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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

July 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:

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Editor's Note:
The latest webinar in the Center's continuing series, Closing the loop on consent: from initial decision, continued participation, through to sharing of results, was held on June 16th 2021. Dr. Katie Gillies of the University of Aberdeen spoke about her work to strengthen the informed consent by developing an understanding of what information matters most to trial participants. She then spoke about how this understanding can lead to increased participant retention and further work to be done.

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
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH
TECHNOLOGY/OTHER MEDIATION

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

Implications and advice on getting COVID-19 vaccine consent

Feature
Jonathan Beebee
Learning Disability Practice, 1 April 2021; 24(2) pp 10-12
Abstract
How to support people with learning disabilities to get vaccinated. Vaccinations against COVID-19 are not mandatory and where people can give or refuse consent we have a responsibility to ensure consent is sought. Many people with learning disabilities will be unable to consent, but others will be able to consent if given the right support. Nurses, carers and families should begin planning as soon as possible, so they are prepared when the invitation to receive the vaccine arrives.

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BIOMEDICAL RESEARCH

Randomized, Double-Blind Trial on the Impact of Word Count in Cancer Clinical Trial Consent Forms

Original Contribution
Yahya Almodallal, Quyen Duong, Daniel Satele, Paul Novotny, Kathryn D. Cook , Cynthia Chauhan, Michelle K. Daiss, Jennifer Le-Rademacher, Sherry Looker, Nichole Martin, Michanda F. Smestad, Stacey J. Winham, Sumithra J. Mandrekar, Aminah Jatoi
JCO Oncology Practice, 14 June 2021
Abstract
Purpose
This randomized, double-blind study sought to understand whether cancer clinical trial consent form verbosity detracts from patients' decision making on trial enrollment.
Methods
This trial tested mock consent forms of 2,000, 4,000, and 6,000 words. The first two comprised the two experimental arms and the third the control arm. Phase II was conducted to identify the promising arm, which, in phase III, was compared with the control arm. Each consent form described the same trial. Eligible

adult patients reported a cancer history and English literacy. The primary end point used a patient-reported Likert scale to assess the relationship between information in the consent form and trial decision making.
Results
In phase II, 93 patients were accrued and prompted the selection of the 2,000-word consent form for phase III. In phase III, 182 patients were recruited, resulting in 240 total evaluable patients to compare the 2,000-word versus the 6,000-word arm (control). For the primary end point, 103 (84%) and 107 (91%) patients in the 2,000- and 6,000-word arms, respectively, strongly agreed or agreed with the following: "The information in this consent form helped me make a decision about whether or not to enroll in the trial" (two-sided, P = .14). Median time to read each consent form was 8 and 12 minutes, respectively (two-sided, P < .0001). Among those assigned these consent forms, 84% and 73%, respectively (two-sided, P = .04) signed or expressed a willingness to sign.
Conclusion
This study's primary end point was not met. However, secondary outcomes suggest a need to further study the efficiency and efficacy of shorter consent forms for cancer clinical trial enrollment.

Implementing stakeholder engagement to explore alternative models of consent: An example from the PREP-IT trials

Guillermo Pechero Jr., Branden Pfaff, Mayank Rao, David Pogorzelski, Paula McKay, Ella Spicer, Andrea Howe, Haley K. Demyanovich, Debra L. Sietsema, Michael F. McTague, Lolita Ramsey, Martha Holden, Joshua Rudnicki, Jeff Wells, Michelle Medeiros, Gerard P. Slobogean, Sheila Sprague
Contemporary Clinical Trials Communications, 14 June 2021; 22
Abstract
Introduction
Cluster randomized crossover trials are often faced with a dilemma when selecting an optimal model of consent, as the traditional model of obtaining informed consent from participant's before initiating any trial related activities may not be suitable. We describe our experience of engaging patient advisors to identify an optimal model of consent for the PREP-IT trials. This paper also examines surrogate measures of success for the selected model of consent.
Methods
The PREP-IT program consists of two multi-center cluster randomized crossover trials that engaged patient advisors to determine an optimal model of consent. Patient advisors and stakeholders met regularly and reached consensus on decisions related to the trial design including the model for consent. Patient advisors provided valuable insight on how key decisions on trial design and conduct would be received by participants and the impact these decisions will have.
Results
Patient advisors, together with stakeholders, reviewed the pros and cons and the requirements for the traditional model of consent, deferred consent, and waiver of consent. Collectively, they agreed upon a deferred consent model, in which patients may be approached for consent after their fracture surgery and prior to data collection. The consent rate in PREP-IT is 80.7%, and 0.67% of participants have withdrawn consent for participation.
Discussion
Involvement of patient advisors in the development of an optimal model of consent has been successful. Engagement of patient advisors is recommended for other large trials where the traditional model of consent may not be optimal.

