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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

August 2020

This digest aggregates and distills key content around 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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We organize content in each edition using subject categories to help readers navigate. We expect that these categories will evolve over time.

No new content identified for the following established categories:
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
RIGHTS/LEGAL/LEGISLATIVE
SOCIAL SCIENCE RESEARCH
TECHNOLOGY/OTHER MEDIATION

Please note that we maintain a glossary, tools for assessment and guidance documents on our website.

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COVID-19

Virtual consent for virtual patients: benefits of implementation in a peri- and post-COVID-19 era

Subhabrata Mukherjee, Asif Raza

British Journal of Hospital Medicine, 20 July 2020

Abstract

The COVID-19 pandemic has caused major disruptions to the healthcare system, including increased reliance on virtual services, particularly clinic appointments. This leads to difficulty in obtaining informed consent; the vast majority of patients now need to be consented on the day of the procedure. To reduce problems with this process, the practice of obtaining electronic consent may be the correct way forward.

The ethics of deferred consent in times of pandemics

Comment

Rieke van der Graaf, Marie-Astrid Hoogerwerf, Martine C. de Vries

Nature Medicine, 10 July 2020

Open Access

Abstract

In the current COVID-19 pandemic, many researchers are applying to research ethics committees for deferred-consent procedures for protocols that aim either to test treatments or to obtain tissue or samples from research participants. However, the deferred-consent procedure has not been developed for pandemics. In this Comment, we interpret existing guidance documents and argue when and under which conditions deferred consent can be considered ethically acceptable in a pandemic.

Informed Consent for Emergency Obstetric Care During COVID-19 Pandemic

Short Commentary

Saswati Tripathy, Satyajit Mohapatra

The Journal of Obstetrics and Gynecology of India, 3 July 2020

Abstract

Informed consent process has become a challenging issue before surgery for any emergency obstetric care during this COVID pandemic. There is an increased risk of morbidity if there is a need of intensive care unit postoperatively and a risk of high mortality if patient has symptoms of COVID-19. Admission to intensive care unit adds on to the financial burden to the patient. Also, there is an increased risk of perinatal anxiety and depression during the COVID pandemic. When an asymptomatic carrier develops symptoms of COVID after delivery or caesarean section, the morbidity increases. So we have designed an informed consent form for patients undergoing emergency obstetric surgeries incorporating some points specific for COVID-19.

How should surgeons obtain consent during the covid-19 pandemic?

Views And Reviews

Daniel Sokol, Rupen Dattani

BMJ, 30 June 2020; 369

Excerpt

…Many surgeons are now resuming elective work, yet we are aware that some make no mention of the additional risks related to covid-19. Although the British Association of Spine Surgeons and some private hospitals have produced information sheets for patients undergoing surgery during the pandemic, to our

knowledge no formal guidance has been published by the General Medical Council or the Royal College of Surgeons on obtaining consent in such circumstances. The surgical community remains unclear as to what to tell patients about to undergo elective surgery…

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BIOMEDICAL RESEARCH

Improving knowledge and decision readiness to participate in cancer clinical trials: Effects of a plain language decision aid for minority cancer survivors

Short Communication
Aisha Langford, Jamie L. Studts, Margaret M. Byrne
Patient Education and Counseling, 7 July 2020
Abstract
Objective
To evaluate the impact of a web-based, plain language decision aid (CHOICES DA) on minority cancer survivors' knowledge of cancer clinical trials (CCTs), readiness for making decisions about clinical trial participation, and willingness to participate in a clinical trial.
Methods
Participants were 64 Black and Hispanic cancer survivors from Miami, Florida. In a single arm intervention study, participants completed self-report assessments of CCT knowledge, decision readiness regarding clinical trial participation, and willingness to participate at three time points.
Results
Black and Hispanic participants did not differ on demographic characteristics. Post-test and follow-up measures of CCT knowledge and decision readiness were significantly greater than pre-test measures for the sample overall, and for Black and Hispanic participants separately. Few significant differences were observed between Black and Hispanic participant outcomes at each survey time point, and willingness to participate did not change overall and for either group independently.
Conclusions
Reviewing the CHOICES DA was associated with significantly improved knowledge and decision readiness to participate in a CCT immediately and at 2-week follow-up.
Practical Implications
These findings suggest that CHOICES DA may support informed decision making about CCT participation within an acute, yet clinically relevant window of time for minority cancer patients who are substantially under-represented in cancer research.

Informed consent for HIV phylogenetic research: a case study of individuals living with HIV in an urban area who were contacted for participation in an HIV study

Abby E. Rudolph, Omar Martinez, Robin Davison, Chineye Brenda Amuchi
Ehquidad International Welfare Policies and Social Work Journal, 4 July 2020; 14
Open Access
Summary
Introduction: Phylogenetic analyzes can provide information on the dynamics of HIV transmission. National and state differences in HIV criminalization and disclosure laws and advances in next-generation sequencing could affect the study's perceived risks. Methods: We present the study opt-out rates and the reasons provided during enrollment for a study conducted in Boston (6 / 2017-8 / 2018). Results: Of the 90 patients who came to participate, 45 did not consent to participate. Reasons for not participating included an unwillingness to discuss their HIV status, privacy and confidentiality concerns, disinterest and lack of time.

