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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

September 2022

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

Each month we monitor *Google Scholar* for the search terms "consent", "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:

Editor
Paige Fitzsimmons, MA
Associate Director, Center for Informed Consent Integrity
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

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
FREE PRIOR INFORMED CONSENT (FPIC)
GENOMIC MEDICINE/GENE EDITING

POLICY GUIDANCE/PROGRAM ACTION
TECHNOLOGY/OTHER MEDIATION

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

COVID-19

Digital Home Health During the COVID-19 Pandemic Challenges to Safety, Liability , and Informed Consent, and the W , and Informed Consent, and the Way to Move Forward

Faculty Books
Sara Gerke
Dickinson Law Idea, 2022
Open Access
Introduction
Artificial intelligence (AI) and other digital health products, such as smart pills, are rapidly entering clinical practice. We live in the age of big data, where massive amounts of data are collected and used to develop or update digital health products and are shared with third parties for research or commercial purposes. Moreover, we can already see a shift in health care from hospitals to people's homes, for example through the use of medical apps, Fitbits, and other wearables. This line between clinic and home will likely become more and more blurry in the near future. According to one estimate, the smart home health care market size is projected to grow from $6.1 billion in 2018 to over $30 billion in 2025. In particular, the COVID-19 pandemic has propelled the adoption of health AI and digital health across multiple applications. For example, the development and use of digital home health products have been expedited to reduce exposure to the coronavirus SARS-CoV-2, such as through remote patient monitoring, and to better control its spread, such as through exposure-notification apps. At the same time, the regulation of medical devices is more flexible during the public health emergency. However, the acceleration of launching new digital home health devices on the US market combined with less regulatory oversight also raises some challenges, including post-pandemic questions. In this chapter, I will first give an overview of the promise of digital home health. I will then discuss the regulation of digital home health before and during COVID19 in the context of the US Federal Food, Drug, and Cosmetic Act (FDCA). This will be followed by a discussion of three digital home health challenges during the pandemic: 1) safety, 2) liability, and 3) informed consent. In this context, I will also make suggestions on how to move forward.

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BIOMEDICAL RESEARCH

A Census of Clinical Trials Conducted Under the US Exception from Informed Consent Rule

Krista L. Snyder, Jon F. Merz
medRxiv, 24 August 2022
Abstract
Background
The US Food and Drug Administration and National Institutes of Health adopted the Exception from Informed Consent (EFIC) rule in 1996, permitting waiver of informed consent for certain emergency research, including trials funded by the federal government. The rule requires that prospective consent be sought when practicable from patients or their Legally Authorized Representative(s) (LAR), and for those enrolled without consent, the patient or their LAR must be given information and an opportunity to opt-out from continued

participation at the earliest opportunity. We sought to census the trials conducted under the EFIC rule to facilitate research to better understand how the rule is being used.

Methods

We conducted a multi-pronged search to try and identify all trials conducted under the EFIC rule, drawing on numerous reviews, Medline and Google searches (including of the clinicaltrials.gov registry), examination of the FDA's docket, posting an inquiry on the IRB Forum, and email requests to lead authors of all published EFIC trials and related review articles. We describe the trials, when they were started and completed, and whether they were terminated early.

Results

We identified a total of 105 trials as of April 1, 2022: 77 complete, 10 recruiting, 10 registered on clinicaltrials.gov but not yet recruiting, 5 trials that were abandoned before enrolling any subjects, and 3 trials in early planning. Nine of the 77 completed trials were pilot or feasibility trials. Of 68 completed full trials, 30 (44.1%) were terminated early. The most common reason for early termination was futility or safety (17 trials, 25.0%) followed by poor recruitment (9 trials, 13.2%). The rate of conduct of trials has been remarkably constant since 2001, with roughly 18 trials started in each 5-year period.

Conclusions

The rate of early termination of EFIC trials for futility or safety appears higher than for other kinds of clinical research. We provide the list of trials in a Supplement for further in-depth data collection and analysis of this set of trials.

Use Of Teach-Back During Informed Consent In Cancer Clinical Trials

Christa Varnadoe

Yale School of Nursing Digital Theses, 2022

Open Access

Abstract

Five percent of the 1.8 million patients diagnosed with cancer in the United States (US) enroll annually in a clinical trial (American Cancer Society, 2021; Institute of Medicine Committee on Cancer Clinical Trials; National Cancer Institute Cooperative Group Program, 2010). Flawed research consent practices are detrimental to patient safety and costly to the US Healthcare system (Eisenberg et al., 2012; Unger et al., 2019). Well trained nurses are imperative to conducting rigorous, reproducible, and quality research (Brandt et al., 2011). Programs designed to educate nurses on how to implement comprehensive communication strategies confidently during the Cancer Clinical Trials (CCT) consent process remain scarce (Nusbaum et al, 2019; Purdom et al., 2017). The purpose of this quality improvement project was to develop, implement, and evaluate the effects of an evidenced-based education program on nurse confidence with use of the teach-back method during the CCT consent process. An evidenced based education program was developed. It was implemented as a synchronous webinar to members of the International Association of Clinical Research Nurses. Pre and post test program surveys measuring confidence levels were disseminated. There was an overall increase in postsurvey responses suggesting an improvement in confidence levels with use of the teach-back method during the CCT IC process. Further study can explore if patient understanding of CCTs during the IC process is developed proportionally to levels of nurse confidence with use of the teach-back method.

Ethical Considerations during the Informed Consent Process for Acute Ischemic Stroke in International Clinical Trials

Tiffany Bellomo, Jennifer Fokas, Noah Tsao, Clare Anderson, Christopher Becker, Rachel Gioscia-Ryan, William Meurer

Ethics & Human Research, 8 July 2022; 44(4) pp 14-25

Abstract

We sought to investigate the experiences of researchers in existing active-control trials in acute ischemic stroke comparing investigational therapy to tissue plasminogen activator (tPA) in order to identify the approaches and challenges in obtaining informed consent. Out of 401 articles evaluated, 14 trials met inclusion criteria. Trial representatives were contacted to complete a survey concerning the consent process. None of the 14 trials published materials related to the informed consent process. Trials with 75% to 100% of patients directly consented had shorter door-to-treatment (DTT) times than trials that directly consented less than 50% of patients. Trials that had translators available (for recruiting participants who were not native speakers in the local language) and translated consent documents had longer DTT times. The study findings suggest that differences in the standards of informed consent internationally may allow more patients with moderate strokes to provide direct consent without delaying DTT time. Future trials should emphasize transparency to the public and scientific community in the informed consent process.

Developing and Implementing Electronic Consent Procedures in Response to Covid-19 Restrictions

Julie R. Bromberg, Evelyn Nimaja, Andrew W. Kiragu, Karla A. Lawson, Lois Lee, Isam W. Nasr, Charles Pruitt, Stephanie M. Ruest, Michael J. Mello

Ethics & Human Research, 8 July 2022; 44(4) pp 34-38

Open Access

Abstract

The Covid-19 pandemic resulted in unprecedented restrictions on many public, private, and workplace activities throughout the United States and elsewhere. When restrictions were imposed, we were conducting a type III hybrid effectiveness-implementation trial in 10 pediatric trauma centers. In response to several pandemic-based restrictions, we had to develop procedures for engaging with potential research participants while limiting nonclinical, in-person interactions. This manuscript describes the procedures and challenges of obtaining electronic informed consent and assent in a multisite trauma center-based research study. We developed, tested, and trained staff to implement three options for obtaining informed consent. Twenty-five participants were enrolled in the effectiveness-implementation multisite trial during the first six months of utilization of the consent options, with eleven of these individuals enrolled using hybrid or electronic consent procedures. The challenges we identified involving electronic consent procedures included confusion over who would complete the electronic consent process and difficulties reconnecting with families. Lessons learned can strengthen electronic consent and assent procedures for future studies. More research is needed to further strengthen this process and increase its utilization.