'To say no wasn't something we could do'; Reflexive accounts and negotiations of the ethical practice of informed consent during the research process and beyond [BOOK CHAPTER]

Johanna Sixtensson
The Politics and Ethics of Representation in Qualitative Research, Routledge, 2021

Abstract
In this chapter, the implementation of the formal ethical principle of informed consent in the research process is discussed. By analyzing encounters and exchanges with a young research participant, both during the fieldwork and after publication, the text examines the meaning of the concept of consent and discloses complexities and ambivalences inherent in asking for and giving consent. It shows that giving consent or 'saying no' is a complicated practice that should not be reduced to a single act or signature on a consent form. Rather, consenting to participate in research is an open-ended, situated, ambivalent and not necessarily verbal process. It might also have an impact on participants beyond the actual research process: for instance, when faced with the researcher's representations of personal interview accounts in research reports. The text captures the relationality that exists between researchers and those we research, especially regarding how dependent researchers are on participants' consent, their acts and the quality of the empirical material that participants 'generate'.

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HEALTH DATA

Managing Consent for Data Access in Shared Databases

Osnat Drien, Antoine Amarilli, Yael Amsterdamer
IEEE Xplore, 22 June 2021
Abstract
Data sharing is commonplace on the cloud, in social networks and other platforms. When a peer shares data and the platform owners (or other peers) wish to use it, they need the consent of the data contributor (as per regulations such as GDPR). The standard solution is to require this consent in advance, when the data is provided to the system. However, platforms cannot always know ahead of time how they will use the data, so they often require coarse-grained and excessively broad consent. The problem is exacerbated because the data is transformed and queried internally in the platform, which makes it harder to identify whose consent is needed to use or share the query results. Motivated by this, we propose a novel framework for actively procuring consent in shared databases, focusing on the relational model and SPJU queries. The solution includes a consent model that is reminiscent of existing Access Control models, with the important distinction that the basic building blocks – consent for individual input tuples – are unknown. This yields the following problem: how to probe peers to ask for their consent regarding input tuples, in a way that determines whether there is sufficient consent to share the query output, while making as few probes as possible in expectation. We formalize the problem and analyze it for different query classes, both theoretically and experimentally.

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CAPACITY TO CONSENT

How to deal with the consent of adults with cognitive impairment involved in European geriatric living labs?

Guillaume Sacco, Frédéric Noublanche, Frédéric Blazek, Catherine Hue, Loïc Carballido, Marine Asfar, Philippe Allain, Cédric Annweiler
Philosophy, Ethics, and Humanities in Medicine, 16 June 2021; 16(3)
Open Access
Abstract
Background

Living labs are realistic environments designed to create links between technology developers and end-users (i.e. mostly older adults). Research in LLH (Living labs in health) covers a wide range of studies from non-interventional studies to CT (clinical trials) and should involve patients with neurocognitive disorders. However, the ethical issues raised by the design, development, and implementation of research and development projects in LLH have been the subject of only little interest thus far.

Objective

Our aim was to determine a pragmatic, ethical and regulatory correct approach to seek the informed consent of patients with neurocognitive disorders according to the different types of studies carried out in European LLH, with a focus on the French context.

Methods

A narrative review of regulatory texts and clinical articles was conducted, and a pragmatic procedure to determine the decision-making capacity of older adults in LLH was proposed.

Results

Individuals must be adequately informed and freely agree to participate in CT. The capacity to consent should be assessed in CT including cognitively impaired older adults. We propose the following steps: first to assess for delirium using the 4 'A's Test (4AT) or the 3-min Diagnostic interview for Confusion Assessment Method (3D-CAM), second to search for medical history of major neurocognitive disorder, and third to assess the decision capacity using the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC).

Conclusions

Including individuals with neurocognitive disorders in research implies using an efficient and pragmatic strategy to inform participants and obtain their consent. The tool we offer here may be useful in the routine operation of LLH but can also be extended to all CT with this population.

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YOUNG PERSONS

Facilitators and barriers for parental consent to pediatric emergency research

Clinical Research Article

Reagan L. Miller, R. Dawn Comstock, Lauren Pierpoint, Jan Leonard, Lalit Bajaj, Rakesh D. Mistry

Pediatric Research, 4 June 2021

Abstract

Background

Obtaining informed consent for clinical research in the pediatric emergency department (ED) is challenging. Our objective was to understand the factors that influence parental consent for ED studies.

Methods

This was a cross-sectional survey assessing parents' willingness to enroll their children into an ED research study. Parents reporting a willingness to enroll in ED studies were presented with two hypothetical scenarios, a low-risk and a high-risk study, and then asked about decision influencers affecting consent. Parents expressing a lack of willingness to enroll were asked which decision influencers impacted their consent decision.

