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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

June 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. 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)
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH

Please note that we present a set of appendices, including a glossary, tools for assessment and guidance documents, on our website.

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COVID-19

COVID-19 and its impact on informed consent: What should health professionals tell their patients or their proxies?

D J McQuoid-Mason

South African Journal of Bioethics Law, 13 May 2020; 13(1)

Open Access

Abstract

Given the increasing number of ethical and legal issues arising from the impact of the COVID-19 epidemic on informed consent by patients, it is necessary for health professionals to explain to patients how the measures taken to combat the spread of the virus impact on their right to give informed consent. Patients need to be reassured that wherever possible, health professionals are ethically bound to obtain informed consent from patients before they subject them to diagnostic testing and treatment, but at the same time, have to comply with the demands of the law. While the South African Constitution, statutory law and the common law all recognise a person's right to consent before being subjected to treatment or surgical operations, it is necessary to take remedial steps, because of the dangers of spreading the potentially fatal COVID-19 virus, to prevent this. Such steps may involve compelling patients to be screened, tested and treated – sometimes without their consent. Guidance is given to healthcare professionals on how they should counsel their patients, and what they should tell patients about the impact of the COVID-19 regulations on healthcare professionals' ethical and legal duties regarding the obtaining of informed consent, as well as on whether, if asked, employers can compel their employees to undergo testing without consent, and what to tell patients about this.

Editor's note: This article also appears under RIGHTS/LEGAL/LEGISLATIVE

Modelling Consent in the Time of COVID-19

Bartha Maria Knoppers, Michael J S Beauvais, Yann Joly, Ma'n H Zawati, Simon Rousseau, Michaël Chassé, Vincent Mooser

Journal of Law and the Biosciences, 8 May 2020

Open Access

Abstract

Effective responses to the COVID-19 pandemic require novel solutions for research and responsible data sharing. Biobanking presents itself as a key priority in furthering our understanding of COVID-19. In this article, we propose a tripartite approach to consent to create resources for research relating to COVID-19. The approach aims to link three levels of participation: COVID-19 patient, respiratory/infectious disease patients, and longitudinal study participants. We explore the potential approaches that can be taken to consent processes with these three participant groups. We furthermore describe an access model for both single-site and multi-site data and sample storage. Through dealing with these topics at a high level, the model may be adapted to local legal and ethical requirements while still pursuing its ultimate goal: the creation of a research infrastructure that supports transparent, strong, and open science.

Editor's note: This article also appears under BIOBANKING

A rationale and framework for seeking remote electronic or phone consent approval in endovascular stroke trials – special relevance in the COVID-19 environment and beyond

Original Research

Ansaar T Rai, Donald Frei

Journal of NeuroInterventional Surgery, 28 April 2020

Open Access

Abstract

Background

Enrollment in time-sensitive endovascular stroke trials can be challenging because of an inability to consent a debilitated patient. Often the legally authorized representative is not on site. Remote consent procedures in the US are inconsistent with the majority of sites shunning these approaches. The current pandemic with visitor restrictions highlights the need for enhancing these options.

Methods

Remote electronic and phone consent procedures specifically for endovascular stroke trials from two comprehensive stroke centers (CSC) are presented. An overview of the genesis of informed consent procedures in the US is also included. Results The two CSCs identified as Institution-1 and Institution-2 are large tertiary systems. Institution-1 is a non-profit university-affiliated academic medical center in rural geography. Institution-2 is an HCA hospital in an urban environment. Both serve patients through a spoke-and-hub network, have participated in multiple randomized endovascular stroke trials, and have successfully used these remote options for enrollment. A tiered approach is employed at both institutions with an emphasis on obtaining informed consent in person and resorting to alternatives methods when efforts to that are unsuccessful. A rationale for electronic and phone consent is included, followed by step-by-step illustration of the process at each institution.

Conclusion

Two examples of remote electronic or phone consent procedures from institutions in different geographic environments and organization structures demonstrate that these options can be successfully used for enrollment in stroke trials. The current pandemic highlights the need to enhance these approaches while maintaining appropriate adherence to ethical and legal frameworks.

Editor's note: This article also appears under MEDICAL/SURGICAL

Informed Consent for Surgery During COVID-19

Neela Bhattacharya, Kaushik Bhattacharya

Indian Journal of Surgery, 24 April 2020

Open Access

Abstract

Informed consent has become a challenging issue when surgery at the time of novel corona virus disease 2019 (COVID-19) is to be performed, in view of increased risk of the need of intensive care unit (ICU) in the post-operative period and the associated high mortality if a patient exhibits COVID-19 symptoms in the post-operative period. We have devised a new informed consent format for all patients undergoing surgery incorporating a few points specific for the disease.

Editor's note: This article also appears under MEDICAL/SURGICAL

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GENOMIC MEDICINE/GENE EDITING

The genomic data deficit: On the need to inform research subjects of the informational content of their genomic sequence data in consent for genomic research

Dara Hallinan

Computer Law & Security Review, July 2020; 37

Abstract

Research subject consent plays a significant role in the legitimation of genomic research in Europe – both ethically and legally. One key criterion for any consent to be legitimate is that the research subject is ‘informed’. This criterion implies that the research subject is given all relevant information to allow them to decide whether engaging with a genomic research infrastructure or project would be normatively desirable and whether they wish to accept the risks associated with engagement. This article makes the normative argument that, in order to be truly ‘informed’, the research subject should be provided with information on the informational content of their genomic sequence data. Information should be provided, in the first instance, prior to the initial consent transaction, and should include: information on the fact that genomic sequence data will be collected and processed, information on the types of information which can currently be extracted from sequence data and information on the uncertainties surrounding the types of information which may eventually be extractable from sequence data. Information should also be provided, on an ongoing basis, as relevant and necessary, throughout the research process, and should include: information on novel information which can be extracted from sequence data and information on the novel uses and utility of sequence data. The article argues that current elaborations of ‘informed’ consent fail to adequately address the requirements set out in the normative argument and that this inadequacy constitutes an issue in need of a solution. The article finishes with a set of observations as to the fora best suited to deliver a solution and as to the substantive content of a solution.

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BIOMEDICAL RESEARCH

To explore the experience of research nurses who obtain consent from adults in emergency settings to participate in clinical trials, either prospectively or post enrolment

Brown P, Newham R, Hewison A

Journal of Clinical Nursing, 22 May 2020

Abstract

Aim

To explore the understanding and experiences of research nurses who obtain informed consent from adult patients participating in emergency care research.

