks are material to patients consenting for urological procedures?

Research Article

Nadine McCauley, Siya Lodhia, Andrea Ong, Calum Clark, Tim Lane

Journal of Clinical Urology, 31 March 2021

Abstract

Objective

This study aimed to assess patient recall of the consent discussion for urological procedures and to identify which risks were material to urology patients.

Methods

A total of 102 patients undergoing urological procedures were interviewed in the 24-hour period surrounding the procedure. A self-designed, piloted questionnaire recorded information from the patient's signed consent form and patient-reported data of the consent discussion.

Results

The mean patient recall was 2.06 risks, whereas the average number of risks listed by the operating surgeon on the consent form was 5.69 risks. The most frequently recalled risk was impotence (91%), followed by urinary incontinence (63%) and haematuria (61%). The risks associated with poorest patient recall were stent symptoms (0%), urethral catheter insertion (5%) and recurrence (8%).

Conclusions

Poor patient recall of the consent discussion has again been demonstrated in this study. However, certain urological procedure risks are better recalled by patients, with impotence, urinary incontinence and haematuria being most frequently recalled. Medical terminology such as stent or catheter may be poorly recalled due to a disparity in understanding between patient and clinician. Clinicians should be aware of poor patient recall when consenting for urology procedures and should ensure precise documentation.

Harming one to benefit another: The paradox of autonomy and consent in maternity care

Original Article

Eselijn Kingma

Bioethics, 11 December 2020

Open Access

Abstract

This paper critically analyses 'the paradox of autonomy and consent in maternity care'. It argues that maternity care has certain features that increase the need for explicit attention to, and respect for, both autonomy and rigorous informed consent processes. And, moreover, that the resulting need is considerably greater than in almost all other areas of medicine. These features are as follows: (1) maternity care involves particularly socially sensitive body parts that are regularly implicated in consent-centred procedures, as well as in unconsented interventions, in ordinary, non-medical life; and (2) much of maternity care (especially intervening in childbirth) is medically unique, in that it harms one patient (the mother) not primarily for the promotion of her own health but for the benefit of another (the baby). The apt comparison, within medicine, is therefore with non therapeutic research and transplantation medicine—both of which have elevated consent requirements characterized by very rigorous consent processes. At the same time—and this delivers the titular paradox—the importance of autonomy and consent in maternity care is at particular risk of being denied or disregarded. Jointly, these considerations make a very strong case for change: attention to and respect for autonomy and consent should be (1) core values; (2) key points of practical attention in the years ahead; and (3) central quality indicators in maternity care.

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GENERAL/OTHER

Medical images, social media and consent

Comment

Jonathan P. Segal, Richard Hansen

Nature Reviews Gastroenterology & Hepatology, 23 April 2021

Excerpt

The popularity of social media amongst medical professionals has led to widespread use for both networking and education. Limited professional guidance exists on the sharing of medical imagery on these platforms. This Comment explores consent and offers reflective advice on the use of medical images on social media...

Meeting Unique Requirements: Community Consultation and Public Disclosure for Research in Emergency Setting Using Exception from Informed Consent

Dickert NW, Metz K, Fetters MD, Haggins AN, Harney DK, Speight CD, Silbergleit R

Academic Emergency Medicine, 19 April 2021

Abstract

Background

Exception from informed consent (EFIC) regulations for research in emergency settings contain unique requirements for community consultation and public disclosure. These requirements address ethical challenges intrinsic to this research context. Multiple approaches have evolved to accomplish these activities that may reflect and advance different aims. This scoping review was designed to identify areas of consensus and lingering uncertainty in the literature.

Methods

Scoping review methodology was used. Conceptual and empirical literature related to community consultation and public disclosure for EFIC research was included and identified through a structured search using EMBASE, HEIN Online, PubMed, and Web of Science. Data were extracted using a standardized tool with domains for major literature categories.

