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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

January 2023 :: Issue 49

This digest aggregates and distills key content addressing informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations.

In preparing this digest, we monitor *Google Scholar* for the search terms "consent", "informed consent", and "assent" in title and available text. After careful consideration, a selection of these results appear in the digest. We also monitor other research analysis and guidance beyond the journal literature globally. 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 (CICI), 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. Active subject areas in this edition include:

No new content was identified for the following established categories:

COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT

Please note that we maintain a glossary, an inventory of tools for assessment, as well as standards and guidance documents on our website.

BIOMEDICAL RESEARCH

Informed Consent: Research Staff's Perspectives and Practical Recommendations to Improve Research Staff-Participant Communication

Delphine Eeckhout, Karolien Aelbrecht, Catherine Van Der Straeten

Journal of Empirical Research on Human Research Ethics, 23 December 2022

Abstract

Informed consent (IC) is the process of communication between research staff and potential research participants. However, ensuring that participants clearly understand what research participation entails, raises significant challenges. The aim of this study is to provide insight into some communication barriers that research staff are confronted with and make practical recommendations to improve communication between research staff and participants. A qualitative research study using semi-structured interviews (n = 13) with research staff from Ghent University Hospital was conducted. Data were transcribed verbatim and coded thematically. Our results indicate that communication- and process-related factors affect the IC process. Emergent recommendations include communication training, more interactive information materials and the use of digital alternatives, increasing general knowledge about research participation and patient- and public involvement.

The Informed Consent Form Navigator: A Tool for Producing Readable and Compliant Consent Documents

Jonathan P. Bona, Joseph Utecht, Aaron S. Kemp, Jennifer M. Gan, Alison Caballero, Christopher R. Trudeau, Mathias Brochhausen, Laura James

Journal of Clinical and Translational Science, December 2022 [preprint]

Open Access

Abstract

Background/Objective

Informed consent forms (ICFs) and practices vary widely across institutions. This project expands on previous work at the University of Arkansas for Medical Sciences (UAMS) Center for Health Literacy to develop a plain language ICF template. Our interdisciplinary team of researchers, comprised of biomedical informaticists, health literacy experts, and stakeholders in the Institutional Review Board (IRB) process, has developed the ICF Navigator, a novel tool to facilitate the creation of plain language ICFs that comply with all relevant regulatory requirements.

Methods

Our team first developed requirements for the ICF navigator tool. The tool was then implemented by a technical team of informaticists and software developers, in consultation with an informed consent legal expert. We developed and formalized a detailed knowledge map modeling regulatory requirements for ICFs, which drives workflows within the tool.

Results

The ICF Navigator is a web-based tool that guides researchers through creating an ICF as they answer questions about their project. The navigator uses those responses to produce a clear and compliant ICF, displaying a real-time preview of the final form as content is added. Versioning and edits can be tracked to facilitate collaborative revisions by the research team and communication with the IRB. The navigator helps

guide the creation of study-specific language, ensures compliance with regulatory requirements, and ensures that the resulting ICF is easy to read and understand.

Conclusion

The ICF Navigator is an innovative, customizable, open-source software tool that helps researchers produce custom readable and compliant ICFs for research studies involving human subjects.

A Review Assessing Participants' Understanding of Informed Consent for Clinical Trials in Africa

Dorothy Maxwell Kazembe, Tigist Mesfin, Abigiya Abebe, Saba Mehari Embaye, Esther Nthenya Muthoka, Kedir Usmael, Mediha Ahmedin, Tsegahun Manyazewal

Medical Research Archives, November 2022; 10(11)

Abstract

Background

Informed consent provides detailed information to the participants to make informed voluntary and rational decision to participate in a study. It is a communication tool between investigator and the subject to ensure that high research ethical standards are followed. This review paper assessed the level of participants' understanding of the information given to them by researchers during the clinical research.

Methods

A review approach was used to achieve the study objective.

Results

The findings showed that the level of comprehension varied from study to study. There was a good comprehension in four domains; purpose, voluntariness, benefits and right to withdraw. Poor comprehensions were mostly in risks, side effects, and blinding. Higher level of education, repeated assessments of comprehension, time spent by the researcher explaining and clarifying the information influenced the comprehension.

Conclusion

The study findings point out that comprehension to informed consent is still a challenge that needs to be addressed during the field study. Once the consent is given it becomes a distant memory for most of the participants. This implies that proper tools and cut off points to determine participants' comprehension need to be developed for standard assessment of such.

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HEALTH DATA

Consent Codes: Maintaining Consent in an Ever-expanding Open Science Ecosystem

Stephanie O. M. Dyke, Kathleen Connor, Victoria Nembaware, Nchangwi S. Munung, Kathy Reinold, Giselle Kerry, Mamana Mbiyavanga, Lyndon Zass, Mauricio Moldes, Samir Das, John M. Davis, Jordi Rambla De Argila, J. Dylan Spalding, Alan C. Evans, Nicola Mulder, Jason Karamchandani

Neuroinformatics, 15 December 2022

Open Access

Abstract

We previously proposed a structure for recording consent-based data use 'categories' and 'requirements' – Consent Codes – with a view to supporting maximum use and integration of genomic research datasets, and reducing uncertainty about permissible re-use of shared data. Here we discuss clarifications and subsequent updates to the Consent Codes (v4) based on new areas of application (e.g., the neurosciences, biobanking, H3Africa), policy developments (e.g., return of research results), and further practical considerations, including developments in automated approaches to consent management.

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BIOBANKING

Attitudes of the Public Toward Consent for Biobank Research in Japan

Masanori Oikawa, Yoshiyuki Takimoto, Akira Akabayashi

Biopreservation & Biobanking, 19 December 2022

Abstract

Background

Parallel to the rapid advancement of biological and information technologies, the role and forms of biobank research have been constantly changing. The ethical, legal, and social implications of consent in biobank research are in a state of flux. This study aimed to clarify current Japanese public preferences regarding the consent model and explore how public attitudes are determined.

Methods

We conducted an online, population-based quantitative survey among Japanese residents aged between 20 and 69 years. Statistical analyses consisted of univariate and multivariate logistic regression.

Results

Of the 1580 respondents, 60.9% preferred autonomy-based consent (specific or dynamic consent) and 23.9% preferred broad-type consent (opt-out or broad consent). Marital status, gender, and privacy concerns were significantly associated with the preference for a consent model.

Conclusions

Our results demonstrated the public's current preference for autonomy-based consent, including dynamic consent. However, our findings also revealed that approximately half of the respondents considered broad consent as somewhat preferable.

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GENOMIC MEDICINE/GENE EDITING

Evaluating visual imagery for participant understanding of research concepts in genomics research

Original Article

Erin Rothwell, Naomi O. Riches, Erin Johnson, Kimberly A. Kaphingst, Kelsey Kehoe, Sabrina Malone Jenkins, Rachel Palmquist, Carrie Torr, Caren J. Frost, Bob Wong, Joshua L. Bonkowsky

Journal of Community Genetics, 19 December 2022

Abstract

Informed consent is crucial for participant understanding, engagement, and partnering for research. However, current written informed consents have significant limitations, particularly for complex topics such as genomics and biobanking. Our goal was to identify how participants visually conceptualize terminology used in genomics and biobanking research studies, which might provide a novel approach for informed consent. An online convenience sample was used from May to July 2020 to collect data. Participants were asked to draw 10 randomly chosen words out of 32 possible words commonly used in consent forms for genomics and biobanking research. An electronic application captured drawings that were downloaded into a qualitative software program for analysis. A total of 739 drawings by 269 participants were captured. Participants were mostly female (61.3%), eight different race/ethnicities were represented (15.6% Black, 13.8% Hispanic), and most had some college education (68.8%). Some words had consistent visual themes such as different types of risky activities for risk or consistent specific images such as a double helix for DNA. Several words were frequently misunderstood (e.g., ascend for assent), while others returned few submissions (e.g., phenotype or whole genome sequencing). We found that although some words used in genomics and biobanking research were visually conceptualized in a common fashion, but misunderstood or

less well-known words had no, few, or mistaken drawings. Future research can explore the incorporation of visual images to improve participant comprehension during consent processes, and how to utilize visual imagery to address more challenging concepts.