Conclusions: Given the low participation rates and concerns related to HIV status disclosure, privacy and confidentiality, these questions remain (1) should informed consent be required for all phylogenetic analyzes, including anonymous information and surveillance data? (2) What additional steps can investigators take to protect people's privacy, particularly in contexts where HIV is criminalized or there have been civil / criminal cases investigating HIV transmission? And (3) what role can community members play to minimize potential risks, particularly for the most marginalized? These questions require input from both researchers and community members living with HIV / AIDS.

Understanding voluntariness of consent in first-in-human cell therapy trials

Perspective

Kristina Hug

Regenerative Medicine, 1 July 2020

Abstract

Consensus about contents of voluntariness in informed consent is lacking. Core criteria for voluntary consent are needed to ensure voluntariness. This article outlines the multidimensionality of voluntariness and identifies what could reduce voluntariness, especially in first-in-human clinical trials involving cell therapies. In such trials, truly voluntary consent is especially important because: such trials may involve risk of serious harm, while in case of some diseases, eligible patients often have potentially effective therapeutic alternatives; patients considering participation in high-risk first-in-human trials may feel more desperate and some may be dependent on their caregivers, including those in the family; implanted cells cannot be taken out of the patient's body if the patient wants to withdraw.

Assessment of the quality of Patient Information Sheets and Informed Consent Forms for clinical trials at a Hospital Neurology Service

Andrea G Jaramillo Vélez, Margarita Aguas Compaired, Montserrat Granados Plaza, Eduardo L. Mariño, Pilar Modamio

European Journal of Neurology, 28 June 2020

Abstract

Background and purpose

Clinical trials (CTs) aimed at vulnerable groups such as patients with mental disorders create ethical complexity. The Patient Information Sheet (PIS) should provide all the information about the CT that is relevant to the subject's decision to participate. After being informed, the subject will decide freely whether to take part in the CT and will read and sign the Informed Consent Form (ICF). The objective was to assess the quality of PIS/ICFs from a Hospital Neurology Service (NS). The assessment was made using validated and reliable checklists of the information included in the PIS/ICFs of CTs with medicinal products.

Methods

Analyses of the compliance with the checklists of 21 PIS and ICFs reviewed/approved during 2016-2017 by a medicinal Research Ethics Committee.

Results

All PIS/ICFs were from multicenter CTs sponsored by pharmaceutical companies in different therapeutic areas, mainly Parkinson's (52.4%) and Alzheimer's (38.1%) diseases. The PISs from the NS demonstrated good compliance (≥ 80%) with the checklist, while ICFs should be improved. Sponsors omitted some relevant information such as study title or that the participant be informed of any information arising from the research that may be relevant to the subject's health, although this information may be in the PIS.

Conclusions

The PIS/ICFs of CTs of medicinal products currently used need improvement. PISs and ICFs should be separate documents for each CT. The PIS/ICFs should consider, in particular, those criteria related to the decision of participants, protect their rights and ensure that the information received is complete.

How Health Literacy Can Enhance the Design and Conduct of Clinical Trials From Consent to Conclusion

Catina O'Leary, Chris Casey, Diane Webb, Deborah Collyar, Andrew Pleasant

Studies in Health Technology and Informatics, 25 Jun 2020; 269 pp 275-284

Abstract

Health literacy research and interventions have provided multiple tools to improve communication between professionals and patients in clinical contexts for many years. Despite the reality that many patients participate in clinical trials in conjunction with standard medical care, only recently have efforts extended to address and improve the health literacy of both clinical trial researchers and participants. To date, the primary focus of health literacy activities in clinical trials has centered on communicating trial results to trial participants. This report describes the opportunities and strategies necessary to layer health literacy activities across the clinical trial process from consent to conclusion.

Clinical correlates of the ability to consent to research participation in brain metastasis

Adam Gerstenecker, Meredith Gammon, Dario Marotta, John Fiveash, Burt Nabors, Kyler Mulhauser, Kristen Triebel

Psycho-Oncology, 20 July 2020

Abstract

Objective

Impairment in the ability to provide informed consent is common in persons with brain metastasis. However, little is known about what factors contribute to this impairment in the patient group. Our objective is to determine if the associations between demographic, cognitive, and clinical variables correlate with the ability to provide informed consent in persons with brain metastasis.

Methods

We administered a comprehensive neuropsychological battery to a group of 61 persons with brain metastasis. Demographic and clinical information was also collected. All diagnoses were made by board-certified oncologists and were verified histologically. Statistical analyses included Pearson's product-moment correlations, point biserial correlations, and linear regression.

Results

Results indicated that combinations of education, verbal memory, executive function, whole brain radiation therapy, and chemotherapy affected various aspects of the ability to provide informed consent. Subsequent regression models demonstrated that these variables contributed a significant amount of shared variance to the ability to provide informed consent.

Conclusion

We found that the ability of persons with brain metastasis to provide informed consent is a cognitively-complex ability that is also affected by education and treatment variables. This information can help clinical researchers in identifying persons with brain metastasis at risk of an impaired ability to provide informed consent and aid in the consenting process.