Issues About Digital Informed Consent in Clinical Research

Freade Akbar, Ray Wagiu Basrowi

Indonesian Journal of Community and Occupational Medicine, July 2022; 2(1) pp 40-7

Open Access

Abstract

Introduction

Informed consent is a concrete form of moral and ethical values that urgently needs to be emphasized, especially in research that requires the role of humans as subjects and is commonly associated with experimental research. Informed consent itself consists of two forms of print and digital, along with the times many parties began to examine how the role of informed consent, the advantages and disadvantages between print and digital, the application of good digital informed consent, and how information about research should be conveyed to the research subject so that it is easy to understand and in accordance with moral and ethical standards. The purpose of this article is to address issues related to digital informed consent in clinical research.

Methods

We conducted a search on the SpingerLink database in March 2022 to see various publications in the last 2 years related to electronic informed consent using keywords: digital, informed consent, research.

Results
Total 4 articles as source of literature review. Recent research shows the tendency of research subjects to choose digital informed consent because content is easier to personalize, makes it easier to understand content that is only needed by the subject, and the ease of adding digital content in certain forms of media such as audio, and video into digital formats. From the researcher's side will increase the active participation and number of study subjects, making it easier for long-term interaction, especially follow-up research. There are 4 types of informed consent based on utilization for research and 5 informed consent processes that must be carried out in clinical research, which is attempted using language that is easily understood by the research subject and dynamic for further research.
Conclusions
Informed consent in any form constitutes the autonomy right of the subject. Digital formats provide better prospects in facilitating communication to research subjects. But this ease must be accompanied by the consistency of the application of the standard informed consent process, even in intervention studies with biological samples this is more stringent. Informed consent given to the subject must use language that is easy to understand, and transparent. The subject of the study is given the right at any time to exit the research. In the future, the issue of morals and ethics of research will grow, and more dynamic informed consent is needed, especially for interventional clinical research.

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SOCIAL SCIENCE RESEARCH

'Scraping' Reddit posts for academic research? Addressing some blurred lines of consent in growing internet-based research trend during the time of Covid-19

Research Article
Nicholas Norman Adams
International Journal of Social Research Methodology, 18 August 2022
Abstract
The global scale of Covid-19 has constrained academics from conducting much person-facing research. Reactively, trend is increasing for digital-based methodologies capturing already existing online data. Scholars often 'scrape' user-postings from internet forums using coding algorithms and text capture tools, before analysing data, drawing conclusions and publishing findings. The online social news aggregation and discussion website Reddit is a particularly rich source of data for researchers. The public nature of Reddit materials may suggest rationale for user-data to be replicated, analysed and archived; indefinitely and in multiple locations, for scholarly research. However, this position overlooks several key ethical considerations. This paper presents an overview and explanation of Reddit, followed by an exploration of studies that use Reddit-acquired data. Arising ethical issues are discussed, and solutions to salient dilemmas presented. This is to enhance awareness of potential problems and improve protections for those whose data is unknowingly used for research.

Privacy Risks in Microbiome Research: Public Perspectives before and during a Global Pandemic

Andrea Shin, Huiping Xu
Ethics & Human Research, 8 July 2022; 44(4) pp 26-33
Abstract
We assessed public perspectives of microbiome research privacy risks before and after a nationwide emergency was declared in the United States regarding the Covid-19 pandemic. From January to July of 2020, we conducted an online survey of perceived privacy risks of microbiome research among U.S. adults. Among 3,106 participants (the preemergency group), most expressed that the microbiome posed privacy risks

similar to those associated with DNA (60.3%) or medical records (50.6%) and that they would prefer detailed explanations (70.2%) of risk in consent materials. Only 8.9% reported moderate to high familiarity with microbiome privacy risks. In adjusted analyses, individuals who participated in the study after the Covid-19 emergency was declared (the Covid-19 emergency group) were less likely to express that microbiome privacy risks were similar to those of DNA or medical records and more likely to report familiarity with the privacy risks of microbiomes. There was a trend toward increased concern after the Covid-19 emergency was declared ($p = 0.053$). Overall, the study revealed that many U.S. adults believe that microbiome privacy risks are similar to those associated with DNA or medical records, and they prefer detailed explanations in consent documents. Individuals who participated after the Covid-19 emergency was declared reported greater knowledge of microbiome privacy risks but had more concern.

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HEALTH DATA

Patients' Willingness to Provide Their Clinical Data for Research Purposes and Acceptance of Different Consent Models: Findings From a Representative Survey of Patients With Cancer

Anja Köngeter, Christoph Schickhardt, Martin Jungkunz, Susanne Bergbold, Katja Mehlis, Eva C Winkler
Journal of Medical Internet Research, 25 August 2022

Abstract

Background

Secondary use of clinical data for biomedical research purposes holds great potential for various types of noninterventional, data-driven studies. Patients' willingness to support research with their clinical data is a crucial prerequisite for research progress.

Objective

The aim of the study was to learn about patients' attitudes and expectations regarding secondary use of their clinical data. In a next step, our results can inform the development of an appropriate governance framework for secondary use of clinical data for research purposes.

Method

A questionnaire was developed to assess the willingness of patients with cancer to provide their clinical data for biomedical research purposes, considering different conditions of data sharing and consent models. The Cancer Registry of the German federal state of Baden-Württemberg recruited a proportionally stratified random sample of patients with cancer and survivors of cancer based on a full census.

Results

In total, 838 participants completed the survey. Approximately all participants (810/838, 96.7%) showed general willingness to make clinical data available for biomedical research purposes; however, they expected certain requirements to be met, such as comparable data protection standards for data use abroad and the possibility to renew consent at regular time intervals. Most participants (620/838, 73.9%) supported data use also by researchers in commercial companies. More than half of the participants (503/838, 60%) were willing to give up control over clinical data in favor of research benefits. Most participants expressed acceptance of the broad consent model (494/838, 58.9%), followed by data use by default (with the option to opt out at any time; 419/838, 50%); specific consent for every study showed the lowest acceptance rate (327/838, 39%). Patients expected physicians to share their data (763/838, 91.1%) and their fellow patients to support secondary use with their clinical data (679/838, 81%).

Conclusions

Although patients' general willingness to make their clinical data available for biomedical research purposes is very high, the willingness of a substantial proportion of patients depends on additional requirements. Taking these perspectives into account is essential for designing trustworthy governance of clinical data reuse and sharing. The willingness to accept the loss of control over clinical data to enhance the benefits of research should be given special consideration.

Digital Transformation of Big Data

Book Chapter

Po-Chang Lee, Chih-Hsing Ho, Joyce Tsung-Hsi Wang

Digital Health Care in Taiwan, 14 August 2022; pp 219–228 [Springer]

Open Access

Abstract

The virtual National Health Insurance (NHI) card not only represents digitization but also enables contactless health care during the pandemic. Under the process of full-scale digitization, the National Health Insurance Administration (NHIA) continues to refine the health service delivery measures, especially in the field of home-based medical care and telemedicine.

Under the personal data protection regulation, the NHI data are opened for academic research purposes. More than 6550 published journal articles have utilized the NHI data, and these articles are made searchable online to support health policy management and clinical research. The NHI medical images combined with the application of artificial intelligence (AI) are the cornerstones of Taiwan's smart health care. Domestic research teams are eligible to use the NHI database to verify or build their AI models after their research proposals are approved by the Management Council of the AI Application of NHI Data. The NHIA also plans to use NHI big data to develop digital patient decision aids by establishing a two-way digital interaction model to address the concerns of the healthcare providers and the public. By comparing the secondary use of health data in different countries, Taiwan is seeking a balance between innovation and conservative policies and is creating an environment that ensures the well-being of the next generation.

Big Health Data Research and Group Harm: The Scope of IRB Review

Megan Doerr, Sara Meeder

Ethics & Human Research, 8 July 2022; 44(4) pp 34-38

Open Access

Abstract

Much of precision medicine is driven by big health data research—the analysis of massive datasets representing the complex web of genetic, behavioral, environmental, and other factors that impact human well-being. There are some who point to the Common Rule, the regulation governing federally funded human subjects research, as a regulatory panacea for all types of big health data research. But how well does the Common Rule fit the regulatory needs of this type of research? This article suggests that harms that may arise from artificial intelligence and machine-learning technologies used in big health data research—and the increased likelihood that this research will affect public policy—mean it is time to consider whether the current human research regulations prohibit comprehensive, ethical review of big health data research that may result in group harm.