Rapid Genome Sequencing: Consent for New Technologies in the Neonatal Intensive Care Context

Fiona Lynch, Trisha Prentice, Lynn Gillam, Zornitza Stark, Christopher Gyngell

Pediatrics, 29 November 2022; 150(6)

Abstract

The clinical utility of rapid genome sequencing (rGS) in critically unwell infants has been consistently demonstrated, and there are calls for rGS to be implemented as a first-line test in the NICU. A diagnosis from rGS can enable rapid initiation of precision treatment, making it potentially lifesaving. However, in many patients rGS leads to the diagnosis of severe and life-limiting conditions, prompting discussion with families about withdrawal of life-sustaining treatment.

The complexity of information about rGS, together with the heightened emotions of parents in the NICU, poses significant challenges for informed decision making in this context. We present a case where both parents are unable to provide informed consent, and the treating team must decide whether to proceed with rGS. Our discussion highlights the important differences between genome sequencing and other types of genetic testing, and the crucial role played by pre-test counseling in facilitating informed consent and preparing parents for a range of possible outcomes. We then discuss the consent paradigms at play in NICUs; whereas admission generally comes with an understanding that the treating team will perform interventions thought to be in the best interest of the child, rGS is substantially different because of its long-term implications for patients and family members. Finally, we look at the ethical interplay between parental consent and the interests of the child. We conclude by showing how cases like this are resolved at our tertiary center and how they may be resolved differently in future.

Patient informed consent for a clinical trial of gene-edited pig kidney transplantation: A representative consent form

Original Article

David K. C. Cooper

Xenotransplantation, 26 November 2022

Abstract

When clinical trials of gene-edited pig organ transplantation are initiated, the consent form that the patient is requested to sign will be an important document. Consent to receive a pig xenograft will have significant differences when compared with the requirements of most experimental clinical procedures. We here suggest a consent form for pig kidney transplantation that addresses the major points that will be required and hope it will provide a basis for discussion and future modification, if necessary. There is purposely some repetition in the document, but we believe this is necessary to ensure that the patient has a clear understanding of what he/she is consenting to.

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CAPACITY TO CONSENT

Assessment of cognitive function among adults aged ≥ 60 years using the Revised Hasegawa Dementia Scale: cross-sectional study, Lao People's Democratic Republic

Research

Sengchanh Kounnavong, Manithong Vonglokham, Somphou Sayasone, Vanthanom Savathdy, Emiko Masaki, Ryoma Kayano, Bounfeng Phoummalaysith, Boungnong Boupha, Nobuyuki Hamajima

Health Research Policy and Systems, 29 November 2022; 20(121)
Open Access
Abstract
Background
Rapid population ageing remains an important concern for health, social and economics systems; thus, a broader assessment of cognitive decline among adults aged ≥ 60 years is essential. It is important to regularly collect reliable data through validated and affordable methods from people living in different areas and in different circumstances to better understand the significance of this health problem. This study aimed to identify the prevalence of cognitive impairment and the related risk factors by reassessing the scoring of the Revised Hasegawa Dementia Scale among older adults in the Lao People's Democratic Republic.
Methods
A community-based cross-sectional investigation was conducted in rural and urban settings in six districts of three provinces in the country from January to July 2020. In total, 2206 individuals aged 60–98 years (1110 men and 1096 women) were interviewed in person using a pretested Lao version of the Revised Hasegawa Dementia Scale and the WHO STEPwise approach to noncommunicable disease (NCD) risk factor surveillance (the STEPS survey tool). The adjusted odds ratios (AORs) and 95% confidence intervals (95% CIs) were estimated using a logistic model.
Results
The study found that 49.3% (1088/2206) of respondents (39.7% [441/1110] of men and 59.0% [647/1096] of women) had scores associated with some level of cognitive impairment. In addition to age, the following factors were significantly associated with cognitive impairment: having no formal education (AOR = 9.5; 95% CI: 5.4 to 16.8, relative to those with a university education), living in the northern region of the country (AOR = 1.4; 95% CI: 1.1 to 1.9, relative to living in the central region), living in a rural area (AOR = 1.5; 95% CI: 1.2 to 1.8), needing assistance with self-care (AOR = 1.8; 95% CI: 1.2 to 2.7) and being underweight (AOR = 1.5; 95% CI: 1.1 to 2.2). Factors associated with no cognitive impairment among older adults include engaging in moderate-intensity physical activity lasting for 10 minutes and up to 1 hour (AOR = 0.6; 95% CI: 0.5 to 0.8) and for > 1 hour (AOR = 0.6; 95% CI: 0.4 to 0.8).
Conclusions
Using the Lao version of the Revised Hasegawa Dementia Scale, this study found that more than half of adults aged ≥ 60 years had cognitive impairment, and this impairment was associated with several risk factors. The limitations of this study may include possible overdetection due to the cutoff point for the assessment of cognitive decline used in the Revised Hasegawa Dementia Scale, given that the participants were not familiar with the instrument. However, the study results can be used to help inform health policy in the Lao People's Democratic Republic regarding the urgent need for a routine data collection system and for providing an environment that addresses and reduces the identified risk factors for cognitive decline to mitigate their impact.

Capacity to Consent of People with Dementia: a Narrative Review from an Ethical Perspective

Urfa Khairatun Hisan, Nurul Qomariyah, Kristina Elizabeth
Jurnal Profesi Medika, 2022
Abstract
People with dementia have impairment to execute daily life activities by presenting as a deterioration of mental processes, such as memory, thinking, reasoning, and judgment. Many participants in dementia research may lack the capacity to provide informed consent. Additional safeguards are needed for dementia research participants' protection because of their vulnerability. Only after carefully weighing the risks and possible benefits for the participants in the research may it be decided to use vulnerable participants. The intention to prevent harm pushes against the removal of autonomy. This dilemma is the driving force behind this article's narrative review of the capacity to consent problems in dementia research. For this critical narrative review, we conducted a thorough search of Scopus, PubMed, and Wiley Open Library for literature addressing the ethical and legal issues on the capacity to consent of people with dementia. We outline the

dilemmas and difficulties that surround them including the related ethical principles, the informed consent process, capacity to consent, and safeguards for the participant in research involving people with dementia.

Editor's note: Jurnal Profesi Medika is an Indonesian journal published by by the Faculty of Medicine UPN Veteran Jakarta

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YOUNG PERSONS

Adolescent Capacity to Consent to Participate in Research: A Review and Analysis Informed by Law, Human Rights, Ethics, and Developmental Science

Ben Mathews

Laws, 23 December 2022; 12(1)

Abstract

Contemporary societies pose major challenges for adolescents and it is essential to conduct research with them to understand their experiences, identify their needs, and discover solutions to major social problems. Social science, humanities and health-related research into violence, technology, and climate change exemplify vital research endeavours requiring adolescent participation to advance Sustainable Development Goals and enhance individual lived experience and societal flourishing for current and future generations. International and national research ethics guidelines emphasise the necessity to conduct research to advance societal benefit, while upholding principles of autonomy and justice, and promoting participant welfare and avoiding harm. International human rights instruments promote adolescents' freedom of expression and right to participate in matters affecting them. The rapid generation of robust research findings is essential, but it remains commonly assumed that adolescents cannot provide their own consent to participate in research studies, and the belief that parental consent is required can impede and impair the entire research process. Debate continues about the proper interpretation of legal principles and research ethics guidelines about who may provide consent. Continuing confusion about who must provide consent, and why, impedes the protection of adolescents' interests and the advancement of society. This article adds to knowledge by providing a multidisciplinary overview of evidence from developmental science, social science, law, human rights, and bioethics about decision-making capacity and entitlements in the context of research participation, and an updated evidence-based analysis of adolescents' capacity to provide their own consent to participate in social, humanities and health-related research. A conservative application of knowledge from these domains both individually and collectively supports conclusions that adolescents aged 16 are able to provide their own consent to participate in research, and no legal or ethical principle requires the provision of parental consent on their behalf. Practical considerations may support parental involvement in conversations about participation, and some types of research require trauma-informed approaches, but adolescents are developmentally, legally and ethically entitled to make their own decision about whether or not to participate.