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BIOBANKING

Enabling data sovereignty for patients through digital consent enforcement

Arno Appenzeller, Ewald Rode profile imageEwald Rode, Erik Krempel profile imageErik Krempel, Jürgen Beyerer profile imageJürgen Beyerer

PETRA '20: Proceedings of the 13th ACM International Conference on PErvasive Technologies Related to Assistive Environments, June 2020; 33 pp 1-4

Abstract

Digital medical data offers an opportunity to improve medical diagnosis and caregiving. While a single doctor might not have enough patients to spot significant factors, data becomes much more evaluable once different doctors combine their data. Data evaluation across multiple data sources will be more practical with the increasing level of digitalization. While the potential benefits of a broad data analysis are enormous, there is a huge potential privacy impact for patients. To cope with legal regulations, for example the European General Data Protection Regulation (GDPR) and to give patients more control over the usage of their data, new tools are needed. Digital distributed patient records need a mechanism to manage a digital declaration of consent. There are some concepts how to digitize medical consent, but still there is no complete workflow that automatically evaluates and enforces consent for the usage of personal medical data. In this paper we will present a continuous digital consent enforcement workflow. Patients can define a detailed declaration of consent for their medical data and researchers can request data through a dedicated interface that enforces that consent. We show the feasibility of this workflow by presenting a prototype implementation and evaluating the system against defined requirements for informed consent.

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COGNITIVE CHALLENGES

Processes of consent in research for adults with impaired mental capacity nearing the end of life: systematic review and transparent expert consultation (MORECare_Capacity statement)

Research Article

C. J. Evans, E. Yorganci, P. Lewis, J. Koffman, K. Stone, I. Tunnard, B. Wee, W. Bernal, M. Hotopf, I. J. Higginson, Deborah Tanner, Claire Henry, Gunn Grande, Steve Dewar, Gareth Owen, Rachel Burman, Dimitrios Adamis, Michael Dunn, Scott Kim, Simon Woods & Rowena Vohora

BMC Medicine, 22 July 2020; 18(221)

Open Access

Abstract

Background

Involving adults lacking capacity (ALC) in research on end of life care (EoLC) or serious illness is important, but often omitted. We aimed to develop evidence-based guidance on how best to include individuals with impaired capacity nearing the end of life in research, by identifying the challenges and solutions for processes of consent across the capacity spectrum.

Methods

Methods Of Researching End of Life Care_Capacity (MORECare_C) furthers the MORECare statement on research evaluating EoLC. We used simultaneous methods of systematic review and transparent expert consultation (TEC). The systematic review involved four electronic databases searches. The eligibility criteria identified studies involving adults with serious illness and impaired capacity, and methods for recruitment in research, implementing the research methods, and exploring public attitudes. The TEC involved stakeholder consultation to discuss and generate recommendations, and a Delphi survey and an expert 'think-tank' to explore consensus. We narratively synthesised the literature mapping processes of consent with recruitment outcomes, solutions, and challenges. We explored recommendation consensus using descriptive statistics. Synthesis of all the findings informed the guidance statement.

Results

Of the 5539 articles identified, 91 met eligibility. The studies encompassed people with dementia (27%) and in palliative care (18%). Seventy-five percent used observational designs. Studies on research methods (37 studies) focused on processes of proxy decision-making, advance consent, and deferred consent. Studies implementing research methods (30 studies) demonstrated the role of family members as both proxy

decision-makers and supporting decision-making for the person with impaired capacity. The TEC involved 43 participants who generated 29 recommendations, with consensus that indicated. Key areas were the timeliness of the consent process and maximising an individual's decisional capacity. The think-tank (n = 19) refined equivocal recommendations including supporting proxy decision-makers, training practitioners, and incorporating legislative frameworks.

Conclusions

The MORECare_C statement details 20 solutions to recruit ALC nearing the EoL in research. The statement provides much needed guidance to enroll individuals with serious illness in research. Key is involving family members early and designing study procedures to accommodate variable and changeable levels of capacity. The statement demonstrates the ethical imperative and processes of recruiting adults across the capacity spectrum in varying populations and settings.

Ethical and Regulatory Issues for Embedded Pragmatic Trials Involving People Living with Dementia

Emily A. Largent, Spencer Phillips Hey, Kristin Harkins, Allison K. Hoffman, Steven Joffe, Julie C. Lima, Alex John London, Jason Karlawish

Journal of the American Geriatrics Society, 26 June 2020

Abstract

Embedded pragmatic clinical trials (ePCTs) present an opportunity to improve care for people living with dementia (PLWD) and their care partners, but they also generate a complex constellation of ethical and regulatory challenges. These challenges begin with participant identification. Interventions may be delivered in ways that make it difficult to identify who is a human subject and therefore who needs ethical and regulatory protections. The need for informed consent, a core human subjects protection, must be considered but can be in tension with the goals of pragmatic research design. Thus it is essential to consider whether a waiver or alteration of informed consent is justifiable. If informed consent is needed, the question arises of how it should be obtained because researchers must acknowledge the vulnerability of PLWD due in part to diminished capacity and also to increased dependence on others. Further, researchers should recognize that many sites where ePCTs are conducted will be unfamiliar with human subjects research regulations and ethics. In this report, the Regulation and Ethics Core of the National Institute on Aging Imbedded Pragmatic Alzheimer's disease (AD) and AD-related dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory discusses key ethical and regulatory challenges for ePCTs in PLWD. A central thesis is that researchers should strive to anticipate and address these challenges early in the design of their ePCTs as a means of both ensuring compliance and advancing science.