Results

Among 118 parents, 90 (76%) stated they would be willing to enroll their child into an ED study; of these, 86 (96%) would consent for a low-risk study and 54 (60%) would consent for a high-risk study. Caucasian parents, and those with previous research exposure, were more likely to report willingness to participate. Those who would consent to the high-risk study cited "benefits that research would provide to future children" most strongly influenced their decision to agree.

Conclusions

ED investigators should highlight the benefits for future children and inquire about parents' previous exposure to research to enhance ED research enrollment. Barriers to consent in non-Caucasian families should be further investigated.

Late adolescents' own and assumed parental preferences towards health-care related confidentiality and consent in Belgium

David De Coninck, Koen Matthijs, Peter de Winter, Jaan Toelen

PLoS One, 2 June 2021

Abstract

Objectives

Health care professionals regularly struggle with issues relating to confidentiality and consent for physical and/or mental health issues among adolescents. We investigate late adolescents' own and assumed parental preferences towards health-care related confidentiality and consent.

Methods

We analyzed online survey data of four vignettes from 463 first-year university students at KU Leuven (Flanders, Belgium). We used paired samples t-tests to assess the (in)consistency between attitudes of late adolescents and their assumed parental attitudes, independent samples t-tests to estimate gender differences, and binomial logistic regressions to analyze the association of assumed parental preferences with late adolescents' own preferences.

Results

Attitudinal inconsistencies were present in all vignettes. Late adolescents were significantly more in favor of confidentiality and adolescent consent than what they believed their parents were. Gender differences were limited. Binomial logistic regressions indicated that assumed parental preferences were strongly associated with late adolescents' own preferences.

Conclusions

Findings suggest a clear difference between late adolescents' preferences and assumed parental preferences: they believe that their parents are less inclined to favor confidentiality and adolescent consent. We also find that this difference depends on the case, indicating that there is no such thing as general 'confidentiality preferences'. Rather, a decision- and/or context-specific perspective should be adopted.

Soliciting parental consent among adolescent minor mothers: A barrier in adolescent HIV research?

L T Gebrekristos

South African Medical Journal, May 2021; 111(6) pp 526-527

Open Access

Excerpt

Adolescents fare worse on the HIV prevention and treatment cascade than adults. This disparity may be particularly acute for adolescent minors (i.e. <18 years of age). Current trends show that adolescents, and especially adolescent minors, are a particularly vulnerable population. The under-representation of adolescent minors (especially unemancipated induviduals) in HIV research negatively affects the development and evaluation of interventions to improve their health. Despite growing consensus regarding the value of conducting HIV research with adolescent minors, concerns about perceived barriers to enrolling them persists. Specifically, researchers and adolescnets minors in studies have voices concerns that requiring parental consent might affect adolescent minors' autonomy and/or confidentiality…

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RIGHTS/LEGAL/LEGISLATIVE

Consent for withholding life-sustaining treatment in cancer patients: a retrospective comparative analysis before and after the enforcement of the Life Extension Medical Decision law

Yu Jin Chung, Incheol Park, Junho Cho, Jin Ho Beom, Ji Eun Lee

BMC Medical Ethics, 17 June 2021; 22(72)

Open Access

Abstract

Background

The Life Extension Medical Decision law enacted on February 4, 2018 in South Korea was the first to consider the suspension of futile life-sustaining treatment, and its enactment caused a big controversy in Korean society. However, no study has evaluated whether the actual implementation of life-sustaining treatment has decreased after the enforcement of this law. This study aimed to compare the provision of patient consent before and after the enforcement of this law among cancer patients who visited a tertiary university hospital's emergency room to understand the effects of this law on the clinical care of cancer patients.

Methods

This retrospective single cohort study included advanced cancer patients aged over 19 years who visited the emergency room of a tertiary university hospital. The two study periods were as follows: from February 2017 to January 2018 (before) and from May 2018 to April 2019 (after). The primary outcome was the length of hospital stay. The consent rates to perform cardiopulmonary resuscitation (CPR), intubation, continuous renal replacement therapy (CRRT), and intensive care unit (ICU) admission were the secondary outcomes.

Results

The length of hospital stay decreased after the law was enforced from 4 to 2 days ($p = 0.001$). The rates of direct transfers to secondary hospitals and nursing hospitals increased from 8.2 to 21.2% ($p = 0.001$) and from 1.0 to 9.7%, respectively ($p < 0.001$). The consent rate for admission to the ICU decreased from 6.7 to 2.3% ($p = 0.032$). For CPR and CRRT, the consent rates decreased from 1.0 to 0.0% and from 13.9 to 8.8%, respectively, but the differences were not significant ($p = 0.226$ and $p = 0.109$, respectively).

Conclusion

After the enforcement of the Life Extension Medical Decision law, the length of stay in the tertiary university hospital decreased in patients who established their life-sustaining treatment plans in the emergency room. Moreover, the rate of consent for ICU admission decreased.

(Un)informed Consent: To What Degree are Research Participants 'Informed' by Common Consent Procedures in Psychology under EU Data Protection Law?