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BIOBANKING

Biobanking and consenting to research: a qualitative thematic analysis of young people's perspectives

Fabian van der Velden, Lily Gills, Jasmin Broadey, Louise Hayes, Eve Roberts, Jack Courtney, Joanne Ball, Marieke Emonts, Emma Lim

BMJ Archives of Disease in Childhood, 17 August 2022

Abstract

Aims
Biobanking biological samples and consenting patients are common practice in paediatric infectious diseases research. We aimed to gain insight into young people's knowledge, views and perspectives around current practices of biobanking and consent, in order to improve consent procedures.
Methods
We designed a structured electronic survey aimed at children and young people (CYP), 11-21 years of age, collecting demographic data, and views on biobanking and consent using four scenarios: 1) prospective consent, 2) deferred consent, 3) reconsent and assent age, and 4) animal studies. The survey was disseminated via Young Person's Advisory Group North England (YPAGne) and other YPAGs social media channels and to the secondary schools of participating young people in this project. Data were analysed utilising a qualitative thematic approach by three independent data reviewers and common themes identified. Triangulation of data by a 4th reviewer occurred independently. Data were collected in two time waves. The second wave ensured data saturation.
Results
102 CYP completed the survey. All were ≥11 years old, the majority between 16-18 years (63.7%, n=65), female (66.7%, n=68), and from North East England and Cumbria (82.4%, n=84). 73 had no prior knowledge of biobanking (72.3%). Prospective consent acceptability for biobanking was high (91.2%, n=93), with main themes being 'altruism' and 'potential benefits outweigh individual risks'. Main themes against were 'increased risk of complications' and 'needle phobia'. Deferred consent acceptability was lower (84.3%, n= 86), common themes were: 'altruism', 'body integrity', and 'sample frugality'. Participants state that prospective consent is preferable, but not always appropriate given the clinical situation. Communication is key and it is important to state why deferred consent is needed, and participation can still be declined. Those opposing deferred consent state it violated their integrity and takes away their control over their own body. Reconsent once children reach the age of informed assent was preferred by 76.5% of CYP (n=78), the majority stating an age >14 years as appropriate. 79.2% would want to be informed if their biobanked sample is used in future research (n=80). Just over half agrees with samples being used for animal testing (54.5%, n=55), which goes up to 80.2% (n=81) if explained as the last necessary step prior to human testing for medical research.
Conclusion
Acceptability of prospective and deferred consent for biobanking is high among CYP, with 'altruism', 'frugality' and 'body integrity' as important themes. Justification and clear communication are paramount and assent should be obtained from any CYP with capacity. CYP should be part of the consenting procedure, not just their parent/legal guardian.

Biobanks in the low-and middle-income countries of the Arab Middle East region: challenges, ethical issues, and governance arrangements—a qualitative study involving biobank managers

Research
Ahmed Samir Abdelhafiz, Mamoun Ahram, Maha Emad Ibrahim, Alya Elgamri, Ehsan Gamel, Rania Labib, Henry Silverman
BMC Medical Ethics volume, 14 August 2022; 23(83)
Open Access
Abstract
Background
Biobanks have recently been established in several low-and middle-income countries (LMICs) in the Arab region of the Middle East. We aimed to explore the views of biobank managers regarding the challenges, ethical issues, and governance arrangements of their biobanks.
Methods
In-depth semi-structured qualitative interviews were conducted with a purposive sample of eight biobank managers from Egypt (6), Jordan (1), and Sudan (1). Interviews were performed either face-to-face, by phone, or via Zoom and lasted approximately 45–75 min. After verbal consent, interviews were recorded and

then transcribed. The authors performed a thematic analysis of the transcripts independently and then integrated the themes via a consensus process.

Results

Biobank managers discussed the main challenges in establishing their biobanks. These included the staff's lack of experience and training, limited funds, deficit awareness of biobanks, obtaining funding from different sources. Only four reported they were active in distributing biospecimens and health data to researchers. Six biobanks used a broad consent model, one used tiered consent, and another allowed participants to opt-out of being recontacted. Five managers avoided partnerships with pharmaceutical companies due to concerns with unfavorable reactions from the community. Five managers did not have clear policies for returning research results to the donors. Five expressed challenges with sample and data sharing with international collaborators; all five used material transfer agreements. The biobank managers revealed variable governance arrangements and activities with community involving awareness and educational efforts rather than active engagement. Several expressed the importance of transparency with the operations of their biobanks and gaining the trust of their stakeholders.

Conclusion

Managers of biobanks in LMICs in the Arab Middle East encounter financial, operational, and social challenges toward their sustainability efforts. Discussions with key stakeholders are warranted to manage ethical issues involving informed consent, privacy, data sharing, and the return of results. We recommend that biobank managers in the Arab Middle East form collaborative networks within the region and internationally, develop trusting governance relationships with their stakeholders, and pursue engagement activities with their communities to enhance trust.

Biological sample donation and informed consent for neurobiobanking: Evidence from a community survey in Ghana and Nigeria

Research Article

Arti Singh, Oyedunni Arulogun, Joshua Akinyemi, Michelle Nichols, Benedict Calys-Tagoe, Babatunde Ojebuyi, Carolyn Jenkins, Reginald Obiako, Albert Akpalu, Fred Sarfo, Kolawole Wahab, Adeniyi Sunday, Lukman F. Owolabi, Muyiwa Adigun, Ibukun Afolami, Olorunyomi Olorunsogbon, Mayowa Ogunronbi, Ezinne Sylvia Melikam, Ruth Laryea, Shadrack Asibey, Wisdom Oguike, Lois Melikam, Abdullateef Sule, Musibau A. Titiloye, Isah Suleiman Yahaya, Abiodun Bello, Rajesh N. Kalaria,Ayodele Jegede, Mayowa Owolabi, Bruce Ovbiagele, Rufus Akinyemi

PLOS One, 11 August 2022

Open Access

Abstract

Introduction

Genomic research and neurobiobanking are expanding globally. Empirical evidence on the level of awareness and willingness to donate/share biological samples towards the expansion of neurobiobanking in sub-Saharan Africa is lacking.

Aims

To ascertain the awareness, perspectives and predictors regarding biological sample donation, sharing and informed consent preferences among community members in Ghana and Nigeria.

Methods

A questionnaire cross-sectional survey was conducted among randomly selected community members from seven communities in Ghana and Nigeria.

Results

Of the 1015 respondents with mean age 39.3 years (SD 19.5), about a third had heard of blood donation (37.2%, M: 42.4%, F: 32.0%, p = 0.001) and a quarter were aware of blood sample storage for research (24.5%; M: 29.7%, F: 19.4%, p = 0.151). Two out of ten were willing to donate brain after death (18.8%, M: 22.6%, F: 15.0%, p<0.001). Main reasons for unwillingness to donate brain were; to go back to God complete (46.6%) and lack of knowledge related to brain donation (32.7%). Only a third of the participants were aware

of informed consent (31.7%; M: 35.9%, F: 27.5%, p<0.001). Predictors of positive attitude towards biobanking and informed consent were being married, tertiary level education, student status, and belonging to select ethnic groups.

Conclusion

There is a greater need for research attention in the area of brain banking and informed consent. Improved context-sensitive public education on neurobiobanking and informed consent, in line with the sociocultural diversities, is recommended within the African sub region.

Perspectives from a Predominantly African American Community about Biobank Research and a Biobank Consent Form

Laura K. Sedig, E. Hill De Loney, Sarah B. Bailey, Kayte Spector-Bagdady, Bianca Ghita, Lydia Koh Krienke, Raymond Hutchinson

Ethics & Human Research, 8 July 2022; 44(4) pp 26-33

Abstract

Minority populations have been underrepresented in clinical trials, as well as in research biobanks that are created to conduct research with participants' biospecimens and related medical and research data. Biobank research raises issues about informed consent and privacy and the confidentiality of participants' personal data. Our study involved three focus groups of 10 adults each that were conducted in a medically underserved, predominantly African American community to elucidate questions and concerns regarding an institutional biobank. Transcripts from the discussion were qualitatively analyzed. Three main themes that arose from the focus groups included the importance of trust, the importance of the community in research, and suggestions to improve trust. The concerns identified in this study provide a starting point for future research to help research institutions become more trustworthy to the communities they serve.