Disability or Death: A Focused Review of Informed Consent in Pediatric Neurosurgery

Nathan A. Shlobin, John Paul G. Kolcun, Brian D. Leland, Laurie L. Ackerman, Sandi K. Lam, Jeffrey S. Raskin

Seminars in Pediatric Neurology, 22 December 2022

Abstract

The management of pediatric neurosurgical disease often requires families to choose between long-term disability and premature death. This decision-making is codified by informed consent. In practice, decision-making is heavily weighted toward intervening to prevent death, often with less consideration of the realities of long-term disability. We analyze long-term disability in pediatric neurosurgical disease from the perspectives of patients, families, and society. We then present a pragmatic framework and conversational

approach for addressing informed consent discussions when the outcome is expected to be death or disability. We performed a focused review of literature regarding informed consent in pediatric neurosurgery by searching PubMed and Google Scholar with search terms including “pediatric neurosurgery,” “informed consent,” and “disability.” The literature was focused on patients with diagnoses including spina bifida, neuro-oncology, trauma, and hydrocephalus. Patient perspective elements were physical/mental disability, lack of autonomy, and role in community/society. The family perspective involves caregiver burden, emotional toll, and financial impact. Societal considerations include the availability of public resources for disabled children, large-scale financial cost, and impacts on global health. Practical conversational steps with patients/caregivers include opening the discussion, information provision and acknowledgement of uncertainty, assessment of understanding and clarifying questions, decision-making, and decision maintenance, all while remaining sensitive to the emotional burden commensurate with these decisions. The “death or disability” paradigm represents a common challenge to informed consent in pediatric neurosurgery. Patient, family, and societal factors that inform surrogate decisions vary and sometimes conflict. Pediatric neurosurgeons must use a comprehensive approach to address the informational and relational needs of caregivers during the informed consent process.

Paediatric surgeons’ current knowledge and practices of obtaining assent from adolescents for elective reconstructive procedures

Original Research

Krista Lai, Nathan S Rubalcava, Erica M Weidler, Kathleen van Leeuwen

JME, 21 December 2022

Abstract

Purpose

Adolescents develop their decision-making ability as they transition from childhood to adulthood. Participation in their medical care should be encouraged through obtaining assent, as recommended by the American Academy of Pediatrics (AAP). In this research, we aim to define the current knowledge of AAP recommendations and surgeon practices regarding assent for elective reconstructive procedures.

*Me*thods

An anonymous electronic survey was distributed to North American paediatric surgeons and fellows through the American Pediatric Surgical Association (n=1353).

Results

In total, 220 surgeons and trainees responded (16.3%). Fifty per cent of the surgeons who are familiar with the concept of assent had received formal training; 12% of the respondents had not heard of assent before the survey. Forty-seven per cent were aware of the 2016 AAP policy statement regarding assent in paediatric patients. Eighty-nine per cent always include adolescents as part of the consent discussion. Seventy-seven per cent solicit an expression of willingness to accept the proposed care from the patient. The majority (74%) of the surgeons perceived patient cooperation/understanding as the biggest barrier to obtaining assent. Over half of the respondents would consider proceeding with elective surgery despite the adolescent patient’s refusal. Reasons cited for proceeding with elective surgery include surgeons’ perception of medical necessity, perceptions of disease urgency, and lack of patient maturity.

Conclusion

Paediatric surgeons largely acknowledge the importance of assent, but variably practice the principles of obtaining assent from adolescent patients undergoing elective reconstructive procedures. Fewer surgeons are explicitly aware of formal policy statements or received formal training. Additional surgeon education and institutional policies are warranted to maximise inclusion of adolescents in their medical care.

Adolescent Confidentiality and Consent in an Emergency Setting

Mientkiewicz L, Grover P

Pediatric Emergency Care, 1 December 2022; 38(12) pp 697-699

Abstract

Objectives

The adolescent population comprises a large volume of emergency department visits each year. A recent study showed that 20% of the ambulatory care visits of adolescent patients aged 15 to 25 years were made to the emergency department. This specific population often has poor access to health care and often is a vulnerable population, causing medical care to be a challenge. The purpose of this article was to review the standard practice and the specific laws regarding confidentiality and consent when treating an adolescent patient to provide the best possible care and treatment.

Methods

A comprehensive literature search was done to examine key aspects of adolescent confidentiality and informed consent in an emergency setting. The literature was then compiled into a review article.

Results

The article outlines the specific laws for emergency providers to be aware of regarding patient confidentiality and consent. The adolescent patient can consent to medical care without parental consent, when involving emergency care, contraceptive services, sexually transmitted infections, prenatal care, drug or alcohol related care, mental health services, and sexual assault services. Also, emancipated minors and mature minors are both situations in which a minor has the legal authority to refuse care and make decisions regarding their health care.

Conclusions

Patient confidentiality and informed consent are complex and complicated topics when dealing with the pediatric patient. Although some laws may vary state to state, there are specific details regarding adolescent confidentiality and informed consent that every provider should be aware of. The adolescent population is more likely to seek emergency care if the visit is confidential and the patient feels a sense of trust. Although it is important for providers to respect patient confidentiality when treating adolescents, it is also important for providers to encourage adolescents to confide in their parents regarding health issues.

Assent in Pediatric Critical Care Research: A Cross-Sectional Stakeholder Survey of Canadian Research Ethics Boards, Research Coordinators, Pediatric Critical Care Researchers, and Nurses

Katie O'Hearn, Florence Cayouette, Saoirse Cameron, Dori-Ann Martin, Anne Tsampalieros, Kusum Menon

Pediatric Critical Care Medicine, 13 October 2022

Abstract

Objectives

Survey of four stakeholder groups involved in defining and obtaining assent for research in Canadian PICUs to better understand their perspectives and perceived barriers to assent.

Design

Cross-sectional survey.

Setting

Fourteen tertiary-care pediatric hospitals in Canada.

Participants

Research Ethics Board Chairs, pediatric critical care nurses, research coordinators, and researchers.

Interventions

None.

Measurements and Main Results

A total of 193 participants responded. Thirty-seven percent (59/159) thought it was "Never/Almost Never" (59/159, 37%) feasible to obtain assent during the first 48 hours of PICU admission, and 112 of 170 (66%) indicated there are unique barriers to assent at the time of enrollment in PICU studies. Asking children for assent was most frequently rated as Important/Very Important for interviews/focus groups with the child

(138/180, 77%), blood sample collection with a needle poke for research (137/178, 77%), and studies involving genetic testing with results communicated to the child/legal guardian (134/180, 74%). In two scenarios where a child and legal guardian disagreed about study participation, most respondents indicated that whether the child should still be enrolled would depend on the patient's age (34-36%), and/or the risk of the study (24-28%). There was a lack of consensus over how the assent process should be operationalized, and when and for how long children should be followed to seek assent for ongoing study participation. Most stakeholders (117/158, 74%) thought that children should have the opportunity to decide if their samples could stay in a biobank once they are old enough to do so.

Conclusions

There was an overall lack of consensus on the feasibility of, and challenges associated with, obtaining assent at the time of study enrollment and on how key aspects of the assent process should be operationalized in the PICU. This highlights the need for guidelines to clarify the assent process in pediatric critical care research.

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TECHNOLOGY/OTHER MEDIATION

Digitalizing the Clinical Research Informed Consent Process: Assessing the Participant Experience in Comparison With Traditional Paper-Based Methods

Michael T. Buckley, Molly R. O'Shea, Sangeeta Kundu, Allison Lipitz-Snyderman, Gilad Kuperman, Suken Shah, Alexia Iasonos, Collette Houston, Stephanie L. Terzulli, Joseph M. Lengfellner, Paul Sabbatini

JCO Oncology Practice, 19 December 2022

Abstract

Purpose

Consent processes are critical for clinical care and research and may benefit from incorporating digital strategies. We compared an electronic informed consent (eIC) option to paper consent across four outcomes: (1) technology burden, (2) protocol comprehension, (3) participant agency (ability to self-advocate), and (4) completion of required document fields.

