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.

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No new content identified for the following established categories:
COMPASSIONATE USE/EXPANDED ACCESS
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POLICY GUIDANCE/PROGRAM ACTION
SOCIAL SCIENCE RESEARCH
TECHNOLOGY/OTHER MEDIATION

Please note that we maintain a glossary, tools for assessment, and guidance documents on our [website].
COVID-19

Let’s Be Reasonable: Surgical Informed Consent in the COVID-19 Era
Surgical Perspectives
Steven E. Raper, Justin T. Clapp, Lee A. Fleisher
Annals of Surgery, December 2020; 1(2) pp e016
Excerpt
...Professional societies such as the American College of Surgeons have articulated elements that when discussed by a surgeon and patient satisfy the reasonableness standard leading to surgical informed consent. The elements of an informed consent conversation should include—among others—the nature of the disease, appropriate details of the proposed operation, the estimated risks of mortality and morbidity, and a discussion of the commonly known complications. Patients should comprehend the risks as well as the benefits of the operative plan. The conversation should include a description of alternative treatments, including nonoperative treatments and what to expect during the perioperative period including recuperative issues...

Surgical consent during the COVID-19 pandemic
O. Rotimi, K. Beatson, A. Aderombi, W. Lam, O. Bajomo, N. Kukreja
Annals of Medicine and Surgery, 9 October 2020; 59 pp 229-233
Open Access
Abstract
Background and aims
During the COVID-19 pandemic, surgical practice may deviate with operative and non-operative management considered. Appropriate discussion of options with patients is paramount to quality surgical care. Intercollegiate and EAES guidelines recommend discussing and documenting risk of COVID-19 exposure in the consent process for patients undergoing surgery.
Materials and methods
Closed-loop audit of consent forms for patients undergoing emergency and elective surgical procedures. Interventions implemented included education of wider surgical teams. Data was collected during a one-week period for each cycle and analysed using Chi-squared test.
Results
In cycle 1, 6/17 (35.3%) case notes documented discussion of COVID-19 risk. Following intervention, compliance improved to 23/29 (79.3%) cases in cycle 2 and 33/45 (73.3%) cases in cycle 3.
Conclusion
Pre-intervention, our consenting practice was non-compliant. Our interventions led to significant and sustained improvements in practice. We recommend provision of wider surgical team education to facilitate good consenting practice.

Consent concerns in clinical trials of investigational therapies for COVID-19: Vulnerability versus voluntariness
Review Article
Arun Bhatt
Perspectives in Clinical Research, 6 October 2020
Abstract
Obtaining informed consent from vulnerable patients participating in clinical trials of investigational therapies for COVID-19 is a major ethical challenge. Ethical and operational considerations – voluntariness, waiver, timing, time, documentation, and responsibilities of the sponsor, the investigator, and the ethics committee – are discussed briefly.

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**BIOMEDICAL RESEARCH**

**Nocebo effects by providing informed consent in shared decision making? Not necessarily: a randomized pilot-trial using an open-label placebo approach**

*Research Article*

Fabian Holzhüter, Johannes Hamann

*BMC Medical Ethics, 14 October 2020; 21(97)*

*Open Access*

*Abstract*

**Background**

Thorough information of the patient is an integral part of the process of shared decision making. We aimed to investigate if detailed information about medication may induce nocebo (or placebo) effects.

**Methods**

We conducted a randomized, single-blind, pilot-study including n = 51 psychiatric in-patients aged between 18 and 80 years with a depressive disorder and accompanying sleeping disorders. In the intervention group we provided thorough information about adverse effects, while the control group received only a simple consent procedure. In both groups, patients received an open-label placebo pill instead of their sleeping medication.

**Results**

No statistically significant differences between the intervention group and the control group were found regarding the main outcome parameter (a visual analogue scale indicating impairment by the new pill).

**Conclusion**

In this study, we were not able detect an effect of informed consent vs. simple consent on the emergence of placebo or nocebo effects. This finding is contrary to most assumptions and publications about this topic.

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**Neuropsychological validation of a brief quiz to examine comprehension of consent information in observational studies of substance users**

*Research Article*

Aldebarán Toledo-Fernández, Ricardo Sánchez-Domínguez, Luis Villalobos-Gallegos, Alejandro Pérez-López, Alan Mañas-Flores, Rodrigo Marín-Navarrete

*Ethics & Behaviour, 12 October 2020*

*Abstract*

The objective of this study was to determine the accuracy of a brief informed consent quiz (ICQ) to detect consent comprehension in individuals with cognitive impairment (as a proxy of incomprehension) and to explore the degree to which cognitive domains and recent substance use, independently, predict comprehension. We performed a secondary analysis of two cross-sectional studies in individuals with substance use disorders. The ICQ total score was used as the index test and the Montreal Cognitive Assessment (MoCA) as reference standard in receiver operating characteristic curves. Two independent multiple binary logistic regression models were performed using cognitive domains and days of recent substance use as predictors of ICQ outcome. We analyzed data from 215 and 251 participants, respectively. The ICQ showed moderate accuracy for major cognitive impairment (MoCA ≤ 21) (area under the curve ~ 77)
and lower accuracy for mild impairment (MoCA ≤ 24) (area under the curve ~ 65). Optimal cutoff score was set at 10 points or less for detecting comprehension difficulty. Lower scores in Short-Term Memory, Attention, Language, and Orientation increased the probability of failing the ICQ. A procedure including both the ICQ and cognitive screening measure could improve the accuracy of consent comprehension assessments.