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CAPACITY TO CONSENT

Valid informed consent and decision-making capacity in clinical trials

Discussion

Vittoria Sorice, Louise Burton, Amy Neal, Jodie Bradder

Nursing Times, 1 August 2022; 118(8)

Abstract

There are ethical and legal requirements involved in the consent process for research involving human participants. The Mental Capacity Act 2005 introduced a framework outlining how choices should be made by, and on behalf of, people lacking decision-making capacity. This ensures vulnerable groups are protected from being enrolled into clinical studies without their informed consent, and gives people access to studies that are of benefit to themselves and the field of clinical research.

Promoting the Values for Surrogate Decision-making

Viewpoint

David Wendler

JAMA, 23 June 2022; 328(3) pp 243-244

Excerpt

The process of making medical decisions used to be straightforward. Clinicians selected the treatment course they determined would best promote the patient's interests. More recently, in response to increased emphasis on individual autonomy, it is the patient, in consultation with their clinicians and loved ones, who makes medical decisions. This approach respects patients who are able to make their own treatment

decisions. However, it poses a challenge for the many adult patients who are unable to understand the information relevant to the decision in question, reason in light of this information and their own values, make a voluntary decision on this basis, or communicate their decision…

Inclusion of older adults and reporting of consent processes in randomized controlled trials in the emergency department: A scoping review

Lauren T Southerland, Katherine K. Benson, Austin J. Schoeffler, Margaret A. Lashutka, Soo Borson, Jason J. Bischof

Journal of the American College of Emergency Physicians Open, May 2022

Open Access

Abstract

Objective

Conducting research in the emergency department (ED) is often complicated by patients' acute and chronic illnesses, which can adversely affect cognition and subsequently capacity to consent for research, especially in older adults. Validated screening tools to assess capacity to consent for research exist, but neither the frequency of use nor which ones are used for ED research are known.

Methods

We conducted a scoping review using standard review techniques. Inclusion criteria included (1) randomized controlled trials (RCTs) from publication years 2014–2019 that (2) enrolled participants only in the ED, (3) included patients aged 65+ years, and (4) were fully published in English. Articles were sourced from Embase and screened using Covidence.

Results

From 3130 search results, 269 studies passed title/abstract and full text screening. Average of the mean or median ages was 55.7 years (SD 14.2). The mean number of study participants was 311.9 [range 8–10,807 participants]. A few (n = 13, 4.8%) waived or had exception from informed consent. Of the 256 studies requiring consent, a fourth (26.5%, n = 68) specifically excluded patients due to impaired capacity to consent. Only 11 (4.3%) documented a formal capacity screening tool and only 13 (5.1%) reported consent by legally authorized representative (LAR).

Conclusions

Most RCTs enrolling older adults in EDs did not report assessment of capacity to consent or use of LARs. This snapshot of informed consent procedures is potentially concerning and suggests that either research consent processes for older patients and/or reporting of consent processes require improvement.

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YOUNG PERSONS

Developmental Stages and Patient Assent for Research Studies or Medical Treatment

Rachel Y. Moo

American Academy of Pediatrics Journal Blogs, 17 August 2022

Excerpt

As a pediatrician and a clinical researcher, I am well aware of the requirements of when we need to obtain parental consent, and when a child needs to assent, meaning the child needs to agree.

In general, we talk about child assent for clinical studies, but there are times when medical treatment and enrollment in a clinical study are one and the same. For instance, most children with cancer are automatically enrolled in a clinical study, because we are still learning the best way to treat many of these cancers. And many children with cancer are alive today because of those before them who entered into these studies. But what does it mean to get assent from a child?

This week, Pediatrics is early releasing a Pediatrics Perspectives by Gianna McMillan, a parent and bioethicist at Loyola Marymount University, entitled “The Parent’s Dilemma: Pediatric Assent in Research”.

Dr. McMillan helps us understand that assent means different things at different developmental stages. At some stages, the parent should make the decision, with or without the child’s input (again, depending on the child’s developmental stage). As the child becomes more developmentally mature, it may become appropriate for the child to make the decision, with parental agreement…

The Parent’s Dilemma: Pediatric Assent in Research

Gianna McMillan

Pediatrics Perspectives, 17 August 2022

Excerpt

Parents and their children rarely understand what it means “to consent” to participate in pediatric clinical research. This became clear during my 15 years as a patient advocate, when I facilitated hundreds of conversations about the implications of aggressive treatment of the very young and the existential crises faced by parents who made life-or death decisions for their children. In the United States, most children with cancer enter a clinical trial,1 and although parents understand enough of the scientific information to deliberate on the pros and cons of research, it is harder to grasp the subtleties of “consenting for” experimental studies, “giving permission to” the investigators, or “gaining assent from” the child. This lack of clarity leaves parents confused about the ethical weight and propriety of their decisions or unaware of any ethical significance at all…

Understanding the Effectiveness of Consent Processes and Conversations in Pediatric Surgery: A Systematic-Scoping Review

Review Article

Zoe Atsaidis, Ryan Antel, Elena Guadagno, Jeffrey Wiseman, Dan Poenaru

Journal of Pediatric Surgery, 11 August 2022

Abstract

Background

The consent conversation in pediatric surgery is an essential part of pre-operative care which, when inadequate, can lead to significant adverse consequences for the child, parents, surgeon, other healthcare workers and the healthcare system. We reviewed the published literature on what key stakeholders perceive are the components of effective and ineffective consenting processes in pediatric surgery.

Methods

A medical librarian searched seven databases to retrieve articles looking at the informed consenting process in surgical care for the pediatric population. Two independent reviewers screened all publications and categorized them by stakeholder perspectives (patient/family, surgical team, other healthcare team, and hospital administration or policy maker). General study characteristics, interventions to improve consent and features of effective and ineffective consent conversations were extracted.

Results

5079 titles and abstracts were screened, resulting in 88 full-text studies and 43 articles included in the final review. Most publications (51%) discussed informed consent only from the patient/family perspective, while 21% added surgeon's perspective. No study approached the consenting process from the perspective of all stakeholder groups. Effective consent components identified included use of multimedia, presence of multiple conversations prior to surgery, and individualized communication catered to unique family knowledge and needs. In contrast, ineffective conversations did not include a clear assessment of parental understanding, delivered too much information, and did not address parental anxiety.

Conclusions

The literature on the consenting process in pediatric surgery is narrow in stakeholder perspectives. Our findings highlight gaps in the literature and opportunities to improve the informed consent processes prior to pediatric surgery.

The Role of Formal Policy to Promote Informed Consent of Psychotropic Medications for Youth in Child Welfare Custody: A National Examination

Original Article

Thomas I. Mackie, Ana J. Schaefer, John S. Palatucci, Laurel K. Leslie, Stephen Crystal, Michael Gusmano, Hannah E. Karpman

Administration and Policy in Mental Health and Mental Health Services Research, 6 August 2022

Open Access

Abstract

Active participation of youth and surrogate decision-makers in providing informed consent and assent for mental health treatment is critical. However, the procedural elements of an informed consent process, particularly for youth in child welfare custody, are not well defined. Given calls for psychotropic medication oversight for youth in child welfare custody, this study proposes a taxonomy for the procedural elements of informed consent policies based upon formal and informal child welfare policies and then examines whether enacted state formal policies across the United States endorsed these elements. A sequential multi-method study design included: (1) semi-structured interviews with key informants (n = 58) primarily from state child welfare agencies to identify a taxonomy of procedural elements for informed consent of psychotropic medications and then (2) a legislative review of the 50 states and D.C. to characterize whether formal policies endorsed each procedural element through February 2022. Key informants reported five procedural elements in policy, including how to: (1) gather social and medical history, (2) prescribe the medication, (3) authorize its use through consent and youth assent, (4) notify relevant stakeholders, and (5) routinely review the consenting decision. Twenty-three states endorsed relevant legislation; however, only two states specified all five procedural elements. Additionally, the content of a procedural element, when included, varied substantively across policies. Further research and expert consensus are needed to set best practices and guide policymakers in setting policies to advance transparency and accountability for informed consent of mental health treatment among youth in child welfare custody.