Methods

We assessed participant experience with eIC processes compared with traditional paper-based consenting using surveys and compared completeness of required fields, over 3 years (2019-2021). Participants who consented to a clinical trial at a large academic cancer center via paper or eIC were invited to either pre-COVID-19 pandemic survey 1 (technology burden) or intrapandemic survey 2 (comprehension and agency). Consent document completeness was assessed via electronic health records.

Results

On survey 1, 83% of participants (n = 777) indicated eIC was easy or very easy to use; discomfort with technology overall was not correlated with discomfort using eIC. For survey 2, eIC (n = 262) and paper consenters (n = 193) had similar comprehension scores. All participants responded favorably to at least five of six agency statements; however, eIC generated a higher proportion of positive free-text comments ($P < .05$), with themes such as thoroughness of the discussion and consenter professionalism. eIC use yielded no completeness errors across 235 consents versus 6.4% for paper ($P < .001$).

Conclusion

Our findings suggest that eIC when compared with paper (1) did not increase technology burden, (2) supported comparable comprehension, (3) upheld key elements of participant agency, and (4) increased completion of mandatory consent fields. The results support a broader call for organizations to offer eIC for clinical research discussions to enhance the overall participant experience and increase the completeness of the consent process.

Animation supported consent before elective laparoscopic cholecystectomy

Emre Doganay, David Wald, Sam Parker, Frances Hughes

British Journal of Surgery, 7 December 2022

Abstract

Background

Patient understanding of surgical procedures is often incomplete at the time they are performed, invalidating consent, and exposing healthcare providers to complaints and claims of failure to inform. Remote consultations, language barriers and patient factors can hinder an effective consent pathway. New approaches are needed to support communication and shared decision-making.

Methods

Multi-language digital animations explaining laparoscopic cholecystectomy were introduced at The Royal London Hospital for patients who attended for elective surgery (www.explainmyprocedure.com). Patients completed questionnaires on the day of their procedure both before and after introduction of the animations. We assessed patient-reported understanding of the procedure, its intended benefits, the possible risks, and alternatives to treatment in 72 consecutive patients, 37 before (no animation group) and after 35 after introducing the animations into the consent pathway (animation group). Patient understanding in the two groups was compared.

Results

The two groups were well matched in respect of age, sex and whether English was their first spoken language. The proportions of patients who reported they completely understood the procedure, its benefits, risks, and alternatives in the no animation group were 54%, 57%, 38% and 24% and in the animation group, 91%, 91%, 74% and 77% respectively; $p<0.01$ for each comparison.

Conclusions

The integration of multi-language laparoscopic cholecystectomy video animations into the patient consent pathway was associated with substantial improvement in reported understanding of the procedure, benefits, risks, and alternatives to treatment. This approach can be applied across all surgical disciplines in a standardised manner in an era of accelerated elective work and remote consultations.

Digital Informed Consent: Modernising Information Sharing in Surgery to Empower Patients

Original Scientific Report

Simon L. Parsons, Prita Daliya, Phil Evans, Dileep N. Lobo

World Journal of Surgery, 3 December 2022

Open Access

Abstract

Background

Despite the 2015 Montgomery Ruling highlighting key requisites for informed consent, little has changed to modernise data-sharing and documentation of the consent process. It can be difficult to gauge patient understanding and address all patient concerns in time-limited appointments. We aimed to assess the feasibility of a digital information-sharing platform to support a move towards a digital informed consent process.

Methods

All adult patients referred to a single centre with symptomatic gallstones were invited to use a digital information-sharing platform to support the informed consent process prior to their first surgical clinic appointment. The platform provided patients with multimedia information on gallstones and available treatment options. It recorded the time spent accessing information, asked patients multiple choice questions (MCQs) to allow a self-test of understanding, documented a summary medical history, and allowed free text for patient questions. This information was summarised into a clinical report to support outpatient clinic consultations.

Results

Of the 349 patients registered to use the digital platform, 203 (58.2%) [165 (81.3%) female, mean age 47.6 years (range 19–84 years)] completed all modules necessary to generate a clinical report. Some 130 patients (64.0%) answered all 10 MCQs correctly and spent a mean of 18.7 min (range 3–88 min) reading the consent information. Most patient-reported medical histories were deemed to be accurate.
Conclusion
Despite difficulties with access, resulting in drop-outs, patients welcomed the opportunity to receive information digitally, prior to their consultation. Patients described feeling empowered and better informed to be involved in decision-making.

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RIGHTS/LEGAL/LEGISLATIVE

Ethics of the fiduciary relationship between patient and physician: the case of informed consent

Sophie Ludewigs, Jonas Narchi, Lukas Kiefer, Eva C Winkler
JME, 8 December 2022
Open Access
Abstract
This paper serves two purposes: first, the proposition of an ethical fiduciary theory that substantiates the often cited assertion that the patient–physician relationship is fiduciary in nature; and second, the application of this theory to the case of informed consent. Patients' decision-making preferences vary significantly. While some seek fully autonomous decision-making, others prefer to delegate parts of their decision. Therefore, we propose an ethical fiduciary theory that allows physician and patient to jointly determine the physician's role on a spectrum from fiduciary as advisor to fiduciary as agent. Drawing on legal concepts of the fiduciary relationship and on phenomenological accounts of obligation by Lévinas and Løgstrup, our theory relies on the key attributes of trust, vulnerability and otherness. Finally, practical implications of this theory for the informed consent process are developed: we propose a preassessment of patients' risk and value profiles as well as a restructuring of the oral consent interview and the written consent materials.

A Comparative Analysis of Informed Consent Legistlation in Ukrainian and Latvia Legislation and Case Law

Anatoliy A. Lytvynenko, Iryna Ya. Senyuta, Tatjana I. Jurkeviča, Volodymyr S. Makarchuk
International Comparative Jurisprudence, 18 October 2022; 8(2)
Open Access
Abstract
Informed consent is one of the key principles in safeguarding human rights in the sphere of healthcare. It presupposes the expression of the patient's free will relating to his medical examinations, treatment and diagnostic procedures, as well as the physician's duty to inform the patient on the forthcoming medical interventions, including the facts regarding the potential risks of these medical interventions. This principle is one of the elements of contemporary medical law, which has marked the transfer from paternalistic medicine to a modern model of medicine, where the patient is an active participant in the process of medical treatment. In this paper, the authors illustrate the legal aspects of safeguarding the patient's right to informed consent in the legislation and legal practices of Ukraine and the Republic of Latvia. The institute of informed consent, which needs to be safeguarded, as a key element of the legitimacy of a medical intervention (such as surgery, or vaccination), requires a specific form of fulfillment, which is conducted in writing. A medical intervention, excluding cases of emergency, is legitimate only when the consent of the patient is provided; unconsented medical interventions frequently cause lawsuits, where plaintiffs seek to

recover damages for performance of a medical intervention without their informed consent. The authors have highlighted these issues while commenting on the recent case law of the Supreme Court of Ukraine and the Supreme Court of the Republic of Latvia.

Age-of-consent requirements and adolescent HIV testing in low-and middle-income countries: multinational insights from 51 population-based surveys

Joseph G Rosen, Elizabeth M Stone, Michael T Mbizvo

International Journal of STD & AIDS, 16 December 2022

Abstract

Background

Pervasive social and structural barriers—including national policies—inhibit HIV testing uptake among priority populations, including adolescents. We assessed the relationship between age-of-consent policies for HIV testing and adolescent HIV testing coverage in 51 low- and middle-income countries.

Methods

We pooled data from household surveys (2010–2020) and calculated the weighted country-level prevalence of lifetime HIV testing separately for adolescent girls and boys (ages 15–19). We then abstracted age-of-consent requirements for HIV testing across countries. Using multivariable linear regression, we estimated the average difference in national HIV testing coverage estimates for adolescent girls and boys by age-of-consent restrictions for HIV testing.

