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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

October 2020

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" and "informed consent" in title and available text. After careful consideration a selection of these results appear in the digest. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

Informed Consent: A Monthly Review is a service of the Center for Informed Consent Integrity, a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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We organize content in each edition using subject categories to help readers navigate. We expect that these categories will evolve over time.

No new content identified for the following established categories:
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH

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

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COVID-19

Consent in the time of COVID-19

Helen Lynne Turnham, Michael Dunn, Elaine Hill, Guy T Thornburn, Dominic Wilkinson
BMJ Medical Ethics, 26 August 2020; 46(9) pp 565-568
Open Access
Abstract
The COVID-19 pandemic crisis has necessitated widespread adaptation of revised treatment regimens for both urgent and routine medical problems in patients with and without COVID-19. Some of these alternative treatments maybe second-best. Treatments that are known to be superior might not be appropriate to deliver during a pandemic when consideration must be given to distributive justice and protection of patients and their medical teams as well the importance given to individual benefit and autonomy. What is required of the doctor discussing these alternative, potentially inferior treatments and seeking consent to proceed? Should doctors share information about unavailable but standard treatment alternatives when seeking consent? There are arguments in defence of non-disclosure; information about unavailable treatments may not aid a patient to weigh up options that are available to them. There might be justified concern about distress for patients who are informed that they are receiving second-best therapies. However, we argue that doctors should tailor information according to the needs of the individual patient. For most patients that will include a nuanced discussion about treatments that would be considered in other times but currently unavailable. That will sometimes be a difficult conversation, and require clinicians to be frank about limited resources and necessary rationing. However, transparency and honesty will usually be the best policy.

The ethics of deferred consent in times of pandemics

Rieke van der Graaf, Marie-Astrid Hoogerwerf, Martine C. de Vries
Nature Medicine, 10 July 2020; 26 pp 1328–1330
Open Access
Excerpt
In the current COVID-19 pandemic, many researchers are applying to research ethics committees for deferred-consent procedures for protocols that aim either to test treatments or to obtain tissue or samples from research participants. However, the deferred-consent procedure has not been developed for pandemics. In this Comment, we interpret existing guidance documents and argue when and under which conditions deferred consent can be considered ethically acceptable in a pandemic…

The Use of Electronic Consent for COVID-19 Clinical Trials: Lessons for Emergency Care research During a Pandemic and Beyond

Eric Jaton, Jamie Stang, Michelle Biros, Abbey Staugaitis, Julie Scherber, Florian Merkle, Nicholas M. Mohr, Christopher Streib, Lauren Klein, Michael A. Puskarich
Academic Emergency Medicine, 24 September 2020
Open Access
Abstract
The novel SARS-CoV-2 coronavirus poses many unique challenges to the implementation of clinical research, particularly as it relates to the processes of informed consent. Traditional methods of in-person informed consent were no longer plausible, as face-to-face discussions may expose researchers and patients to increased risk of contracting and spreading the virus. In many circumstances the research personnel

obtaining consent were considered non-essential workers, and thus did not have priority for personal protective equipment in light of national shortages.

The Forgotten Element in the Resumption of Elective Bariatric Surgery During the COVID-19 Pandemic: the Patient Consent!

Brief Communication

Mohammed Said, Hosam Hamed

Obesity Surgery, 19 September 2020

Abstract

Safety comes first, and the sympathy with the postponed bariatric patients should not come at the expense of the proper standard of care. This study presents a survey of 266 bariatric candidates who were rescheduled for bariatric surgery after postponement during the COVID-19 pandemic. The aim was to assess their knowledge and expectations regarding bariatric surgery and the risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. A total of 233 (87.6%) candidates believed that they were prone to a higher risk of severe SARS-CoV-2 infection, and 24.4% of them believed that bariatric surgery, during the pandemic, would improve their immunity. A total of 27.8% of candidates attributed the responsibility regarding potential perioperative SARS-CoV-2 infection to the medical personnel, and 10.7% of them believed it to be the surgeon's responsibility.

COVID-19 consent and return to elective orthopaedic surgery allowing a true patient choice?

Timothy M. Clough, Nikhil Shah, Hiren Divecha, Sumedh Talwalkar

Bone Joint Open 2020, 14 September 2020; 1(9) pp 556–561

Abstract

Aims

The exact risk to patients undergoing surgery who develop COVID-19 is not yet fully known. This study aims to provide the current data to allow adequate consent regarding the risks of post-surgery COVID-19 infection and subsequent COVID-19-related mortality.

Methods

All orthopaedic trauma cases at the Wrightington Wigan and Leigh NHS Foundation Trust from 'lockdown' (23 March 2020) to date (15 June 2020) were collated and split into three groups. Adult ambulatory trauma surgeries (upper limb trauma, ankle fracture, tibial plateau fracture) and regional-specific referrals (periprosthetic hip fracture) were performed at a stand-alone elective site that accepted COVID-19-negative patients. Neck of femur fractures (NOFF) and all remaining non-NOFF (paediatric trauma, long bone injury) surgeries were performed at an acute site hospital (mixed green/blue site). Patients were swabbed for COVID-19 before surgery on both sites. Age, sex, nature of surgery, American Society of Anaesthesiologists (ASA) grade, associated comorbidity, length of stay, development of post-surgical COVID-19 infection, and post-surgical COVID-19-related deaths were collected.

Results

At the elective site, 225 patients underwent orthopaedic trauma surgery; two became COVID-19-positive (0.9%) in the immediate perioperative period, neither of which was fatal. At the acute site, 93 patients underwent non-NOFF trauma surgery, of whom six became COVID-19-positive (6.5%) and three died. A further 84 patients underwent NOFF surgery, seven becoming COVID-19 positive (8.3%) and five died.

Conclusion

At the elective site, the rate of COVID-19 infection following orthopaedic trauma surgery was low, at 0.9%. At the acute mixed site (typical district general hospital), for non-NOFF surgery there was a 6.5% incidence of post-surgical COVID-19 infection (seven-fold higher risk) with 50% COVID-19 mortality; for NOFF surgery,

there was an 8.3% incidence of post-surgical COVID-19 infection, with 71% COVID-19 mortality. This is likely to have significance when planning a resumption of elective orthopaedic surgery and for consent to the patient.

Allocation of Resources and Health Professionals' Burden During the Covid-19 Pandemic: Reflection on Advanced Directives, Informed Consent, And Social Perception in Mexico

Karen Herrera-Ferrá, Leonardo Souza-García, Antonio Muñoz-Torres

Online Journal of Health Ethics, 11 August 2020; 16(2)

Open Access

Abstract

One of the main problems in the COVID-19 pandemic is the insufficient availability of resources. This deficiency has resulted in emotional and moral burdens of health professionals. Decisions are having to be made as to who will live and who will die. Moreover, given the global impact of this pandemic, negative impacts are heightened in low and middle-income countries such as Mexico. Authors focus on two issues related to, but not exclusive, to the Mexican healthcare system in an attempt to partially address scarce resources and health professionals' burden. First, is the empowerment of patients' autonomy through the incorporation of advanced directives (i.e. nonresuscitate order, the use of intensive care unit and/or ventilator) within informed consent. And second, the socio-cultural perception of risk as relevant for public engagement on protective behavioral patterns. We argue that addressing these issues could possibly lessen the burden of healthcare professionals and bring about greater autonomy among the public.

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BIOMEDICAL RESEARCH

An audit of questions asked by participants during the informed consent process for regulatory studies at a tertiary referral centre – An analysis of consent narratives

Research Article

Unnati Saxena, Debdipta Bose, Mitesh Kumar Maurya, Nithya Jaideep Gogtay, Urmila Mukund Thatte

Clinical Ethics, 20 September 2020

Abstract

Objective

To evaluate the questions asked during the informed consent process by adult and adolescent participants as well as their parents in five interventional regulatory studies conducted at our center from 2018 to 2019.