Ethical issues concerning the use of commercially available wearables in children: Informed consent, living in the spotlight, and the right to an open future

Andrie G. Panayiotou, Evangelos D. Protopapadakis

European Journal of Bioethics, July 2022; 13(25)

Open Access

Summary

Wearable and mobile technology has advanced in leaps and bounds in the last decade with technological advances creating a role from enhancing healthy living to monitoring and treating disease. However, the discussion about the ethical use of such commercial technology in the community, especially in minors, is lacking behind. In this paper, we first summarize the major ethical concerns that arise from the usage of commercially available wearable technology in children, with a focus on smart watches, highlighting issues around the consent process, mitigation of risk and potential confidentiality and privacy issues, as well as the potential for therapeutic misconceptions when used without medical advice. Then through a relevant thought experiment we move on to outline some further ethical concerns that are connected to the use of wearables by minors, to wit the issue of informed consent in the case of minors, forcing them to live in the spotlight, and compromising their right to an open future. We conclude with the view that mitigating potential pitfalls and enhancing the benefits of wearable technology especially for minors requires brave and comprehensive moral debates.

Consent forms: the participation of children in research

Research

Flavia Andrade Nunes Fialho, Ieda Maria Ávila Vargas Dias, Marisa Palacios de Almeida Rego

Revista Bioética, April – June 2022; 30(2)

Abstract

The Resolution 466/2012 of the National Council of Health establishes the term of assent as compulsory for research carried out with children. However, the resolution presents the definition of assent without specifying the terms necessary for the document. This gap makes current and pertinent the approach of this topic by this study, which aims to discuss the participation of children in research. The results present a theoretical framework from which we can reflect on the ethics of Research with children, considering their vulnerability, which can lead to irreparable situations. We conclude that the theme must remain in the academic and professional debates since, on top of being a dynamic reality, this population segment has many specificities.

Editor's note: This abstract refers to the National Council of Health in Brazil.

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RIGHTS/LEGAL/LEGISLATIVE

Informed Consent in Medical Law in the Romanian Legal System: A Comparative Perspective

Camelia Mihăilă

Journal of Intercultural Management and Ethics, 2022

Open Access

Abstract

This paper aims to analyse the principle of consent in the medical act from a comparative law perspective. While the introduction gives a brief presentation of the definition of consent from the perspective of legal doctrine, the content of the paper analyses some legislative landmarks in the Romanian legal system, as well as in the French and Spanish legal systems. Consent is one of the basic principles of modern medical bioethics and an essential element of the validity of the medical contract, ensuring respect for human dignity and protection of the patient's bodily integrity. While Romanian law is based more on the idea of information, Spanish law analyses consent from the point of view of a personalist right, including it in the short list of personal rights enshrined in Law 1/1982 on the protection of honour, image and privacy. French law, on the other hand, has a long history of case law regulating consent in medical acts, with the Teysier and Mercier cases being worth mentioning.

Cameroon: New Law on Medical Research Involving the "Human Person" Adopted

Article

Nicolas Boring

The Global Legal Monitor, Library of Congress, 2022

Excerpt

On April 27, 2022, the Parliament of Cameroon adopted a law providing a new framework for medical research involving the "human person." This law places a particular emphasis on the right to information and the free, informed, and written consent of the participants. It also provides guarantees regarding respect for privacy and confidentiality of personal data and respect for human integrity, dignity, and vulnerability…

Background to the Law

According to Cameroonian press reports, the new law was drafted in reaction to a scandal involving the trial of a preventive treatment for AIDS conducted in 2004 by the American NGO Family Health International on sex workers in Douala "in violation of [their] ethical and deontological rights." The new law also represents a

response to the recent proliferation in Cameroon of clinical trials of COVID-19 treatments conducted without rigorous controls.

Content of the Law

The newly enacted law delimits the scope of consent for medical research involving minors (articles 15 and 16), disabled persons (articles 17 and 18), and pregnant women (articles 19 and 20). It also provides a framework for medical research on in vivo fetuses and in vivo embryos (articles 19 to 22). Finally, the law addresses research conducted on stillborn children (articles 23 and 24) and on the dead (articles 27 and 28)…

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HUMANITARIAN CONTEXT

Navigating accountability in humanitarian photography at sea: a snapshot of embedded photographer practices in obtaining informed consent during I/NGO search and rescue operations in the Mediterranean

Masters Thesis

Arran Smith

Uppsala University, 2022

Abstract

This thesis aims to contribute to ethical discussions on the production of photography in different humanitarian contexts, and in circumstances where it is facilitated by nongovernmental and international non-governmental organisations (I/NGOs). Humanitarian photography is often reproduced and circulated in various forms by different actors, highlighting the need for research on the actions, decisions, and interactions that influence how these images are produced. An extensive literature review captures the many ethical challenges surrounding humanitarian photography and provides an overview of related standards. A conceptual framework is then built around informed consent as an accountability mechanism, with consideration for certain relational and situational factors that influence the quality and effectiveness of the process of obtaining consent. Emphasising photographer and organisational accountability, an analysis of how photographers apply the concept of informed consent and its potential as an accountability mechanism is explored through the case study of embedded photographers in search and rescue (SAR) I/NGO operations in the Mediterranean Sea. Four semi-structured in-depth interviews were completed with photographers involved in SAR I/NGO missions in the Mediterranean from 2015 to 2021. The interviews suggest that a continuous and deliberate process of individual, organisational, and collaborative self-regulation unfolds throughout a mission, largely through verbal communication and body language, in an effort to obtain consent to take or use images of people who have been rescued. Use of formal means such as written consent forms are only rarely used. Photographs during the rescues were generally taken without prior consent, and photographers' ability to obtain meaningful subsequent informed consent was easily compromised due to the unpredictable conditions during SAR operations and the variation across I/NGO-photographer partnerships. These findings support the need for further dialogue in this context to ensure that practices and processes related to the production of humanitarian photography, such as obtaining informed consent, are compatible with humanitarian principles, respect the rights and dignity of people affected by crisis, and foster greater accountability.

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CULTURAL/COUNTRY CONTEXT

Refugee Attitudes Towards Patient Autonomy-Based Ethics of Informed Consent

Book Chapter

Sukran Sevimli

Practices, Challenges, and Prospects of Digital Ethnography as a Multidisciplinary Method, 2022 [IGIG Global]

Abstract

The objective of this study was to identify refugees' attitudes concerning the autonomy-based ethics of informed consent and to determine whether these attitudes varied by gender. A quantitative methodology was adopted for this study. Questions were scored using a Likert-type scale and face-to-face interviews were conducted with 610 refugees who had migrated to Turkey from MENA and Caucasia countries. Refugees from eleven countries participated in the survey, of whom the majority were men (62.5% male versus 37.5% female). Autonomy is a fundamental principle of human rights and medical ethics. Refugees from MENA countries, where the concept of autonomy is contrary to the deeply-held traditional religious views of much of the population, in general, have a poor grasp of informed consent as a patient right. Traditional values steeped in patriarchy constitute an obstacle to women making decisions regarding their own lives in MENA and Caucasia countries. Therefore, the practice of informed consent is of critical importance in helping to reduce gender differentials in healthcare.

Informed consent for surgical case reports

Mohamed Onyango, Brian Kariuki

The Annals of African Surgery, 30 June 2022

Open Access

Excerpt

Informed consent is one of the most essential pillars of medical research ethics (1). It encompasses the medical ethical principle of autonomy which enables the participants to decide on whether or not to partake in a study without any coercion (2). It also enables patients to make informed decisions after critically analyzing the implications of the facts presented by the surgeon (3). It is of great importance that surgeons apply specific informed consent rules for specific study designs they undertake. The majority of studies submitted to surgical journals are case reports, but the process for obtaining quality informed consent is still insufficient. In addition, some journals do not have well-defined informed consent protocols for case report studies. This editorial thus aims to highlight case report specific rules for informed consent for surgeons to employ prior to commencement of their research…

Are Consent Forms Used in Cardiology Clinics Easy to Read?