Results

National HIV testing coverage estimates ranged from 0.7% to 72.5% among girls (median: 18.0%) and 0% to 73.2% among boys (median: 7.5%) in Pakistan and Lesotho, respectively. In adjusted models, HIV testing coverage in countries requiring parental consent for individuals <18 years was, on average, 9.4 percentage-points (pp) lower (95% confidence interval [95%CI] −17.9pp to −0.9pp) among girls and 9.3pp lower (95%CI: −17.3pp to −1.2pp) among boys, relative to countries with less restrictive policies (age-of-consent: ≤16 years). Compared to countries with less restrictive (age-of-consent: ≤14 years) policies, HIV testing prevalence was significantly lower among girls (β −10.5pp, 95%CI: −19.7pp to −1.3pp) and boys (β −10.5pp, 95%CI –19.2pp to −1.8pp) in countries with more restrictive (age-of-consent: 18 years) parental consent requirements.

Conclusions

Age-of-consent policies are persistent obstacles to adolescent HIV testing. Repealing parental consent requirements for HIV testing is needed to expand coverage and accelerate progress towards global HIV treatment and prevention targets.

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CULTURAL/COUNTRY CONTEXT

Remote consent approaches for mobile phone surveys of non-communicable disease risk factors in Colombia and Uganda: A randomized study

Research Article

Joseph Ali, Madhuram Nagarajan, Erisa S. Mwaka, Elizeus Rutebemberwa, Andres I. Vecino-Ortiz, Angelica Tórres Quintero, Mariana Rodriguez-Patarroyo, Vidhi Maniar, Gulam Muhammed Al Kibria, Alain B. Labrique, George W. Pariyo, Dustin G. Gibson

PLOS ONE, 21 December 2022

Open Access

Abstract

Introduction

Automated mobile phone surveys (MPS) can be used to collect public health data of various types to inform health policy and programs globally. One challenge in administering MPS is identification of an appropriate and effective participant consent process. This study investigated the impact of different survey consent approaches on participant disposition (response characteristics and understanding of the purpose of the survey) within the context of an MPS that measured noncommunicable disease (NCD) risk factors across Colombia and Uganda.
Methods
Participants were randomized to one of five consent approaches, with consent modules varying by the consent disclosure and mode of authorization. The control arm consisted of a standard consent disclosure and a combined opt-in/opt-out mode of authorization. The other four arms consist of a modified consent disclosure and one of four different forms of authorization (i.e., opt-in, opt-out, combined opt-in/opt-out, or implied). Data related to respondent disposition and respondent understanding of the survey purpose were analyzed.
Results
Among 1889 completed surveys in Colombia, differences in contact, response, refusal, and cooperation rates by study arms were found. About 68% of respondents correctly identified the survey purpose, with no significant difference by study arm. Participants reporting higher levels of education and urban residency were more likely to identify the purpose correctly. Participants were also more likely to accurately identify the survey purpose after completing several survey modules, compared to immediately following the consent disclosure (78.8% vs 54.2% correct, $p<0.001$). In Uganda, 1890 completed surveys were collected. Though there were differences in contact, refusal, and cooperation rates by study arm, response rates were similar across arms. About 37% of respondents identified the survey purpose correctly, with no difference by arm. Those with higher levels of education and who completed the survey in English were able to more accurately identify the survey purpose. Again, participants were more likely to accurately identify the purpose of the survey after completing several NCD modules, compared to immediately following the consent module (42.0% vs 32.2% correct, $p = 0.013$).
Conclusion
This study contributes to the limited available evidence regarding consent procedures for automated MPS. Future studies should develop and trial additional interventions to enhance consent for automated public health surveys, and measure other dimensions of participant engagement and understanding.

Knowledge about and attitudes toward medical informed consent: a Lebanese population survey

Research Article

Mary Deeb, Dana Alameddine, Rasha Abi Radi Abou Jaoudeh, Widian Laoun, Julian Maamari, Rawan Honeini, Alain Khouri,F adi Abou-Mrad, Nassib Elia, Aniella Abi-Gerges

Ethics & Behaviour, 19 December 2022

Abstract
As Medicine shifts from a paternalistic practice to a patient-centered approach, the concept of medical informed consent (IC) has evolved to safeguard patient autonomy. However, its current implementation still presents many challenges in clinical practice. We assessed the knowledge and attitudes of the general Lebanese population regarding the IC process as well as their sociodemographic and medical correlates. An anonymous online survey was distributed to the Lebanese population using social media channels. A sample of 500 adults with an average age of 36.2 ± 13.5 years, including 319 females and 181 males, was recruited. Most of the respondents had a university degree (85.8%), reported previous hospital admissions (75.9%) and had signed an IC for surgical procedures (40.7%). Few participants were knowledgeable about IC Lebanese law. Variability in knowledge level was significantly related to gender and a previous hospitalization history. Positive attitudes toward patient autonomy (53.1%) and shared decision-making (57.5%) correlated with older age, female gender, graduate education, and a previous history of signing an IC document. Males were more likely to believe that IC has positive effects on health than females. This is the first study that provides novel findings regarding Lebanese peoples' awareness of the ethico-legal components of medical IC.

Analyzing online public commentary responding to the announcement of deemed consent organ donation legislation in the Canadian province of Nova Scotia

Alessandro R. Marcon, Darren N. Wagner, Christen Rachul, Matthew J. Weiss

Plos One, 15 December 2022

Open Access

Abstract

Background

The Canadian province of Nova Scotia recently became the first jurisdiction in North America to pass deemed consent organ donation legislation. The announcement of this legislation generated substantial online discussion, which we analyzed to provide insights on public perception.

Methods

We performed directed content analysis on 2663 user-generated comments appearing on two widely-shared Canadian Broadcasting Company (CBC) articles published online in April 2019. We determined levels of support and opposition in comments and described the specific rhetoric used for doing so. We also performed one-way ANOVA and Pearson chi-square tests to determine how the comments were being received and engaged by other users.

Results

A range of commentary was present in both support and opposition to the changes in legislation. There were more negative than positive comments, and negative commentary generated more replies. Positive comments were received more positively by other users while negative comments were received more negatively. The total sum of negative comments was greatly influenced by a small number of very active participants. Negative commentary focused more on broad concepts and principles related to government, power, and individual rights rather than specific issues in the Nova Scotian context. Substantial issues of trust in the government and healthcare system were evident.

Conclusions

There were strong positive and negative sentiments expressed in the comments, but the total sum of negativity in the comments was significantly influenced by a small number of commentators. Analysis on the presumed consent concerns can be helpful to inform public outreach efforts.

Nurse knowledge and attitudes towards organ donation and deemed consent: the Human Organ and Tissue Donation Act in Nova Scotia

Reports of Original Investigations

Robin Urquhart, Nelofar Kureshi, Jade Dirk, Matthew Weiss, Stephen Beed

Canadian Journal of Anesthesia, 1 December 2022

Abstract

Purpose

In April 2019, the Human Organ and Tissue Donation Act (HOTDA) in Nova Scotia was modified to incorporate a deemed consent model. In this study, we sought to understand intensive care unit (ICU) and emergency department (ED) nurses' knowledge of and confidence around organ donation and transplantation, experiences with organ donors and recipients, attitudes toward organ donation and deemed consent, and perceived opportunities and barriers to a deemed consent approach in view of the legislative change.

Methods

We sent an electronic, self-administered survey to all ICU and ED nurses in Nova Scotia. The survey queried respondents on their knowledge of, experience with, and attitudes around organ donation and HOTDA, and opportunities and barriers to the implementation of HOTDA in clinical practice. Survey results were analyzed using descriptive statistics.

Results

One-hundred and ninety-four nurses responded to the survey. Nearly all (98%) supported organ donation, with 86% having signed an organ donor card to donate organs and/or tissues after death. A considerable majority (89%) also supported the new legislation. Nevertheless, a minority of respondents (13%) believed that deemed consent legislation would be considered a violation of the general principles of freedom and autonomy. The three most identified topics for ongoing training were coordination of the donation process (70%), clinical management of donors (70%), and family issues in decision-making (70%).

Conclusion

Intensive care unit and ED nurses had positive attitudes toward organ donation, including deemed consent model. The findings should inform educational initiatives in Nova Scotia and beyond to optimize organ donation processes and outcomes.