**Researchers’ views on, and experiences with, the requirement to obtain informed consent in research involving human participants: a qualitative study**

*Research Article*
Antonia Xu, Melissa Therese Baysari, Sophie Lena Stocker, Liang Joo Leow, Richard Osborne Day & Jane Ellen Carland

*BMC Medical Ethics, 2 October 2020; 21(93)*

*Open Access*

*Abstract*

**Background**
Informed consent is often cited as the “cornerstone” of research ethics. Its intent is that participants enter research voluntarily, with an understanding of what their participation entails. Despite agreement on the necessity to obtain informed consent in research, opinions vary on the threshold of disclosure necessary and the best method to obtain consent. We aimed to investigate Australian researchers’ views on, and their experiences with, obtaining informed consent.

**Methods**
Semi-structured interviews were conducted with 23 researchers from NSW institutions, working in various fields of research. Interviews were analysed and coded to identify themes.

**Results**
Researchers reported that consent involved information disclosure, understanding and a voluntary decision. They emphasised the variability of consent interactions, which were dependent on potential participants’ abilities and interests, study complexity and context. All researchers reported providing written information to potential participants, yet questioned the readability and utility of this information. The majority reported using signed consent forms to ‘operationalise’ consent and reported little awareness of, and lack of support in implementing more dynamic informed consent procedures, such as verbal informed consent, that was fit for the purposes of their studies. Views on Human Research Ethics Committees (HRECs) varied. Some reported inconsistent, arduous inputs on the information form and consent process. Others expressed reliance on HRECs for guidance, viewing them as institutional safeguards.

**Conclusions**
This study highlights the importance of transparent relationships, both between researchers and participants, and between researchers and HRECs. Where the relationship with study participants was reported as more robust, researchers felt that they were better able to ensure participants made better, more informed decisions. Where the relationship with HRECs was reported as more robust, researchers were more likely to view them as institutional safeguards, rather than as bureaucratic hindrances. Conscientious and mindful researchers are paramount to ensuring the procedure accommodates individual requirements. This study advocates that when designing ethical informed consent practices, researchers should be integrated as autonomous players with a positive input on the process, rather than, in the worst case, predatory recruiters to be curtailed by information forms and oversight.

**High-impact RCTs without prospective informed consent: a systematic review**

*Review*
Roma Dhamanaskar, Jon F Merz

*Journal of Investigative Medicine, 1 October 2020*

*Abstract*
The prevalence of randomized controlled trials (RCTs) performed without fully informed prospective consent from subjects is unknown. We performed this study to estimate the prevalence of high-impact RCTs performed without informed consent from all subjects and examine whether such trials are becoming more prevalent. We performed a systematic review of English-language RCTs published from 2014 through 2018 identified in Scopus and sorted to identify the top 100 most highly cited RCTs each year. Text search of title and abstract included terms randomized controlled or clinical trial and spelling variants thereof, and excluded metaanalyses and systematic reviews. We independently identified the most highly cited RCTs based on predefined criteria and negotiated to agreement, then independently performed keyword searches, read, abstracted and coded information regarding informed consent from each paper and again negotiated to agreement. No quality indicators were assessed. We planned descriptive qualitative analysis and appropriate quantitative analysis to examine the prevalence and characteristics of trials enrolling subjects with other than fully informed prospective consent. We find that 44 (8.8%, binomial exact 95% CI 6.5% to 11.6%) of 500 high-impact RCTs did not secure informed consent from at least some subjects. The prevalence of such trials did not change over the 5 years (OR=1.09, z=0.78, p=0.44). A majority (66%) of the trials involved emergency situations, and 40 of 44 (90.9%) of the trials involved emergency interventions, pragmatic designs, were cluster randomized, or a combination of these factors. A qualitative analysis explores the methods of and justifications for waiving informed consent in our sample of RCTs.

Implementation of Electronic Informed Consent in Biomedical Research and Stakeholders’ Perspectives: Systematic Review

Evelien De Sutter, Drieda Zaçe, Stefania Boccia, Maria Luisa Di Pietro, David Geerts, Pascal Borry, Isabelle Huys

Journal of Medical Research, October 2020; 22(10)

Open Access

Abstract

Background

Informed consent is one of the key elements in biomedical research. The introduction of electronic informed consent can be a way to overcome many challenges related to paper-based informed consent; however, its novel opportunities remain largely unfulfilled due to several barriers.

Objective

We aimed to provide an overview of the ethical, legal, regulatory, and user interface perspectives of multiple stakeholder groups in order to assist responsible implementation of electronic informed consent in biomedical research.