İbrahim Etem Dural

Archives of the Turkish Society of Cardiology, 30 June 2022

Open Access

Abstract

Objective

Informed consent forms are a contract between the patient and the doctor before the medical diagnosis and treatment. It is extremely important that the patient can read and understand such forms. The purpose of the present study was to investigate the readability levels of consent forms recommended by the Turkish Society of Cardiology used in cardiology clinics.

Methods

The number of words, syllables, letters, and characters of 20 consent forms that are used in cardiology clinics were calculated. The readability scores were calculated by using the formulas of Ateşman and Bezirci–Yılmaz.

Results

It was found that the cardiology consent forms were readable at the 11th or 12th grade according to the Ateşman Index and at the high school level according to the Bezirci–Yılmaz Index.

Conclusion
We suggest that the informed consent forms recommended by the Turkish Society of Cardiology must be simplified from the level that requires high school education to the level that requires 6 years of education, which is the average schooling year in Turkey.

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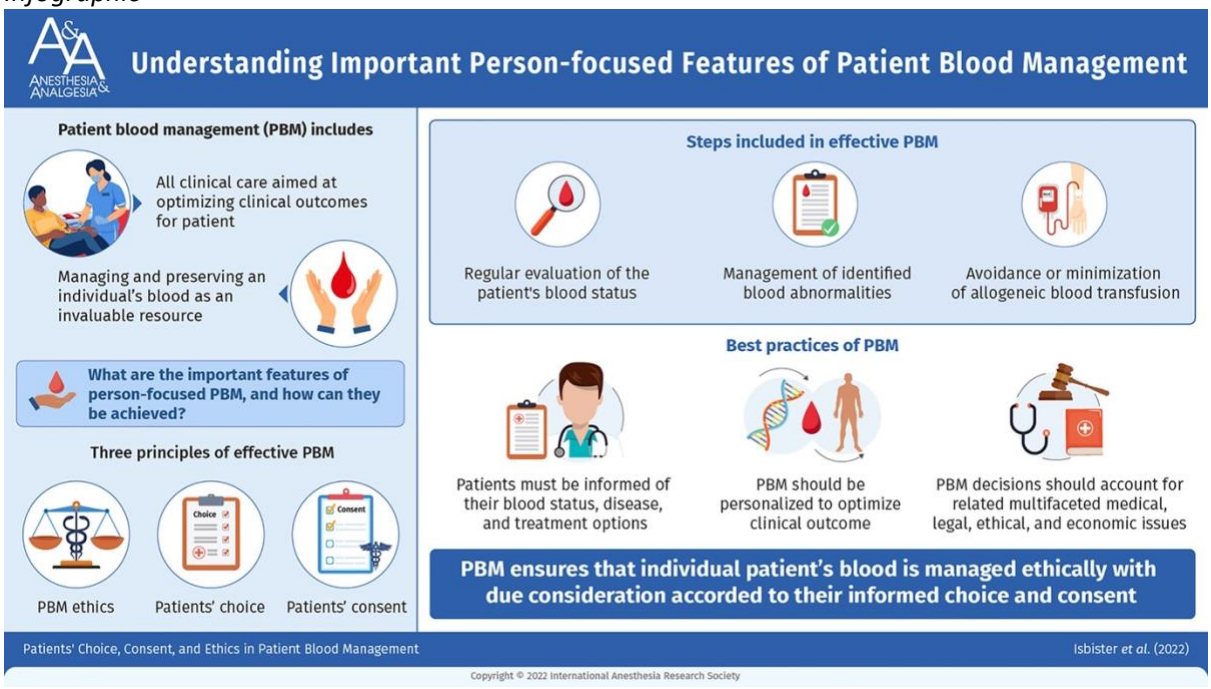
MEDICAL/SURGICAL

Patients' Choice, Consent, and Ethics in Patient Blood Management

James P. Isbister, Bronwyn L. Pearse, Alana S. Delaforce, Shannon L. Farmer
Anesthesia & Analgesia, September 2022; 135(3) pp 489-500
Infographic



Abstract
…Patients must be informed of their diagnosis, the nature, severity and prognosis of the disease, and treatment options along with risks and benefits. They should be involved in decision-making regarding their management. However, as part of this process, there are multifaceted medical, legal, ethical, and economic issues, encompassing shared decision-making, patient choice, and informed consent. Furthermore, variability in patient circumstances and preferences, the complexity of medical science, and the workings of health care systems in which consent takes place can be bewildering, not only for the patient but also for clinicians obtaining consent…

How Informed Is Your Informed Consent: Evaluating Differences Between Resident and Attending Obtained Consents for Cholecystectomy

Kathleen E. Singer, Jennifer E. Baker, Nora C. Elson, Taylor E. Wallen, Ann Salvator, Ralph C. Quillin, Jeffrey J. Sussman, Amy T. Makley, Michael D. Goodman
Journal of Surgical Education, 24 August 2022
Abstract
Objective

There is considerable variability in surgeons' approach to write and obtain informed consent for surgery, particularly among resident trainees. We analyzed differences in procedures and complications described in documented surgical consents for cholecystectomy between residents and attendings. We hypothesized that attending consents would describe more comprehensive procedures and complications than those done by residents.

Design

This is a retrospective analysis of 334 patients who underwent cholecystectomy. Charts were queried for demographics, surgical approach, whether the consent was completed electronically, and which provider completed the consent. Specifically, consents were evaluated for inclusion of possible conversion to open procedure, intraoperative cholangiogram, bile duct injury, injury to nearby structures, reoperation, bile leak, as well as if the consent matched the actual procedure performed.

Setting

This study was conducted at an accredited general surgery training program at an academic tertiary care center in the Midwest.

Participants

This was a review of 334 patients who underwent cholecystectomy over a 1 year period.

Results

Of all documented consents analyzed, 153 (47%) specifically included possible intraoperative cholangiogram, 156 (47%) included bile duct injury, 76 (23%) included injury to nearby structures, 22 (7%) included reoperation, and 62 (19%) included bile leak. In comparing residents and attendings, residents were more likely to consent for bile duct injury ($p = 0.002$), possible intraoperative cholangiogram ($p = 0.0007$), injury to nearby structures ($p < 0.0001$), reoperation ($p < 0.0001$), and bile leak ($p < 0.0001$).

Conclusions

Significant variation exists between documentation between resident and attending cholecystectomy consents, with residents including more complications than attendings on their consent forms. These data suggest that experience alone does not predict content of written consents, particularly for common ambulatory procedures. Education regarding the purpose of informed consent and what should be included in one may lead to a reduction in variability between providers.

Shared Consent: Acknowledging the Subjectivity of Surgical Decision-making

Surgical Perspectives

Paul J.Kepper, Sean C. Wightman, Baddr A. Shakhsheer

Annals of Surgery, 22 August 2022

Excerpt

Surgeons aspire to make data-driven decisions to provide the highest level of patient care. Evidence-based medicine mandates utilization of the best available data to guide decision making. The decision to offer an operation, however, is more than an evaluation of clinical evidence. Clinical expertise applies evidence-based medicine to a specific patient and tailors the practice of medicine to individual patient situations and preferences. Clinicians fill the gaps in the evidence with expertise developed over years of experience and training. Bridging these gaps is often described as the "art of surgery"; it is inherently subjective. Shared consent is the process that acknowledges subjectivity in decision-making. Shared consent is the foundation for a cooperative cognitive model between patient and surgeon, interpreting the available data through the lens of patient preference while relying on surgeon expertise…

Regional Audit: Valid and Informed Consent for Lower Limb Arthroplasty in Orthopaedic Surgery: Are We Doing Enough?