Results

Among 84 manuscripts, major domains included: conceptual or policy issues; reports of community consultation processes and results; and reports of public disclosure processes and results. Areas of consensus related to community consultation included the need for a two-way exchange of information and use of multiple methods. Public acceptance of personal EFIC enrollment is commonly 64-85%. There is less consensus regarding how to assess attitudes, what "communities" to prioritize, and how to determine adequacy for individual projects. Core goals of public disclosure are less well-developed, no metrics exist for assessing adequacy.

Conclusions

Multiple methods are used to meet community consultation and public disclosure requirements. There remain no settled norms for assessing adequacy of public disclosure, and there is lingering debate about needed breadth and depth of community consultation.

Public Attitudes toward Consent When Research Is Integrated into Care—Any “Ought” from All the “Is”?

Article

Stephanie R. Morain, Emily A. Largent

The Hastings Center Report, 11 April 2021

Abstract

Research that is integrated into ongoing clinical activities holds the potential to accelerate the generation of knowledge to improve the health of individuals and populations. Yet integrating research into clinical care

presents difficult ethical and regulatory challenges, including how or whether to obtain informed consent. Multiple empirical studies have explored patients' and the public's attitudes toward approaches to consent for pragmatic research. Questions remain, however, about how to use the resulting empirical data in resolving normative and policy debates and what kind of data warrants the most consideration. We recommend prioritizing data about what people consider acceptable with respect to consent for pragmatic research and data about people's informed, rather than initial, preferences on this subject. In addition, we advise caution regarding the weight given to majority viewpoints and identify circumstances when empirical data can be overridden. We argue that empirical data bolster normative arguments that alterations of consent should be the default in pragmatic research; waivers are appropriate only when the pragmatic research would otherwise be impracticable and has sufficiently high social value.

The Consent Continuum: A New Model of Consent, Assent, and Nondissent for Primary Care

Article

Marc Tunzi, David J. Satin, Philip G. Day

The Hastings Centre Report, 11 April 2021

Abstract

The practice around informed consent in clinical medicine is both inconsistent and inadequate. Indeed, in busy, contemporary health care settings, getting informed consent looks little like the formal process developed over the past sixty years and presented in medical textbooks, journal articles, and academic lectures. In this article, members of the Society of Teachers of Family Medicine (STFM) Collaborative on Ethics and Humanities review the conventional process of informed consent and its limitations, explore complementary and alternative approaches to doctor-patient interactions, and propose a new model of consent that integrates these approaches with each other and with clinical practice. The model assigns medical interventions to a consent continuum defined by the discrete categories of traditional informed consent, assent, and nondissent. Narrative descriptions and clinical exemplars are offered for each category. The authors invite colleagues from other disciplines and from the academic ethics community to provide feedback and commentary.

[A few reflective remarks on the notion of consent].

Berard K

Soins Psychiatrie, 23 March 2021; 42(333) pp 12-15

Abstract

Medical paternalism has given way to the autonomy of the patient, who remains master of the decisions he makes concerning his health. His consent, free and informed, has no value unless it is preceded by information adapted to his degree of understanding. The notion of consent raises the question of freedom, and therefore of the autonomy left to patients in their choices. Individual freedom occupies a particular place in psychiatry where it comes into confrontation with constraint. The tensions generated must lead caregivers to ask themselves the right questions in accordance with the principles of medical ethics.

Editor's note: This is a French language publication

Assessment of the All of Us research program's informed consent process

Megan Doerr, Sarah Moore, Vanessa Barone, Scott Sutherland, Brian M. Bot, Christine Suver, John Wilbanks

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Abstract

Informed consent is the gateway to research participation. We report on the results of the formative evaluation that follows the electronic informed consent process for the All of Us Research Program. Of the nearly 250,000 participants included in this analysis, more than 95% could correctly answer questions distinguishing the program from medical care, the voluntary nature of participation, and the right to

withdraw; comparatively, participants were less sure of privacy risk of the program. We also report on a small mixed-methods study of the experience of persons of very low health literacy with All of Us informed consent materials. Of note, many of the words commonly employed in the consent process were unfamiliar to or differently defined by informants. In combination, these analyses may inform participant-centered development and highlight areas for refinement of informed consent materials for the All of Us Research Program and similar studies.

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