Methods

The study protocol was approved by Institutional Ethics Committee [EC/OA-116/2019]. Consent narratives in the source documents for the studies were evaluated. Questions asked were classified as per Indian Council of Medical Research's (ICMR) guidelines (2017). We evaluated total number of questions, nature of questions and whether there was an association between education, gender, phase of trials, physician taking consent and number questions being asked.

Results

A total of five studies that had N = 297 consent narratives were evaluated. Narratives of n = 284 adult participants/Guardians and of n = 13 children were analysed. A total of 374 questions were asked of which children asked only 10 questions. A total of 131/284 (40%) of the participants did not ask any question. Among the participants who asked questions, the majority132/171 (77%) participants asked about risks related to investigational products followed by questions related to study procedures 83/171 (49%). Participants/guardians with higher education (relative to those who were educated upto the secondary

school and primary school) and those who consented for Phase III studies (relative to Phase I studies) asked significantly more questions ($p < 0.0001$).

Conclusion

A majority of the queries were related to the risks associated with the investigational products. Educational status and the Phase of the trial were found to be significantly associated with the number of questions being asked.

Characteristics Associated With Consent and Reasons for Declining in a Randomized Trial in Pregnancy

Original Research

Gail Mallett, Kim Hill, Jessica de Voest, Sabine Bousleiman, Donna Allard, Stacy Harris, Ashley Salazar, Kelly Clark, Felecia Ortiz, Anna Bartholomew, Wendy Dalton, Jennifer Craig, Melissa Bickus,

Obstetrics & Gynecology, 10 September 2020

Abstract

Objective

To evaluate the maternal characteristics associated with consent to a randomized trial of labor induction in pregnancy.

Methods

This is a secondary analysis of low-risk nulliparous women randomized to induction of labor at 39 weeks or expectant management. During the trial, the Data and Safety Monitoring Committee requested additional fields on the screening log, which already included race and ethnicity: maternal age, type of insurance, and the reason for declining consent if declined.

Results

From August 2016 (start of additional data collection) to August 2017, 1,965 (28%) of the 7,112 eligible women consented to the trial. Consent was more likely for Black women (41%, adjusted odds ratio [aOR] 1.47, 95% CI 1.24–1.74), and less likely for Asian women (15%, aOR 0.64, 95% CI 0.48–0.84), compared with White women (24%). Women without private insurance were more likely to consent (38%, aOR 1.55, 95% CI 1.34–1.79), compared with those with private insurance (22%). Younger women were also more likely to consent. Among eligible women who declined participation and provided a reason (68%), preference to be expectantly managed (85%) was most common, a response more common in Asian women (aOR 1.75, 95% CI 1.31–2.33) and less common in women without private insurance (aOR 0.60, 95% CI 0.51–0.70). Not wanting to participate in research was more common in Asian women (aOR 2.41, 95% CI 1.44–4.03). Declining consent because family or friends objected was more common in Asian women (aOR 2.51, 95% CI 1.27–4.95) and women without private insurance (aOR 1.68, 95% CI 1.10–2.59).

Conclusion

Frequency of consent and reasons for declining consent were associated with age, type of insurance, and race and ethnicity. These findings should be considered when developing recruitment strategies that promote diverse participant representation.

The Informed Consent Process in Health Research with Under-served Populations: A Realist Review Protocol

Eleanor Hoverd, Sophie Staniszewska, Jeremy Dale

Research Square, 9 September 2020

Open Access

Abstract

Background

The informed consent process aims to provide potential participants with information about health research that enables them to make an informed decision as to whether they choose to participate, or not. However,

it remains unclear as to whether the process is effective for those whom are under-served in health research. It is a pivotal issue within health research that the diversity of people who participate is broadened. The National Institute for Health Research (NIHR) pledges to support equality, diversity and inclusion, actively creating opportunities for all citizens whom are eligible, to take part in health research.

Methods

In order to understand how the informed consent process for under-served populations in health research works, under what circumstances and in what respects, a realist review approach will be undertaken. Searches will be carried out using electronic databases (EMBASE, MEDLINE, Web of Science and PsychInfo), along with selected websites and grey literature. Development of initial rough programme theory(ies) will lead to a more refined programme theory that will provide an explanation of context, mechanism and outcomes. Stakeholder involvement by NIHR (Public) Research Champions, health professionals and clinical academics will provide expert opinion about concepts and programme theory.

Discussion

Findings of this realist review will highlight how the informed consent process in health research affects the experience and decision-making process of potential participants from under-served populations. They will be written up in accordance with RAMESES guidelines and disseminated to patients and the public, health researchers, health professionals and policymakers through peer-reviewed publication, presentations and discussions. The review will contribute to our understanding of the mechanisms that trigger both positive and negative outcomes in the informed consent process for those whom are often under-represented in health research to inform policy, study design and delivery.

Readability and understandability of clinical research patient information leaflets and consent forms in Ireland and the UK: a retrospective quantitative analysis

Original Research

Lydia O'Sullivan, Prasanth Sukumar, Rachel Crowley, Eilish McAuliffe, Peter Doran

Ethics, 3 September 2020

Abstract

Objectives

The first aim of this study was to quantify the difficulty level of clinical research Patient Information Leaflets/Informed Consent Forms (PILs/ICFs) using validated and widely used readability criteria which provide a broad assessment of written communication. The second aim was to compare these findings with best practice guidelines.

Design

Retrospective, quantitative analysis of clinical research PILs/ICFs provided by academic institutions, pharmaceutical companies and investigators.

Setting

PILs/ICFs which had received Research Ethics Committee approval in the last 5 years were collected from Ireland and the UK.

Intervention

Not applicable.

Main outcome measures

PILs/ICFs were evaluated against seven validated readability criteria (Flesch Reading Ease, Flesh Kincaid Grade Level, Simplified Measure of Gobbledegook, Gunning Fog, Fry, Raygor and New Dale Chall). The documents were also scored according to two health literacy-based criteria: the Clear Communication Index (CCI) and the Suitability Assessment of Materials tool. Finally, the documents were assessed for compliance with six best practice metrics from literacy agencies.

Results

A total of 176 PILs were collected, of which 154 were evaluable. None of the PILs/ICFs had the mean reading age of <12 years recommended by the American Medical Association. 7.1% of PILs/ICFs were evaluated as

'Plain English', 40.3%: 'Fairly Difficult', 51.3%: 'Difficult' and 1.3%: 'Very Difficult'. No PILs/ICFs achieved a CCI >90. Only two documents complied with all six best practice literacy metrics.

Conclusions

When assessed against both traditional readability criteria and health literacy-based tools, the PILs/ICFs in this study are inappropriately complex. There is also evidence of poor compliance with guidelines produced by literacy agencies. These data clearly evidence the need for improved documentation to underpin the consent process.

Seven-step framework to enhance practitioner explanations and parental understandings of research without prior consent in paediatric emergency and critical care trials

Original Research

Louise Roper, Mark D Lyttle, Carrol Gamble, Amy Humphreys, Shrouk Messahel, Elizabeth D Lee, Joanne Noblet, Helen Hickey, Naomi Rainford, Anand Iyer, Richard Appleton

BMJ Emergency Medicine Journal, 29 August 2020

Abstract

Background

Alternatives to prospective informed consent enable the conduct of paediatric emergency and critical care trials. Research without prior consent (RWPC) involves practitioners approaching parents after an intervention has been given and seeking consent for their child to continue in the trial. As part of an embedded study in the 'Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus in children' (EcLiPSE) trial, we explored how practitioners described the trial and RWPC during recruitment discussions, and how well this information was understood by parents. We aimed to develop a framework to assist trial conversations in future paediatric emergency and critical care trials using RWPC.

