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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

January 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 GE2P2 Global Foundation's Center for Informed Consent Integrity, which is solely responsible for its content. Comments and suggestions should be directed to:

Editor
Paige Fitzsimmons, MA
Associate Fellow
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

Publisher
David R. Curry
President & CEO
GE2P2 Global Foundation
david.r.curry@ge2p2global.org

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 categories:
HUMANITARIAN CONTEXT
REAL WORLD POLICY/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH

Please note at the end of each edition appears an evolving set of appendices including a glossary, tools for assessment and guidance documents.

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GENOMIC MEDICINE/GENE EDITING

Why parents consent to their children's participation in genetic research: A study of parental decision making

Kumari S, Bhatia T, Mishra NN, Kumari N, Narayanan SS, Malik D, Deshpande SN
Indian journal of medical ethics, October-December 2019
Abstract
Parents need to be asked to provide informed consent on behalf of their child for participation in genetic research. Decision making for such parents is difficult because ethical challenges in paediatric genetic research studies are different from similar adult studies. This paper focuses on interviews conducted with parents who were asked to consent to their children's participation (or not) in a genetic research study of intellectual disability and/or autism.

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COMPASSIONATE USE/EXPANDED ACCESS

Navigating the Informed Consent Process When Using Innovative Surgery

Research Article
Daniel Wehrmann, Glenn E. Green, MD, Kevin J. Weatherwax, Andrew G. Shuman
Otolaryngology–Head and Neck Surgery, 24 December 2019
Excerpt
… Expanded access (EA), also referred to as “compassionate use,” is a Food and Drug Administration (FDA) mechanism by which patients with serious or life-threatening conditions for which there is no approved treatment may access novel investigational drugs, biologics, or medical devices. The benefits of the proposed drug/device must outweigh the risks to that patient or group of patients… Obtaining informed consent in this setting is complicated due to the conflation of clinical care and research, with each directed at different primary goals. Traditionally, clinicians are expected to solely focus on the best possible outcome for the patients they are treating. Researchers, on the other hand, are primarily focused on creating generalizable knowledge to help all patients. Of course, these goals may be more or less divergent, especially when surgeon-scientists are acting in both capacities… Surgical innovation using the EA program represents a thoughtful balance between patient/family choices, our duty to potential future patients, and the regulatory landscape in which we practice. The informed consent process represents an amalgam of standard clinical components, as well as clinical research regulations that necessarily meet a higher standard and level of scrutiny. As such, our obligations as researchers, clinicians, and our dual roles as both, highlight the need for us to uphold the highest levels of morality, ethics, and professionalism.

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BIOMEDICAL RESEARCH

Parental opinions regarding consent for observational research of no or minimal risk in the pediatric intensive care unit

Research
Jessica Hodson, Christiana Garros, Jodie Jensen, Jonathan P. Duff, Gonzalo Garcia Guerra, Ari R. Joffe
Journal of Intensive Care, 16 December 2019; 7(60)
Open Access
Abstract
Background
The aim of the study was to determine opinions and knowledge regarding the process of obtaining informed consent to participate in observational research in pediatric intensive care.
Methods
Survey 1 asked decision makers what model(s) of consent was acceptable for each type of observational research both before and after background information. Survey 2 asked decision makers about the experience of being asked for consent to observational research, and knowledge regarding the consent process both before and after background information.
Results
Cooperation rate was 100/117 (85%). The proportion in favor of any of the offered alternatives to signed informed consent for observational research, after receiving all the background information, was 74-80%, lowest for observational prospective research with a minimal risk intervention 37/50 (74%; 95% CI 60–84%). The proportion who agreed they felt overwhelmed by being approached for consent to observational research was 26 (52%; 95% CI 39-65%). Most respondents (from 60 to 74%) felt they understood the concepts regarding observational research; however, after reading background information, most (from 60 to 74%) felt their understanding had improved “a great deal”.
Conclusion
Understanding of risk, practical difficulties, consent bias, and Research Ethics Board safeguards was poor. Future study is needed to confirm our finding that most agreed with alternative methods of consent for observational research.

Research without prior consent in paediatric emergency and critical care medicine

Symposium: research
Aled Picton, Kerry Woolfall, Mark D. Lyttle, Stuart Hartshorn
Paediatrics and Child Health, 14 December 2019
[country of publication: UK]
Abstract
Children and young peoples' healthcare should be evidence-based yet many treatments are unlicensed or prescribed off-label. Research is needed, but prospective informed consent for many emergency and critical care trials is neither feasible nor ethical – treatments are time critical, and delays for research discussions may cause harm. Research without prior consent (RWPC) is a practical approach which facilitates such research. Trial interventions are administered immediately to eligible patients, and consent for ongoing study involvement is sought after the emergency situation has passed. This has been permitted in the United Kingdom since an amendment to legislation in 2008, and subsequently employed by several trials. Studies demonstrate that most parents are supportive of this approach provided their child's safety is not compromised, and research discussions are appropriately timed. Practitioners with no experience of RWPC often initially report anxiety about taking this approach, but study experience and training helps change perspectives. Sadly, some children enrolled into such studies will die. Approaching bereaved families for consent requires a bespoke approach, conducted with care and sensitivity. Future research should explore the acceptability of higher risk trials, the viewpoints of children with first-hand experience of this method, and international perspectives.

Editor’s note: This article also appears under YOUNG PERSONS.

Reporting of ethical approval and informed consent in clinical research published in leading nursing journals: a retrospective observational study

Research Article

Yanni Wu, Michelle Howarth, Chunlan Zhou, Mingyu Hu, Weilian Cong

BMC Medical Ethics, 5 December 2019; 20(94)

Open Access

Abstract

Background

Ethical considerations play a prominent role in the protection of human subjects in clinical research. To date the disclosure of ethical protection in clinical research published in the international nursing journals has not been explored. Our research objective was to investigate the reporting of ethical approval and informed consent in clinical research published in leading international nursing journals.

Methods

This is a retrospective observational study. All clinical research published in the five leading international nursing journals from the SCI Journal Citation Reports between 2015 and 2017 were retrieved to evaluate for evidence of ethical review.

Results

A total of 2041 citations have been identified from the contents of all the five leading nursing journals that were published between 2015 and 2017. Out of these, 1284 clinical studies have been included and text relating to ethical review has been extracted. From these, most of prospective clinical studies (87.5%) discussed informed consent. Only half of those (52.9%) reported that written informed consent had been obtained; few (3.6%) reported oral consent, and few (6.8%) used other methods such as online consent or completion and return of data collection (such as surveys) to denote assent. Notably, 36.2% of those did not describe the method used to obtain informed consent and merely described that "consent was obtained from participants or participants agreed to join in the research". Furthermore, whilst most of clinical studies (93.7%) mentioned ethical approval; 92.5% of those stated the name of ethical committee and interestingly, only 37.1% of those mentioned the ethical approval reference. The rates of reporting ethical approval were different between different study type, country, and whether financial support was received (all $P < 0.05$).