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YOUNG PERSONS

Adolescent Barriers to HIV Prevention Research: Are Parental Consent Requirements the Biggest Obstacle?

Original Article

Seema K. Shah, Zaynab Essack, Katherine Byron, Catherine Slack, Daniel Reirden, Heidi van Rooyen, Nathan R. Jones, David S. Wendler

Journal of Adolescent Health, 5 July 2020

Abstract

Purpose

One third of people newly living with HIV/AIDS are adolescents. Research on adolescent HIV prevention is critical owing to differences between adolescents and adults. Parental permission requirements are often

considered a barrier to adolescent enrollment in research, but whether adolescents view this barrier as the most important one is unclear

Methods

Adolescents were approached in schools in KwaZulu-Natal, South Africa, and at a sexually transmitted infection clinic at the Children's Hospital of Aurora, Colorado. Surveys with a hypothetical vignette about participation in a pre-exposure prophylaxis trial were conducted on smartphones or tablets with 75 adolescents at each site. We calculated descriptive statistics for all variables, using 2-sample tests for equality of proportions with continuity correction. Statistical significance was calculated at $p < 0.05$. Multivariate analyses were also conducted.

Results

Most adolescents thought side effects (77%) and parental consent requirements (69%) were very important barriers to research participation. When asked to rank barriers, adolescents did not agree on a single barrier as most important, but the largest group of adolescents ranked parental consent requirements as most important (29.5%). Parental consent was seen as more of a barrier for adolescents in South Africa than in the United States. Concerns about being experimented on or researchers' mandatory reporting to authorities were ranked much lower. Finally, most (71%, n = 106) adolescents said they would want to extra support from another adult if parental permission was not required.

Conclusion

Adolescents consider both parental permission requirements and side effects important barriers to their enrollment in HIV prevention research. Legal reform and better communication strategies may help address these barriers.

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CULTURAL/COUNTRY CONTEXT

Level of education and preferred language of informed consent for clinical research in a multi-lingual community

Grace Muzanyi, Isaac Sekitoleko, John L Johnson, Jane Lunkuse, Gladys Nalugwa, Joanita Nassali, David Kaawa Mafigiri

African Health Sciences, June 2020; 20(2)

Open Access

Abstract

Background

Low education levels and language barriers present challenges in obtaining informed consent for clinical research.

Objective

To describe and correlate the association between the level of education and the participant's preferred language of consent.

Design

Descriptive-analytical cross-sectional study.

Participants

Adults being consented for participation in tuberculosis (TB) research studies in an East African community with varying levels of education.

Procedures

We analyzed data on demographic and educational characteristics collected from adults being consented for participation in TB studies. Only participants who could understand and speak Luganda (the main local language) or English (the official language of Uganda) were included in this analysis.

Results

A total of 523 participants were consented between April 2015 and December 2017 and included in this analysis; 250 below Senior four (< 11yrs of education), 114 senior four (at 11yrs of education),73 senior five-senior six (12-13yrs of education) and 86 beyond senior six (> 13yrs of education). We noted that the preference for English rises with the rising levels of education and peaked at beyond senior six (83%Vs17%,OR=49,95%CI:22.8-106.3,p<0.001).Participants below senior four preferred Luganda Vs senior four and above(OR=16.9,95%CI:9.9-28.8,p<0.001)

Conclusion

Rising education levels of participants were associated with preference for English language usage during initial consent for clinical research studies.

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MEDICAL/SURGICAL

Training Surgeons and the Informed Consent Discussion in Paediatric Patients: A Qualitative Study Examining Trainee Participation Disclosure

J. Chang, K. Bhanot, S. Grant, A. Fecteau, M. Camp

Orthopaedic Proceedings, 17 July 2020; 102-B supplement 6

Open Access

Excerpt

The process of obtaining informed consent is an important and complex pursuit, especially within a paediatric setting. Medical governing bodies have stated that the role of the trainee surgeon must be explained to patients and their families during the consent process. Despite this, attitudes and practices of surgeons and their trainees regarding disclosure of the trainee's participation during the consent process has not been reported in the paediatric setting.

Nineteen face-to-face interviews were conducted with surgical trainees and staff surgeons at a tertiary level paediatric hospital in Toronto, Canada. These were transcribed and subsequently thematically coded by three reviewers…

Evaluating the Patient and Setting-Specific Factors That Influenced the Quality of Informed Consent in a Retrospective Cohort of Subtotal Cholecystectomy Patients

Mina Mesri, Ikemsinachi C. Nzenwa, Raimundas Lunevicius

Journal of Laparoendoscopic & Advanced Surgical Techniques, 13 July 2020

Abstract

Introduction

Cholecystectomy is the most frequently performed procedure in general surgery. The consent procedure for cholecystectomy needs to inform patients about the possibility of subtotal cholecystectomy (STC) as an alternative procedure used for “difficult gallbladders” as it is associated with increased postoperative morbidity. We sought to determine the quality of informed consent for patients who were scheduled for cholecystectomy but underwent STC, and evaluate whether patient or procedural factors influenced the information discussed in consenting.