Methods

Qualitative methods embedded within the EcLiPSE trial processes, including audiorecorded practitioner–parent trial discussions and telephone interviews with parents. We analysed data using thematic analysis, drawing on the Realpe et al (2016) model for recruitment to trials.

Results

We analysed 76 recorded trial discussions and conducted 30 parent telephone interviews. For 19 parents, we had recorded trial discussion and interview data, which were matched for analysis. Parental understanding of the EcLiPSE trial was enhanced when practitioners: provided a comprehensive description of trial aims; explained the reasons for RWPC; discussed uncertainty about which intervention was best; provided a balanced description of trial intervention; provided a clear explanation about randomisation and provided an opportunity for questions. We present a seven-step framework to assist recruitment practice in trials involving RWPC.

Conclusion

This study provides a framework to enhance recruitment practice and parental understanding in paediatric emergency and critical care trials involving RWPC. Further testing of this framework is required.

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GENOMIC MEDICINE/GENE EDITING

Participant Reactions to a Literacy-Focused, Web-Based Informed Consent Approach for a Genomic Implementation Study

Research Article

Stephanie A. Kraft, Kathryn M. Porter, Devan M. Duenas, Claudia Guerra, Galen Joseph, Sandra Soo-Jin Lee, Kelly J. Shipman, Jake Allen, Donna Eubanks, Tia L. Kauffman, Nangel M. Lindberg, Katherine Anderson,

Jamilyn M. Zepp, Marian J. Gilmore, Kathleen F. Mittendorf, Elizabeth Shuster, Kristin R. Muessig, Briana Arnold, Katrina A.B Goddard, Benjamin S. Wilfond

AJOB Empirical Bioethics, 26 September 2020

Abstract

Background

Clinical genomic implementation studies pose challenges for informed consent. Consent forms often include complex language and concepts, which can be a barrier to diverse enrollment, and these studies often blur traditional research-clinical boundaries. There is a move toward self-directed, web-based research enrollment, but more evidence is needed about how these enrollment approaches work in practice. In this study, we developed and evaluated a literacy-focused, web-based consent approach to support enrollment of diverse participants in an ongoing clinical genomic implementation study.

Methods

As part of the Cancer Health Assessments Reaching Many (CHARM) study, we developed a web-based consent approach that featured plain language, multimedia, and separate descriptions of clinical care and research activities. CHARM offered clinical exome sequencing to individuals at high risk of hereditary cancer. We interviewed CHARM participants about their reactions to the consent approach. We audio recorded, transcribed, and coded interviews using a deductively and inductively derived codebook. We reviewed coded excerpts as a team to identify overarching themes.

Results

We conducted 32 interviews, including 12 (38%) in Spanish. Most (69%) enrolled without assistance from study staff, usually on a mobile phone. Those who completed enrollment in one day spent an average of 12 minutes on the consent portion. Interviewees found the information simple to read but comprehensive, were neutral to positive about the multimedia support, and identified increased access to testing in the study as the key difference from clinical care.

Conclusions

This study showed that interviewees found our literacy-focused, web-based consent approach acceptable; did not distinguish the consent materials from other online study processes; and valued getting access to testing in the study. Overall, conducting empirical bioethics research in an ongoing clinical trial was useful to demonstrate the acceptability of our novel consent approach but posed practical challenges.

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BIOBANKING

Research participant understanding and engagement in an institutional, self-consent biobank model

Original Article

Andrew Schmanski, Emily Roberts, Marilyn Coors, Stephen J. Wicks, Jaron Arbet, Rachel Weber, Kristy Crooks, Kathleen C. Barnes, Matthew R. G. Taylor

Journal of Genetic Counselling, 20 September 2020

Abstract

The number of institutional and governmental biobanks and the target enrollment sizes of modern biobanks are increasing, affording more opportunities for the public to participate in biobanking efforts. In parallel with these expansions are pressures to increase the efficiency of obtaining informed consent using shorter consent forms that cover a broader scope of research and increasingly include provisions for return of research or clinical genetic test results to participants. Given these changes, how well these participants understand genetics, their level of understanding of what they are consenting to, and their wishes to engage longitudinally and receive biobank results are not well understood. We surveyed participants in a large, medical system-based biobank who had enrolled through a two-page, self-consent process about their baseline knowledge of genetics, understanding and recall of the consent process, wishes for future contact

and engagement, and level of interest in receiving clinical genetic testing results. A total of 856 consented persons participated in the survey (67% women; 67% white). Participants' general reported genetics knowledge was relatively high (mean 11.60 of 15 questions answered correctly) as was recall of key elements from the two-page consent form. Overall participant enthusiasm for future contact by the biobank and for receiving clinical genetic testing results was high. The use of a two-page, self-consent process in a large, institutional biobank resulted in high levels of consent recall and enthusiasm for future ongoing engagement and receipt of genetic testing results by participants.

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TECHNOLOGY/OTHER MEDIATION

Informed Consent Smart Phone App Improved Level of Comfort and Knowledge Amongst Pediatric Residents

Cassandra Koid Jia Shin, Tania Lopez, Edwin Forman, Gwen Raphan
Academic Pediatrics, September–October 2020; 20(7) pp e12-e13
Abstract
Background
Obtaining informed consent is an integral part of medicine yet is a skill set that is not typically taught to residents formally. Lack of skill and confidence obtaining informed consent can have dire medical-legal consequences. Therefore, we created an informed consent smartphone app to give providers this information at their fingertips so they can successfully obtain informed consent on several common pediatric procedures in a more standardized fashion. Our objective was to assess if pediatric residents knowledge and comfort with obtaining informed consent would increase with an informed consent app.
Methods
A prototype smartphone app was designed on Adobe XD with a standardized approach to obtaining informed consent for pediatric procedures (RBC and platelet transfusions, LP, conscious sedation, central lines and vitamin K refusal). In 2020, an anonymous pre-intervention questionnaire was circulated amongst pediatric residents in Elmhurst Hospital Center. Participants were given an opportunity to navigate the informed consent app and given a post-intervention survey.
Results
Of the 25 residents who participated, all had previously obtained consent. Most learned how to obtain consent by observing another resident (72%) and surprisingly, 12% report that they obtained consent without any preparation at all. Self-reported level of comfort for procedures increased proportionally with every year of training. Residents' comfort obtaining informed consent improved for every procedure after use of the informed consent app. 100% were comfortable obtaining informed consent with the app for all procedures with the exception of central lines which was not functioning on the app. 96% of residents agree that they would benefit from additional training in obtaining informed consent. 100% of residents agree that they would use the informed consent app.
Conclusions
With the informed consent app, residents' level of comfort increased for all procedures. This quick intervention showed promise as an easy way for residency programs to standardize an approach to obtaining informed consent.

Effect of video-assisted education on informed consent and patient education for peripherally inserted central catheters: a randomized controlled trial

Perspective Clinical Research Report
Jia Li, Xue-fang Huang, Jie-lin Luo, Jiang-yun Zhang, Xiao-lin Liang, Chun-li Huang, Hui-ying Qin
Journal of International Medical Research, 10 September 2020; 48(9)

Open Access
Abstract
Objective
To evaluate the effects of a video-assisted education intervention on informed consent and patient education for peripherally inserted central catheters (PICCs).
Methods
We conducted a randomized controlled trial comparing the effects on informed consent of video-assisted patient education and traditional face-to-face discussion in a catheter outpatient ward of a cancer centre in Guangzhou, China, in 2018. Participants were 140 patients randomly allocated (1:1 ratio) to two groups: video-assisted or traditional intervention. General information, patient retention of PICC-related information, working time spent by nurses on the procedure, and patient and nurse satisfaction with the procedure were assessed.
Results
The time used for informed consent was significantly shorter in the experimental group (1.02 ± 0.24 minutes) than in the control group (6.87 ± 1.10 minutes). The time used for PICC-related education was significantly shorter in the experimental group (1.03 ± 0.28 minutes) than in the control group (5.11 ± 0.57 minutes). Nurses' degree of satisfaction with the procedure was significantly higher in the experimental group (4.10 ± 0.57) than in the control group (2.60 ± 0.70).
Conclusion
The use of video-assisted informed consent and patient education in this cancer centre decreased nurses' working time and improved nurses' satisfaction.