Conclusion

The reporting of ethics in leading international nursing journals demonstrates progress, but improvement of the transparency and the standard of ethical reporting in nursing clinical research is required.

Dual consent? Donors' and recipients' views about involvement in decision-making on the use of embryos created by gamete donation in research

Research Article

I. Baía, C. de Freitas, C. Samorinha, V. Provoost, S. Silva

BMC Medical Ethics, 2 December 2019; 20(90)

Open Access

Abstract

Background

Reasonable disagreement about the role awarded to gamete donors in decision-making on the use of embryos created by gamete donation (EGDs) for research purposes emphasises the importance of considering the implementation of participatory, adaptive, and trustworthy policies and guidelines for consent procedures. However, the perspectives of gamete donors and recipients about decision-making regarding research with EGDs are still under-researched, which precludes the development of policies and guidelines informed by evidence. This study seeks to explore the views of donors and recipients about who should take part in consent processes for the use of EGDs in research.

Methods

From July 2017 to June 2018, 72 gamete donors and 175 recipients completed a self-report structured questionnaire at the Portuguese Public Bank of Gametes (response rate: 76%). Agreement with dual consent

was defined as the belief that the use of EGDs in research should be consented by both donors and recipients.

Results

The majority of participants (74.6% of donors and 65.7% of recipients) were willing to donate embryos for research. Almost half of the donors (48.6%) and half of the recipients (46.9%) considered that a dual consent procedure is desirable. This view was more frequent among employed recipients (49.7%) than among non-employed (21.4%). Donors were less likely to believe that only recipients should be involved in giving consent for the use of EGDs in research (25.0% vs. 41.7% among recipients) and were more frequently favourable to the idea of exclusive donors' consent (26.4% vs. 11.4% among recipients).

Conclusions

Divergent views on dual consent among donors and recipients indicate the need to develop evidence-based and ethically sustainable policies and guidelines to protect well-being, autonomy and reproductive rights of both stakeholder groups. More empirical research and further theoretical normative analyses are needed to inform people-centred policy and guidelines for shared decision-making concerning the use of EGDs for research.

Authority and the Future of Consent in Population-Level Biomedical Research

Mark Sheehan, Rachel Thompson, Jon Fistein, Jim Davies, Michael Dunn, Michael Parker, Julian Savulescu, Kerrie Woods

Public Health Ethics, 30 October 2019; 12(3) pp 225–236

Abstract

Population-level biomedical research has become crucial to the health system's ability to improve the health of the population. This form of research raises a number of well-documented ethical concerns, perhaps the most significant of which is the inability of the researcher to obtain fully informed specific consent from participants. Two proposed technical solutions to this problem of consent in large-scale biomedical research that have become increasingly popular are meta-consent and dynamic consent. We critically examine the ethical and practical credentials of these proposals and find them lacking. We suggest that the consent problem is not solved by adopting a technology driven approach grounded in a notion of 'specific' consent but by taking seriously the role of research governance in combination with broader conceptions of consent. In our view, these approaches misconstrue the rightful location of authority in the way in which population-level biomedical research activities are structured and organized. We conclude by showing how and why the authority for determining the nature and shape of choice making about participation ought not to lie with individual participants, but rather with the researchers and the research governance process, and that this necessarily leads to the endorsement of a fully articulated broad consent approach.

Experimental infections in humans—historical and ethical reflections

W. G. Metzger, H.-J. Ehni, P. G. Kremsner, B. G. Mordmüller

Tropical Medicine & International Health, 26 October 2019

Open Access

Abstract

Vaccine efficacy and prophylactic treatment of infections are tested best when the vaccinated or treated individual is challenged through deliberate infection with the respective pathogen. However, this trial design calls for particular ethical caution. Awareness of the history of challenge trials is indispensable, including trials that were problematic or even connected to abuse. We briefly introduce historical aspects of experimental infections in humans and the ethical debate around them and give estimates of the numbers of volunteers participating in human experimental infection models. Challenge models can offer a great chance and benefit for the development of medical interventions to fight infectious diseases, but only when they are appropriately controlled and regulated.

Public Deliberation as a Novel Method for an Exception From Informed Consent Community Consultation

Original Contribution

Patricia E. Powers, Karen K. Shore, Susan Perez, Dominique Ritley, Nathan Kuppermann, James F. Holmes, Leah S. Tzimenatos, Hiwote Shawargga, Daniel K. Nishijima

Society for Academic Emergency Medicine, October 2019; 26(10) pp 1158-1168

Open Access

Abstract

Objectives

Community consultation is required for clinical trials considering federal exception from informed consent (EFIC) procedures. Questions remain about the value of the community consult process and whether it adds intended protections to study subjects. Public deliberation methods that provide baseline participant education and elicit values and opinions about consent options is a novel approach for community consultation. This study evaluated the use of structured public deliberation methods to assess a community's values and opinions about informed consent procedures for a pediatric trauma trial.

Methods

This was a mixed-methods descriptive study of public deliberation sessions assessing participants' opinions about informed consent procedures for a pediatric trauma randomized controlled trial (RCT). Participants from communities with high rates of pediatric trauma were recruited via community-based organizations and social media. Deliberation focused on three consent options for a proposed RCT: 1) enrollment using EFIC procedures with no attempt to obtain informed consent, 2) enrollment using EFIC procedures after attempting to reach a parent, or 3) enrollment only with informed consent. Participant demographic data and their opinions about the proposed study and deliberative session were also collected.

Results

There were 102 participants across eight sessions (range of nine to 15/session, mean of 13). Most participants were female (n = 78, 76%) and a plurality were black (n = 48, 47%). The majority of participants preferred enrollment using EFIC procedures only after an attempt was made to reach a parent and informed consent was not possible (n = 56, 55%), followed by enrollment using EFIC procedures with no attempt to obtain informed consent (n = 32, 32%), and enrollment only with written informed consent (n = 13, 13%). One participant declined all options. Eighty-four participants (82%) agreed or strongly agreed that the RCT was important to do, and 79 participants (77%) said that the sessions provided enough information to make an informed decision about the proposed RCT.

Conclusions

Structured public deliberation is an effective approach when consulting communities for trials considering EFIC procedures. Future studies are needed to evaluate whether public deliberation methods provide participants with enhanced understanding of clinical trials compared to other community consultation methods.

Informed consent and comprehensibility issues

Research Project

Gianni De Nardi, Maureen Ehrensberger-Dow, Igor Matic, Felix Steiner

ZHAW Zurich, University of Applied Sciences Publications, 2019

Open Access

Abstract

The Federal Office for Public Health has commissioned a project to investigate a key requisite for research with humans: Any person who consents to participate in health-related research must have understood the purpose, the risks and the course of the study in question. Building on the research reports, the present summary is intended to separately illustrate each of the following three levels of the problems associated

with the understanding of Informed Consent, namely the results and the recommendations relating thereto. We forego any detailed derivation and discussion of the results that are contained in the four research reports. 1. Intelligibility of the written Informed Consent explanation 2. Intelligibility of the oral Informed Consent explanation 3. Combination of the oral and written Informed Consent explanation.