Estimated Impact of Deemed Consent Legislation for Organ Donation on Individuals With Kidney Failure: A Dynamic Decision Analytic Model

Koto P., Vinson A. J., Kiberd B. A., Beed S., Krmpotic K., Dirk J., Weiss M. J., Karthik K. Tennankore

Canadian Journal of Kidney Health and Disease, 25 November 2022

Abstract

Background

There is little data modeling the impact of deemed consent legislation (eligible individuals who do not register their decision to decline to be a donor are presumed to consent after death) on outcomes for individuals with kidney failure.

Objective

To estimate the change in life-years (LYs) and quality-adjusted life-years (QALYs) resulting from different changes in the rate of deceased donor kidney transplantation associated with deemed consent legislation and health system transformation.

Design

Dynamic Decision Analytic Model.

Setting

This modeling study included kidney failure patients in Atlantic Canada (all of whom receive their kidney transplants in Halifax, Nova Scotia). The adoption of deemed consent legislation was the intervention, and opt-in (the status quo) was the reference comparator.

Patients

Prevalent kidney failure patients at the end of 2019 in all of Atlantic Canada (N = 3615) served as the starting population.

Methods

We compared expected outcomes between the intervention and comparator. Changes in QALYs and total LYs were modeled under different changes to the proportion of patients receiving a deceased donor kidney transplant (from –10% to 20%) resulting from deemed consent relative to the status quo. Changes in QALYs and LYs were reported for 3 different time horizons (5, 10, and 30 years). Uncertainty around QALYs and total LYs was reported using 95% confidence intervals (CIs) constructed from a probabilistic sensitivity analysis using 1000 Monte Carlo Simulations.

Results

The increase in QALYs ranged from 7 QALYs (95% CI: 5-10) with a 5% increase using a 5-year time frame to 882 QALYs (95% CI: 619-1144) with a 20% increase over a 30-year time frame. Parallel changes in total LYs were also observed. In contrast, decreases in deceased donor kidney transplantation resulted in a loss of QALYs (for example, –463 QALYs; 95% CI: –633 to –306 for a 10% decrease over a 30-year time frame). Using the most optimistic scenario (a 20% increase), there was an 18% increase in the cumulative number of deceased donor kidney transplant recipients over a 30-year observation period.

Limitations

The results are subject to uncertainty depending on changes to the dialysis or transplant population that were not modeled and that may not be fully captured with probabilistic sensitivity analysis.

Conclusions
Deemed consent legislation will lead to variable changes in QALYs and total LYs for the kidney failure population, depending on the degree to which deceased donor transplantation rates change and the time horizon of observation. This modeling study may serve as a baseline to monitor the future impact of deemed consent legislation.

Assent, parental consent and reconsent for health research in Africa: thematic analysis of national guidelines and lessons from the SickleInAfrica registry

Research
Nchangwi Syntia Munung, Victoria Nembaware, Lawrence Osei-Tutu, Marsha Treadwell, Okocha Emmanuel Chide, Daima Bukini, Hilda Tutuba, SickleInAfrica ELSI WG, Ambroise Wonkam
BMC Medical Ethics volume, 8 December 2022; 23(130)
Open Access
Abstract
The enrolment of children and adolescents in health research requires that attention to be paid to specific assent and consent requirements such as the age range for seeking assent; conditions for parental consent (and waivers); the age group required to provide written assent; content of assent forms; if separate assent and parental consent forms should be used, consent from emancipated young adults; reconsent at the age of adulthood when a waiver of assent requirements may be appropriate and the conditions for waiving assent requirements. There is however very little available information for researchers and ethics committees on how to navigate these different issues. To provide guidance to research initiatives, the SickleInAfrica consortium conducted a thematic analysis of a sample of research ethics guidelines and procedures in African countries, to identify guidance for assent requirements in health research. The thematic analysis revealed that 12 of 24 African countries specified the age group for which assent is required. The minimum age for written assent varied across the countries. Five countries, Algeria, Botswana, Cameroon, Nigeria and The Democratic Republic of Congo require consent from both parents/family council in certain circumstances. Botswana, Nigeria, South Africa and Uganda have specific assent/consent requirements for research with emancipated minors. South Africa and Algeria requires re-consent at onset of adulthood. Five countries (Botswana, Cameroon, Nigeria, South Africa and Tanzania) specified conditions for waiving assent requirements. The CIOMS and the ICH-GCP guidelines had the most comprehensive information on assent requirements compared to other international guidelines. An interactive map with assent requirements for different African countries is provided. The results show a major gap in national regulations for the inclusion of minors in health research. The SickleInAfrica experience in setting up a multi-country SCD registry in Africa highlights the need for developing and harmonising national and international guidelines on assent and consent requirements for research involving minors. Harmonisation of assent requirements will help facilitate collaborative research across countries.

Guardians and research staff experiences and views about the consent process in hospital-based paediatric research studies in urban Malawi: A qualitative study

Research Article
Mtisunge Joshua Gondwe, Neema Mtunthama Toto, Charity Gunda, Markus Gmeiner, Ian J. C. MacCormick, David Lalloo, Michael Parker, Nicola Desmond
BMC Medical Ethics, 5 December 2022; 23(125)
Open Access
Abstract
Background
Obtaining consent has become a standard way of respecting the patient's rights and autonomy in clinical research. Ethical guidelines recommend that the child's parent/s or authorised legal guardian provides informed consent for their child's participation. However, obtaining informed consent in paediatric research

is challenging. Parents become vulnerable because of stress related to their child's illness. Understanding the views held by guardians and researchers about the consent process in Malawi, where there are limitations in health care access and research literacy will assist in developing appropriate consent guidelines.
Methods
We conducted 20 in-depth interviews with guardians of children and research staff who had participated in paediatric clinical trial and observational studies in acute and non-acute settings in the Southern Region of Malawi. Interviews were audio-recorded, transcribed verbatim, and thematically analysed. Interviews were compared across studies and settings to identify differences and similarities in participants' views about informed consent processes. Data analysis was facilitated by NVIVO 11 software.
Results
All participants across study types and settings reported that they associated participating in research with therapeutic benefits. Substantial differences were noted in the decision-making process across study settings. Guardians from acute studies felt that the role of their spouses was neglected during consenting, while staff reported that they had problems obtaining consent from guardians when their partners were not present. Across all study types and settings, research staff reported that they emphasised the benefits more than the risks of the study to participants, due to pressure to recruit. Participants from non-acute settings were more likely to recall information shared during the consent process than participants in the acute setting.
Conclusion
The health care context, culture and research process influenced participants' understanding of study information across study types and settings. We advise research managers or principal investigators to define minimum requirements that would not compromise the consent process and conduct study specific training for staff. The use of one size fits all consent process may not be ideal. More guidance is needed on how these differences can be incorporated during the consent process to improve understanding and delivery of consent.

Informed Consent Implementation at Leona Hospital in Kupang City

Debi F. Ng. Fallo, Heryanto Amalo
South East Asia Journal of Contemporary Business, Economics and Law, August 2022; 27(1)
Abstract
Informed Consent is a patient's approval on medical action that will be performed on one after one has received a complete explanation of it. It is done to protect patients against all medical actions that are carried out without the patient's knowledge and at the same time provide legal protection to doctor against unexpected negative consequences, for example against the risk of inevitable treatment even though the doctor has tried his/her best and acted circumspect. Therefore, the principle of informed consent doctrine is a patient's autonomy right to himself to decide what is desired in the matter of treatment. It is an empirical legal research or non-doctrinal legal research. The data required is primary data obtained directly from respondents/informants, and secondary data obtained from the literature with data collection techniques are in the form of observations, interviews, document studies and group discussions. This study resulted in information regarding informed consent implementation at the Leona Hospital, Kupang City, and the obstacles faced in the informed consent implementation in the form of patient/patient's family being heterogeneous groups patient's perceptions of her/his illness, doctors' explanations contain medical technical terms, and the limited time. This study suggests that doctors are still obliged to provide information to patients either orally or in writing form and that doctors need to improve their communication skills with patients from different backgrounds so that the goal of delivering information to patients is achieved.