Pictorial Consent in Cardiac Surgery: A far better option rather than Standard Informed Written Consent

Debmalya Saha, Pawan Singh, Soumyaranjan Das, Ravi Kumar Gupta, Satyajit Samal, Muhammad Abid Geelani
International Journal of Scientific and Research Publications, September 2020; 10(9)
Open Access
Abstract
Because of the complexity of the procedures, high level of clarification for the patients as well as their attendants while taking consent is a must as cardiac surgery is associated with significant morbidity and mortality. Pictorial consent with preoperative education is a far better option in this regard. We randomly took a total of 150 patients within the age group of 18 to 70 years, and they were explained with standard consent followed by pictorial consent and vice versa by the same informant. And they were given a preset questionnaire format after both consents. Later, based on their answers, comparison in relation to the level of clarity was done. Questionnaire was formatted after rigorous modification from the reviews of literature.

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CAPACITY TO CONSENT

How do dementia researchers view support tools for informed consent procedures of persons with dementia?

Original Contributions
Theresa S. Wied, Aoife Poth, Johannes Pantel, Frank Oswald, Julia Haberstroh
Zeitschrift für Gerontologie und Geriatrie, 19 September 2020
Open Access
Abstract

The study aimed to assess how dementia researchers view eight support tools that have been defined to enhance informed consent (IC) procedures for people with dementia (PwD). In an online survey, 19 dementia researchers from Germany and Portugal evaluated the tools in terms of 4 implementation criteria. Overall, they all had a very positive attitude towards the support tools, whereby the tools person-centered attitude of the researcher and elaborated plain language were the most highly rated of the eight tools. Our findings also indicated that familiar support tools were assessed more favorably than those that were previously unknown. Overall, the results of this study showed that the participating dementia researchers were open to the use of decision support measures in PwD and were willing to apply the support tools in practice.

Awareness and Understanding of Decision-Making Capacity and Its Relationship to Legally Valid Consent for Older Patients in Dentistry

Research Article

Amardeep Singh Dhadwal, Lwazi Sibanda, Igor R. Blum

Primary Dental Journal, 17 September 2020

Abstract

With a growing ageing population and increased life expectancy in the UK, oral healthcare professionals will be exposed to a greater number of patients with health conditions which may affect cognitive function, communication and capacity to consent to treatment. This often gives rise to a conundrum which clinicians may face when considering capacity, consent and the legal implications and frameworks surrounding this. Assessing patient capacity is encountered routinely in dental practice and so oral healthcare professionals should be well informed of their responsibilities in this context. This article summarises and introduces readers to key concepts regarding consent and capacity with reference to relevant cross-jurisdictional legislation.

Constructing authentic decisions: proxy decision-making for research involving adults who lack capacity to consent

Victoria Shepherd, Mark Sheehan, Kerenza Hood, Richard Griffith, Fiona Wood

BMJ Medical Ethics, 2 September 2020

Open Access

Abstract

Research involving adults who lack capacity to consent relies on proxy (or surrogate) decision-making. Proxy decisions about participation are ethically complex, with a disparity between normative accounts and empirical evidence. Concerns about the accuracy of proxies' decisions arise, in part, from the lack of an ethical framework which takes account of the complex and morally pluralistic world in which proxy decisions are situated. This qualitative study explored the experiences of family members who have acted as a research proxy in order to develop an understanding of the ethical concepts involved, and the interactions between those concepts. Proxies described a complex process of respecting the wishes and preferences of the person they represented, whist integrating preferences with what they viewed as being in the interests of the person. They aimed to make a decision that was 'best' for the person and protected them from harm; they also aimed to make the 'right' decision, viewed as being authentic to the person's values and life. Decisions were underpinned by the relationship between the person and their proxy, in which both trust and trustworthiness were key. Proxies' decisions, based both on respect for the person and the need to protect their interests, arose out of their dual role as both proxy and carer. The findings raise questions about accounts which rely on existing normative assumptions with a focus on accuracy and discrepancy, and which fail to take account of the requirement for proxies to make authentic decisions that arise out of their caring obligations.

POLST Signature Requirements: Responding With Compassion While Ensuring Informed Consent

Research Article

Robert Macauley, Susan Tolle

American Journal of Hospice and Palliative Medicine, 1 September 2020

Open Access

Abstract

The majority of states require the signature of a surrogate decision maker on a POLST form for a patient who lacks decisional capacity. While commendable in its intention to ensure informed consent, in some cases this may lead the surrogate to feel that they are signing their loved one's "death warrant," adding to their emotional and spiritual distress. In this paper we argue that such a signature should be recommended rather than required, as it is neither a sufficient nor necessary condition of informed consent. Additional steps—such as requiring the attestation and documentation of the signing health care professional that verbal consent was fully informed and voluntary—can achieve the ultimate goal of respecting patient autonomy without adding to the surrogate's burden.

Who Has the Ability to Consent?

Downey VA, Zun L

The Primary Care Companion for CNS Disorders, 19 August 2020; 22(4)

Abstract

Objective

Previous studies have shown no consistent examinations for testing the ability of patients to consent in hospital emergency departments (EDs). The primary objective of this study was to compare providers' opinions with 3 capacity assessment tools to determine the ability of medical and psychiatric patients to consent in the ED.

Method

The study was conducted at a level 1 inner-city general hospital ED from June 2016 to October 2017. The study participants comprised a random sample of English-speaking patients aged ≥ 18 years who presented with any medical or psychiatric complaint. Each patient was administered 3 tools: the standard ED consent form, the Aid to Capacity Evaluation (ACE), and the Mini-Mental State Examination. The results of these assessments were then compared to the provider's opinion of the patient's ability to provide consent.

Results

A total of 283 patients participated in the study, and 84.4% were able to consent according to providers. There was a high level of consistency with the provider's assessment and the other assessment tools on the patient's ability to consent. Most patients, both medical and psychiatric, showed the ability to consent. However, this was less true for psychiatric patients with schizophrenia, as 32.6% (n = 14) were unable to consent.

Conclusions

The study revealed that the ACE capacity assessment was highly consistent with the providers' assessment for medical (88.3%) and psychiatric patients (80.3%), but not for psychiatric patients with schizophrenia. Using the ACE, patients with schizophrenia presenting to the ED were significantly less able to understand their illnesses (0.01) and treatments (0.04) and thus were less able to give consent.

Investigating assumptions of vulnerability: A case study of the exclusion of psychiatric inpatients as participants in genetic research in low- and middle-income contexts

Andrea C. Palk, Mary Bitta, Eunice Kamaara, Dan J. Stein, Ilina Singh

Bioethics, 14 January 2020

Abstract

Psychiatric genetic research investigates the genetic basis of psychiatric disorders with the aim of more effectively understanding, treating, or, ultimately, preventing such disorders. Given the challenges of

recruiting research participants into such studies, the potential for long-term benefits of such research, and seemingly minimal risk, a strong claim could be made that all non-acute psychiatric inpatients, including forensic and involuntary patients, should be included in such research, provided they have capacity to consent. There are tensions, however, regarding the ethics of recruiting psychiatric inpatients into such studies. In this paper our intention is to elucidate the source of these tensions from the perspective of research ethics committee interests and decision-making. We begin by defining inpatient status and outline some of the assumptions surrounding the structures of inpatient care. We then introduce contemporary conceptions of vulnerability, including Florencia Luna's account of vulnerability which we use as a framework for our analysis. While psychiatric inpatients could be subject to consent-related vulnerabilities, we suggest that a particular kind of exploitation-related vulnerability comes to the fore in the context of our case study. Moreover, a subset of these ethical concerns takes on particular weight in the context of genetic research in low- and middle-income countries. At the same time, the automatic exclusion of inpatients from research elicits justice-related vulnerabilities.