The Role of Informed Consent for Thrombolysis in Acute Ischemic Stroke

Comer AR, Damush TM, Torke AM, Williams LS

Journal of Clinical Ethics, 2019; 30(4) pp 338-346

Abstract

Although tissue plasminogen activator (tPA) is the only medication approved by the United States Food and Drug Administration (FDA) for acute ischemic stroke, there is no consensus about the need for informed consent for its use. As a result, hospitals throughout the U.S. have varying requirements regarding obtaining informed consent from patients for the use of tPA, ranging from no requirement for informed consent to a requirement for verbal or written informed consent. We conducted a study to (1) determine current beliefs about obtaining patients' informed consent for tPA among a large group of stroke clinicians and (2) identify the ethical, clinical, and organizational factors that influence tPA consent practices. Semi-structured interviews were conducted by trained and experienced investigators and research staff to identify key barriers to implementing acute stroke services. Part of the interview explored current beliefs and practices around informed consent for tPA. This was a multicenter study that included 38 Veterans Health Administration (VHA) hospital locations. Participants were 68 stroke team clinicians, serving primarily on the neurology (35 percent) or emergency medicine (41 percent) service. We conducted thematic analysis based on principles of grounded theory to identify codes about consent for tPA. We used interpretive convergence to ensure consistency among the individual investigators' codes and to ensure that all of the investigators agreed on coding and themes. We found that 38 percent of the stroke clinicians did not believe any form of consent was necessary for tPA, 47 percent thought that some form of consent was necessary, and 15 percent were unsure. Clinicians who believed tPA required informed consent were divided on whether consent should be written (40 percent) or verbal (60 percent). We identified three factors describing clinicians' attitudes about consent: (1) legal and policy factors, (2) ethical factors, and (3) medical factors. The lack of consensus regarding consent for tPA creates the potential for delays in treatment, uneasiness among clinicians, and legal liability. The identified factors provide a potential framework to guide discussions about developing a standard of care for acquiring the informed consent of patients for the administration of tPA.

Informed Consent in Diagnostic and Therapeutic Lumbar Puncture: Are Patients Aware of the Risks?

Muhammed Nur Ögün, Merve Önerli, Şule Aydın Türkoğlu, Serpil Yıldız

Turkish Journal of Neurology, 2019; 25(4) pp 229-232

Open Access

Abstract

Objective

To determine whether the type of informed consent (verbal or written and verbal) influenced the awareness of patients about the risks of lumbar puncture (LP).

Materials and Methods

An “informed consent form” was given to the patients in group 1 24 h before the procedure, and the patients were requested to read and sign the form. The informed consent form was given to patients in group 2, and then, a neurologist verbally explained the complications mentioned in the form to the patients. After the procedure, patients in both groups were asked whether they were aware of the complications mentioned in the consent form.

Results

We included 43 patients (group 1, n=23 and group 2, n=20) in the study; 14% (n=6) of the patients were university graduates, 18% (n=8) had completed high-school education, and 67% (n=29) had completed primary education. No significant difference was observed between the two groups in terms of age, sex, and education level. The mean value of the number of complications that the patients were aware of was 1.17±1.02 and 7.35±1.26 in groups 1 and 2, respectively. We observed a significant difference in the number of complications that the patients were aware of between both groups ($p<0.001$).
Conclusion
The responsibilities of physicians are not solely limited to giving the informed consent form to the patients before LP. Physicians should explain the contents of the form verbally to the patients.

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TECHNOLOGY/OTHER MEDIATION

Making clinical trials more patient-centered using digital interactive e-consent tools

Barbara Bowles Biesecker, Melissa R. Raspa, Douglas J. Rupert, Rebecca Munch Moultrie, Robert D. Furberg, Lauren A. McCormack
Occasional Paper, RTI International (published by RTI Press), October 2019
Open Access
Abstract
Research participants are required to give their consent to participate in clinical trials and nonexempt government-funded studies. The goal is to facilitate participant understanding of the intent of the research, its voluntary nature, and the potential benefits and harms. Ideally, participants make an informed choice whether to participate; one that is based on having sufficient relevant knowledge and that is consistent with their values and preferences. Achieving this objective can be challenging, and as such, many scholars have declared the consent process flawed or "broken." Moreover, clinical trials are complex studies, and compelling evidence suggests that current consent processes are inadequate in achieving informed choice. E-consent offers a dynamic, engaging consent delivery mode that can effectively support making informed decisions about whether to participate in a trial.

Improved parental understanding by an enhanced informed consent form: a randomized controlled study nested in a paediatric drug trial

Nut Koonrungsesomboon, Chanchai Traivaree, Charnunnut Tiyapsane, Juntra Karbwang
BMJ Open, 26 November 2019; 9(11)
Open Access
Abstract
Objective
This study was designed to evaluate the applicability and effectiveness of the enhanced informed consent form (ICF) methodology, proposed by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), in paediatric research requiring parental consent. The objective of this study was to compare the parental understanding of information between the parents who read the SIDCER ICF and those who read the conventional ICF.
Design
A prospective, randomized, controlled design.
Setting
Paediatric Outpatients Department, Phramongkutklao Hospital, Thailand.
Participants
210 parents of children with thalassemia (age=35.6 ± 13.1 years).
Interventions

The parents were randomly assigned to read either the SIDCER ICF (n=105) or the conventional ICF (n=105) of a paediatric drug trial.
Primary and secondary outcome measures
Parental understanding of trial information was determined using 24 scenario-based questions. The primary endpoint was the proportion of parents who obtained the understanding score of more than 80%, and the secondary endpoint was the total score.
Results
Forty-five parents (42.9%) in the SIDCER ICF group and 29 parents (27.6%) in the conventional ICF group achieved the primary endpoint (relative risk=1.552, 95% CI 1.061 to 2.270, p=0.021). The total score of the parents in the SIDCER ICF group was significantly higher than the conventional ICF group (18.07±3.71 vs 15.98±4.56, p=0.001).
Conclusions
The SIDCER ICF was found to be superior to the conventional ICF in improving parental understanding of trial information.

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BIOBANKING

Jordanians' Perspectives On Open Consent In Biomedical Research

Original Research
Nasr Alrabadi, Hanin Makhlouf, Omar F Khabour, Karem H Alzoubi
Risk Management and Healthcare Policy, 2 December 2019; 2019(12) pp 265—273
Introduction
The informed consent process is an integral step in biomedical research. However, the emergence of biobanks and the need for open consent (also called "broad" or "blanket" consent) create challenges to this process.
Aims and methodology
A survey was used to examine Jordanians' perspectives on open consent and reuse of stored samples in future research.
Results
The majority of participants had positive perceptions of informed consent and its importance. In addition, they appreciated the challenges that are associated with multiple uses of their biospecimens. About 55% agreed to provide open consent for reuse of their donated biospecimens. Participants (75–80%) also agreed that issues such as the possibility of sharing samples with international research centers, storage duration, and use of biospecimens after their death should be clarified as part of open consent. The inconvenience of the re-contact process, trust in the research team, and the importance of biobanks were all associated with participants' willingness to provide open consent ($P<0.05$). On the other hand, privacy and confidentiality, doubt about future use of samples, unknown storage period, and the possibility of cross-border sample sharing were significantly associated with participants' reluctance to provide open consent.
Conclusion
The majority of Jordanians accept the idea of open consent. Clarification of issues such as international sample sharing, duration of storage, domains of intended research, confidentiality, and privacy can provide more support for the use of open consent.
Editor's note: This article also appears under CULTURAL/COUNTRY CONTEXT.