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MEDICAL/SURGICAL

Navigating the perils and pitfalls throughout the consent process in hematopoietic cell transplantation

Review

Rachel Cusatis, Carlos Litovich, Ryan Spellecy, Andrew Liang, Anita D'Souza

Blood Reviews, 20 December 2022

Abstract

Hematopoietic cell transplantation (HCT) is a complex treatment used in malignancies and some non-malignant diseases. The informed consent process for HCT can also be complex due to patient- and process-related barriers. The informed consent process needs to be a dynamic and ongoing process, not simply a checklist. As a result of the realities of HCT, we highlight some potential pitfalls to the informed consent process including uncertainty, sociocultural and communication barriers, and decisional regret. The purpose of this comprehensive review is to highlight unique situations which can result in failure of the informed consent process. We also offer potential solutions to these pitfalls, primarily making the informed consent more patient focused through dynamic and continuous processes to mitigate decisional regret.

Hands-on Clinical Clerkship at the Department of General Medicine in a University Hospital Improves Medical Students' Self-Evaluation of Skills of Performing Physical Examinations and Informed Consent: A Questionnaire-Based Prospective Study

Yoshinori Tokushima, Masaki Tago, Midori Tokushima, Shun Yamashita, Yuka Hirakawa, Hidetoshi Aihara, Naoko E Katsuki, Motoshi Fujiwara, Shuichi Yamashita

International Journal of General Medicine, 19 December 2022; pp 8647–8657

Open Access

Abstract

Introduction

The educational effects of a hands-on clinical clerkship on medical students at the Department of General Medicine of Japanese university hospitals remain to be clarified. This study aimed to determine how such education affects medical students' self evaluation of their clinical skills.

Methods

We enrolled 5th-year-grade students at the Department of General Medicine, Saga University Hospital, Japan in 2017. The students were divided into those who were going to have Japanese traditional-style observation based training mainly in the outpatient clinic (Group O) and those in the 2018, new-style, hands-on clinical clerkship as one of the group practice members in outpatient and inpatient clinics (Group H). A questionnaire survey using the 4-point Likert scale for self-evaluation of the students' clinical skills at the beginning and the end of their training was conducted in both groups. The pre- and post-training scores of each item in both groups were compared and analyzed using the Mann–Whitney test.

Results

All 99 students in Group O and 121 of 123 students in Group H answered the questionnaires. The response rate was 99%. Two items regarding the abilities of "can perform a systemic physical examination quickly and efficiently" and "can clearly explain the current medical condition, therapeutic options, or risks associated with treatment, and discuss the process for obtaining informed consent" showed higher scores in the post-training survey in Group H than in Group O. There were no differences in these scores in the pre-training survey between the two groups.

Conclusion

A hands-on clinical clerkship at the Department of General Medicine in a university hospital in Japan provided medical students with higher self-confidence in their skills of performing a physical examination and better understanding of patients' treatment options and the process of informed consent than observation-based training.

Dispelling the ethical apprehensions surrounding same day cataract consent

Comment

Rosina Zakri, Hasan Naveed, Robert Hill, Rashid Zia

Eye, 12 December 2022

Open Access

Excerpt

…Despite there being no legal length of time between obtaining consent and performing a procedure, the Department of Health clearly states that consent cannot be taken under duress [4]. It is therefore stipulated by Kerns J. in the Fitzpatrick case (2008), risks of surgery should not be provided to the patient at the 'eleventh hour' and thus a 'cooling off' period may be required [5]. Although the same day procedures for many retinal conditions, such as intravitreal injections and laser, are commonly recognised as patient centric, there is still opposition to similar benefits when it comes to cataract surgery…

Surgical Informed Consent: New Challenges

Claire Hoppenot, Ava Ferguson Bryan, Sean C. Wightman, Victoria Yin, Benjamin D. Ferguson, Sanam Bidadi, Margaret B. Mitchell, Alexander J. Langerman, Peter Angelos, Puneet Singh

Current Problems in Surgery, 10 December 2022

Introduction

Informed consent in medicine has evolved considerably over the 19th and 20th centuries to its current form which represents a practical application of the ethical principle respect for autonomy. Global and national historical events, rapid advances in medicine, the digital age, and shared decision making in the doctor-patient relationship have contributed and continue to shape our informed consent processes. This monograph highlights the history and current state of informed consent, intersection with the legal system, vulnerable populations, involvement of trainees, research and innovation, concurrent surgery, and non-medical factors to disclose. Informed consent refers to agreements with patients for treatment and also with subjects for experimentation. Thus, informed consent for treatment and informed consent for research, although distinctly different, both rely on the central ethical principle of respect for autonomy.

Role of electronic consent in emergency surgery – A QIP in a high volume surgical emergency unit at a tertiary hospital

Afroza Sharmin, Vishani Loyala, Ola Shams, Giles Bond-Smith

British Journal of Surgery, 7 December 2022

Abstract

Background

The Royal College of Surgeons of England discusses the significance of maintaining a written record of consent in addition to completing the consent form under section 4.10 of the supported decision-making guide to good practice - "any written information given to the patient should also be recorded and copies should be included in the patient's notes". Studies show high error rates (27–50%) with handwritten consent forms due to poor legibility, incomplete/ inaccurate information, increased variability, and risk of misplacement. The consequences of these errors can lead to poor patient experience as well as unfavourable outcomes at the operational and institutional levels. Missing or incomplete consent is also the most common reason for first case delay (average 1–75mins). This prompted the QIP and generation of a standard template for the common emergency general surgery procedures in a high-volume Surgical Emergency Unit (SEU) at the John Radcliffe Hospital.

Methods

Procedure-specific Electronic Surgical Consent (eSConsent) template for common emergency general surgery operations was added to the online database to easily be added to the electronic patient record. The format, as outlined below, was designed to allow even junior surgical trainees to adapt and perform the consent process early on in their placement-

- Patient details and occupation
- Operation
- Intended benefit
- All common procedures listed, risks and additional procedures pre-populated
- Additional information (eg: discussion with next of kin, P-POSSUM score, NELA score etc)
- Sign off

Results

The consent for all the emergency general surgery cases in a given week was reviewed and the compliance to maintaining eSConsent was audited. The first cycle between 20th-26th September 2021 showed compliance of only 18% (9 out of 49 operations). After discussing the audit findings with the members of the surgical team involved in the consenting process in the local meeting and implementing eSConsent, the compliance increased to 83.7% (36 of 43 cases) in the following week, 78% (33 of 43 cases) between 12th-18th November 2021 and 73% (28/38 operations) in the beginning of March 2022.

Conclusions

A consent form is a medicolegal document. Health care systems have taken advantage of technology to facilitate accuracy and robust monitoring. The emergency surgical consent process can benefit from this to avoid delays, errors and litigation. This transition is justifiable from our results and easily translated to practice particularly by using simple technology demonstrated in our QIP. Challenges including trainee changeover and new recruitments will expectedly affect the compliance of eSConsent but a proper induction to ensure adequate staff education will help overcome this. Weekly data capture has been adopted in our department as a surveillance protocol to ensure adherence and to standardize our practice.

Procedure Specific Consent Forms for Laparoscopic Cholecystectomy

David Manson, Gerard McKnight, Meabh Johnston, David O'Reilly, Giorgio Alessandri

British Journal of Surgery, 7 December 2022

Abstract

Background

Surgical consent forms can be difficult for patients to read and understand. Important points including procedure details, relevant complications and alterative treatment options are often lost in the communication process. Furthermore, surveys have found that patients struggle to grasp basic surgical concepts. Procedure specific consent forms (PSCFs) have been shown to improve the process of surgical consent. This is partly because they provide a standardised list of complications and their incidence, presented in a uniform, legible format without any abbreviations. However, despite their benefits, PSCFs are nationally underused. Cholecystectomy is one of the most common operations performed in the United Kingdom. Due to the pandemic disrupting elective surgical lists, the backlog of patients with biliary pathology has increased. More patients are therefore presenting to the on-call surgical team with biliary disease. Many trusts employ an Emergency Surgery Ambulatory Care (ESAC) list to offload the stretched emergency service. Our aim was to assess the variability of cholecystectomy consent forms amongst this cohort of patients, subsequently review patient understanding and evaluate whether the introduction of a procedure specific consent form improved this understanding.