Prevalence of the Inability to Give Informed Consent in the Elderly Orthopaedic Trauma Population [DISSERTATION]

David G. Clossey

Harvard Medical School Doctoral Dissertation, 2020

Abstract

Purpose

Despite the fact that fractures are a leading cause of morbidity in the elderly, a study of the prevalence of the inability to give informed consent in the elderly orthopaedic trauma population has, to the best of our knowledge, not been performed. In addition, the condition of mild cognitive impairment (MCI) has become increasingly recognized since the introduction of the Montreal Cognitive Assessment (MoCA). By simultaneously determining capacity for consent (by clinician gestalt – the gold standard) and degree of cognitive impairment (by utilizing the MoCA), we hope to better understand the relationship between the ability to consent and MCI as well as the specific components of cognition that may allow for decision-making capacity (DMC).

Methods

This prospective study was carried out at Brigham and Women's Hospital (BWH). English and Spanish speaking patients older than 65 who were admitted for orthopaedic injury requiring surgical management were included in the study. Those who had previously known dementia and delirium were excluded from the study, as well as those who were unable to communicate. (NB: A recent IRB amendment has now allowed us going forward to approach certain patients with known dementia and delirium). Attending physicians determined whether or not a patient had DMC. Independently, a research staff member administered the confusion assessment method (CAM) short form to screen for delirium and the MoCA to screen for cognitive impairment. Various other background data were obtained retrospectively.

Results

While the prevalence of the inability to give informed consent cannot be determined since the project is still actively recruiting patients, we hypothesize that this prevalence is at least 15.6%. While patients with DMC had various demographic data characteristic of the elderly orthopaedic trauma population, 81.8% had an abnormal total MoCA score. Participants generally scored worse on tasks assessing for certain cognitive domains, such as visuospatial/executive function tasks (mean score: 46.7%) and the delayed recall task (mean score: 40%). The vast majority of participants (90.5%) who struggled with the delayed recall task were, however, able to remember additional words with category and/or multiple choice clues. None of the participants had a positive screen for delirium.

Conclusions

Mild cognitive impairment at the time of consent appears not to preclude a patient from having DMC. Although the relationship between cognitive ability and DMC remains not well understood, further conclusions regarding early cases of dementia should be studied going forward. Deficits in certain domains of

cognitive thinking may be correlated with an inability to give informed consent, although a comparison of testing results between patients with versus without DMC will be required to further understand this idea.

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YOUNG PERSONS

Consent to Trainee Involvement in Pediatric Care

Emily A. Largent
New England Journal of Medicine, 17 September 2020
Audio Interview
Interview with Dr. Michael Greene on considerations regarding the consent process for procedures performed by medical students and residents. [09:09]
Excerpt
…Consent to the involvement of students, interns, and residents in the care of children has received scant attention as compared with consent for either care or research. But there are compelling reasons for routinely obtaining children's assent to trainee involvement…

Enrolment of children in clinical research: Understanding Ghanaian caregivers' perspectives on consent/assent procedures, and their attitudes towards storage of biological samples for future use

Research Article
George O Adjei, Amos Laar, Jorgen AL Kurtzhals, Bamenla Q Goka
Clinical Ethics, 13 September 2020
Abstract
Child assent is recommended in addition to parental consent when enrolling children in clinical research; however, appreciation and relevance ascribed to these concepts vary in different contexts, and information on attitudes towards storage of biological samples for future research is limited, especially in developing countries. We assessed caregivers' understanding and appreciation of consent and assent procedures, and their attitudes towards use of stored blood samples for future research prior to enrolling a child in clinical research. A total of 17 in-depth interviews were conducted with primary caregivers of children (fathers [n = 3], mothers [n = 12], and grandmothers [n = 2]) at enrolment or on the immediate follow-up date. All caregivers recalled significant amount information from the study information sheet and were able to appropriately link such information to the consent process. While all participants confirmed information received prior to blood sampling as adequate, a few noted that the purpose was not sufficiently well communicated. Caregivers felt children were cognitively vulnerable, and prone to decisions that were not necessarily in their best interest. Nearly all caregivers felt it was their right and responsibility to overrule objections from their ward's regarding enrolment into specific study or receipt of a therapeutic procedure. There were no objections or concerns regarding use of stored biological samples for future research purposes. There is thus, a need to improve understanding of caregivers on the information provided during the informed consent process. Context-specific studies on the age of assent in specific populations are needed.

Editor's note: This article also appears under CULTURAL/COUNTRY CONTEXT

A Consent Support Resource with Benefits and Harms of Vaccination Does Not Increase Hesitancy in Parents—An Acceptability Study

Ciara McDonald, Julie Leask, Nina Chad, Margie Danchin, Judith Fethney, Lyndal Trevena

Vaccines, 2 September 2020; 8(500)
Open Access
Abstract
It is unclear whether information given about the benefits and risks of routine childhood vaccination during consent may cue parental vaccine hesitancy. Parents were surveyed before and after reading vaccine consent information at a public expo event in Sydney, Australia. We measured vaccine hesitancy with Parent Attitudes about Childhood Vaccine Short Scale (PACV-SS), informed decision-making with Informed Subscale of the Decisional Conflict Scale (DCS-IS), items from Stage of Decision Making, Positive Attitude Assessment, Vaccine Safety and Side Effect Concern, and Vaccine Communication Framework (VCF) tools. Overall, 416 parents showed no change in vaccine hesitancy (mean PACV-SS score pre = 1.97, post = 1.94; diff = −0.02 95% CI −0.10 to 0.15) but were more informed (mean DCS-IS score pre = 29.05, post = 7.41; diff = −21.63 95% CI −24.17 to −18.56), were more positive towards vaccination (pre = 43.8% post = 50.4%; diff = 6.5% 95% CI 3.0% to 10.0%), less concerned about vaccine safety (pre = 28.5%, post = 23.0%, diff = −5.6% 95% CI −2.3% to −8.8%) and side effects (pre = 37.0%, post = 29.0%, diff = −8.0% 95% CI −4.0% to −12.0%) with no change in stage of decision-making or intention to vaccinate. Providing information about the benefits and risks of routine childhood vaccination increases parents' informed decision-making without increasing vaccine hesitancy.

Article 5: The Role of Parents in the Proxy Informed Consent Process in Medical Research involving Children

Research Article
Sheila Varadan
The International Journal of Children's Rights 24 August 2020; 28(3) pp 521-546
Open Access
Abstract
Medical research involving child subjects has led to advances in medicine that have dramatically improved the lives, health and well-being of children. Yet, determining when and under what conditions a child should be enrolled in medical research remains an ethically vexing question in research ethics. At the crux of the issue is the free and informed consent of the child participant. A child, who is presumed legally incompetent, or lacks sufficient understanding to exercise autonomous decision-making, will not be able to express free and informed consent in the research setting. Rather than exclude all such children from medical research, a parent (or legal guardian) is designated as a proxy to consent on the child's behalf. However, the concept of proxy informed consent and the framework for its implementation present practical and ethical challenges for researchers, particularly in navigating the relationship between proxy decision-makers and child subjects in the medical research setting. Article 5 of the uncrc may offer guidance on this point: (1) it places boundaries around how parental authority should be exercised; (2) it offers a model for parent-child decision-making that is participatory, collaborative and linked to the child's enjoyment of rights under the uncrc; (3) it respects and supports the autonomy of child participants by recognising their evolving capacities to give informed consent. This paper concludes that greater consideration should be given to Article 5 as a complementary framework for researchers engaged in medical research involving children.