Design

Qualitative phenomenographic descriptive study.

Methods

Ten research nurses from six hospitals in England were recruited. Data were collected using semi-structured face-to-face and telephone interviews between January 2019 and March 2019. Interviews were transcribed verbatim and analysed thematically, informed by phenomenography. COREQ was followed.

Results

Three main themes were identified (1) Emergency research is different (2) Protecting the patient and (3) Experience and confidence with recruitment. It was found that obtaining patient consent in emergency care research was challenging and timing of the process was crucial. Nurses with more experience of emergency care were more confident in approaching patients and their families. There was variability in out-of-hours recruitment which was a consequence of the range of informed consent processes used and the different levels of engagement of clinical teams.

Conclusion

There is a variety of organisational cultures, processes and procedures which affect the way consent is obtained in emergency care research. A team approach was evident in the hospitals where consent rates were high and was more successful than those reliant solely on the presence of a research nurse. Organisations were able to recruit successfully to emergency care research studies irrespective of size and configuration. Further investigation of their models of working and strategies for engagement is needed. Experienced research nurses made a positive difference to recruitment and were more likely to approach patients to obtain consent.

Relevance to Clinical Practice

The understanding and experiences of recruitment to clinical trials in emergency care research by research nurses can help identify barriers to recruitment. This study provides useful insights for healthcare practitioners, clinical trials coordinators and sponsors about how best to develop protocols and policies to increase recruitment to emergency care research.

Patient and Surrogate Postenrollment Perspectives on Research Using the Exception From Informed Consent: An Integrated Survey

Ethics/brief research report

Victoria M. Scicluna, Michelle Biros, Deneil K. Harney, Elizabeth B. Jones, Andrea R. Mitchell, Rebecca D. Pentz, Robert Silbergleit, Candace D. Speigheit, David W. Wright, Neal W. Dickert

Annals of Emergency Medicine, 21 May 2020

Abstract

Study objective

It is important for researchers interested in trials using the exception from informed consent to understand the views and experiences of enrolled individuals. Previous studies have shown that patient and surrogate attitudes are generally positive. These studies were small and did not include pediatric patients, and interviews were often conducted long after trial enrollment. This study sought to explore attitudes toward exception from informed consent in a larger sample and more contemporaneous setting.

Methods

A 10-item paper-and-pencil survey was integrated into the Established Status Epilepticus Treatment Trial, a randomized trial of 3 treatments for benzodiazepine-refractory status epilepticus in pediatric and adult patients. Primary domains included attitudes toward trial enrollment, exception from informed consent, and community consultation. Simple descriptive statistics, $\chi 2$, and Fisher's exact tests were conducted.

Results

Of 317 patients and surrogates, 90% agreed with or were neutral about the statement "I am glad that I/my family member was included in the Established Status Epilepticus Treatment Trial research study," whereas 10% disagreed. Twenty-seven percent disagreed with enrollment in the study without prospective consent. Black participants were more likely than white, other race, and unknown-race participants to disagree with enrollment without prospective consent (36% versus 23%, 14%, and 14%, respectively). Participants indicated that patients (81%), their families (65%), and those at risk for seizures (51%) were most important to include in community consultation.

Conclusion

This study aimed to explore attitudes toward exception from informed consent enrollment among participants at all sites in a large, multicenter exception from informed consent trial. General acceptance of trial enrollment was high; acceptance of exception from informed consent specifically was somewhat lower, especially among black participants. Our findings provide further support for targeted community consultation focusing on individuals with connections to the disease under study. Future research should focus on communication in the postenrollment period, especially with individuals who may have concerns about exception from informed consent.

IRB Policies for Obtaining Informed Consent from Non-English-Speaking People

Gianna McMillan

Ethics & Human Research, 18 May 2020

Abstract

United States regulations for the protection of human research subjects prescribe parameters for documentation of valid informed consent, which include the stipulation that the process be in a "language understandable to the subject." While significant energy has been devoted to improving the readability of consent documents, supplemental educational tools, and nuanced measurements of individual decisional

capacity, there is little guidance about how to best meet the informational needs of adults with decisional capacity who do not speak English. This article reviews the institutional review board policies from the twenty-one research centers that received the most funding from the National Institutes of Health in 2018 and compares their guidelines for obtaining informed consent from non-English speakers. Inconsistent practices suggest the need for more assertive federal direction on what parameters constitute valid consent for this population. These practices also indicate a reluctance to directly engage the ethical underpinnings of consent policies for non-English speakers.

Can Consent to Participate in Clinical Research Involve Shared Decision Making?

Case and Commentary
Haley Moulton, Benjamin Moulton, Tim Lahey, Glyn Elwyn
AMA Journal of Ethics, May 2020
Open Access
Abstract

Shared decision making honors patient autonomy and improves patient comprehension and therefore should be a part of every clinical decision a patient makes. Use of shared decision making in research informed consent conversations is more complicated due to diverse and potentially divergent investigator and patient interests, along with the presence of clinical equipoise. This article clarifies these different interests and discusses ways in which shared decision making can be applied in research. Provided there is transparency about competing interests, patient-centered and values-focused communication approaches embodied in shared decision making can support the ethical recruitment of patients for clinical research.

From “Informed” to “Engaged” Consent: Risks and Obligations in Consent for Participation in a Health Data Repository

Research Article
Elizabeth Bromley, Alexandra Mendoza-Graf, Sandra Berry, Camille Nebeker, Dmitry Khodyakov
The Journal of Law, Medicine & Ethics, 28 April 2020
Abstract

The development and use of large and dynamic health data repositories designed to support research pose challenges to traditional informed consent models. We used semi-structured interviewing (n=44) to elicit diverse research stakeholders' views of a model of consent appropriate to participation in initiatives that entail collection, long-term storage, and undetermined future research use of multiple types of health data. We demonstrate that, when considering health data repositories, research stakeholders replace a concept of consent as informed with one in which consent is engaged. In engaged consent, a participant's ongoing relationship with a repository serves as a substitute or adjunct to information exchange at enrollment. We detail research stakeholders' views of the risks of engaged consent and suggest questions for further study about engagement and consent procedures in initiatives that aim to store data for future unspecified research purposes.