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COGNITIVE CHALLENGES

What is needed to obtain informed consent and monitor capacity for a successful study involving People with Mild Dementia? Our experience in a multi-centre study [CONFERENCE PAPER]

Jennifer Lim, Rosa Almeida, Vjera Holthoff-Detto, Geke Ludden, Kristina Niedderer

International MinD Conference 2019, 19-12 September 2019; Dresden, Germany

Open Access

Abstract

Strategies on informed consent process and capacity monitoring for mild dementia research are at developing state. We reflected on our experience in the MinD project, and found that the successful collection of informed consent and full participation of PwD required the involvement of familiar healthcare professionals/care workers/staff at the recruitment and data collection stages and this needs to occur in an active support environment. Time is another important factor affecting the success of the study.

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YOUNG PERSONS

Research without prior consent in paediatric emergency and critical care medicine

Symposium: research

Aled Picton, Kerry Woolfall, Mark D. Lyttle, Stuart Hartshorn

Paediatrics and Child Health, 14 December 2019

Abstract

Children and young peoples' healthcare should be evidence-based yet many treatments are unlicensed or prescribed off-label. Research is needed, but prospective informed consent for many emergency and critical care trials is neither feasible nor ethical – treatments are time critical, and delays for research discussions may cause harm. Research without prior consent (RWPC) is a practical approach which facilitates such research. Trial interventions are administered immediately to eligible patients, and consent for ongoing study involvement is sought after the emergency situation has passed. This has been permitted in the United Kingdom since an amendment to legislation in 2008, and subsequently employed by several trials. Studies demonstrate that most parents are supportive of this approach provided their child's safety is not compromised, and research discussions are appropriately timed. Practitioners with no experience of RWPC often initially report anxiety about taking this approach, but study experience and training helps change perspectives. Sadly, some children enrolled into such studies will die. Approaching bereaved families for consent requires a bespoke approach, conducted with care and sensitivity. Future research should explore the acceptability of higher risk trials, the viewpoints of children with first-hand experience of this method, and international perspectives.

Editor's note: This article also appears under BIOMEDICAL RESEARCH.

Adolescent Consent to Vaccination in the Age of Vaccine-Hesitant Parents

Viewpoint

Y. Tony Yang, Robert S. Olick, Jana Shaw

JAMA Pediatrics, 7 October 2019;173(12) pp 1123-112

Excerpt

As children of vaccine-hesitant parents become adolescents, they develop their individual perspectives on vaccination. One of these adolescents, Ethan Lindenberger, researched vaccines, discussed them with trusted adults, and ultimately got vaccinated.1 His testimony to the Senate Committee on Health, Education, Labor and Pensions made national headlines.1 Many other adolescents are similarly seeking advice on how to get vaccinated. While vaccination against measles and other conditions occurs in early childhood, vaccine-

hesitant parents have also refused human papillomavirus vaccination, routinely provided for adolescents beginning at age 11 or 12 years. And they have refused to let their children catch up on any missed early childhood vaccinations. Prior research has shown that adolescents feel generally marginalized in the decision-making process, yet they desire to participate in decisions.2 Their main obstacle to vaccination is that most states require an individual to be 18 years or older to consent to medical procedures.3 We argue for expansion of the rights of adolescents to make their own decisions to be vaccinated against serious and potentially life-threatening diseases without requiring parental consent and involvement…

Consent in children's intensive care: the voices of the parents of critically ill children and those caring for them

Original research

Phoebe Aubugeau-Williams, Joe Brierley

Journal of Medical Ethics, 27 November 2019

Abstract

Despite its invasive nature, specific consent for general anaesthesia is rarely sought—rather consent processes for associated procedures include explanation of risk/benefits. In adult intensive care, because no one can consent to treatments provided to incapacitated adults, standardised consent processes have not developed. In paediatric intensive care, despite the ready availability of those who can provide consent, no tradition of seeking it exists, arguably due to the specialty's evolution from anaesthesia and adult intensive care. With the current Montgomery-related focus on consent, this seems untenable. We undertook a qualitative study in a specialist children's hospital colocated paediatric/neonatal intensive care (same medical team) in which parental acceptance of admission and entailed procedures is considered implied by virtue of that admission. Semistructured interviews were carried out with both staff and parents to investigate their views about consent, the current system and a proposed blanket consent system, in which parents actively consent at admission to routine procedures. Divergent views emerged: staff were worried that requiring consent at admission might prove a further emotional burden, whereas parents found providing consent a way of coping, feeling empowered and maintaining control. Inconsistencies were found in the way consent is obtained for your routine procedures. Practice does seem inconsistent with contemporary consent standards for medical intervention. Our findings support the introduction of a blanket consent system at admission together with ongoing bedside dialogue to ensure continuing consent. Both parents and staff expressed concern about avoiding possible harmful delays to children due to parental emotional overload and language difficulties.

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RIGHTS/LEGAL/LEGISLATIVE

Legal and Ethical Considerations for Radiology Procedural Consent [CHAPTER]

Adrienne N. Dixon, Meghan Stepanek

Advanced Practice and Leadership in Radiology Nursing

Springer, 17 December 2019; pp 225-234

Abstract

This chapter will introduce readers to the legal and ethical principles of patient autonomy as well as the consenting process in the context of scenarios such as types of consents, capacity determination, communication, and liability risks.

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

National Electronic Health Record Systems and Consent to Processing of Health Data in the European Union and Australia

Danuta Mendelson

Legal Tech and the New Sharing Economy, 13 December 2019; pp 83-99

Abstract

This study focuses on the single most important regulatory aspect of data processing, namely consent to data processing. It compares approaches to consent under the General Data Protection Regulation (EU 2016/679) of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data (and on the free movement of such) (GDPR) in the context of European Union (EU) national electronic health record (NEHR) schemes (also referred to as "national digital health networks") with the approach of the Australian national health record scheme called My Health Record (MHR). The GDPR, subject to derogation in limited circumstances, is binding on all 27 EU member countries. Under Articles 168 (2) and (7) of the Treaty on the Functioning of the European Union (2007), while the EU has a duty to "encourage cooperation between the Member States…to improve the complementarity of their health services in cross-border areas," the European Union Member States retain the power to manage their own health services. However, in doing so, subject to narrow derogations, the management of their NEHR systems must conform to the GDPR. The GDPR governs the processing of data in any form including data contained in national electronic health systems (European Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019… Given that, unlike the Australian MHR scheme, national electronic medical/health records systems of EU Member States are at different stages of development, and that derogations enable a measure of variance in compliance, individual European systems will not be discussed. Australia is a non-EU jurisdiction, and does not have the European Commission's certificate of adequate level of data protection (GDPR Article 45 empowers the European Commission to determine whether a country outside the EU offers an adequate level of data protection, whether by its domestic legislation or of the international commitments it has entered into. For further discussion, see below). One of the reasons for the absence of certification might be the effectively non-consensual nature of the My Health Record system that administers, collects, stores, and provides access to health and clinical data of Australians.