Materials and Methods

We classified 57 components of information necessary for a patient to give informed consent for cholecystectomy. We retrospectively reviewed the consent forms of patients scheduled for conventional cholecystectomy but instead undergoing STC between 2011 and 2017. Consent quality was measured as the percentage of components completed. Subgroup analyses were conducted to determine whether age, gender, American Society of Anesthesiologists grade, setting (elective/nonelective), operation mode (open/laparoscopic), or the responsible surgeon affected consent quality.

Results
Across 174 patients, just 9 (5.2%) had been informed about the possibility of undergoing STC, whereas the overall quality of consent was 37.5%. Patient and setting-specific factors affected the completion of specific consent components. Patients were more likely to receive a patient information leaflet if they were female (relative risk [RR] 2.76; 95% confidence interval [CI] 1.09–7.00), <60 years (RR 3.32; 95% CI 1.39–7.90) or undergoing laparoscopic surgery (RR 8.04; 95% CI 2.50–25.88).
Conclusion
The suboptimal quality of consent and multiple inconsistencies in the information disclosed to different patient cohorts emphasize the need for a more transparent and consistent consenting process.

The patient and clinician experience of informed consent for surgery: a systematic review of the qualitative evidence

Research Article
L. J. Convie, E. Carson, D. McCusker, R. S. McCain, N. McKinley, W. J. Campbell, S. J. Kirk & M. Clarke
BMC Medical Ethics, 11 July 2020; 21(58)
Open Access
Abstract
Background
Informed consent is an integral component of good medical practice. Many researchers have investigated measures to improve the quality of informed consent, but it is not clear which techniques work best and why. To address this problem, we propose developing a core outcome set (COS) to evaluate interventions designed to improve the consent process for surgery in adult patients with capacity. Part of this process involves reviewing existing research that has reported what is important to patients and doctors in the informed consent process.
Methods
This qualitative synthesis comprises four phases: identification of published papers and determining their relevance; appraisal of the quality of the papers; identification and summary of the key findings from each paper while determining the definitiveness of each finding against the primary data; comparison of key themes between papers such that findings are linked across studies.
Results
Searches of bibliographic databases returned 11,073 titles. Of these, 16 studies met the inclusion criteria. Studies were published between 1996 and 2016 and included a total of 367 patients and 74 health care providers. Thirteen studies collected data using in-depth interviews and constant comparison was the most common means of qualitative analysis. A total of 94 findings were extracted from the primary papers and divided into 17 categories and ultimately 6 synthesised findings related to: patient characteristics, knowledge, communication, the model patient, trust and decision making.
Conclusions
This qualitative meta-aggregation is the first to examine the issue of informed consent for surgery. It has revealed several outcomes deemed important to capture by patients and clinicians when evaluating the quality of a consent process. Some of these outcomes have not been examined previously in research comparing methods for informed consent. This review is an important step in the development of a COS to evaluate interventions designed to improve the consent process for surgery.

Readability of the informed consent forms in Flanders using the Douma index: Analyzing the documents that help patients make decisions

Research Article
María del Valle Ramírez-Durán, María del Valle Coronado-Vázquez, María Isabel Mariscal-Crespo
Clinical Ethics, 9 July 2020

Abstract

Informed consent forms have been useful in clinical practice and they constitute a part of the shared decision making in the informed consent process. They provide information to patients about clinical procedures and techniques. They also act as a remainder of the information discussed after the medical interview. Sometimes these documents are not readable to everybody. Belgian law specifies that all information that patients receive has to be proportionate verbally, but written information is also handled. The present research analyzes the readability of the Flemish informed consent forms located in the webs of all General Hospitals using a simple random sample of 75 informed consent forms.

By using the Douma tool, which bases its analysis in the length of words and sentences, the readability mean of the sample was 46, level "Difficult". The 59% of them had a difficult level. The 11% were normal. It is a fact, then, that the 59% of the informed consent forms evaluated in this study are not suitable for everybody in Flanders, especially those people with low literacy. There were some researches made in other countries that agreed with these results. Written clinical information was poorly written so the informed consent forms were not working helping patients to recall information nor helping patients to become a part in the shared decision making about their health. The use of readability formulas represented a simple way to discriminate those informed consent forms that had normal readability scores from those that should be adapted.

Exploring the concept of 'informed consent' within the context of paramedic practice

Helen Taylor, James Brogan

Journal of Paramedic Practice, 7 July 2020; 12(7)

Abstract

The phrase 'informed consent' is used widely in healthcare. Practitioners ask their patients for their consent to a treatment or a diagnostic or monitoring procedure and, if consent is given, will document this. There is a general understanding that consent is a prerequisite for care and signifies the patient's permission for the paramedic to proceed with assessments and other therapeutic interventions. Obtaining the patient's informed consent is fundamental to contemporary healthcare: what is informed consent and why is it so important? This article explores the meaning of consent in practice and the purpose it serves. It will then go on to consider complex circumstances, including emergencies, young people aged under 18 years, when a patient is unable to give consent or where a person has capacity to consent but refuses.