Evidence-Based Communication in Clinical, Mass Media, and Social Media Contexts to Enhance Informed Consent for Participation in Clinical Trials and Precision Medicine Initiatives [BOOK CHAPTER]

Susan E. Morgan, Aurora Occa, Wei Peng, Soroya J. McFarlane
The Handbook of Applied Communication Research
John Wiley & Sons, 17 April 2020; Chapter 49
Summary

This chapter explains that improved clinical trial communication will result in better informed patients who demonstrate greater willingness to participate in a system that is intended to produce significant advances in

medical treatment. It centers on the factors where communication scholars and practitioners can best apply their energy and insights. These include clinical communication interventions, including training of physicians, study nurses, and clinical research staff; public communication messages designed to inform a broad audience about scientific concepts that are central to meaningful and informed consent; and the use of social media platforms for participant recruitment and retention. The chapter discusses the implications of these findings for the development of new interventions designed to enroll members of the public in emerging precision medicine (PM) initiatives, particularly among minority populations. It also reviews communication-based interventions, including interpersonal communication trainings, public communication campaigns, persuasive message design, and targeted message delivery.

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TECHNOLOGY/OTHER MEDIATION

A randomized controlled trial comparing video-assisted informed consent with standard consent for Mohs micrographic surgery

Original Article

Yueyue Miao, Victoria L. Venning, Kylie-Ann Mallitt, Julia E. J. Rhodes, Noah J. Isserman, Gilberto Moreno, Simon Lee, William Ryman, Gayle Fischer, Rebecca B. Saunderson

Journal of the American Academy of Dermatology International, July 2020; 1(1) pp 13-20

Open Access

Abstract

Background

There is a need for improvement in informed medical consent to address the lack of standardization and to increase patient engagement.

Objective

To investigate the use of a video to aid informed consent for Mohs micrographic surgery and evaluate patient understanding, satisfaction, anxiety, and time savings relative to verbal consent.

Methods

A 2-armed randomized controlled trial involving 102 patients compared video-assisted consent with a control group who underwent consent in the standard verbal manner. All participants underwent questionnaire-based testing of knowledge, satisfaction, and anxiety, and the time of each consultation was measured.

Results

Patients who watched the video performed significantly better in the knowledge questionnaire compared with the control group (P = .02), were more satisfied with their understanding of the risks of Mohs micrographic surgery (P = .013), and spent less time with their physician (P = .008). Additionally, 78.4% of video group patients reported that they preferred seeing the video before speaking with their physician.

Limitations

The study design may not replicate day-to-day clinical practice.

Conclusion

Video-assisted consent for Mohs micrographic surgery improves patient knowledge, leads to a better understanding of the risks, and saves physicians time without compromising patient satisfaction and anxiety levels in this study setting.

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BIOBANKING

Developing model biobanking consent language: what matters to prospective participants?

Research Article

Laura M. Beskow, Catherine M. Hammack-Aviran, Kathleen M. Brelsford

BMC Medical Research Methodology, 15 May 2020; 20(119)

Open Access

Abstract

Background

Efforts to improve informed consent have led to calls for providing information a reasonable person would want to have, in a way that facilitates understanding of the reasons why one might or might not want to participate. At the same time, advances in large-scale genomic research have expanded both the opportunities and the risks for participants, families, and communities. To advance the use of effective consent materials that reflect this landscape, we used empirical data to develop model consent language, as well as brief questions to assist people in thinking about their own values relative to participation.

Methods

We conducted in-person interviews to gather preliminary input on these materials from a diverse sample (n = 32) of the general population in Nashville, Tennessee. We asked them to highlight information they found especially reassuring or concerning, their hypothetical willingness to participate, and their opinions about the values questions.

Results

Consent information most often highlighted as reassuring included the purpose of the biobank, the existence and composition of a multidisciplinary oversight committee, the importance of participants' privacy and efforts to protect it, and controlled access to a scientific database. Information most often highlighted as concerning included the deposition of data in a publicly accessible database, the risk of unintended access to data, the potential for non-research use of data, and use of medical record information in general. Seventy-five percent of participants indicated initial willingness to participate in the hypothetical biobank; this decreased to 66% as participants more closely considered the information over the course of the interview. A large majority rated the values questions as helpful.

Conclusions

These results are consistent with other research on public perspectives on biobanking and genomic cohort studies, suggesting that our model language effectively captures commonly expressed reasons for and against participation. Our study enriches this literature by connecting specific consent form disclosures with qualitative data regarding what participants found especially reassuring or concerning and why. Interventions that facilitate individuals' closer engagement with consent information may result in participation decisions more closely aligned with their values.

Modelling Consent in the Time of COVID-19

Bartha Maria Knoppers, Michael J S Beauvais, Yann Joly, Ma'n H Zawati, Simon Rousseau, Michaël Chassé, Vincent Mooser

Journal of Law and the Biosciences, 8 May 2020

Open Access

Abstract

Effective responses to the COVID-19 pandemic require novel solutions for research and responsible data sharing. Biobanking presents itself as a key priority in furthering our understanding of COVID-19. In this article, we propose a tripartite approach to consent to create resources for research relating to COVID-19. The approach aims to link three levels of participation: COVID-19 patient, respiratory/infectious disease patients, and longitudinal study participants. We explore the potential approaches that can be taken to consent processes with these three participant groups. We furthermore describe an access model for both single-site and multi-site data and sample storage. Through dealing with these topics at a high level, the model may be adapted to local legal and ethical requirements while still pursuing its ultimate goal: the creation of a research infrastructure that supports transparent, strong, and open science.

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COGNITIVE CHALLENGES

Informed Consent in Patients With Frailty Syndrome

Brendan Silbert, David Scott

Anesthesia & Analgesia, June 2020; 130(6) pp 1474–1481

Abstract

Frailty is present in more than 30% of individuals older than 65 years of age presenting for anesthesia and surgery, and poses a number of unique issues in the informed consent process. Much attention has been directed at the increased incidence of poor outcomes in these individuals, including postoperative mortality, complications, and prolonged length of stay. These material risks are not generally factored into conventional risk predictors, so it is likely that individuals with frailty are never fully informed of the true risk for procedures undertaken in the hospital setting. While the term “frailty” has the advantage of alerting to risk and allowing appropriate care and interventions, the term has the social disadvantage of encouraging objectivity to ageism. This may encourage paternalistic behavior from carers and family encroaching on self-determination and, in extreme cases, manifesting as coercion and compromising autonomy. There is a high prevalence of neurocognitive disorder in frail elderly patients, and care must be taken to identify those without capacity to provide informed consent; equally important is to not exclude those with capacity from providing consent. Obtaining consent for research adds an extra onus to that of clinical consent. The informed consent process in the frail elderly poses unique challenges to the busy clinical anesthesiologist. At the very least, an increased time commitment should be recognized. The gap between theoretical goals and actual practice of informed consent should be acknowledged.