Too Dense and Too Detailed: Evaluation of the Health Literacy Attributes of an Informed Consent Document

Vanessa W. Simonds, Dedra Buchwald

Journal of Racial and Ethnic Health Disparities, 10 December 2019

Abstract

The US government recently updated the Common Rule, a set of federal regulations to ensure the ethical conduct of human subjects research. The new regulations require that consent documents provide information that is clear and concise enough to enable truly informed consent. This study explores potential American Indian research participants' understanding and perceptions of an example consent document, focusing on possible improvements to better serve the requirements of the revised Common Rule. Participants completed a survey that collected demographic data and measured health literacy, numeracy, and comprehension of the example document. Next, they participated in focus groups to answer open-ended questions regarding their views on the example document. We calculated mean scores and frequencies of response to analyze quantitative survey data and performed a qualitative thematic analysis of focus group transcripts. Results demonstrated that American Indian participants with relatively strong health literacy skills clearly understood key elements of the consent document, including the purpose of signing it, confidentiality, compensation, and whom to contact for questions. However, they were overwhelmed by details on research procedures and were concerned about the document's layout. To make consent documents more readily comprehensible, participants recommended the addition of headings, bullets, graphics, and relevant pictures. They also recommended a two-step consent process, comprising a short introduction to the research project followed by a longer explanation of procedures. These results illustrate

the potential advantages of community engagement in drafting consent materials. Health researchers would likely benefit from community recommendations like the ones we elicited as they design consent documents adherent to the revised Common Rule.

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FREE PRIOR INFORMED CONSENT

Articulating 'free, prior and informed consent' (FPIC) for engineered gene drives

Research Articles
Dalton R. George, Todd Kuiken and Jason A. Delborne
Proceedings of the Royal Society B, 11 December 2019; 286 (1917)
Abstract
Recent statements by United Nations bodies point to free, prior and informed consent (FPIC) as a potential requirement in the development of engineered gene drive applications. As a concept developed in the context of protecting Indigenous rights to self-determination in land development scenarios, FPIC would need to be extended to apply to the context of ecological editing. Without an explicit framework of application, FPIC could be interpreted as a narrowly framed process of community consultation focused on the social implications of technology, and award little formal or advisory power in decision-making to Indigenous peoples and local communities. In this paper, we argue for an articulation of FPIC that attends to issues of transparency, iterative community-scale consent, and shared power through co-development among Indigenous peoples, local communities, researchers and technology developers. In realizing a comprehensive FPIC process, researchers and developers have an opportunity to incorporate enhanced participation and social guidance mechanisms into the design, development and implementation of engineered gene drive applications.

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CULTURAL/COUNTRY CONTEXT

Knowledge, attitude, and practices regarding informed consent for research purposes among postgraduate resident doctors

Original Research
Noopur Vyas, Pradeep Jadhav, Rohit Sane.
National Journal of Physiology Pharmacy and Pharmacology. 2020; 10(1): 54-58
[country of publication: India]
Open Access
Abstract
Background
Informed consent is an ethical and legal requirement for research involving human participants. Postgraduate (PG) residents are budding doctors who are in their interim phase of education and are engaged in thesis/research work, which mandates adequate knowledge of informed consent and regulatory guidelines. There exists paucity of data in literature on the informed consent process with regard to PG residents; therefore, this study was conducted to assess the knowledge, attitude, and practices (KAP) of informed consent among PG residents.
Aims and Objectives
The aim of the study was to assess the level of knowledge and attitude about the informed consent process and assess practices adopted by PG residents for research purposes.
Materials and Methods

It was a cross-sectional, observational and questionnaire-based study conducted from January 2018 to March 2018 at a tertiary care teaching hospital, Navi Mumbai. The study included PG residents of either sex pursuing specialty MD/MS courses. A validated KAP questionnaire was used to assess KAP of the informed consent process. Responses from the eligible participants were obtained and analyzed.

Results

A total of 100 PG residents participated; 39% of males and 61% of females. Overall, the knowledge score was high and attitude toward informed consent was average. However, 34% participants felt that witness is not necessary, 20% felt that once the patient participates, they should not be allowed to withdraw and few felt that on voluntary withdrawal, participants are not liable for further standard care and compensation. In practice, few participants failed to explain consent in the local language and neglected to take the signature of an impartial witness.

Conclusions

Overall, the KAP of informed consent among PG residents were adequate. Structured continuing medical education/workshops are necessary to advance informed consent practices.

Jordanians' Perspectives On Open Consent In Biomedical Research

Original Research

Nasr Alrabadi, Hanin Makhlouf, Omar F Khabour, Karem H Alzoubi

Risk Management and Healthcare Policy, 2 December 2019; 2019(12) pp 265—273

Introduction

The informed consent process is an integral step in biomedical research. However, the emergence of biobanks and the need for open consent (also called "broad" or "blanket" consent) create challenges to this process.

Aims and methodology

A survey was used to examine Jordanians' perspectives on open consent and reuse of stored samples in future research.

Results

The majority of participants had positive perceptions of informed consent and its importance. In addition, they appreciated the challenges that are associated with multiple uses of their biospecimens. About 55% agreed to provide open consent for reuse of their donated biospecimens. Participants (75–80%) also agreed that issues such as the possibility of sharing samples with international research centers, storage duration, and use of biospecimens after their death should be clarified as part of open consent. The inconvenience of the re-contact process, trust in the research team, and the importance of biobanks were all associated with participants' willingness to provide open consent ($P<0.05$). On the other hand, privacy and confidentiality, doubt about future use of samples, unknown storage period, and the possibility of cross-border sample sharing were significantly associated with participants' reluctance to provide open consent.

Conclusion

The majority of Jordanians accept the idea of open consent. Clarification of issues such as international sample sharing, duration of storage, domains of intended research, confidentiality, and privacy can provide more support for the use of open consent.

Editor's note: This article also appears under BIOBANKING.