Assessing Children's Capacity: Reconceptualising our Understanding through the UN Convention on the Rights of the Child

Research Article
Aoife Daly
The International Journal of Children's Rights, 24 August 2020; 28(3) pp 471-499
Open Access
Abstract

This article seeks to reconceptualise approaches to assessing children's capacity, particularly in light of Article 5 of the crc, which enshrines the principle of the evolving capacities of the child. Professionals regularly assess children's capacity, for example when doctors treat children, or when lawyers represent child clients. They usually do this assessment intuitively however, as there is little guidance on how assessment should work in practice. Medical law in England and Wales serves as a case study to examine law and practice as well as challenges in the area. It is concluded that it may not necessarily be possible objectively to measure children's capacity, and it may need to be done intuitively. Yet it should be done via a process which is rights-based. An approach to children's capacity is proposed through four concepts based on the UN Convention on the Rights of the Child: Autonomy, Evidence, Support and Protection.

Challenges in obtaining consent for caesarean delivery in minors in South Africa

N C Ngene, T Bodiba

South African Journal of Obstetrics and Gynaecology, June 2020; 26(1)

Open Access

Abstract

A 16-year-old primigravida at term developed fetal compromise in the second stage of labour and had a delayed caesarean delivery (CD) because she declined the procedure after the medical manager had consented on her behalf following the unavailability of her parents. The baby that was delivered suffered neonatal encephalopathy. This report provides a recommendation on how to improve the process of obtaining consent for CD in minors in South Africa.

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RIGHTS/LEGAL/LEGISLATIVE

Informed consent to clinical research in India: A private law remedy

Research Article

Himani Bhakuni

Medical Law International, 23 September 2020

Abstract

There is a well-established common law doctrine for ascertaining information disclosure in informed consent claims within the treatment context that governs the doctor–patient relationship. But there is no such doctrine in clinical research governing the researcher–participant relationship in India. India, however, is not exceptional in this regard. Common law countries like the United States and Canada at most have sparse, non-systematised, criteria for such cases; arguably, a doctrine for research is at its nascent stage. But the adequacy of the existing criteria for settling informed consent claims in research has hardly ever been discussed. Furthermore, a specific discussion on the applicability of this 'nascent doctrine' to India is non-existent. This article discusses both. The article examines case law from India and other common law jurisdictions that hint at developments in this area. It suggests that Indian courts need to move abreast with other jurisdictions to better protect India's patients and research participants.

Informed consent, Montgomery and the duty to discuss alternative treatments in England and Australia

Research Article

Tracey Carver

Journal of Patient Safety and Risk Management, 9 September 2020

Abstract

The UK Supreme Court in Montgomery v Lanarkshire Health Board imposes a duty on healthcare professionals in relation to information disclosure. The obligation is to take reasonable care to ensure that patients are aware, not just of material risks inherent in any recommended treatment, but of any reasonable alternative treatments. While liability for information non-provision was previously decided according to whether the profession would deem disclosure appropriate, the law now judges the sufficiency of information from a patient's perspective. In doing so, it adopts the approach advocated for Australia in Rogers v Whitaker. However, commentators, in this journal and elsewhere, have expressed concern that the disclosure obligation is unclear. Although Montgomery defines what is 'material' for the purpose of identifying notifiable treatment risks, it offers less guidance as to when alternative treatments will be sufficiently 'reasonable' to warrant disclosure. Through an analysis of Australian and UK case law and examples, this article considers the ambit of a practitioner's duty to discuss alternatives. It concludes that although likely subject to further litigation, the identification of reasonable treatment options requiring disclosure will be influenced by the patient's clinical condition, their prognosis and viable options from a medical perspective, and various non-clinical matters influenced by the test of materiality.

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CULTURAL/COUNTRY CONTEXT

Informed Consent for Mobile Phone Health Surveys in Colombia: A Qualitative Study

Research Article

Mariana Rodriguez-Patarroyo, Angelica Torres-Quintero, Andres I. Vecino-Ortiz, Kristina Hallez, Aixa Natalia Franco-Rodriguez, Eduardo A. Rueda Barrera, Stephanie Puerto, Dustin G. Gibson, Alain Labrique, George W. Pariyo, Joseph Ali

Journal of Empirical Research on Human Research Ethics, 25 September 2020

Abstract

Public health surveys deployed through automated mobile phone calls raise a set of ethical challenges, including succinctly communicating information necessary to obtain respondent informed consent. This study aimed to capture the perspectives of key stakeholders, both experts and community members, on consent processes and preferences for participation in automated mobile phone surveys (MPS) of non-communicable disease risk factors in Colombia. We conducted semi-structured interviews with ethics and digital health experts and focus group discussions with community representatives. There was meaningful disagreement within both groups regarding the necessity of consent, when the purpose of a survey is to contribute to the formulation of public policies. Respondents who favored consent emphasized that consent communications ought to promote understanding and voluntariness, and implicitly suggested that information disclosure conform to a reasonable person standard. Given the automated and unsolicited nature of the phone calls and concerns regarding fraud, trust building was emphasized as important, especially for national MPS deployment. Community sensitization campaigns that provide relevant contextual information (such as the name of the administering institution) were thought to support trust-building. Additional ways to achieve the goals of consent while building trust in automated MPS for disease surveillance should be evaluated in order to inform ethical and effective practice.

Enrolment of children in clinical research: Understanding Ghanaian caregivers' perspectives on consent/assent procedures, and their attitudes towards storage of biological samples for future use

Research Article

George O Adjei, Amos Laar, Jorgen AL Kurtzhals, Bamenla Q Goka

Clinical Ethics, 13 September 2020

Abstract

Child assent is recommended in addition to parental consent when enrolling children in clinical research; however, appreciation and relevance ascribed to these concepts vary in different contexts, and information on attitudes towards storage of biological samples for future research is limited, especially in developing countries. We assessed caregivers' understanding and appreciation of consent and assent procedures, and their attitudes towards use of stored blood samples for future research prior to enrolling a child in clinical research. A total of 17 in-depth interviews were conducted with primary caregivers of children (fathers [n = 3], mothers [n = 12], and grandmothers [n = 2]) at enrolment or on the immediate follow-up date. All caregivers recalled significant amount information from the study information sheet and were able to appropriately link such information to the consent process. While all participants confirmed information received prior to blood sampling as adequate, a few noted that the purpose was not sufficiently well communicated. Caregivers felt children were cognitively vulnerable, and prone to decisions that were not necessarily in their best interest. Nearly all caregivers felt it was their right and responsibility to overrule objections from their ward's regarding enrolment into specific study or receipt of a therapeutic procedure. There were no objections or concerns regarding use of stored biological samples for future research purposes. There is thus, a need to improve understanding of caregivers on the information provided during the informed consent process. Context-specific studies on the age of assent in specific populations are needed.