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YOUNG PERSONS

The Importance of Engaging Children in Research Decision-Making: A Preliminary Mixed-Methods Study

Erin Talati Paquette, Hannah Palac, Elizabeth Bair, Blake Schultz, Nicole Stenquist, Steven Joffe, Avani Shukla

Ethics & Human Research, 18 May 2020

Abstract

Studies demonstrate deficiencies in parents' and children's comprehension of research and lack of child engagement in research decision-making. We conducted a cross-sectional and interview-based study of 31 parent-child dyads to describe decision-making preferences, experiences, and comprehension of parents and children participating in research. Parents and children reported that parents played a greater role in decisions about research participation than either parents or children preferred. The likelihood of child participation was associated with the extent of input the parent permitted the child to have in the decision-making process, the child's comprehension, whether the study team asked the child about participation, whether the child read study-related materials, the parent's marital status, and the child's race. Children had lower comprehension than adults. Comprehension was related to age, education, verbal intelligence, and reading of study-related information. Parent understanding was associated with prospect for benefit and illness severity. Child participation may be improved by increasing parent-child communication, emphasizing important relational roles between parent and child, respecting the developing autonomy of the child, increasing engagement with the study team, providing appropriate reading materials, and assessing comprehension.

‘It’s never okay to say no to teachers’: children’s research consent and dissent in conforming schools contexts

Perpetua Kirby

British Educational Research Journal, 5 May 2020

Abstract

This paper examines the limits to children giving research consent in everyday school contexts that emphasises their conformity to comply with adult expectations, and highlights children’s competence and agency in navigating this conformity through different practices of dissent. It draws on research into children’s agency, using a multimodal ethnography of Year One classrooms in two English primary schools. The paper includes a reflexive methodological focus, exploring the extent to which I counter the schools’ emphasis on conformity. This includes creating visuals for children to practice consent; positioning myself as the researcher in a non-teacher role, as ‘least adult’, and the one who ‘least knows’; and designing interview spaces markedly different from classrooms. The paper examines how children navigate conforming discourses by finding different ways to dissent in the research. Firstly, children demonstrate a sophisticated awareness of the cultural norms of indicating refusals beyond saying the word ‘No’. Secondly, children achieve unnoticeablity, by which they absent themselves from the ‘on-task’ classroom culture, and by extension, the research process. Thirdly, they engage in playful dissent demonstrating their political knowingness of the classroom social order. The paper discusses the implications for educational research when the values of consent are in conflict with a schooling focused on conformity. This includes emphasising the limits of consent procedures, paying closer attention to how researchers recognise and respond ethically to children’s multiple practices of dissent, and using research to disrupt problematic power structures in education settings that limit possibilities for children’s consent.

Case for persuasion in parental informed consent to promote rational vaccine choices

Original Research

Jennifer O'Neill

Journal of Medical Ethics, 4 May 2020

Abstract

There have been calls for mandatory vaccination legislation to be introduced into the UK in order to tackle the national and international rise of vaccine-preventable disease. While some countries have had some success associated with mandatory vaccination programmes, the Royal College of Paediatrics and Child Health (RCPCH) insist this is not a suitable option for the UK, a country which has seen historical opposition to vaccine mandates. There is a lack of comprehensive data to demonstrate a direct link between mandatory vaccination legislation and increased uptake. While there are examples whereby there has been an improvement, some studies suggest that comparable results can be obtained by strongly recommending vaccinations instead. The RCPCH insist that healthcare workers are ideally placed to engage and inform parents to make every interaction a ‘vaccine opportunity’. This paper calls for a principled, rational approach to interpretations of autonomy which underpin parental informed consent. MacLean’s concept of mutual persuasion could be a vehicle to ensuring parents are suitably informed of both the material risks associated with vaccine choices and to consider the rationality of their decisions, while ultimately upholding parental autonomy. It is argued that this, alongside infrastructural improvement, could create a more sustainable, long-term improvement in childhood vaccination rates in the UK than mandatory vaccination.

Literacy as a Distinct Developmental Domain in Children

Viewpoint

Perri Klass, John S. Hutton, Thomas G. DeWitt

JAMA Pediatrics, 30 March 2020; 174(5) pp 407-408

Abstract

The acquisition of literacy, from earliest emergent stages to full fluency with understanding and self-expression in written language, represents a distinct developmental trajectory. Unlike other developmental arenas, achieving literacy combines environmental stimulation and informal interaction in the preschool years with formal school-based instruction in decoding print and reflects the integration of multiple neuronal networks. Skills children acquire along this literacy trajectory powerfully influence life course, from early school achievement to earning potential to lifelong self-expression and civic engagement. Recognizing this, many pediatric health care professionals have incorporated literacy promotion into primary care, often through Reach Out and Read, an evidence-based model (supported by a national network) that provides parental guidance and children's books at health supervision visits.

Providing Incentives to Youth Participants in Research: A Literature Review

Research Article

Jenny L. Afkinich, Dara R. Blachman-Demner

Journal of Empirical Research on Human Research Ethics, 19 December 2019

Abstract

The provision of financial incentives to youth involved in research remains an understudied and contentious issue. Although the practice is common and often accepted, a comprehensive understanding of the current status of the literature regarding the potential benefits and limitations is lacking. The primary question this article seeks to answer is as follows: "What are the concerns and best practices identified in the literature for the appropriate and ethical provision of incentives to children and adolescents?" Following a thorough review and screening process, 25 articles were selected and central themes were identified within them. Themes include the following: the wage-payment model, effectiveness for recruitment, effectiveness for retention, financial versus alternative incentives, coerciveness, influence on validity of results, and other ethical dilemmas. Gaps in the literature are discussed. Overall, the literature suggests financial incentives can be provided appropriately to children as long as necessary precautions are taken.

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RIGHTS/LEGAL/LEGISLATIVE

Digital Nudges for Privacy Awareness: From consent to informed consent?