Malte Elsonab, Dara Hallinanc, Annika Külpmannа, Franziska Boehmc

PsychArchives, 31 May 2021

Open Access

Abstract

There is reason to believe that consent forms may routinely do not fulfill the requirements for consent outlined in EU data protection law. Where this is the case, the legitimacy of the conduct of research may be undermined and could result in restrictions on the subsequent conduct of research, obligations to delete data, or obligations to limit the sharing of psychological research data. However, so far, there are no empirical data to support the proposition that compliance may not be the norm. We propose a study design in which we draw a random sample of psychological research reports and systematically compare the research practices (i.e., reported data collection procedures, sharing practices) with the details provided in the respective participant information and consent form and compare each of these with the legal requirements outlined in EU data protection law.

Presumed Consent for Organ Donation: An Incoherent Justification

Vicente Formoso, Sílvia Marina, Miguel Ricou

Acta Bioethica, 2021; 27(1) pp 27-35

Open Access

Abstract

The difference between supply and demand of transplantable organs is a global problem, and one of the most discussed measures aiming to solve it is the implementation of a presumed consent (opt-out) policy in cadaveric organ donation. This type of system is controversial when it comes to its direct effects on organ donation rates as well as its ethical base. We aim to present the latest perspectives concerning the ethical implications of the policy, especially regarding consent: its need, the coherence of presuming it and the policy's capacity to fulfill its requirements. From a community perspective, we advocate a default change in societies with an opt-out system, with a strong population education in that direction. The potential rights of family objection are also approached as well as the differences between theoretical discussion and concrete application of public policy.

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CULTURAL/COUNTRY CONTEXT

Egyptian patients'/guardians' experiences and perception about clinical informed consent and its purpose: Cross sectional study

Ammal M. Metwally, Hala A. Amer, Hend I. Salama, Safaa I. Abd El Hady, Raefa R. Alam, Ahmed Aboulghate, Hanan A. Mohamed, Hanan M. Badran, Amal A. Saadallah, Marwa M. El-Sonbaty, Eman Eltahlawy, Walaa Saad, Amira Mohsen, Ghada A. Abdel-Latif, Asmaa M. Fathy, Amal I. Hassanain, Abdelmoneim Eldali

PLoS One, 14 June 2021

Abstract

Background

Informed consent (IC) is a healthcare standard emphasizing the meaning of human dignity as clarified in the Universal Declaration of Human Rights. Data about IC practices in Egypt is insufficient. This study aimed to assess the Egyptian patients'/guardians' experiences about IC and their expectations about its practices' purposes in general and according to the type of the healthcare facility.

Methods

Self-administered questionnaire was carried out for 1092 participants who had undergone or were scheduled to a procedure requiring an IC at three studied types for Egyptian health care facilities. Ten statements were ranked twice by the participants to reflect their perception of IC purpose as per what is currently practiced and what they believe should be practiced.

Results

IC implementation varies significantly ($p<0.05$) across the health care facilities in Egypt. The percentage of its implementation at the non-governmental facilities, governmental facilities, and university hospital was 85.9%, 77.8%, and 63.8 respectively. The first three ranked purposes of the current IC practices were: "Helping patient/guardian decide (64.9%)", "Documenting patient's/guardian's decision (59.3%)", and "Having shared decision (57.3%)". The perceived purposes of IC to be practiced were: "Informing the patient/guardian (68.4%)", "Making sure patient/guardian understand (65.3%)" and "Documenting patients/guardians decisions (65.1%)". "Being a meaningless routine" was reported by the majority to be ranked as a low purpose for IC current and preferred practices.

Conclusion

The practice of IC is common within the Egyptian medical community. Participants believe that information disclosure "Making sure patients understand" has to help in IC decision making and its main purpose. However, unfortunately, this is not perceived as a current purpose of IC. There was consensus agreement

that documenting the patient's/guardian's decision and informing the patient/guardian are perceived as both important current and preferred purposes for IC practices.

Promoting Patient Engagement in Medical Informed Consent – A Qualitative Study of Chinese Doctors' Communication Strategies

Research Article

Qianwen Joyce Yu, ack Pun

Health Communication, 3 June 2021

Abstract

Patient engagement is now widely endorsed as an essential ingredient for high-quality healthcare, yet there has been limited research on how patient engagement can be facilitated in medical informed consent (IC) communication. To address this gap, a fine-grained discourse analysis was conducted to identify communication strategies adopted by doctors to facilitate information delivery and ascertain patients' understanding, which translate into an increase in patient engagement. Data was collected from a public hospital in mainland China. Nonparticipating observations of 14 IC sessions were audio-recorded, followed by in-depth, semi-structured interviews with those observed patients. Four communication strategies emerged from the analysis: 1) seeking patients' understanding of their condition; 2) explaining medical information by reference to shared knowledge and practice; 3) recognizing and addressing patients' psychological concerns; 4) repeating critical information and checking patients' understanding through teach-back. The adoption of these strategies enables doctors to tailor the scope and delivery of information to accommodate and address patients' preferences, rather than defaulting to one-way information dumping. This study sheds light on the complexity of IC and further contributes to the ongoing endeavors to improve IC communication by raising the awareness of the role of patients in making mutually acceptable decisions. These identified strategies can be incorporated into medical communication training to facilitate delivery of healthcare that is sensitive to patients' needs and expectations.