Promoting informed consent in a children's hospital in Tabriz, Iran: a best practice implementation project

Neda Kabiri, Sakineh Hajebrahimi, Gisoo Alizadeh, Solmaz Azimzadeh, Nayyereh Farajzadeh, Amin Talebpour

JBI Database of Systematic Reviews and Implementation Reports, December 2019; 17(12) pp 2570–2577

Abstract

Introduction

Informed consent is a continuous and dynamic process. It is a crucial part of healthcare procedures that becomes more complex in a pediatric clinical practice, where parents must make decisions for their children.
Objectives
The aim of this implementation project was to evaluate the current practice and implement the best practice related to obtaining informed consent in a children's hospital in Tabriz, Iran.
Methods
A clinical audit was undertaken using the JBI Practical Application of Clinical Evidence System (JBI PACES) tool. Five audit criteria representing the best-practice recommendations for informed consent were used. A baseline audit was conducted, followed by the implementation of multiple strategies. The project was finalized with a follow-up audit to determine change in practice.
Results
The compliance rate of all criteria improved from baseline to follow-up audit. Criteria 1 (obtaining informed consent prior to all nursing procedures) and 5 (provision of information related to the necessity of the treatment) reached 97% compliance in the follow-up cycle. Criterion 4 (provision of information related to the nature and effect of the treatment) achieved 74% compliance. Both criteria 2 and 3 (provision of information related to alternative treatments and consequences of refusing treatment) reached 57% in the follow-up cycle. To improve compliance, meetings were organized with the heads of departments, nurses and residents regarding informed consent. Also, staff were encouraged to report cases where informed consent was not obtained.
Conclusion
The audit results indicated an improvement in obtaining informed consent in the included departments. The interventions that were employed can facilitate the implementation of evidence into clinical practice.

The factors associated with maternal consent to human papillomavirus vaccination among adolescents in Israel

Research Paper

Rana Shibli, Shmuel Rishpon

Human Vaccines & Immunotherapeutics, 24 Jul 2019

Abstract
Purpose
To evaluate the knowledge and attitudes toward the human papillomavirus (HPV) vaccine among mothers of 8th graders in Israel, and to determine the factors associated with maternal consent to the HPV vaccine.
Methods
We conducted a cross-sectional study among mothers of 8th grade students in 27 schools in Haifa and Northern districts of Israel during the 2016–17 school year. Data were collected using a structured telephone questionnaire.
Results
313 mothers answered the questionnaire (response rate = 91.8%). The mean knowledge level score was low (3.96 points [out of 10] ±2.68). Knowledge level was positively associated with Jewish nationality, being secular in religious practice and higher education. The attitude mean score was low-moderate (11.22 points [out of 18] ± 5.01). Attitude score was positively associated with Arab nationality. No significant association was found between knowledge level and attitudes. According to multivariate analysis, mothers' consent to the HPV vaccine was associated with the knowledge level score (OR = 0.82; 95%CI 0.68–0.98), the attitude score (OR = 1.76; 95%CI 1.53–2.02) and nationality (OR = 27.86, 95%CI 3.41–227.56).
Conclusions
The knowledge level and attitudes toward the HPV vaccine were found to be unsatisfactory with racial disparities between Arabs and Jews. Jewish mothers compared with Arab mothers, mothers with a higher knowledge level or less positive attitudes were less likely to consent to the vaccine. These findings could contribute toward adapting programs to the different Israeli sectors in order to improve the rates of HPV vaccine receipt among adolescents.

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MEDICAL/SURGICAL

What do patients want? Surgical informed-consent and patient-centered care – An augmented model of information disclosure

Original Article
Gillie Gabay, Yaarit Bokek-Cohen
Bioethics, 2 December 2019
Abstract
The ideal moral standard for surgical informed-consent calls upon surgeons to carry out a disclosure dialogue with patients so they have as full as possible an understanding of the procedure before they sign the informed-consent form. This study is the first to empirically explore patient preferences regarding disclosure dialogue. Twelve Israelis who underwent life-saving surgeries participated in a narrative study. Three themes emerged from the analysis: objectification of patients, anxiety provoking processes and information, and lack of information that was essential for patients. Findings contribute to existing debates among surgeons regarding the scope and importance of some disclosure components. Analysis led to our formulation of an augmented subjective model of information disclosure that participants prefer, which extends beyond the immediate present of the surgery to the period after discharge, and until return to routine. Surgeons should be aware of patient preferences in disclosure, and gaps between perceptions of surgeons, and preferences and needs of patients.

Perception and confidence of medical students in informed consent: A core EPA

Tiffany N. Anderson, Lauren R. Aalami, Edmund W. Lee, Sylvia Bereknyei Merrell, Michael D. Sgroi, Dana T. Lin, James N. Lau
Surgery, 24 December 2019
Abstract
Background
Informed consent discussions have been identified as a core entrustable professional activity for medical students by the Association of American Medical Colleges. Medical students, however, rarely receive formal instruction on how to appropriately conduct informed consent discussions before residency, resulting in inconsistent levels of experience and deficiencies in performance. This study explores medical students' understanding of the elements of informed consent discussions and their readiness to perform a comprehensive informed consent discussion.
Methods
Using expert consensus, cognitive interviews, and piloting, we iteratively developed a 15-item survey aligned with entrustable professional activity guidelines concerning informed consent discussions consisting of multiple choice, free text, and 5-point Likert-type questions. The instrument covered domains of experience, confidence, medical-legal knowledge, and recall of informed consent discussion elements. The full survey was distributed anonymously to undergraduate medical students at our institution. An abbreviated survey was administered to postgraduate students who were new interns at our institution. Responses were analyzed quantitatively using descriptive statistics. The free text data were coded for inclusion in this analysis.
Results
A total of 75 undergraduate medical students across all years responded (response rate [RR] = 86%), and 34 (RR = 77%) of the postgraduate students who were new interns participated. A total of 45 (75%) undergraduate medical students reported no training on informed consent discussions, and 9 (15%) undergraduate medical students had never witnessed an informed consent discussion. The undergraduate

medical students agreed that informed consent discussions could be legally performed by residents and advance practice providers but were unsure whether the same applied to medical students. On a 5-point scale (anchored to “Not at all,” “Somewhat,” and “Extremely”), they were “somewhat confident” in their ability to perform an informed consent discussion. When asked to list the 7 elements of an informed consent discussion, 2 undergraduate medical students (3%) were able to identify all the elements. Although 3 undergraduate medical students (9%) had experience leading an informed consent discussion and 11 (32%) reported formal instruction in informed consent, the ability (3.7 ± 0.9 standard deviation [SD]) of the postgraduate students who were new interns to recall the 7 elements was similar to that of the undergraduate medical students (3.4 ± 1.2 SD); P = .31.

Conclusion

These findings suggest that undergraduate medical students and postgraduate students who are new interns are not confident or competent in their ability to perform an appropriate informed consent discussion. Our study findings support the creation of a needs-based, entrustable professional activity–aligned informed consent discussion teaching program and the need for an ongoing evaluation of the success of such a program.

Legal and Ethical Considerations for Radiology Procedural Consent [CHAPTER]

Adrienne N. Dixon, Meghan Stepanek

Advanced Practice and Leadership in Radiology Nursing

Springer, 17 December 2019; pp 225-234

Abstract

This chapter will introduce readers to the legal and ethical principles of patient autonomy as well as the consenting process in the context of scenarios such as types of consents, capacity determination, communication, and liability risks.