Research Paper

Kristoffer Bergram, Valéry Bezençon, Paul Maingot, Tony Gjerlufsen, Adrian Holzer

Association for Information Systems, 15 June 2020

Open Access

Abstract

Maintaining a private life in our digital world is gradually becoming harder. With Internet services having ever increasing access to personal data, it is crucial to raise user awareness about what privacy guarantees they offer. Regulations have recently been enacted such as the European General Data Privacy Regulation (GDPR). Yet, online service providers still have terms and privacy policies to which users tend to agree without ever viewing or reading them. By using digital nudges, this paper explores how small changes in the choice architecture can be designed to increase the informed consent and privacy awareness of users. The results from a double-blind online experiment (n = 183) show that phrasing the agreement differently and providing a highlights alternative to the existing quick-join choice architecture can significantly increase the number of users who view and read the terms and privacy policy. However, these digital nudges seem to not increase the users' recollection of what they have agreed to. The experimental results are complemented by a field test using one of the proposed designs in the IKEA Place app (n = 81'431).

Shared decision making and consent post-Montgomery, UK Supreme Court judgement supporting best practice

Discussion

Joel Ward, Dilraj Kalsi, Anirudh Chandrashekar, Bill Fulford, Regent Lee, Jonathan Herring, Ashok Handa

Patient Education and Counseling, 15 May 2020

Abstract

The UK Supreme Court Montgomery judgement marks a decisive shift in the legal test of duty of care in the context of consent to treatment from the perspective of the clinician (as represented by Bolam rules) to that of the patient. This has important implications in the surgical field worldwide, where informed consent is critical. This paper aims to explain the ruling and how it impacts the consent process.

The case and ruling are outlined and summarised as pertaining to consent and requirements for validity; a shift from the clinician's interpretation about what would be best for patients to the values of the particular patient concerned in the decision in question. A sample of recent commentaries is reviewed.

Four examples illustrate some of the practical applications of the Montgomery ruling on consent and how the ruling can empower doctors and patients to make mutually beneficial shared decisions. Future consent should be obtained using a Montgomery compliant strategy in accordance with the principles of shared decision making.

COVID-19 and its impact on informed consent: What should health professionals tell their patients or their proxies?

D J McQuoid-Mason

South African Journal of Bioethics Law, 13 May 2020; 13(1)

Open Access

Abstract

Given the increasing number of ethical and legal issues arising from the impact of the COVID-19 epidemic on informed consent by patients, it is necessary for health professionals to explain to patients how the measures taken to combat the spread of the virus impact on their right to give informed consent. Patients need to be reassured that wherever possible, health professionals are ethically bound to obtain informed consent from patients before they subject them to diagnostic testing and treatment, but at the same time, have to comply with the demands of the law. While the South African Constitution, statutory law and the common law all recognise a person's right to consent before being subjected to treatment or surgical operations, it is necessary to take remedial steps, because of the dangers of spreading the potentially fatal COVID-19 virus, to prevent this. Such steps may involve compelling patients to be screened, tested and treated – sometimes without their consent. Guidance is given to healthcare professionals on how they should counsel their patients, and what they should tell patients about the impact of the COVID-19 regulations on healthcare professionals' ethical and legal duties regarding the obtaining of informed consent, as well as on whether, if asked, employers can compel their employees to undergo testing without consent, and what to tell patients about this.

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CULTURAL/COUNTRY CONTEXT

Ethical challenges regarding the use of stem cells: interviews with researchers from Saudi Arabia

Research Article

Ghiath Alahmad, Sarah Aljohani & Muath Fahmi Najjar

BMC Medical Ethics, 12 May 2020; 21(35)

Open Access

Abstract

Background

With the huge number of patients who suffer from chronic and incurable diseases, medical scientists continue to search for new curative methods for patients in dire need of treatment. Interest in stem cells is growing, generating high expectations in terms of the possible benefits that could be derived from stem cell research and therapy. However, regardless of the hope of stem cells changing and improving lives, there are many ethical, religious, and political challenges and controversies that affect the research, and mandated to establish ethical guidelines and regulations. In Saudi Arabia, key stakeholders play an active role in discussing the ethics of stem cell research and therapy. The focus of the study was to explore professionals' perceptions related to the ethical challenges of using stem cells in research and treatment in Saudi Arabia.

Results

A qualitative research study was conducted to explore and describe the perceptions of 25 professionals employed at different tertiary hospitals in the various regions of Saudi. A thematic analysis was performed to search for and identify the most significant perceptions shared by the participants. Four themes were generated based on the ethical challenges of four areas related to stem cell use, including (1) forbidden and permitted sources of stem cells, (2) informed consent, (3) beneficence, and (4) ethical regulations and guidelines.

Conclusion

The study identified that there is a growing need to advance the knowledge, education, and awareness related to stem cell research and treatment in Saudi Arabia.

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MEDICAL/SURGICAL

Consensus on Language for Advance Informed Consent in Health Care–Associated Pneumonia Clinical Trials Using a Delphi Process

Original Investigation

Amy Corneli, Sara B. Calvert, John H. Powers III, Teresa Swezey, Deborah Collyar, Brian Perry, John J. Farley, Jonas Santiago, Helen K. Donnelly, Carisa De Anda, Katelyn Blanchard, Vance G. Fowler Jr, Thomas L. Holland

JAMA, 22 May 2020

Open Access

Abstract

Importance

Information to be included in advance informed consent forms for health care–associated pneumonia treatment trials remains to be determined.

Objective

To identify and determine how to describe information to be included in an advance informed consent form for an early-enrollment noninferiority hospital-acquired and/or ventilator associated bacterial pneumonia (HABP/VABP) clinical trial.

Design, Setting and Participants

A Delphi consensus process with stakeholders in HABP/VABP clinical trials was conducted using qualitative semistructured telephone interviews from June to August 2016, followed by 2 online surveys, the first from

April to May 2017, and the second from September to October 2017. All stakeholders who participated in the interview were invited to participate in the first survey. Stakeholders who participated in the first survey were invited to participate in the second survey. Stakeholders were patients at risk of pneumonia, caregivers, representatives of institutional review boards, investigators, and study coordinators.

Main Outcomes and Measures

Description and consensus of information to be included in advance informed consent forms for early enrollment in noninferiority HABP/VABP clinical trials.

Results

Suggestions from 52 stakeholders about what key informed consent concepts to include and how to explain them were used to create 3 categories to be included in an advance consent form: (1) reassurances on patient health and treatment, (2) rationale for advance consent and early enrollment, and (3) an explanation of noninferiority. At the end of the Delphi process, at least 80% consensus was reached among the 40 stakeholders who participated in the second online survey on each of the statements to include in the proposed consent text. Throughout the process, however, describing and reaching consensus on statements about noninferiority was more problematic than the other categories.