Z Sohail, R Mills, O Adebayo, G Mamarelis, F Acquaah, S Subhash, I Liew

British Journal of Surgery, 19 August 2022; 109(Supplement 6)

Abstract

Aim
To investigate regionally the validity of the patient consent process for lower limb arthroplasty, compared to set data standards, with a view to investigating whether the consent process could be improved, and if so, how?
Method
Regional data from 8 hospital trusts (50 data sets collected from each hospital) across England was collected retrospectively from May 1st, 2021, (25 THR, 25 TKR), collated and collectively analysed against agreed, pre-determined set criterion. Data standards included ascertaining whether alternatives to surgery were offered and exploring the likely benefits and risks. Capacity to consent for procedure-specific surgery was measured as patients' ability to understand, weigh up, retain, and communicate their decisions regarding surgery. Hospitals regional data was collectively analysed.
Results
Capacity was only successfully fulfilled and documented regionally in 11.6% of hip and 13.9% of knee replacement surgeries, despite Consent Form 1 having been filled out in 94.8% and 88.5% of cases respectively, which were procedure specific in only 74.0% and 72.1% of cases.
Conclusions
Significant improvement can clearly be made to an area of already such high clinical negligence claims. We propose a novel solution involving the digitalisation of the consent process, including multimedia surgical videos to better inform patients and reliably assist in establishing the validity of a patient's consent. The implications of this are limited not only to Orthopaedic surgery but could have far-reaching consequences across all surgical (and indeed medical) specialties, where obtaining valid and informed consent for procedures remains integral to quality patient care.

Standardizing Consent Forms for Outpatient Urology Procedures

S Shrestha, E Jiang, A Sandhu, P Pinnamaraju, T Swallow, A Pai
British Journal of Surgery, 19 August 2022; 109(Supplement 6)
Abstract
Introduction
British Association of Urological Surgeons (BAUS) guidelines have provided comprehensive and standardized guidelines for urological procedures, including indications, benefits, risks involved, and alternatives. At our institution, currently, consent forms are handwritten resulting in generalized or incomplete information given to patients.
Aim
To improve patient understanding of the procedures they are undergoing by providing standardized consent form stickers for procedures as per BAUS guidelines.
Method
Single institution data were collected retrospectively for flexible cystoscopy, stent removal, transrectal ultrasonography (TRUS), and transurethral laser ablation (TULA). Consent forms compared to BAUS guidelines. A standardized consent form sticker for each procedure was developed in accordance with BAUS guidelines and reviewed via the trust's clinical governance process. Clinicians were educated in their use for future consenting.
Results
Consent forms of consecutive patients over a two-month period were analyzed. The initial audit showed that the proportion of patients who had all risks included was 0% for flexible cystoscopy, 0% for TRUS, and 100% for stent removal. Common and rare, but serious risks were not mentioned in all cases. 100% of patients had all risks mentioned for TULA. After education on the consent process and the introduction of consent form stickers, all risks (100%) were mentioned for all procedures.
Conclusions

It is imperative that patients are fully informed about the risks, indications, and alternatives of their treatment. Failure to provide this information in full may lead to unnecessary angst, morbidity, and litigation. Simple quality improvement projects can lead to measurable improvement in patient information.

Improving Consent Forms for Laparoscopic Cholecystectomy; a Visual Consent Form Toolkit

M Jeilani, J Super, M Riad, B Jayasankar

British Journal of Surgery, 19 August 2022; 109(Supplement 6)

Abstract

Aim

Laparoscopic cholecystectomy is a common elective operation with significant complication risks. GMC guidance on consent emphasises informed consent, and failure to warn patients of significant complications can lead to medico-legal implications. We aimed to assess the quality of risk documentation for laparoscopic cholecystectomies performed at our trust. In particular, we aimed to assess improvement since previous cycles after circulation of our boutique 'Visual Consent Form Toolkit', an easily accessible resource for risks associated with common procedures.

Method

Consent forms for 49 elective laparoscopic cholecystectomies performed at a busy district general hospital between September and November 2021 were retrospectively analysed. Risk documentation was audited against a standard of 15 common complications associated with laparoscopic cholecystectomy.

Results

There was significant improvement across the board. Risks previously documented at 100% remained at this level (infection & bleeding). Those previously well-documented showed further improvement (CBD injury, bile leak, damage to local structures, open conversion & VTE). Of those not previously well-documented (the rest), all except two (diarrhoea & pancreatitis) showed improvement. In particular anaesthetic risks, which was emphasised in our toolkit, saw the largest improvement.

Conclusions

Risk documentation on consent forms has overall considerably improved with the circulation of our 'Visual Consent Form Toolkit'. More risks now fully or partially meet the expected standard. From those risks not meeting the expected standard despite numerous audit cycles, we understand that surgeons do not feel these risks should be documented in all situations for all patients, and therefore that an expected standard does not necessarily apply for these risks.

Improving the Quality of Consent Forms in Emergency Laparotomy

S Probert, N Ballanamada Appaiah, L Khan

British Journal of Surgery, 19 August 2022; 109(Supplement 6)

Abstract

Aim

To improve the quality and completion of consent forms for patients undergoing emergency laparotomy.

Methods

A standard for emergency laparotomy consent forms, guided by recommendations from the National Emergency Laparotomy Audit (NELA) was established. This standard was used to score consent forms. Our initial audit of 20 consent forms scored an average of 41.9%. A template sticker, specific to emergency laparotomy, was created. This contains all of the information deemed important by our standard. The sticker allows the surgeon completing the consent process to simply tick off the individual components once discussed with the patient and apply it to the regular consent form. The stickers were introduced to all of those involved in consenting patients, and their use was strongly encouraged.

Results

Consent forms were collected and scored over the following 2-months. Of the 18 consent forms, 33% made use of the consent form sticker, with an average score of 65.2% (improvement of 23.3%). In analysing scores for both the pre- and post-intervention consent forms, we found a P value of < 0.0001.

Conclusions

The use of consent templates specific to surgical procedures improves the quality of consent forms and ensures that all possible complications are discussed with patients. The use of stickers for emergency laparotomy has improved the quality of our consent forms. With ongoing use, we aim to ensure that all patients undergoing this procedure are adequately consented. There remains room for continued improvement, and we believe ongoing exposure to these stickers will lead to an up-take in use.

Patients' views on laparoscopic cholecystectomy consent process: Consent in clinic improves quality of informed consent and patient satisfaction

Peiming Yang

British Journal of Surgery, 9 August 2022; 109(Supplement 5)

Abstract

Aims

Informed consent for elective laparoscopic cholecystectomy should begin at first clinic consultation. Due to clinic time pressures, informed consent is often obtained on the morning of surgery for the first time. This study aims to assess whether consent quality and patients' consent satisfaction are better in clinic compared to day of surgery.

Methods

Retrospective review of all elective laparoscopic surgeries between April and June 2021. Self-administered questionnaire was also completed by the same cohort to ascertain consent satisfaction.

Results

38 patients in total during study period. 16(42.1%) were consented in clinic, and 22 were first consented on day of surgery. 25/38(65.8%) patients prefer to be consented in clinic, 13(34.2%) prefer consent on day of surgery. Significantly higher proportion of consent forms from clinic had full documentation of risks and benefits of cholecystectomy (P<0.001) compared to consents from day of surgery. Significantly higher proportion of patients consented in clinic felt adequately informed of procedure, had alternative options explained to them, were informed regarding recovery process, and felt there was adequate time for consent (P<0.05). Insignificantly higher proportion of patients consented in clinic received information leaflet about procedure. Overall consent satisfaction was significantly higher in patients consented in clinic (77% versus 55%, P=0.048%)

Conclusions

Consent quality and patient satisfaction levels for elective cholecystectomy were statistically significantly higher when consent was carried out in clinic prior to surgery compared to on the day of surgery. We recommend that all elective cholecystectomy consent is performed formally in clinic prior to surgery.

Development of a core outcome set for informed consent for therapy: An international key stakeholder consensus study

Research

Liam J. Convie, Joshua M. Clements, Scott McCain, Jeffrey Campbell, Stephen J. Kirk, Mike Clarke

BMC Medical Ethics, 9 August 2022; 23(79)

Open Access

Abstract

Background

300 million operations and procedures are performed annually across the world, all of which require a patient's informed consent. No standardised measure of the consent process exists in current clinical practice. We aimed to define a core outcome set for informed consent for therapy.