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

Association Between the Communication Skills of Physicians and the Signing of Do-Not-Resuscitate Consent for Terminally Ill Patients in Emergency Rooms (Cross-Sectional Study)

Original Research

Chih-Hung Chen, Ya-Hui Cheng, Fen-Ju Chen, Eng-Yen Huang, Po-Ming Liu, Chia-Te Kung, Chao-Hui Su, Shu-Hwa Chen, Peng-Chen Chien, Ching-Hua Hsieh

Risk Management and Healthcare Policy, 11 December 2019; 12 pp 307—315

Abstract

Background

The signing of do-not-resuscitate (DNR) consent is mandatory in providing a palliative approach in the end-of-life care for the terminally ill patients and requires an effective communication between the physician and the patients or their family members. This study aimed to investigate the association between the communication skills of physicians who participated in the SHARE (supportive environment, how to deliver the bad news, additional information, reassurance, and emotional support) model course on the patient notification and the signing of do-not-resuscitate (DNR) consent by the terminally ill patients at emergency rooms.

Methods

Between May 1, 2017 and April 30, 2018, a total of 109 terminally ill patients were enrolled in this study, of which 70 had signed a DNR and 39 had not. Data regarding the patients’ medical records, a questionnaire survey completed by family members, and patient observation forms were used for the assessment of physicians’ communication skills during patient notification. The observation form was designed based on the SHARE model. A multivariate logistic regression model was applied to identify the independent significant factors of the patient and family member variables as well as the four main components of the observation

form.
Results
The results revealed that knowing how to convey bad news and providing reassurance and emotional support were significantly correlated with a higher rate of signing DNR consent. Additionally, physician-initiated discussion with family members and a predicted limited life expectancy were negative independent significant factors for signing DNR consent.
Conclusion
This study revealed that good communication skills help to increase the signing of DNR consent. The learning of such skills from attendance of the SHARE model course is encouraged for the physicians in the palliative care of terminally ill patients in an emergency room.

Informed consent for anaesthesia: Presential or non-presential information?

Faura A, Izquierdo E, Escriche L, Nogué G, Videla S
Journal of Healthcare Quality Research, 21 Nov 2019
Abstract
Introduction
The anaesthesia informed consent (AIC) is a process of communication between a clinician and a patient that results in the patient agreeing to undergo a specific anaesthetic procedure after understanding all the information needed to make a free, voluntary and conscious decision. This information is traditionally given during a face-to-face pre-operative visit.
Objective
To evaluate patient perceptions when they receive the information about AIC, face-to-face or by phone.
Patients and Methods
A single centre, randomised, double-blind, parallel-group pilot clinical trial was conducted on patients > 18 years of age undergoing major ambulatory surgery procedures with a surgical complexity that did not require a face-to-face pre-operative visit. Patients were randomly assigned to be informed by telephone (experimental group) or in a face-to-face visit (control group). Fifteen days after the surgery a questionnaire was used to gather patient perceptions in understanding the anaesthetic procedure and risks, autonomy (to ask for explanations), as well as and satisfaction.
Results
Of the 160 patients that gave their consent, 142 were interviewed: 70 from the experimental group and 72 from the control group. Both groups were comparable in age, gender, anaesthetic risk, and surgical complexity. The percentage of patients that understood the information provided on the anaesthetic technique was 71% and 81%, respectively (P=.429); on its risks: 67% and 69% (P=.951); autonomy: 56% and 74% (P=.036) and satisfaction rate: 46% and 46% (P=.835).
Conclusion
There is no difference between the groups in the level of understanding of the information that the patient perceives and the level of satisfaction. Nevertheless, almost half of them did not remember to have been given the possibility to clear-up doubts.

Compassionate and Clinical Behavior of Residents in a Simulated Informed Consent Encounter

Waisel DB, Ruben MA, Blanch-Hartigan D, Hall JA, Meyer EC, Blum RH
Anesthesiology, 20 November 2019
Abstract
What We Know About This Topic
Compassionate behavior in clinicians includes understanding patients' psychosocial, physical, and medical needs; promptly attending to needs; and engaging patients to the extent they wish.
What This Article Will Tell Us That Is New

The investigators evaluated compassionate behavior of anesthesia residents in a simulated preoperative encounter with a patient in pain before urgent surgery. Anesthesia residents had variable and, at times, flawed recognition of patient cues, responsiveness to patient cues, pain management, and patient interactions.

Background

Compassionate behavior in clinicians is described as seeking to understand patients' psychosocial, physical and medical needs, timely attending to these needs, and involving patients as they desire. The goal of our study was to evaluate compassionate behavior in patient interactions, pain management, and the informed consent process of anesthesia residents in a simulated preoperative evaluation of a patient in pain scheduled for urgent surgery.

Methods

Forty-nine Clinical Anesthesia residents in year 1 and 16 Clinical Anesthesia residents in year 3 from three residency programs individually obtained informed consent for anesthesia for an urgent laparotomy from a standardized patient complaining of pain. Encounters were assessed for ordering pain medication, for patient-resident interactions by using the Empathic Communication Coding System to code responses to pain and nausea cues, and for the content of the informed consent discussion.

Results

Of the 65 residents, 56 (86%) ordered pain medication, at an average of 4.2 min (95% CI, 3.2 to 5.1) into the encounter; 9 (14%) did not order pain medication. Resident responses to the cues averaged between perfunctory recognition and implicit recognition (mean, 1.7 [95% CI, 1.6 to 1.9]) in the 0 (less empathic) to 6 (more empathic) system. Responses were lower for residents who did not order pain medication (mean, 1.2 [95% CI, 0.8 to 1.6]) and similar for those who ordered medication before informed consent signing (mean, 1.9 [95% CI, 1.6 to 2.1]) and after signing (mean, 1.9 [95% CI, 1.6 to 2.0]; $F (2, 62) = 4.21$; $P = 0.019$; partial $\eta = 0.120$). There were significant differences between residents who ordered pain medication before informed consent and those who did not order pain medication and between residents who ordered pain medication after informed consent signing and those who did not.

Conclusion

In a simulated preoperative evaluation, anesthesia residents have variable and, at times, flawed recognition of patient cues, responsiveness to patient cues, pain management, and patient interactions.

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GENERAL/OTHER

Informed about Informed Consent: A Qualitative Study of Ethics Education

Rocksheng Zhong, John K. Northrop, Puneet K.C. Sahota, Anthony L. Rostain

Online Journal of Health Ethics, January 2019 ;15(2)

Open Access

Abstract

Informed consent is a foundational concept in modern medicine. Despite physicians' ethical and legal obligations to obtain informed consent, no standard curriculum exists to teach residents relevant knowledge and skills. This paper presents a qualitative study of residents at one academic medical center. The authors conducted focus groups with trainees in the Departments of Internal Medicine, Emergency Medicine, and Ob/Gyn and analyzed their responses using rigorous qualitative methods. Four themes emerged: First, participants agreed that informed consent and decision-making capacity were relevant in many clinical situations. Second, participants varied widely in their understandings of consent. Third, current resident training was insufficient. Fourth, more training was needed. These results add to the growing literature that ethics education in residency is desired and useful. The findings will help educators craft instruments assessing the prevalence and degree of deficiencies related to informed consent competencies and aid in the development of a model curriculum.