Conclusions and Relevance

The stakeholders endorsed consent language to be used in combination with a strategy for enrolling patients at highest risk for pneumonia before infection onset. Data-driven consent language may help potential participants make informed decisions about their involvement in clinical research and improve enrollment rates, which are necessary to evaluate new treatments and improve patient care. The proposed consent language may be adapted for other trials using an early enrollment strategy and for noninferiority trials.

An instrument for assessing the quality of informed consent documents for elective procedures: development and testing

Original Research

Erica S Spatz, Lisa G Suter, Elizabeth George, Mallory Perez, Leslie Curry, Vrunda Desai, Haikun Bao, Lori L Geary, Jeph Herrin, Zhenqiu Lin, Susannah M Bernheim, Harlan M Krumholz

BMJ Open: Ethics, 19 May 2020; 10(5)

Open Access

Abstract

Objective

To develop a nationally applicable tool for assessing the quality of informed consent documents for elective procedures.

Design

Mixed qualitative-quantitative approach.

Setting

Convened seven meetings with stakeholders to obtain input and feedback on the tool.

Participants

Team of physician investigators, measure development experts, and a working group of nine patients and patient advocates (caregivers, advocates for vulnerable populations and patient safety experts) from different regions of the country.

Interventions

With stakeholder input, we identified elements of high-quality informed consent documents, aggregated into three domains: content, presentation and timing. Based on this comprehensive taxonomy of key elements, we convened the working group to offer input on the development of an abstraction tool to assess the quality of informed consent documents in three phases: (1) selecting the highest-priority elements to be operationalised as items in the tool; (2) iteratively refining and testing the tool using a sample of qualifying informed consent documents from eight hospitals; and (3) developing a scoring approach for the tool. Finally, we tested the reliability of the tool in a subsample of 250 informed consent documents from 25 additional hospitals.

Outcomes
Abstraction tool to evaluate the quality of informed consent documents.
Results
We identified 53 elements of informed consent quality; of these, 15 were selected as highest priority for inclusion in the abstraction tool and 8 were feasible to measure. After seven cycles of iterative development and testing of survey items, and development and refinement of a training manual, two trained raters achieved high item-level agreement, ranging from 92% to 100%.
Conclusions
We identified key quality elements of an informed consent document and operationalised the highest-priority elements to define a minimum standard for informed consent documents. This tool is a starting point that can enable hospitals and other providers to evaluate and improve the quality of informed consent.

Quality of informed consent documents among US. hospitals: a cross-sectional study

Original Research
Erica S Spatz, Haikun Bao, Jeph Herrin, Vrunda Desai, Sriram Ramanan, Lynette Lines, Rebecca Dendy, Susannah M Bernheim, Harlan M Krumholz, Zhenqiu Lin, Lisa G Suter
BMJ Open: Cardiovascular Medicine, 19 May 2020; 10(5)
Open Access
Abstract
Objective
To determine whether informed consent for surgical procedures performed in US hospitals meet a minimum standard of quality, we developed and tested a quality measure of informed consent documents.
Design
Retrospective observational study of informed consent documents.
Setting
25 US hospitals, diverse in size and geographical region.
Cohort
Among Medicare fee-for-service patients undergoing elective procedures in participating hospitals, we assessed the informed consent documents associated with these procedures. We aimed to review 100 qualifying procedures per hospital; the selected sample was representative of the procedure types performed at each hospital.
Primary outcome
The outcome was hospital quality of informed consent documents, assessed by two independent raters using an eight-item instrument previously developed for this measure and scored on a scale of 0–20, with 20 representing the highest quality. The outcome was reported as the mean hospital document score and the proportion of documents meeting a quality threshold of 10. Reliability of the hospital score was determined based on subsets of randomly selected documents; face validity was assessed using stakeholder feedback.
Results
Among 2480 informed consent documents from 25 hospitals, mean hospital scores ranged from 0.6 (95% CI 0.3 to 0.9) to 10.8 (95% CI 10.0 to 11.6). Most hospitals had at least one document score at least 10 out of 20 points, but only two hospitals had >50% of their documents score above a 10-point threshold. The Spearman correlation of the measures score was 0.92. Stakeholders reported that the measure was important, though some felt it did not go far enough to assess informed consent quality.
Conclusion
All hospitals performed poorly on a measure of informed consent document quality, though there was some variation across hospitals. Measuring the quality of hospital's informed consent documents can serve as a first step in driving attention to gaps in quality.

The Effect of the Consent Process on Patient Satisfaction With Pain Management: A Randomized Controlled Trial

Pain management and sedation/original research

Safire Valentine, James Majer, Nicole Grant, Antony Ugoni, David M. Taylor

Annals of Emergency Medicine, 15 May 2020

Abstract

Study objective

We aim to determine whether the timing and context of informed consent affects the subjective outcome of patient satisfaction with pain management.

Methods

We conducted a randomized controlled trial in a single emergency department (ED). Patients aged 18 years or older with a triage pain score of greater than or equal to 4 provided consent to participate in a pain management study. They were randomized to consent in the ED or at follow-up. All patients were followed up at 48 hours post–ED discharge. Patients who consented at follow-up were unaware of the study until cold called. The primary outcome was patient satisfaction with pain management. Secondary analyses examined effects on follow-up and participation rates. Variables associated with patients' being very satisfied were determined with multivariate logistic regression.

Results

Outcome data were obtained on 655 of 825 patients enrolled (79.4%). Patients who provided consent at follow-up were less likely to be very satisfied compared with those who consented in the ED (difference in proportions 11.5%; 95% confidence interval 3.5 to 19.4). Follow-up and participation rates did not differ between the groups. Patients who received pain advice and adequate analgesia (both as defined in this study) were more likely to be very satisfied (odds ratio 5.18, 95% confidence interval 2.82 to 9.52; and odds ratio 1.54, 95% confidence interval 1.07 to 2.22, respectively).

Conclusion

The timing and context of informed consent significantly affect the subjective outcome of patient satisfaction, and this should be considered during study design. Clinicians should strive to provide pain advice and adequate analgesia to maximize their patients' satisfaction.

Capacity to consent to medical procedures [BOOK CHAPTER]

Deborah Slater

Assessing Mental Capacity: A Handbook to Guide Professionals from Basic to Advanced Practice

Routledge, 4 May 2020; Chapter 13

Abstract Only Available

The law requires professionals to ensure that a person is able to give consent before any form of treatment, investigation or care is given. Consent must be valid and it should be given freely and voluntarily (Royal College of Nursing, 2017). This section will explore what you need to know and the process you need to follow to carry out an assessment of capacity to consent to treatment.