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MEDICAL/SURGICAL

Autonomy and consent assessment for electroconvulsive therapy (ECT). A retrospective study of medical records

Jørgen Dahlberg Siri Øverstad, Vegard Dahl, Alina Coman

International Journal of Law and Psychiatry, July–August 2021; 77

Abstract

The Norwegian Mental Health Act allows involuntary treatment for patients who lack consent capacity, however it allows only administration of pharmaceutical treatment and nutrition and not ECT. In lack of specific regulations, the legal access to ECT without valid consent has been grounded on the general rule of necessity in the Norwegian Penal code. This restriction and lack of legal regulation has implications for patients' rights and legal security.

The study's aim was to assess the documented consent provided by patients for electroconvulsive therapy (ECT), whether ECT was administered without valid consent or under coercion, and the documented reasons, and ultimately compare practice with the legal requirements. We analysed systematically all the relevant medical records for hospitalised patients and outpatients receiving ECT during 2011–2016. We categorized data from these two groups into seven defined categories describing the attitude and quality of the consents to the ECT (or lack thereof).

378 patients received 498 ECT series´. The noted consents varied from treatment based on request (54 treatments), consent upon recommendation (209 treatments), consent after hesitation (88 treatments),

consent presumed or noted without specification (114 treatments), to no consent (21 treatments) whereof the majority with documented coercion applied (19 treatments). All cases of ECT without consent referred to a “plea of necessity”. The remaining treatments (12) lacked notifications specifying the consent (or attitude) expressed. Specific notes on the patient's capacity to consent for the respective ECT were generally lacking.

This study indicates a large spread in patients´ acceptance and valid consent to ECT. The main reason for administering ECT without consent and/or against patients' will was for life-saving reasons. Such treatments were justified legal under a plea of necessity in the Penal Code or lacked noted legal justification. The legal vacuum for ECT without a valid consent needs to be addressed as this kind of disputed treatment is used in some cases.

Junior doctor experiences and challenges in obtaining surgical informed consent: A qualitative systematic review & meta-ethnography

Josephine de Costa, Mandy Shircore, Alande Costa

Journal of Surgical Research, November 2021; 267 pp 143-150

Abstract

Introduction

Surgical informed consent (SIC) to procedures is necessary to ensure patient autonomy is adequately respected. It is also necessary to protect doctors, and their institutions, from claims of negligence. While SIC is often acquired by senior consultants, it also commonly falls to the junior doctors on a team to ensure SIC is adequately acquired and documented. A growing body of literature suggests that junior doctors are not sufficiently educated about the legal and practical issues concerned with obtaining medical consent. This may open up this cohort, and their hospitals, to medico-legal liability.

Aims

to provide a systematic review of the qualitative literature on junior doctors’ experiences and challenges in consenting surgical patients and to synthesize evidence on this issue in order to guide policy-makers in the medicolegal and medical education spheres.

Methods

a systematic review of qualitative literature was performed. Analysis of the literature was guided by Noblit and Hare's seven-step approach to meta-ethnography, with the final synthesis presented as a thematic analysis of the literature.

Conclusion

This research concludes that a significant proportion of SIC is likely to be acquired by junior doctors, many of whom are Post-Graduate Year (PGY) 1-2 and who lack adequate training and education. This cohort face challenges in assessing capacity, in ensuring adequate disclosure related to surgical procedures, and in adequately documenting consent. This may impact the validity of any SIC they acquire. Medical educators and policy-makers should be aware of these issues when creating policies impacting SIC, and when designing surgical education programs for medical students and junior doctors alike.

Principles related to informed consent in functional and aesthetic rhinoplasty: A prospective study

Aloua Rachid, Sabr Ayoub, Kerdoud Ouassime, Opoko Ulrich, Savadogo Sayouba, Belem Ousmane, Konsem Tarcissus, Slimani Faiçal

International Journey of Surgery Open, 17 June 2021

Open Access

Abstract

Introduction

Rhinoplasty is one of the most complex surgical procedures in plastic surgery.

Context

Patient requirement is often mixed, aesthetic and functional, for resolution of functional respiratory problems is therefore as important as correction of nasal deformity. Informed consent in rhinoseptoplasty is a difficult process because of the complexity of the operative technique, which presents a wide range of potential complications.