Methods

We performed a prospective audit of laparoscopic cholecystectomy consent forms using the ESAC service. These consent forms were all obtained from patient's paper notes and assessed individually for variables. The first loop of the audit assessed the consent form used for the first 20 patients allocated to the ESAC list. Subsequently, each patient was telephoned post-operatively and asked a series of standardised questions which were adapted from a published questionnaire. Following this, we introduced a Procedure Specific Consent Form (PCSF) for laparoscopic cholecystectomies, with the agreement of all consultant surgeons who perform this operation in the trust. The second loop of the audit assessed another 20 patients from the emergency list, after the introduction of the PCSF. Similarly, patients were later telephoned to assess understanding. Over both loops, each consent form was assessed for the scope of their included

complications and measured against the NHS-recognised list of potential adverse outcomes. Secondly, the legibility of the consenter's writing and the use of any abbreviations was noted. Legibility was evaluated by two doctors independently to reduce subjectivity.

Results

The first loop revealed that all forms contained infection and bleeding; 90% included injury to bile duct; 80% included injury to viscera and risks from general anaesthetic; 75% included blood clots and bile leak; and only 55% included post-cholecystectomy syndrome. The additional complications included were pain, herniae, covid risk, retained stone, collection, pancreatitis, failure and death; with an even higher degree of variability. The 20 forms were 95% legible, with 50% of them containing one or more acronyms. Relating to the post-op questionnaire, >80% of patients remembered details surrounding their operation, however only 60% could recall basic potential complications. After PCSF introduction, it was used in 10 of the second loop cases, with the remaining 10 using traditional Consent Form 1 (non-PSCF). The non-PSCF group demonstrated similar variability in the complications included, with identical legibility rates and acronym usage. Again, only 60% of patients were able to accurately define the associated complications. Of the PSCFs, 100% were legible and 0% used acronyms, and the list of complications was standardised with 100% compliance with NICE and RCS England guidance. Notably, 90% of patients accurately recalled potential complications and nearly all were satisfied with their level of understanding prior to signing the consent form.

Conclusions

This Quality Improvement Project demonstrated that hand written Consent Forms are highly variable, especially regarding the list of complications. We also found that while they were largely legible, half of the consent forms contained acronyms. Lastly, patients were satisfied with the information provided to them and could recall knowledge on the nature of the surgery, but many were not able to recollect important potential complications. The use of a PSCF allowed for a standardised, easily accessible, legible consent form devoid of misinterpretable acronyms. This was reflected in the patient questionnaire, where patients were able to recall details of the surgery and were satisfied with their level of understanding. This was reaffirmed by their grasp of the complications, where 90% of patients could recall potential adverse risks, compared to 60% in the Form 1 groups. This audit demonstrates the benefit of PSCFs from a legislative and litigative standpoint, but more importantly from the standpoint of patient understanding and holistic care. We recommend the use of PSCFs in the process of all surgical consent, to help ensure patient understanding and subsequent satisfaction.

[Knowledge, use and opinion about written informed consent in primary healthcare nurses: CONOSER pilot project]

Cabrera-Rodríguez A, Rico-Blázquez M, Sanz-Álvarez EJ, Schmidt-RioValle J

Atencion Primaria, 3 December 2022; 55(2)

Abstract

To know the knowledge, implementation and opinion on informed consent of generalist nurses, specialists and primary care residents. Descriptive cross-sectional study using an online self-administered 'ad hoc' questionnaire. Primary care nurses in Madrid, from November 2020 to March 2021. Sample of 114 nurses: 91 generalist, 20 specialists and 3 residents. Sociodemographics, knowledge, implementation and opinion. The response rate was 27.7%. As a general rule, 48.2% indicated that informed consent was collected verbally, as established by law, with differences being found between categories, this percentage being higher in specialists and residents (P=0.004), and within specialists in those who had obtained their speciality by internal resident nurse (IRN) (P<0.0001). In addition, specialists and residents were those who most identified the legal norm regulating informed consent (P<0.0001). In terms of implementation and opinion, all groups obtained similar results. There are no previous studies that have analysed these aspects of informed consent comparing the different categories. Studies from other healthcare and geographical areas show that nurses have greater knowledge, although the demand for specific training in bioethics and biolaw is greater in the nurses participating in this study. Nurses have adequate knowledge about informed consent,

use it in clinical practice and have an appropriate conception of it, being higher in some items in specialist nurses IRN and in residents.

Editor's note: Atencion Primaria is a Spanish language publication that publishes works relative to the field of Primary Healthcare

Informed Consent in Anesthesiology: An exploratory Study

Bárbara Fontes, Sílvia Marina, Diana Andrade, Sofia Dias, Miguel Ricou

Acta Bioethica, November 2022; 28(2) pp 281-289

Open Access

Abstract

In the literature Informed consent (IC) assumptions is well established. However, the different stages and the conditions under which the IC for anesthetic practices is obtained, is scarce. The aim of the present study is to explore the phases and conditions of IC in anesthesiology. Anonymized clinical records of 325 patients submitted to anesthetic procedures at the Institute of Oncology of Porto were analyzed. A total agreement between the anesthetic techniques established in the IC and those performed, was reach with 270 patients. The importance of IC in clinical practice is discussed and an ideal process for IC is argued.

Editor's note: Acta Bioethica is publication of the University of Chile

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GENERAL/OTHER

The Inconsistencies of Consent

Chunlin Leonhard

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Abstract

U.S. legal scholars have devoted a lot of attention to the role that consent has played in laws and judicial consent jurisprudence. This essay contributes to the discussion on consent by examining judicial approaches to determining the existence of consent in three selected areas – contracts, tort claims involving medical treatment, and criminal cases involving admissibility of confessions, from the late nineteenth century until the present. This article examines how courts have approached the basic factual question of finding consent and how judicial approaches in those areas have evolved over time. The review shows that the late 19th century saw courts adopting a similar approach for finding consent across the three areas. Courts focused on observable signs of consent, verbal or nonverbal communications, to determine existence of consent. They found consent unless circumstances suggested that the consenting party lacked the power to use their will. However, courts began to diverge in the early and mid-twentieth century in their approaches to ascertaining consent. In contract disputes, courts' consent approach has remained static, focusing on observable signs of consent or, in contract law parlance, "manifestations of assent." In tort cases involving medical treatment, courts began requiring more than observable signs of consent; instead, courts focused on the consenting party's access to information and comprehension, described by scholars as the informed consent doctrine. The judicial consent approach undertook the most dramatic change in criminal cases involving admissibility of confessions with judicial adoption of presumption of non-consent in custodial interrogation without the required warnings.

This article suggests that multiple factors appear to have contributed to divergent consent approaches across the three areas. Consent plays a different role in contract disputes from that in medical treatment and criminal confession cases. Courts have adopted a heightened consent inquiry in medical treatment and criminal confession cases as responses to significant social changes and increased public awareness of individual rights and the need to protect individuals from potential abuses and arbitrary government power.

In addition, human cognitive biases—our flawed decision-making process, may have also contributed to the divergence.

Autonomy and Consent

Book Chapter

Neil C. Manson

The Routledge Handbook of Autonomy, 2022 [Routledge]

Abstract

In the philosophy of consent, the notion of autonomy is widely appealed to for a number of reasons. The philosophy of consent has tended to focus on certain types of consent, in certain domains where consent plays an important normative role. But consent is also a key part of everyday social interactions beyond the special domains of interest of the philosophy of consent. Because the relationship between autonomy and consent in the philosophy of consent has been discussed by others (Dworkin 1988; Beauchamp and Childress 2001; O'Neill 2002; Beauchamp 2010; Walker 2018), the aim here is to take a slightly different approach and to consider what kinds of autonomy might be relevant to a proper characterization of everyday consent. We will then briefly return to consider the significance of autonomy in the philosophy of consent.

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