Bundled Consent in US Intensive Care Units

Maria L. Espinosa, Aaron M. Tannenbaum, Megha Kilaru, Jennifer Stevens, Mark Siegler, Michael D. Howell, William F. Parker

American Journal of Critical Care, 1 May 2020; 29(3) e44–e51

Open Access

Abstract

Background

Bundled consent, the practice of obtaining anticipatory consent for a predefined set of intensive care unit procedures, increases the rate of informed consent conversations and incorporation of patients' wishes into medical decision-making without sacrificing patients' or surrogates' understanding. However, the adoption rate for this practice in academic and nonacademic centers in the United States is unknown.

Objective

To determine the national prevalence of use of bundled consent in adult intensive care units and opinions related to bundled consent.

Methods

A random sample of US hospitals with medical/surgical intensive care units was selected from the AHA [American Hospital Association] Guide. One intensive care unit provider (bedside nurse, nurse manager, or physician) from each hospital was asked to self-report use of per-procedure consent versus bundled consent, consent rate for intensive care unit procedures, and opinions about bundled consent.

Results

Of the 238 hospitals contacted, respondents from 100 (42%) completed the survey; 94% of respondents were nurses. The prevalence of bundled consent use was 15% (95% CI, 9%–24%). Respondents using per-procedure consent were more likely than those using bundled consent to self-report performing invasive procedures without consent. Users of bundled consent unanimously recommended the practice, and 49% of respondents using per-procedure consent reported interest in implementing bundled consent.

Preoperative Patient Education Class during an Orthopaedic Mission Trip: Effects on Knowledge, Anxiety, and Informed Consent

Mitchell A. Solano, Kaaleswar K. Ramcharran, Lynne C. Jones, Robert S. Sterling, David R. Samaroo, Harpal S. Khanuja

The Journal of Arthroplasty, 1 May 2020

Abstract

Background

Patient knowledge about arthritis and risks, benefits, and outcomes of joint replacement in developing countries is unknown. We evaluated the effectiveness of a preoperative class on improving knowledge and decreasing anxiety during a surgical mission trip offering total joint replacement surgery.

Methods

A team of U.S. healthcare providers taught a preoperative class to 41 patients selected for total joint replacement during a surgical mission trip to Guyana. Participants completed a 32-point survey about arthritis; indications, risks, and benefits of joint replacement; and postoperative, in-patient rehabilitation expectations. The State-Trait Anxiety Inventory was used to measure participant anxiety. Participants completed identical surveys before and after class. Matched-pairs Student's t-tests were used to compare means between pre- and post-class surveys. Significance was accepted at $P < .05$.

Results

Seventy-eight percent of patients (31/41) scored less than 12 of 32 possible points (40%) on the pre-class knowledge questionnaire. Mean ± standard deviation knowledge scores improved from 14.0 ± 4.5 before the class to 16.5 ± 6.5 after the class ($P = .008$). Anxiety scores ($n = 33$) improved from 35 ± 13 before the class to 33 ± 12 after the class ($P = .047$).

Conclusion

On this surgical mission trip, underserved patients' knowledge about total joint replacement increased only modestly after taking a preoperative class. Greater understanding of how to educate patients and reduce their anxiety on medical missions is needed.

Patient Preferences Regarding Informed Consent Models for Participation in a Learning Health Care System for Oncology

Rochelle D. Jones, Chris Krenz, Michele Gornick, Kent A. Griffith, Rebecca Spence, Angela R. Bradbury, Raymond De Vries, Sarah T. Hawley, Rodney A. Hayward, Robin Zon, Sage Bolte, Navid Sadeghi, Richard L. Schilsky, Reshma Jagsi

JCO Oncology Practice, 30 April 2020

Abstract

Purpose

The expansion of learning health care systems (LHSs) promises to bolster research and quality improvement endeavors. Stewards of patient data have a duty to respect the preferences of the patients from whom, and for whom, these data are being collected and consolidated.

Methods

We conducted democratic deliberations with a diverse sample of 217 patients treated at 4 sites to assess views about LHSs, using the example of CancerLinQ, a real-world LHS, to stimulate discussion. In small group discussions, participants deliberated about different policies for how to provide information and to seek consent regarding the inclusion of patient data. These discussions were recorded, transcribed, and de-identified for thematic analysis.

Results

Of participants, 67% were female, 61% were non-Hispanic Whites, and the mean age was 60 years. Patients' opinions about sharing their data illuminated 2 spectra: trust/distrust and individualism/collectivism. Positions on these spectra influenced the weight placed on 3 priorities: promoting societal altruism, ensuring respect for persons, and protecting themselves. In turn, consideration of these priorities seemed to inform preferences regarding patient choices and system transparency. Most advocated for a policy whereby patients would receive notification and have the opportunity to opt out of including their medical records in the LHS. Participants reasoned that such a policy would balance personal protections and societal welfare.

Conclusion

System transparency and patient choice are vital if patients are to feel respected and to trust LHS endeavors. Those responsible for LHS implementation should ensure that all patients receive an explanation of their options, together with standardized, understandable, comprehensive materials.

Editor's note: JCO Oncology Practice is an American Society of Clinical Oncology Journal.

A rationale and framework for seeking remote electronic or phone consent approval in endovascular stroke trials – special relevance in the COVID-19 environment and beyond

Original Research

Ansaar T Rai, Donald Frei

Journal of NeuroInterventional Surgery, 28 April 2020

Open Access

Abstract

Background

Enrollment in time-sensitive endovascular stroke trials can be challenging because of an inability to consent a debilitated patient. Often the legally authorized representative is not on site. Remote consent procedures in the US are inconsistent with the majority of sites shunning these approaches. The current pandemic with visitor restrictions highlights the need for enhancing these options.

Methods

Remote electronic and phone consent procedures specifically for endovascular stroke trials from two comprehensive stroke centers (CSC) are presented. An overview of the genesis of informed consent procedures in the US is also included. Results The two CSCs identified as Institution-1 and Institution-2 are large tertiary systems. Institution-1 is a non-profit university-affiliated academic medical center in rural geography. Institution-2 is an HCA hospital in an urban environment. Both serve patients through a spoke-and-hub network, have participated in multiple randomized endovascular stroke trials, and have successfully used these remote options for enrollment. A tiered approach is employed at both institutions with an emphasis on obtaining informed consent in person and resorting to alternatives methods when efforts to that are unsuccessful. A rationale for electronic and phone consent is included, followed by step-by-step illustration of the process at each institution.