Editor's note: This article also appears under YOUNG PERSONS

Graduate students reported practices regarding the issue of informed consent and maintaining of data confidentiality in a developing country

Research Article

Samer Swedan, Omar F. Khabour, Karem H. Alzoubi, Alaa A.A. Aljabali

Heliyon, 9 September 2020; 6(9)

Abstract

Research involving human subjects requires strict adherence to ethical principles, including informed consent and assuring data confidentiality. Herein, a questionnaire was utilized to assess compliance of graduate students who conduct research involving human subjects in Jordan with proper practices related to informed consent and maintaining of data confidentiality. Among the 251 respondents, 55.4% were from health-related fields, 61.4% undertook research involving humans, and 48.6% did research requiring institutional review board approval. Only 37.1% of respondents reported exposure to research ethics education during their graduate study. Satisfactory adherence to informed consent practices was reported at rates of 56.0%–67.5%. Satisfactory adherence to practices related to data confidentiality and study participants' anonymity was reported at rates of 67.3%–74.7%. Sharing of data or samples with others was reported at a rate of 24.3%. The rates of adherence to proper informed consent practices and practices that maintain data confidentiality were less than ideal. Significant policy changes need to be implemented to address these issues.

Prioritising African perspectives in psychiatric genomics research: Issues of translation and informed consent

Eunice Kamaara, Camillia Kong, Megan Campbell

Bioethics, 14 November 2019

Abstract

Psychiatric genomics research with African populations comes with a range of practical challenges around translation of psychiatric genomics research concepts, procedures, and nosology. These challenges raise deep ethical issues particularly around legitimacy of informed consent, a core foundation of research ethics. Through a consideration of the constitutive function of language, the paper problematises like-for-like, designative translations which often involve the 'indigenization' of English terms or use of metaphors which misrepresent the risks and benefits of research. This paper argues that effective translation of psychiatric

genomics research terminology in African contexts demands substantive engagement with African conceptual schemas and values. In developing attenuated forms of translational thinking, researchers may recognise the deeper motivational reasons behind participation in research, highlighting the possibility that such reasons may depart from the original meaning implied within informed consent forms. These translational issues might be ameliorated with a critical re-examination of how researchers develop and present protocols to institutional ethics review boards.

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MEDICAL/SURGICAL

Impact of new consent procedures on uptake of the schools-based human papillomavirus (HPV) vaccination programme

Harriet Fisher, Matthew Hickman, Joanne Ferrie, Karen Evans, Michael Bell, Julie Yates, Marion Roderick, Rosy Reynolds, John MacLeod, Suzanne Audrey

Journal of Public Health, 26 September 2020

Open Access

Abstract

Background

Local policy change initiating new consent procedures was introduced during 2017–2018 for the human papillomavirus (HPV) vaccination programme year in two local authorities in the south–west of England. This study aims to assess impact on uptake and inequalities.

Methods

Publicly available aggregate and individual-level routine data were retrieved for the programme years 2015–2016 to 2018–2019. Statistical analyses were undertaken to show: (i) change in uptake in intervention local authorities in comparison to matched local authorities and (ii) change in uptake overall, and by local authority, school type, ethnicity and deprivation.

Results

Aggregate data showed uptake in Local Authority One increased from 76.3% to 82.5% in the post-intervention period (risk difference: 6.2% P = 0.17), with a difference-in-differences effect of 11.5% (P = 0.03). There was no evidence for a difference-in-differences effect in Local Authority Two (P = 0.76). Individual-level data showed overall uptake increased post-intervention (risk difference: +1.1%, P = 0.05), and for young women attending school in Local Authority One (risk difference: 2.3%, P < 0.01). No strong evidence for change by school category, ethnic group and deprivation was found.

Conclusion

Implementation of new consent procedures can improve and overcome trends for decreasing uptake among matched local authorities. However, no evidence for reduction in inequalities was found.

Implications and discussion

The new consent procedures increased uptake in one of the intervention sites and appeared to overcome trends for decreasing uptake in matched sites. There are issues in relation to the quality of data which require addressing.

Consent In Forefoot Surgery; What Does It Mean To The Patient?

Leo D. Baxendale-Smith, Scott D. Middleton, John C. McKinley, Colin E. Thomson

The Foot, 25 September 2020

Abstract

Aims

This study aimed to assess patient risk recall and find risk thresholds for patients undergoing elective forefoot procedures.

Methods

Patients were interviewed in the pre-assessment clinic (PAC) or on day of surgery (DOS); some in both settings. A standardised questionnaire was used for all interviews, regardless of setting. Patients were tested on which risks they recalled from their consent process, asked for thresholds for five pre-chosen risks and asked about a sham risk.

Results

Across all interviews, risk recall on DOS (2.34 risks/patient interview) was significantly lower ($p = .05$) than in PAC (2.95 risks/patient interview) – this was repeated when comparing results from patients interviewed in both settings only with PAC mean recall of 2.93 risks/patient interview and DOS mean recall of 2.57 risks/patient interview. The mean reported risk thresholds greatly exceeded X's observed complication rates for forefoot procedures. The five risks tested for thresholds produced the same order in each interview setting, suggesting a patient-perceived severity ranking. Patients answering the sham risk question incorrectly tended to recall fewer risks across all interviews.

Conclusions

This study shows that patient risk recall is poor, as previous literature outlines, reinforcing that consent process improvements could be made. It also illustrates the value of PAC visits in patient education, as shown by higher levels of recall when compared to DOS.

Unplanned Cesarean Birth: Can the Quality of Consent Affect Birth Experiences?

Paul Burcher,Shazneen Hushmendy, Meredith Chan-Mahon, Megha Dasani, Jazmine Gabriel, Erin Crosby

AJOB Empirical Bioethics, 18 September 2020

Abstract

Background: Unplanned cesarean birth is associated with high levels of patient dissatisfaction and negative birth experiences, which in turn can negatively impact birth outcomes. Previous research has demonstrated that issues of physician-patient communication, mistrust, fear of the operating room (OR), and loss of control contribute to patient dissatisfaction with unplanned cesarean birth. We hypothesized that altering the nature and structure of the informed consent prior to the surgery might improve patient satisfaction and birth experience. Specifically, we explored whether educating resident physicians in counseling skills could shift the focus of informed consent from a checklist merely informing the patient of the risks, benefits, and alternatives to a discussion that informs the physician of the patient's concerns and fears. By approaching consent in this manner, the goal of informed consent expands beyond autonomy rights to include beneficence as well. Methods: Residents received education to discuss issues of communication, fear, mistrust, and loss of control when seeking consent for an unplanned cesarean birth. Patients were randomized to receive either additional counseling that encouraged a discussion or a standard informed consent for cesarean birth. Participants were interviewed two weeks later and scored their satisfaction using a Likert scale on the four themes: communication, mistrust, fear of OR, and loss of control. Results: Both groups had very high patient satisfaction scores; there was no statistical difference between them. Conclusions: Both groups exhibited significantly higher levels of birth satisfaction than present in prior research. Training residents to discuss these issues while seeking consent for an unplanned cesarean birth may have improved patient satisfaction for all participants in this study. This suggests that educating residents to engage patients in a dialogue during informed consent counseling is more important than a specific script.

Informed consent: a shared decision-making process that creates a new professional obligation for care

Guidelines

Arthur Rawlings, Lelan Sillin, Phillip Shadduck, Marian McDonald, Peter Crookes, Bruce MacFadyen Jr, John Mellinger, SAGES Ethics Committee

Surgical Endoscopy, 15 September 2020

Abstract

This statement on informed consent, developed by the SAGES Ethics Committee, has been reviewed and approved by the Board of Governors of SAGES. This statement is provided to offer guidance about the purpose and process of obtaining informed consent, and it is intended for practicing surgeons as well as patients seeking surgical intervention. It is an expression of well-established principles and extensive literature. Excluded from this document are discussions of informed consent for research and informed consent for introduction of new technology, as that has been addressed in previous publications (Strong in Surg Endosc 28:2272, 2014; Stefanidis in Surg Endosc 28:2257, 2014; as reported by Sillin (in: Stain (ed) The SAGES Manual Ethics of Surgical Innovation, Springer, Switzerland, 2016)).