Patients and method

Type of study: This is a prospective, descriptive study conducted in the department of oral and maxillofacial surgery. Fifty-two patients, who consulted for rhinoplasty, participated in the study. Patients were informed about the complications commonly discussed during the consent process in rhinoplasty surgery. Each patient was contacted one month after the initial consultation to assess recall of complications and acceptance of surgery.

Conclusion

The aim of our study is to highlight the importance of informed consent in rhinoplasty surgery in terms of complications, and to identify gaps in the consent process.

Confidence level, challenges, and obstacles faced by orthopedic residents in obtaining informed consent

Abdulaziz Z. Alomar

Journal of Orthopaedic Surgery and Research, 17 June 2021; 16(390)

Open Access

Abstract

Objectives

The objective is to evaluate the opinions of orthopedic residents on current practices, experiences, training, confidence level, difficulties, and challenges faced when obtaining informed consent.

Design

This is a cross-sectional, multi-center, and questionnaire-based study.

Setting

The study was done in forty-four training centers across Saudi Arabia.

Participants

In total, 313 orthopedic residents participated.

Material and methods

The web-based questionnaire examined the perceptions of residents regarding practices, experience, training, difficulties, and challenges surrounding the obtention of informed consent, as well as residents' confidence in obtaining informed consent for different orthopedic situations and eight common orthopedic procedures.

Results

Most residents were allowed to obtain consent independently for all emergency, trauma, primary, and revision cases at their institution (92.7%). Only 33.5% of the residents received formal training and teaching on obtaining informed consent, with 67.1% having believed that they needed more training. Only 4.2% of the residents routinely disclosed all essential information of informed consent to patients. Inadequate knowledge (86.3%) and communication barriers (84.7%) were the most reported difficulties. Generally, 77.3% of the residents described their confidence level in obtaining informed consent as good or adequate, and 33.9% were confident to discuss all key components of the informed consent. Residents' confidence level to independently obtain informed consent decreased with procedure complexity. Receiving formal training, senior level (postgraduate year (PGY) 4 and 5), and being frequently involved in obtaining informed consent correlated with increased confidence level.

Conclusion

Many residents incompletely disclosed key information upon obtaining informed consent and reported lacking confidence in their ability to perform the procedure in their daily practices. To improve patient care and residents' performance and overcome these difficulties and challenges, institutions should develop

effective strategies to standardize the informed consent process, provide formal training for obtaining informed consent, and provide supervision for residents during obtention of informed consent.

Obstetrician–Gynecologists' Practices in Postpartum Sterilization Without a Valid Medicaid Consent Form

Kavita Shah Arora, Roselle Ponsaran, Laura Morello, Leila Katabi, Rosemary T. Behmer Hansen, Nikki Zite, Kari White

Obstetrics & Gynecology, 10 June 2021

Abstract

Objective

To explore the practices of obstetrician–gynecologists (ob-gyns) in the United States surrounding postpartum sterilization when the Medicaid consent form was not valid.

Methods

Using the American College of Obstetricians and Gynecologists' online directory, we conducted a qualitative study where we recruited ob-gyns practicing in 10 geographically diverse U.S. states for a qualitative study using semi-structured interviews conducted by telephone. We analyzed interview transcripts using the constant comparative method and principles of grounded theory.

Results

Thirty ob-gyns (63% women, 77% nonsubspecialized, and 53% academic setting) were interviewed. Although most physicians stated that they did not perform sterilizations without a valid Medicaid sterilization form, others noted that they sometimes did due to a sense of ethical obligation toward their patient's health, being in a role with more authority or seniority, interpreting the emergency justification section of the form more broadly, or backdating the form. The physicians who said that they never went ahead without a signed form tended to work at large institutions and were concerned with losing funding and engaging in potentially illegal or fraudulent behavior.

Conclusion

Physicians' varied behaviors related to providing postpartum sterilization without a valid Medicaid consent form demonstrate that the policy is in need of revision. Unclear terminology and ramifications of the Medicaid sterilization policy need to be addressed to ensure equitable care.

Antenatal and intrapartum consent: Implications of the NSW Consent Manual 2020

Opinion

Hans Peter Dietz, Jessica Caudwell Hall, Natalie Weeg

ANZJOG, 7 June 2021

Abstract

The provision of informed consent for antenatal and intrapartum care remains a contentious issue among healthcare professionals and has been the topic of controversies in the pages of this journal. Recently, the New South Wales (NSW) Department of Health has fundamentally changed the ground rules for the provision of maternity care within the state. In this opinion piece, we try to provide guidance to clinicians to help them deal with the medicolegal environment created by this document which is likely to affect practitioners not just in NSW.