Is there a standardised consent process within the surgical specialties?

James Hall, Ian Farrell, Sujala Kalipershad, James Hill

The Surgeon, 5 July 2020

Abstract

Introduction

The consent process is central to surgical practice. Subsequent to landmark cases such as Montgomery and Thefaut there is increasing consensus that consent should be a staged process. The aim of our survey was to identify if there was any homogeneity in the practice of surgeons with regards to the consent process in comparison to national guidelines.

Methods

Our survey was distributed to a broad range of surgical specialties via an anonymous Google Forms questionnaire available online. Consultant Surgeons and Specialist registrars across the United Kingdom were then contacted via their relevant surgical societies and professional. Data collection was based on the Montgomery principles: consent location; face to face meetings; information leaflets (including their source); distribution of copies of letters and consent forms; use of percentage risks; use of pre-printed consent forms.

Results

The total number of replies was 325. The majority of consent was taken on the day of surgery (166/319; 50.8%). Scheduled meeting for the consent process occurred routinely in only 87 cases (87/319; 27.3%). 103

(103/319; 32.9%) responders indicated the use of pre-printed consent forms. Of which 93 (93/103; 90.3%) were produced locally. Risk percentages were routinely used by 103 responders (103/319; 32.9%) Nearly two-thirds never write specific risk percentages routinely (205/319; 64.3%). Copies of consent forms were routinely given out by 210 responders (210/319; 65.8%). Supporting information was routinely given to patients in 248 cases (248/319; 77.7%).

Conclusion

Our survey documents significant variation in the practice of consent despite clear guidance on best practice. We believe that most surgeons welcome a more thorough and robust consent process, but hey need the time and infrastructure to be able to do it Introduction.

Informed Consent in Patients Undergoing Primary Hip and Knee Arthroplasty: What Do Patients Want to Know?

Nemandra A Sandiford, Maalee Mahendra, Lilanthi Wickramarachchi, Diane Back, Mohit Bansal

Cureus, 5 June 2020; 12(6)

Abstract

Introduction

The consenting process has been surgeon-focused traditionally, but there is a recent trend towards making the process more patient and procedure-focused. The primary aims were to identify the risks considered most important and requiring further discussion by the patients undergoing primary total hip arthroplasty (THA) and primary total knee arthroplasty (TKA), as well as to identify the sporting and recreational activities these patients would like to pursue after surgery according to the age group, taking into consideration their values and expectations. The secondary aim is to assess the compliance of the current consenting process with guidelines set out by a governing body in a tertiary referral arthroplasty unit.

Material and method

A prospective study reviewing the consenting process was carried out on 137 patients undergoing THA or TKA over a 12-month period in a tertiary teaching hospital. Patients unable to complete a questionnaire and undergoing revision or uni-compartment arthroplasty were excluded. A standardized anonymous questionnaire was administered. Patients were asked to fill in the specific activities they considered important to be discussed. The data were tabulated in Microsoft Excel (Microsoft Corporation, Redmond, Washington) and subgroup analysis was performed using the student's t-test. The level of statistical significance was p=0.05. Two-hundred consent forms were reviewed to assess whether the information entered correlated to the guidelines presented in Ortho-Consent.

Results

One-hundred thirty-seven questionnaires were reviewed. The mean age was 66 (range 45-91), with the majority of patients undergoing TKA (114) versus THA (23). The patients in active employment were more concerned about blood clots, pain, joint failure, limb length discrepancy, and infection. Patients undergoing TKA wanted more information on pain management and joint longevity, which achieved statistical significance. There was a significant difference in the activities patients would like to pursue as well as in expectations amongst different age groups. The quality of documentation in the consent form was quite variable in discussing complications, surgery benefits, and alternative treatments.

Conclusion

Obtaining consent is a patient-specific process. Patient perception of important points that merit discussion can vary with age and employment status. Return to driving is important for all ages, however, as the population ages, the ability to return to activities of daily living becomes an increasingly important discussion point during the consent process.

Editor's Note: the Cureus Journal of Medical Science is an open access general medical journal based in San Francisco, California.

Rethinking counselling in prenatal screening: An ethical analysis of informed consent in the context of non-invasive prenatal testing (NIPT)

Adriana Kater-Kuipers, Inez D. de Beaufort, Robert-Jan H. Galjaard, Eline M. Bunnik

Bioethics, 4 July 2020

Open Access

Abstract

Informed consent is a key condition for prenatal screening programmes to reach their aim of promoting reproductive autonomy. Reaching this aim is currently being challenged with the introduction of non-invasive prenatal testing (NIPT) in first-trimester prenatal screening programmes: amongst others its procedural ease—it only requires a blood draw and reaches high levels of reliability—might hinder women's understanding that they should make a personal, informed decision about screening. We offer arguments for a renewed recognition and use of informed consent compared to informed choice, and for a focus on value-consistent choices and personalized informational preferences. We argue for a three-step counselling model in which three decision moments are distinguished and differently addressed: (1) professionals explore women's values concerning whether and why they wish to know whether their baby has a genetic disorder; (2) women receive layered medical-technical information and are asked to make a decision about screening; (3) during post-test counselling, women are supported in decision-making about the continuation or termination of their pregnancy. This model might also be applicable in other fields of genetic (pre-test) counselling, where techniques for expanding genome analysis and burdensome test-outcomes challenge counselling of patients.