Methods
The core outcome set was developed in accordance with a predefined research protocol and the Core OutcoMes in Effectiveness Trials (COMET) methodology comprising systematic review, qualitative semi structured interviews, a modified Delphi process and consensus webinars to ratify outcomes for inclusion in the final core outcome set. (Registration—https://www.comet-initiative.org/Studies/Details/1024). Participants from all key stakeholder groups took part in the process, including patients and the public, healthcare practitioners and consent researchers.
Results
36 outcome domains were synthesised through systematic review and organised into a consent taxonomy. 41 semi-structured interviews were performed with all consent stakeholders groups. 164 participants from all stakeholder groups across 8 countries completed Delphi Round 1 and 125 completed Round 2. 11 outcomes met the 'consensus in' criteria. 6 met 'consensus in' all stakeholder groups and were included directly in the final core outcome set. 5 remaining outcomes meeting 'consensus in' were ratified over two consensus webinars. 9 core outcomes were included in the final core outcome set: Satisfaction with the quality and amount of information, Patient feeling that there was a choice, Patient feeling that the decision to consent was their own, Confidence in the decision made, Satisfaction with communication, Trust in the clinician, Patient satisfaction with the consent process, Patient rated adequacy of time and opportunity to ask questions.
Conclusion
This international mixed-methods qualitative study is the first of its kind to define a core outcome set for informed consent for intervention. It defines what outcomes are of importance to key stakeholders in the consent process and is a forward step towards standardising future consent research.

Informed Consent Practices in Global Surgery among Plastic Surgery Organizations

Special Topic
Kishan Thadikonda, Rosaline Zhang, Jonathan Bruhn, Phuong D. Nguyen, Samuel O. Poore
Plastic and Reconstructive Surgery, 8 August 2022
Abstract
Background
Global surgery organizations often serve vulnerable and complex patient populations, but there is limited knowledge on the protocols used to obtain informed consent for procedures and content sharing.
Methods
The Plastic Surgery Foundation Volunteers in Plastic Surgery (VIPS) database was queried for organizations actively involved in global surgery. Seventy-nine organizations received email invitations to participate in a survey study regarding their protocols for obtaining consent for procedures and sharing multimedia content.
Results
A total of 17 (22% yield) organizations completed the survey. All were active for at least 10 years and 88% (15/17) organized at least two mission trips annually. Eighty-eight percent (15/17) reported obtaining written consent for surgical procedures. Less than half (46%, 8/17) of used a written consent form that was created jointly with the local hospital. For sharing content related to global surgery experiences, 75% (12/16) obtained some form of written consent while 6% (1/16) did not routinely obtain any consent. Organizations shared content most commonly through their websites and Facebook. All organizations reported using interpreters to obtain informed consent at least some of the time. 62% (10/16) reported that they relied primarily on volunteers or community members to provide informal interpretation assistance, rather than formally trained professional interpreters.
Conclusion
Practices related to obtaining informed consent vary widely among global surgery organizations. The development of standardized protocols and guidelines will ensure that global health organizations, in collaboration with their local partners, properly obtain informed consent for procedures and sharing publicly viewable content.

Are we meeting the standards set for informed consent in spinal surgery?

Y Esemen, A Mostofi, D Richardson, EAC Pereira

Annals of Royal College of Surgeons, 29 July 2022

Abstract

Introduction

Informed consent empowers patients to exercise their autonomy and actively participate in their medical care. Guidance published by the British Association of Spine Surgeons (BASS) lists three components of consent: provision of information booklets, patient-centred dialogue and completion of appropriate consent forms. The aim of the study was to review the quality of the spinal surgery consent process against the BASS guidance in a single tertiary neurosurgery centre in London.

Methods

Retrospective review of clinic letters and consent forms was performed for 100 consecutive cases of elective, non-instrumented spinal decompression surgeries performed in 2019. Documentation was graded for inclusion of the intended benefit (improvement of pain/prevention of neurological deterioration), alternative management options (including no treatment), surgical options and risks (infection, bleeding, paralysis, sphincter disturbances, dural tear and recurrence). Provision of supplementary information booklets was recorded. Two-tailed Fisher exact test was used to calculate statistical significance where appropriate.

Results

Documentation of indications and risks of elective spinal surgery, specifically risk of recurrence (62%) and sphincter disturbance (85%), was suboptimal on the consent forms. Documentation of these risks was also poor in clinic letters (<50%). Alternative treatment options were explained in less than half of the clinic letters, and there was no documentation of information booklet provision prior to elective surgeries.

Conclusion

Lack of informed consent plays a major role in medical malpractice claims in spinal surgery. Poor documentation puts the surgeon in a liable position. BASS guidance could be implemented to create a more standardised process of consent in spinal surgery.

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GENERAL/OTHER

"What are my options?": Physicians as ontological decision architects in surgical informed consent

Original Article

Stacy S. Chen, Sunit Das

Bioethics, 1 August 2022

Abstract

The aim of a theoretically ideal process of informed consent is to promote the autonomy of the patient and to limit unethical physician paternalism. However, in practice, the nature of the medical profession requires physicians to act as ontological decision architects—based on the medical knowledge that they acquire through their experience and training, physicians ontologically determine a subset of viable courses of action for their patient. What is observed is not an unethical physician limitation or biasing of the patient towards certain treatment options that violates patient autonomy or consciously undermines informed consent, but rather a more foundational paternalism that is necessarily inherent to the physician–patient relationship. In this article we argue for a recognition of this underlying physician paternalism and posit that this necessary paternalism is not a foil to patient autonomy, but rather a foundational aspect of the duties of the medical professional within the physician–patient relationship.

Consent — Informed Consent and Requirements of Consent

Book

Kumari K. Nirmala

Health Laws in India, 2022 [Routledge]

Abstract

In the medical treatment, the relationship between the doctor and the patient has been in terms of benevolent paternalism. In ancient times, the obligation of the physician was solely in terms of promoting the welfare of the patient, diagnosing the ailment, and prescribing medicine or surgery, but seldom had they thought about patient's right. But nowadays this locus of the authority in decision making has been shifted from the physician to the patient. A patient will receive all the information that he or she needs in order to make decision as to take treatment or not or a particular operation. There involves the consent of the patient. Consent to treatment is the principle that a person must give permission before they receive any type of medical treatment, test or examination. This must be done on the basis of an explanation by a clinician. Consent from a patient is needed regardless of the procedure, whether it a physical examination, organ donation or something else. The principle of consent is an important part of medical ethics and the international human rights law.

80 The earliest expression of this fundamental principle, based on autonomy, is found in the Nuremberg Code of 1947. The code makes it mandatory to obtain voluntary and informed consent of human subjects. Similarly, the Declaration of Helsinki adopted by the World Medical Association in 1964 emphasizes the importance of obtaining freely given informed consent for medical research by adequately informing the subjects of the aims, methods, anticipated benefits, potential hazards, and discomforts that the study may entail. Several international conventions and declarations have similarly ratified the importance of obtaining consent from patients before testing and treatment.

In India the principle of autonomy is enshrined within Art. 21 of the Indian Constitution, which deals with the right to life and personal liberty. Sec 88 of IPC, provides- Nothing which is not intended to cause death, is an offence to any person for whose benefit it is done in good faith, and who has given a consent. When a tort is committed, meaning that a defendant's actions interfered with the plaintiff's person or property, a plaintiff's consent will excuse the defendant of the wrongdoing.

In the view of the above background, the present chapter proposes to deal briefly with the aspects of laws concerning consent in medical cases, and their implications. The chapter discusses about the capacity to give consent, 'Real' consent in the United Kingdom (UK) and as 'Informed' consent in the United States (US). To account for the Indian position, unlike in the West, the courts have assigned immense significance to the requirement of informed consent. The Honorable Court has in different cases summarized principles relating to consent and the necessity to enact full-fledged laws so as to adjust to the need of the day.

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