Anxiety is associated with unfulfilled information needs and pain at the informed consent consultation of spine surgery patients: a longitudinal study

Original Article

Sabine Fischbeck, Katja Petrowski, Mirjam Renovanz, Rebecca Nesbigall, Julian Haaf, Florian Ringel

European Spine Journal, 5 June 2021

Open Access

Abstract

Purpose

Meeting the information needs of patients adequately is of high importance in informed consent consultations in surgery. However, information needs often remain unmet in the informed consent consultation. The aim of this study was to assess anxiety and pain in relation to the patients' information needs fulfillment perioperatively.

Methods

We applied a question prompt list (QPL) for patients undergoing spine surgery (SN-QPL) before (t1) and a question answering list (SN-QAL) after (t2) the informed consent consultation. The patients additionally completed the "State-Trait Anxiety Operation Inventory" (STOA, cognitive and affective scale) at t1, as well as a pain numerical rating scale (NRS) at t2 and postoperative (t3). We analyzed (1) the association between anxiety, information needs and pain and (2) anxiety and pain scores regarding information needs fulfillment after the consent consultation.

Results

A total of n = 118 patients was included. Affective and cognitive state anxiety was only reduced postoperatively (affective $p < .001$, cognitive $p < .05$). The higher trait anxiety was, the more patients longed for information at t1–t3 (t1: $r = .58/r = .74$, each $p < .001$), (t2: $r = .38/r = .49$, each $p < .001$) and (t3: $r = .29$, $p < .01/r = 34$, $p < .001$). Higher grades of trait anxiety resulted in lower information needs fulfilment. Higher state anxiety levels were associated with higher pain levels. Information needs more often remained unfulfilled in high trait and state anxiety patients.

Conclusion

Patients' anxiety was associated with (un)fulfilled information needs. Meeting information needs should be optimized in the process of surgeon–patient communication. Adapting the information to the patients' anxiety levels seem to be an effective way to reduce anxiety.

Arthroscopic Surgery Is Not Minor Surgery: Shared Decision Requires Comprehensive Informed Consent

Editorial Commentary

Arthroscopy, 1 June 2021; 37(6) pp 1755-1756

Kwadwo Adu Owusu-Akyaw

Open Access

Abstract

Arthroscopic surgery of the shoulder has revolutionized the way we address intra-articular and tendinous injuries about the joint. Nevertheless, despite the apparent minimally invasive nature of our trade, there remain potential long-term consequences to every operation. This is especially true if future arthroplasty is indicated, as the risk of prosthetic joint infection is increased in patients having a previous procedure. True partnership with our patients necessitates that they have a clear understanding of the full implications of any surgery, no matter how small it may seem. True informed consent necessitates that our patients understand not only the immediate implications of the current operation but the potential effects on a future operation. This can only be accomplished by effective and honest communication about the full scope of the risk undertaken when an arthroscopic surgery is performed.

[The "right" patient for implant surgery in urology : Why patient selection, informed consent, and communication are so important for patient satisfaction].

Leiber C, Katzenwadel A, Schlager D

The Urologist, 1 June 2021, 60(6) pp 732-739

Abstract

In implant surgery for erectile dysfunction and urinary incontinence, adequate patient selection is essential for postoperative therapy success. Several scientific studies report patient satisfaction rates for penile

implants and artificial urinary sphincter implantation of over 90%. Nevertheless, studies also report, that between 5 and 30% of the patients are not satisfied with the result of their operation. Sufficient patient information and consent prior surgical procedure in urological prosthetics are a key determinant for later patient satisfaction and therapy success. Diligent assessment of realistic expectations, possible complications, and risks must be made. Unrealistic and exaggerated expectations need to be met and discussed with the patient. Therefore adequate physician-patient communication is essential. Especially in the case of surgical revision or for patients with risk factors, the probability of complications is higher and may significantly increase later dissatisfaction. Also, the involvement of the partner plays a major role in later patient satisfaction in urological implant surgery. Finally, there is a group of patients for which the risk of later dissatisfaction is particularly high. These are patients with compulsive/obsessive behavior, unrealistic expectations, patients after revision surgery, self-entitled patients, as well as those patients who deny the extent of their illness, visit multiple surgeons (surgeon hopping) or have psychiatric illnesses. These patients are referred to with the acronym "CURSED" patients.

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

A Novel Blended Curriculum for Communication of Informed Consent With Surgical Interns

Tiffany N. Anderson, Aboubacar Kaba, Eniola Gros, Ingrid S. Schmiederer, Robert Shi, Lauren R. Aalami, Dana T. Lin, James N. Lau

Journal of Graduate Medical Education, June 2021; 13(3) pp 411–416

Abstract

Background

Interns often conduct procedural informed consent discussions (ICDs), identified as a core entrustable professional activity. Deficiencies in the training process for ICDs span across specialties.

Objective

We provide evidence for a curriculum and assessment designed to standardize the training process and ensure ICD competency in surgical interns.