Informed consent within a learning health system: A scoping review

Research Report

Annabelle Cumyn, Adrien Barton, Roxanne Dault, Anne-Marie Cloutier, Rosalie Jalbert, Jean-François Ethier

Learning Health Systems, 4 December 2019

Open Access

Abstract

Introduction

A major consideration for the implementation of a learning health system (LHS) is consent from participants to the use of their data for research purposes. The main objective of this paper was to identify in the literature which types of consent have been proposed for participation in research observational activities in a LHS. We were particularly interested in understanding which approaches were seen as most feasible and acceptable and in which context, in order to inform the development of a Quebec-based LHS.

Methods

Using a scoping review methodology, we searched scientific and legal databases as well as the gray literature using specific terms. Full-text articles were reviewed independently by two authors on the basis of the following concepts: (a) LHS and (b) approach to consent. The selected papers were imported in NVivo software for analysis in the light of a conceptual framework that distinguishes various, largely independent dimensions of consent.

Results

A total of 93 publications were analysed for this review. Several studies reach opposing conclusions concerning the best approach to consent within a LHS. However, in the light of the conceptual framework we developed, we found that many of these results are distorted by the conflation between various characteristics of consent. Thus, when these characteristics are distinguished, the results mainly suggest the prime importance of the communication process, by contrast to the scope of consent or the kind of action required by participants (opt-in/opt-out). We identified two models of consent that were especially relevant for our purpose: metaconsent and dynamic consent.

Conclusions

Our review shows the importance of distinguishing carefully the various features of the consent process. It also suggests that the metaconsent model is a valuable model within a LHS, as it addresses many of the issues raised with regards to feasibility and acceptability. We propose to complement this model by adding the modalities of the information process to the dimensions relevant in the metaconsent process.

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Informed Consent: A Monthly Review Addendum

GLOSSARY

Blockchain

Using cryptography to keep exchanges secure, blockchain provides a decentralized database, or "digital ledger", of transactions that everyone on the network can see. This network is essentially a chain of computers that must all approve an exchange before it can be verified and recorded.
Initial citation from Informed Consent Monthly Review

Deferred Consent

Informed consent obtained after a specific intervention which it references, termed deferred consent or retrospective consent.
Editor's note: Sometimes referred to as waived consent
Initial citation from Informed Consent Monthly Review

Dynamic Consent

Term used to describe personalised online consent and communication platforms. Such platforms are primarily designed to achieve two objectives: 1) facilitate the consent process and 2) facilitate two-way, ongoing communication between researchers and research participants.
Initial citation from Informed Consent Monthly Review

eConsent

Electronic informed consent (eConsent) provides the same information, but in an electronic format that may include multimedia components such as images, audio, video, diagrams, reports, call out boxes and a digital signature which may aid the consenting process.
Initial citation from Informed Consent Monthly Review

Exception from Informed Consent (EFIC)

A pathway that allows investigators to enroll patients without consent from the patient, their family, or their legally authorized representatives.
Initial citation from Informed Consent Monthly Review

Free, Prior and Informed Consent (FPIC)

The standard FPIC, as well as Indigenous Peoples' rights to lands, territories and natural resources are embedded within the universal right to self-determination. The normative framework for FPIC consists of a series of international legal instruments including the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), the International Labour Organization Convention 169 (ILO 169), and the Convention on Biological Diversity (CBD), among many

	others, as well as national laws… FPIC is a specific right that pertains to Indigenous Peoples and is recognized in the UNDRIP. It allows them to give or withhold consent to a project that may affect them or their territories. Once they have given their consent, they can withdraw it at any stage. Furthermore, FPIC enables them to negotiate the conditions under which the project will be designed, implemented, monitored and evaluated. *Editor's Note: We see this term of art as potentially contributing more widely because of its clarification of what IC might mean.* *Initial citation from Informed Consent Monthly Review*
Learning Health System (LHS)	A Learning Healthcare System is defined… as a system in which, "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience." *Initial citation from Informed Consent Monthly Review*
Presumed Consent	The idea that someone is believed to have given permission for something unless they say they do not, used, for example, in some countries for organ donation. *Initial citation from Informed Consent Monthly Review*
Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)	The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) is a network of independently established regional fora for ethical review committees, health researchers and invited partner organizations. The primary objective of SIDCER is to contribute to human subject protections globally by developing local capacity for ethical review of research involving human subjects and for developing policies on the ethics of health research. *Initial citation from Informed Consent Monthly Review*

TOOLS FOR ASSESSMENT

Atlas.ti	ATLAS.ti is a powerful workbench for the qualitative analysis of large bodies of textual, graphical, audio and video data. *Initial citation from Informed Consent Monthly Review*
Constant Comparison Method	Constant comparison is the data-analytic process whereby each interpretation and finding is compared with existing findings as it emerges from the data analysis. *Initial citation from Informed Consent Monthly Review*
DICE	Web-based electronic informed consent application. *Initial citation from Informed Consent Monthly Review*

Flesch-Kincaid Readability Scale	Readability test that tell what level of education someone needs to easily read a piece of text. *Initial citation from Informed Consent Monthly Review*
Gillick Competence	The [term used] … to identify children aged under 16 who have the legal competence to consent to immunization, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions. Gillick competence is a functional ability to make a decision. *Initial citation from Informed Consent Monthly Review*
Grounded Theory approach	Grounded theory sets out to discover or construct theory from data, systematically obtained and analysed using comparative analysis. *Initial citation from Informed Consent Monthly Review*
Likert Scale	A five (or seven) point rating scale [used] to measure attitudes directly, it allow[s] the individual to express how much they agree or disagree. *Initial citation from Informed Consent Monthly Review*
Meaning Equivalence Reusable Learning Objectives (MERLO)	Multi-dimensional database that allows the sorting and mapping of important concepts through exemplary target statements of conceptual situations, and relevant statements of shared meaning. *Initial citation from Informed Consent Monthly Review*
Oxford Video Informed Consent Tool (OxVIC)	Personalised video consent tool to enhance patient satisfaction in the preoperative consenting process. *Initial citation from Informed Consent Monthly Review*
REDCap	REDCap is a secure web application for building and managing online surveys and databases. *Initial citation from Informed Consent Monthly Review*
The System Usability Scale (SUS)	Provides a quick and reliable tool for measuring usability. It consists of a 10-item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree. *Initial citation from Informed Consent Monthly Review*

GUIDANCE DOCUMENTS

Declaration of Helsinki (DOH)	The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. *Initial citation from Informed Consent Monthly Review*
International Ethical Guidelines for Health-Related Research Involving Humans/ CIOMS Guidelines	The aim of the guidelines is to provide internationally vetted ethical principles and detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research in low-resource settings. *Initial citation from Informed Consent Monthly Review*
PRISMA Guidelines	PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions. *Initial citation from Informed Consent Monthly Review*
Revised Common Rule Guidelines	On January 19, 2017, the US Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subjects research (called the Common Rule)... The Revised Common Rule broadens the types of research that qualify for exemption. Several exempt categories have been revised, and there are new categories of exemptions. These changes to exemption will apply to research that is federally funded or supported. *Initial citation from Informed Consent Monthly Review*