Knowledge and Perception of Ethiopian Surgical Patients to Informed Consent Practice for Surgical Procedures

Original Research

Open Access Surgery, 7 September 2020; 13 pp 65-70

Befekadu Lemmu, Abebe Megersa, Engida Abebe, Kirubel Abebe

Open Access

Abstract

Background

Surgical informed consent (SIC) is an established ethical and legal requirement for surgical treatment. Patient understanding of the process is essential for efficient surgical care. This study aimed to assess the knowledge and perception of operated patients towards surgical informed consent.

Methods

An institution-based cross-sectional study of all adult surgical patients who signed informed consent and underwent surgery at St. Paul's Hospital Millennium Medical College (SPHHMC) from February 1st to March 30th, 2018, was performed. Data were collected postoperatively before discharge using a pretested structured questionnaire.

Results

Of 420 patients identified, 385 (91.7%, M:F=2:1) agreed and interviewed. The mean age was 40.3 years (SD± 15.1), and many of the respondents (285, 74.0%) had some level of formal education. Even if most (336, 87.3%) knew the reason why they had surgery, less knowledge and awareness was reported regarding the options of alternative treatments (153, 39.7%), identifying the operating surgeon (129, 33.5%), the type of surgery (160, 41.6%), anesthesia-related risks (96, 24.9%), complications of surgery (69, 17.9%) and postoperative care (4, 1.0%). The legal requirement of surgical informed consent was reported by 267 (69.4%) subjects; however, more than half had no information on the right to change their mind after signed surgical informed consent (223, 57.9%) and whom it protects (224, 58.2%). Only 40 (10.5%) respondents had a good level of knowledge, and it was significant in those with some level of formal education (OR=4.8; 95% CI 1.45–16.01; P=0.010) and in patients who live in an urban area (OR=4.7; 95% CI 1.81–12.35; p=0.002) than their respective groups.

Conclusion

Our patients had limited knowledge and perception regarding surgical informed consent. Hence, the current consent process seems inadequate and needs a revisit.

Universal tumor screening for lynch syndrome: perspectives of patients regarding willingness and informed consent

Research Article

Anusree Subramonian, Doug Smith, Elizabeth Dicks, Lesa Dawson, Mark Borgaonkar, Holly Etchegary

Personalized Medicine, 2 September 2020

Open Access

Abstract

Aim: Lynch Syndrome is associated with a significant risk of colorectal carcinoma (CRC) and other cancers. Universal tumor screening is a strategy to identify high-risk individuals by testing all CRC tumors for molecular features suggestive of Lynch Syndrome. Patient interest in screening and preferences for consent have been underexplored. Methods: A postal survey was administered to CRC patients in a Canadian province. Results: Most patients (81.4%) were willing to have tumors tested if universal tumor screening were available and were willing to discuss test results with family members and healthcare professionals. The majority (62.6%) preferred informed consent be obtained prior to screening. Conclusion: Patients were supportive of universal screening. They expected consent to be obtained, contrary to current practice across Canada and elsewhere.

Comparison of information delivery methods for informed consent for blood transfusions

April Jones, Krishna Badami

New Zealand Journal of Medical Laboratory Science, August 2020; 74(2) pp 149

Abstract

Objectives: Informed consent is a process in which patients are educated about their treatment options, allowing them to make autonomous decisions about whether they consent to treatment. Blood transfusions are a treatment option associated with a multitude of risks which require patient consent. There is evidence the information provided for informed consent, particularly around the risks associated with blood transfusions, is not adequately understood by patients. This project aimed to investigate whether the process of patient education can be improved by use of an information sheet. Methods: A randomised controlled trial was performed using members of the public and medical staff. Participants were randomly assigned to the control or intervention group. The control group received an audio recording replicating the current education process. The intervention group received an A4 sheet of information. Understanding and recall of the information provided was assessed using a questionnaire. The mode for each group was calculated and used to compare the survey results. Results: The results implied neither form of information was adequate in promoting understanding of the risks associated with blood transfusions. There was some evidence suggesting the intervention improved understanding and recall of the frequency of transfusion associated risks. The severity of such events appeared to be unclear irrespective of the type of information received. Conclusion: With further development of the information given, routine use of supplementary paper based information could assist understanding of the frequency and severity of transfusion associated risks through reinforcement of information given during a discussion.

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GENERAL/OTHER

Researching consent in veterinary practice: The use of interpretive description as a multidisciplinary methodology

Carol A Gray

Methodological Innovations, September-December 2020

Open Access

Abstract
Informed consent in the veterinary sphere has been surprisingly under-researched, despite it being a professional ethical requirement. As consent is given by animal owners on behalf of patients who are unable to consent for themselves, its underpinning ethical basis cannot exactly mirror consent given by adult human patients with capacity. Any attempt to research consent in the veterinary context requires consideration of its legal, ethical and practical applications. This investigation of consent practices in veterinary settings in the United Kingdom was undertaken using interpretation of medicolegal cases, together with three discrete empirical studies comprising the textual analysis of consent forms, consent discussions for the elective neutering of companion animal patients, and interviews with key participants in the consent process. The chosen approach required a methodology that would facilitate triangulation between empirical data analysis and doctrinal legal research. Here, I describe the first use of interpretive description as a methodology of veterinary socio-legal studies, in the context of practice-based research. With foundations in traditional social science methodologies such as hermeneutics, grounded theory, ethnography and symbolic interactionism, interpretive description provided a multi-disciplinary methodological perspective. Its underpinning methodologies informed the methods that were used for data collection, and for subsequent analysis. I combined interpretation of legal decisions and professional ethical guidance with thematic surveys of empirical data to reach higher levels of analysis. The resulting conceptual description of consent in veterinary practice enabled the production of normative guidance appropriate for those in practice, thus fulfilling the methodological aims of interpretive description. Specifically, the key findings were that the consent form should act as a fuller record of the consent discussion, that attention should be paid to achieving an appropriate balance between client autonomy and patient 'best interests' and that consent should provide protection to all three parties (client, patient and veterinary professional).

More than consent for ethical open-label placebo research

Original Research
Laura Specker Sullivan
BMJ Medical Ethics, 3 September 2020
Abstract
Recent studies have explored the effectiveness of open-label placebos (OLPs) for a variety of conditions, including chronic pain, cancer-related fatigue and irritable bowel syndrome. OLPs are thought to sidestep traditional ethical worries about placebos because they do not involve deception: with an OLP, patients or subjects are told outright that they are not given an active substance. As deception is framed as the primary hurdle to ethical placebo use, the door is ostensibly opened to ethical studies of OLPs. In this article, I suggest that even though OLPs seemingly do not involve deception, there are other ethical considerations in their clinical investigation and subsequent use. Research ethics often focusses on informed consent—of which, deception and honesty are a piece—as a means to justify research practices with human subjects. Yet, it is but one of the ethical considerations that should be taken into account. With research into placebo effects in particular, I argue that the history of clinical placebo use grounds special considerations for OLP research that go beyond respect for the autonomy of individual patients through informed consent and encompass structural concerns about the type of patient for whom a placebo has historically been thought appropriate.

The Cohen problem of informed consent

William Simkulet
BMJ Medical Ethics, 26 August 2020; 46(9) pp 617-622
Abstract
To avoid potential abuse and respect patient autonomy, physicians have a moral obligation to obtain informed consent before performing any significant medical intervention. To give informed consent, a patient must be competent, understand her condition, options and their expected risks and benefits and must freely and expressly consent to one of those options. Shlomo Cohen challenges this conception of

informed consent by constructing cases based on Edmund Gettier's classic counterexamples to traditional theories of knowledge. In this paper, I argue Cohen-style cases are not genuine threats to the concept of informed consent, however they provide an interesting challenge to theories of conscientious objection.

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