A multistage process leading to the development of a structured consent form and patient information leaflet for complex abdominal wall reconstruction (CAWR)

Original Article

M. Asarbakhsh, O. Smith, P. Chitsabesan, T. MacLeod, P. Lim, S. Chintapatla Hernia

Hernia, July 2020

Abstract

Purpose

Informed consent is vital in surgery. The General Medical Council, UK and Royal College of Surgeons of England provide clear guidance on what constitutes the process of informed patient consent. Despite this, evidence suggests that the consent process may not be performed well in surgery. We utilised a staged patient-centred approach and rigorous methodology to develop a standardised patient information leaflet (PIL) and pre-written structured consent form for complex abdominal wall reconstruction (CAWR).

Methods

We utilised the principles of Deming's Plan-Do-Study-Act (PDSA) cycles to approach the process. Buzan's mind maps were used to identify the stakeholders and deficiencies in the consent process ('Plan' phase). The content of the PIL and pre-written consent form was then developed in collaboration with stakeholders ('Do' phase). Multidisciplinary and multidepartmental feedback was obtained on the proposed content and amendments were made ('Study' and 'Act' phases).

Results

We successfully produced a clear, focused PIL and structured consent form, in Plain English, presenting accurate, relevant and detailed information in a highly understandable way. The PIL had a Flesch Reading Ease score of > 80, demonstrating a high level of readability and comprehensibility, with positive implications for informed patient decision making and preparedness for surgery.

Conclusion

Through sharing the process that we undertook, we aim to support other abdominal wall units who wish to develop and improve their own consent process.

Can incoming United States pediatric interns be entrusted with the essential communication skills of informed consent?

Research Article

Nicholas Sevey, Michelle Barratt, Emma Omoruyi

Journal of Educational Evaluation for Health Professions, 29 June 2020; 17(18)

Open Access

Abstract

Purpose

According to the Entrustable Professional Activities (EPA) for Entering Residency by the Association of American Medical Colleges, incoming residents are expected to independently obtain informed consent for procedures they are likely to perform. This requires residents to not only inform their patients but to ensure comprehension of that information. We assessed the communication skills demonstrated by 372 incoming pediatric interns between 2007 and 2018 at the University of Texas Health Science Center at Houston, obtaining informed consent for a lumbar puncture.

Methods

During a simulated case in which interns were tasked with obtaining informed consent for a lumbar puncture, a standardized patient evaluated interns by rating 7 communication-based survey items using 5-point Likert scale from “poor” to “excellent.” We then converted the scale to a numerical system and calculated intern proficiency scores (sum of ratings for each resident) and average item performance (average item rating across all interns).

Results

Interns received an average rating of 21.6 per 28 maximum score,) of which 227 interns (61.0%) achieved proficiency by scoring 21 or better. Notable differences were observed when comparing groups before and after EPA implementation (76.97% vs 47.0% proficient, respectively). Item-level analysis showed that interns struggled most to conduct the encounter in a warm and friendly manner and encourage patients to ask questions (average ratings of 2.97/4 and 2.98/4, respectively). Interns excelled at treating the patient with respect and actively listening to questions (average ratings of 3.16, each). Both average intern proficiency scores and each average item ratings were significantly lower following EPA implementation ($P<0.001$).

Conclusion

Interns demonstrated moderate proficiency in communicating informed consent, though clear opportunities for improvement exist such as demonstrating warmth and encouraging questions.

Evaluation of an Innovative Informed Consent Support Program for Individuals Considering a Living Kidney Donation

Chantal Fortin, Deitan Bourget

Nephrology Nursing Journal, May-June 2020; 47(3) pp 245-251

Abstract

Regulations require that consent be obtained before accepting a kidney donation, and respect for the competent adult requires the living donor to think, decide, and act freely, without any form of pressure or coercion. This article describes the results of a program, Les Compagnons de la Donation (Donation Companions), that attempts to meet these needs. A descriptive, non-experimental study was conducted to evaluate the degree of participant satisfaction and the program's influence on consent. Thirty-nine (n = 39) potential donors took part in the study. For each of the items evaluated, the mean change of participants pre- and post-intervention perception was statistically significant. The change was even more marked for feeling informed or prepared compared to being convinced or confident about the decision. Almost all participants strongly agreed the program was satisfactory. This study demonstrated a structured program, such as the Les Compagnons de la Donation program, meets the needs of the target audience and appears to provide significant support to the decision-making process.