Methods

In March 2019, PowerPoint educational materials were emailed to one academic institution's new surgical interns, who in June participated in an onsite 1-hour role-play "hot seat" group activity (GA) with an untrained simulated patient, and in October completed a single trained simulated patient (real-time raters) verification of proficiency (VOP) assessment. Curriculum evaluation was measured through intern pre-/post-confidence (5-point scale), and the VOP's Cronbach's alpha and test-retest were examined. Data were analyzed with descriptive statistics, paired t tests, and 2-way random effects models.

Results

Of 44 new interns, 40 (91%) participated in the remote teaching and live GA and were assessed by the VOP. Pre-/post-GA confidence increased a mean difference of 1.3 (SD = 0.63, $P < .001$). The VOP's Cronbach's alpha was 0.88 and test-retest was 0.84 (95% CI 0.67–0.93, $P < .001$), with a 95% pass rate. The 2 first-time fail students required remediation. Time commitment included 1 hour maximum for individual training and implementation and 30 minutes for assessment. The use of volunteers and donated space mitigated additional costs.

Conclusions

Remote asynchronous and group skills teaching for new general surgical interns improved their confidence in conducting procedural ICDs. A patient-simulation verification process appeared feasible with preliminary evidence of retest and internal consistency.

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GENERAL/OTHER

Lessons Learned for Identifying and Annotating Permissions in Clinical Consent Forms

Elizabeth E. Umberfield, Yun Jiang, Susan H. Fenton, Cooper Stansbury, Kathleen Ford, Kaycee Crist, Sharon L. R. Kardia, Andrea K. Thomer, Marcelline R. Harris

Applied Clinical Information, 23 June 2021; 12(3) pp 429-435

Abstract

Background

The lack of machine-interpretable representations of consent permissions precludes development of tools that act upon permissions across information ecosystems, at scale.

Objectives

To report the process, results, and lessons learned while annotating permissions in clinical consent forms.

Methods

We conducted a retrospective analysis of clinical consent forms. We developed an annotation scheme following the MAMA (Model-Annotate-Model-Annotate) cycle and evaluated interannotator agreement (IAA) using observed agreement (A o), weighted kappa (κw), and Krippendorff's α.

Results

The final dataset included 6,399 sentences from 134 clinical consent forms. Complete agreement was achieved for 5,871 sentences, including 211 positively identified and 5,660 negatively identified as permission-sentences across all three annotators (A o = 0.944, Krippendorff's α = 0.599). These values reflect moderate to substantial IAA. Although permission-sentences contain a set of common words and structure, disagreements between annotators are largely explained by lexical variability and ambiguity in sentence meaning.

Conclusion

Our findings point to the complexity of identifying permission-sentences within the clinical consent forms. We present our results in light of lessons learned, which may serve as a launching point for developing tools for automated permission extraction.

"No Consent, No Access" The Indigenous-Environmentalist Middle Ground in Protests against the Arctic Railway in Sápmi [DISSERTATION]

Eeva-Maija Kakko

University of Helsinki, Masters Thesis, 2021

Abstract

The Arctic is home to many Indigenous peoples, including the Sámi. It is also an economically attractive area for governments and companies. Arctic Railway has been planned by the Finnish government and private parties to span over Sápmi, the Sámi homeland. Sámi youth association Suoma Sámi Nuorat, Sámi art collective Suohpanterror, and environmental NGO Greenpeace Finland have collaborated to fight against the railway and organized demonstrations and other campaigning.

The goals of this thesis are to find out what kind of themes have been present in these Sámi organizations and Greenpeace's protests and communication related to the Arctic Railway. Shared priorities and differences in their priorities are also determined. Moreover, this thesis explores how the Sámi are portrayed in the protests against the Arctic Railway. The data of this thesis is derived from public media sources, including news articles, social media content, and press releases. Case study is used as a research approach, and qualitative content analysis is used as a method. A middle ground concept functions as an analytical tool. It refers to a creative process where groups from different cultures find ways to work together. Indigenous peoples and environmentalists have often built strategic alliances, although also having differences in their priorities. In the middle ground, Indigenous peoples are recognized as active, creative agents, but also the use of stereotypes of Indigenous peoples have been present in these kinds of alliances.

The results of this thesis show that the Sámi organizations have discussed the railway´s impacts on the Sámi livelihoods, lands, and culture, affecting their future as a people. They have also brought up that the

railway has been planned without their consent, and the project has violated both Finnish law and international Indigenous rights. Greenpeace has focused on protecting the northern forests while raising awareness of Sámi issues and appearing as a supporter of Sámi people. They have had their unique middle ground where both priority differences and convergences have been present. In the protests against the Arctic Railway, the Sámi are portrayed as active agents. They have taken action in different ways: through demonstrations, participation in international events, art, and social media activism. This research can raise awareness about the potential of Indigenous-environmental alliances in promoting Indigenous rights and environmental protection and help build better alliances in the future. Further research could look at how these kinds of alliances have been negotiated.

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