Conclusion

Two examples of remote electronic or phone consent procedures from institutions in different geographic environments and organization structures demonstrate that these options can be successfully used for enrollment in stroke trials. The current pandemic highlights the need to enhance these approaches while maintaining appropriate adherence to ethical and legal frameworks.

Informed Consent for Surgery During COVID-19

Neela Bhattacharya, Kaushik Bhattacharya
Indian Journal of Surgery, 24 April 2020
Open Access
Abstract

Informed consent has become a challenging issue when surgery at the time of novel corona virus disease 2019 (COVID-19) is to be performed, in view of increased risk of the need of intensive care unit (ICU) in the post-operative period and the associated high mortality if a patient exhibits COVID-19 symptoms in the post-operative period. We have devised a new informed consent format for all patients undergoing surgery incorporating a few points specific for the disease.

The effect on consent rates for deceased organ donation in Wales after the introduction of an opt-out system

Original Article
S. Madden, D. Collett, P. Walton, K. Empson, J. Forsythe, A. Ingham, K. Morgan,
P. Murphy, J. Neuberger, D. Gardiner
Anaesthesia, 16 March 2020
Open Access
Summary

Organ transplantation saves and transforms lives. Failure to secure consent for organ retrieval is widely regarded as the single most important obstacle to transplantation. A soft opt-out system of consent for deceased organ donation was introduced into Wales in December 2015, whilst England maintained the existing opt-in system. Cumulative data on consent rates in Wales were compared with those in England, using a two-sided sequential procedure that was powered to detect an absolute difference in consent rates between England and Wales of 10%. Supplementary risk-adjusted logistic regression analysis examined whether any difference in consent rates between the two nations could be attributed to variations in factors known to influence UK consent rates. Between 1 January 2016 and 31 December 2018, 8192 families of eligible donors in England and 474 in Wales were approached regarding organ donation, with overall consent rates of 65% and 68%, respectively. There was a steady upward trend in the proportion of families consenting to donation after brain death in Wales as compared with England and after 33 months, this reached statistical significance. No evidence of any change in the donation after circulatory death consent rate was observed. Risk-adjusted logistic regression analysis revealed that by the end of the study period the probability of consent to organ donation in Wales was higher than in England (OR [95%CI] 2.1 [1.26–3.41]). The introduction of a soft opt-out system of consent in Wales significantly increased organ donation consent though the impact was not immediate.

Surgeon clinical practice variation and patient preferences during the informed consent discussion: a mixed-methods analysis in lumbar spine surgery

Ali Zahrai, Kunal Bhanot, Xin Y. Mei, Eric Crawford, Zachary Tan, Albert Yee, Valerie Palda
Canadian Journal of Surgery, 10 October 2019; 63(3)
Open Access
Abstract
Background

Patients with lumbar disc herniation may greatly benefit from microdiscectomy. Although spine surgeons performing microdiscectomy routinely obtain informed consent, the potential adverse events they disclose often vary. Moreover, little is known about what disclosures are deemed most valuable by patients. The aim of this mixed-methods study was to determine practice variations among spine surgeons in regard to the disclosure of potential adverse events during informed consent discussions
for lumbar microdiscectomy and to determine which topics patients perceived to be valuable in the consent discussion.

Methods

A survey evaluating the frequency with which spine surgeons disclose 15 potential adverse events related to lumbar microdiscectomy during informed consent discussions was distributed among Canadian Spine Society members. Additionally, semistructured interviews were conducted with preoperative patients, postoperative patients, attending spine surgeons, spine fellows and orthopedic residents. Interview transcripts were analyzed using thematic analysis with open coding.

Results

Fifty-one Canadian Spine Society members completed the survey. The number of potential adverse events not routinely discussed was greater among orthopedic surgeons than among neurosurgeons (relative risk 1.83; 95% confidence interval 1.22–2.73; p = 0.003). Three preoperative patients, 7 postoperative patients, 6 attending spine surgeons, 3 spine fellows and 5 orthopedic residents participated in the semistructured interviews. The interviews identified gaps in information provided to patients, particularly on topics relating to postoperative care such as expected recovery time, activity restrictions and need for a caregiver.

Conclusion

There is variation in the disclosure of potential adverse events during informed consent discussions for lumbar microdiscectomy among Canadian spine surgeons. Patients desire more information regarding their postoperative care. Further research should focus on developing guidelines to reduce practice variation and optimize the effectiveness of consent discussions.

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GENERAL/OTHER

Partnering With Patients to Bridge Gaps in Consent for Acute Care Research

Neal W. Dickert, Amanda Michelle Bernard ,JoAnne M. Brabson, Rodney J. Hunter, Regina McLemore, Andrea R. Mitchell, Stephen Palmer, Barbara Reed, Michele Riedford, Raymond T. Simpson, Candace D. Speight, Tracie Steadman, Rebecca D. Pentz

The American Journal of Bioethics, 4 May 2020; 5 pp 7-14

Abstract

Clinical trials for acute conditions such as myocardial infarction and stroke pose challenges related to informed consent due to time limitations, stress, and severe illness. Consent processes should be sensitive to the context in which trials are conducted and to needs of patients and surrogate decision-makers. This manuscript describes a collaborative effort between ethicists, researchers, patients, and surrogates to develop patient-driven, patient-centered approaches to consent for clinical trials in acute myocardial infarction and stroke.

Our group identified important ways in which existing consent processes and forms for clinical trials fail to meet patients’ and surrogates’ needs in the acute context. We collaborated to create model forms and consent processes that are substantially shorter and, hopefully, better-matched to patients’ and surrogates’ needs and expectations from the perspective of content, structure, and tone. These changes, however, challenge some common conventions regarding consent.

What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?

History of Medicine

James F. Childress, Marcia Day Childress

AMA Journal of Ethics, May 2020

Open Access

Abstract

This article examines the legal doctrine and ethical norm of informed consent and its deficiencies, particularly its concentration on physician disclosure of information rather than on patient understanding, which led to the development of shared decision making as a way to enhance informed consent. As a vague and imprecise rubric, shared decision making encompasses several different approaches. Narrower approaches presuppose an individualistic account of autonomy, while broader approaches view autonomy as relational and hold that clinician-patient relationships grounded in good communication can assist decision making and foster autonomous choices. Shared decision making faces conceptual, normative, and practical challenges, but, with its goal of respecting, protecting, and promoting patients' autonomous choices, it represents an important cultural change in medicine.

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