Cancer: a perspective of human dignity and informed consent from ethics and justice

Dora E. García-González, Xenia A. Rueda

National University of Colombia Journal of Public Health, 15 May 2020; 22(3) pp 1-5

Open Access

Abstract

This article attempts to reflect on the importance of thinking in general about illness and about cancer, from an ethical perspective. This approach reveals the central role of personal dignity and the moral relevance that supports the reasons for respecting people. The ethical values that sustain the practice of medicine must aim at uplifting this dignity and seeking situations of justice, since living in a community expresses intersubjectivity that cannot be truncated by illnesses like cancer. Therefore, situations involving poverty cannot justify the lack of health care, and if such lacks occur, they run counter to ethical awareness in the deepest sense and destroy intersubjectivity. As a result, cancer is suffered as a vital experience, in a framework of lives that are lived and are not simply objects of study; those stricken with cancer are individuals who are denied the human right to health, and undergo the elimination of their dignity, the cancelation of justice, and a death sentence. Society is part of these actions and at the same time, suffers from the disappearance of hope. In this sense, the process of informed consent is used as a tool that encourages dialog and understanding between doctors and patients during proper treatment, on a shared path.

Using biomarkers in acute medicine to prevent hearing loss: should this require specific consent?

Peta Coulson-Smith, Anneke Lucassen

Journal of Med Ethics, 11 March 2020

Open Access

Introduction

In this round table response, we discuss some of the problems inherent in insisting on specific consent for an activity that needs to happen rapidly as part of a package of care. The Human Tissue Authority (the UK regulator for human tissue and organs) consider that specific consent is mandatory to assess which antibiotics are appropriate on the neonatal unit, but this insistence may actually limit the autonomy which consent aims to promote. While genetic testing to determine which child will react adversely to particular antibiotics has been available clinically for several years, the research proposed here is to assess whether improving the speed of testing allows decisions to be made before treatment starts. Insisting on specific consent before this activity can take place is likely to delay appropriate care in some cases.

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GENERAL/OTHER

Evaluation of donor informed consents and associated predonation educational materials in the United States and Canada: variability in elements of consent and measures of readability and reading burden

Original Research

Mary Townsend, Terri Buccino, Louis Katz

Transfusion, 4 July 2020

Abstract

Background

Every day, approximately 30,000 donors present to blood collection establishments in the United States or Canada, where they are provided information about donation and asked to sign a consent before donating.

We evaluated elements of informational and consent documents and measures of readability that may influence their comprehension.
Materials and Methods
Consents for whole blood (WB) and automated collections and predonation reading materials (PRMs) representing over 93% of WB collections in the United States and Canada were evaluated. Elements, including risks of donation, were cataloged. Word count, Flesch-Kinkaid (F-K) reading ease/grade level scores, Simple Measure of Gobbledygook grade, and percentage of complex words were measured.
Results
F-K grade levels ranged from 9.2 to 16.9 for WB consents, 7.8 to 16.0 for apheresis consents, and 6.7 to 10.9 for PRMs, above the recommended level of eighth grade or lower for general audiences. F-K reading ease scores were below the cutoff of 60 for readability. Reading burden was substantial, with word count ranging from 131 to 885, 131 to 996, and 649 to 2743 for WB and apheresis consents and PRMs, respectively. Use of jargon and the absence of consent elements such as confidentiality, voluntariness, ability to withdraw consent, and risks of deferral were common.
Conclusions
Donor consent documents and associated materials vary widely, are written at challenging grade levels, present considerable reading burden, contain substantial jargon, and are missing key elements of consent. The authors recommend an organized effort, including blood donors, legal experts, and blood collection experts, to reach consensus on the minimal requirements for standardized clear and concise consent documents in an optimized format.

Consent, Advance Directives, and Decision by Proxies [BOOK CHAPTER]

Annette Robertsen, Susanne Jöbges, Nicholas Sadovnikoff
Compelling Ethical Challenges in Critical Care and Emergency Medicine
Springer, 23 July 2020; pp 35-47
Abstract
The ethical principle of autonomy, the right of a patient to determine what therapies or interventions to accept or decline, has wide support in modern medical ethics and is strongly buttressed legally. Accordingly, clinicians need to have a robust familiarity with the statutes governing their practice, notably in such realms as advance directives and proxy decision-making. Ethical challenges frequently arise in the context of emergency and critical care medicine in which time-sensitive or highly consequential decisions must be made when the patient's decision-making capacity is impaired or subject to question. This chapter addresses these challenges and offers potential approaches and solutions.

Distributed consent and its impact on privacy and observability in social networks

Juniper Lovato, Antoine Allard, Randall Harp, Laurent Hebert-Dufresne
Cornell University, Physics and Society, 29 June 2020
Open Access
Abstract
Personal data is not discrete in socially-networked digital environments. A single user who consents to allow access to their own profile can thereby expose the personal data of their network connections to non-consented access. The traditional (informed individual) consent model is therefore not appropriate in online social networks where informed consent may not be possible for all users affected by data processing and where information is shared and distributed across many nodes. Here, we introduce a model of "distributed consent" where individuals and groups can coordinate by giving consent conditional on that of their network connections. We model the impact of distributed consent on the observability of social networks and find that relatively low adoption of even the simplest formulation of distributed consent would allow macroscopic

subsets of online networks to preserve their connectivity and privacy. Distributed consent is of course not a silver bullet, since it does not follow data as it flows in and out of the system, but it is one of the most straightforward non-traditional models to implement and it better accommodates the fuzzy, distributed nature of online data.

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