Methods

We conducted a systematic literature search using Web of Science (Core collection), PubMed, EMBASE, ACM Digital Library, and PsycARTICLES. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were used for reporting this work. We included empirical full-text studies focusing on the concept of electronic informed consent in biomedical research covering the ethical, legal, regulatory, and user interface domains. Studies written in English and published from January 2010 onward were selected. We explored perspectives of different stakeholder groups, in particular researchers, research participants, health authorities, and ethics committees. We critically appraised literature included in the systematic review using the Newcastle-Ottawa scale for cohort and cross-sectional studies, Critical Appraisal Skills Programme for qualitative studies, Mixed Methods Appraisal Tool for mixed methods studies, and Jadad tool for randomized controlled trials.

Results

A total of 40 studies met our inclusion criteria. Overall, the studies were heterogeneous in the type of study design, population, intervention, research context, and the tools used. Most of the studies’ populations were research participants (ie, patients and healthy volunteers). The majority of studies addressed barriers to achieving adequate understanding when using electronic informed consent. Concerns shared by multiple
stakeholder groups were related to the security and legal validity of an electronic informed consent platform and usability for specific groups of research participants.

**Conclusions**

Electronic informed consent has the potential to improve the informed consent process in biomedical research compared to the current paper-based consent. The ethical, legal, regulatory, and user interface perspectives outlined in this review might serve to enhance the future implementation of electronic informed consent.

**Exception From Informed Consent: How IRB Reviewers Assess Community Consultation and Public Disclosure**

*Research Article*

Makini Chisolm-Straker, Denise Nassisi, Mohamud R. Daya, Jennifer N.B. Cook, Ilene F. Wilets, Cindy Clesca, Lynne D. Richardson

**AJOB Empirical Bioethics, 29 September 2020**

**Abstract**

Exception from Informed Consent (EFIC) regulations detail specific circumstances in which Institutional Review Boards (IRB) can approve studies where obtaining informed consent is not possible prior to subject enrollment.

To better understand how IRB members evaluate community consultation (CC) and public disclosure (PD) processes and results, semi-structured interviews of EFIC-experienced IRB members were conducted and analyzed using thematic analysis.

Interviews with 11 IRB members revealed similar approaches to reviewing EFIC studies. Most use summaries of CC activities to determine community members’ attitudes; none reported using specific criteria nor recalled any CC reviews that resulted in modifications to or denials of EFIC studies. Most interviewees thought metrics based on Community VOICES’s domains (feasibility, participant selection, quality of communication, community perceptions, investigator/IRB perceptions) would be helpful.

IRB members had similar experiences and concerns about reviewing EFIC studies. Development of metrics to assess CC processes may be useful to IRBs reviewing EFIC studies.

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**GENOMIC MEDICINE/GENE EDITING**

**The Meaning of Informed Consent: Genome Editing Clinical Trials for Sickle Cell Disease**

Stacy Desine, Brittany M. Hollister, Khadijah E. Abdallah, Anitra Persaud, Sara Chandros Hull, Vence L. Bonham

**AJOB Empirical Bioethics, 12 October 2020; 11(4) pp 195-207**

**Open Access**

**Abstract**

**Background**

A first therapeutic target of somatic genome editing (SGE) is sickle cell disease (SCD), the most commonly inherited blood disorders, affecting more than 100,000 individuals in the United States. Advancement of SGE is contingent on patient participation in first in human clinical trials. However, seriously ill patients may be vulnerable to overestimating the benefits of early phase studies while underestimating the risks. Therefore, ensuring potential clinical trial participants are fully informed prior to participating in a SGE clinical trial is critical.

**Methods**
We conducted a mixed-methods study of adults with SCD as well as parents and physicians of individuals with SCD. Participants were asked to complete a genetic literacy survey, watch an educational video about genome editing, complete a twopart survey, and take part in focus group discussions. Focus groups addressed topics on clinical trials, ethics of gene editing, and what is not understood regarding gene editing. All focus groups were audio-recorded, transcribed, and analyzed using conventional content analysis techniques to identify major themes.

Results
Our study examined the views of SCD stakeholders regarding what they want and need to know about genome editing to make an informed decision to participate in a SGE clinical trial. Prominent themes included stakeholders’ desire to understand treatment side effects, mechanism of action of SGE, trial qualification criteria, and the impact of SGE on quality of life. In addition, some physicians expressed concerns about the extent to which their patients would understand concepts related to SGE; however, individuals with SCD demonstrated higher levels of genetic literacy than estimated by physicians.

Conclusions
Designing ethically robust genome editing clinical trials for the SCD population will require, at a minimum, addressing the expressed information needs of the community through culturally sensitive engagement, so that they can make informed decisions to consider participation in clinical trials.

BIOBANKING

Context-Relative Norms Determine the Appropriate Type of Consent in Clinical Biobanks: Towards a Potential Solution for the Discrepancy between the General Data Protection Regulation and the European Data Protection Board on Requirements for Consent

Original Research/Scholarship
R. Indrakusuma, S. Kalkman, M. J. W. Koelemay, R. Balm & D. L. Willems

Science and Engineering Ethics, 13 October 2020

Open Access

Abstract
Clinical biobanks processing data of participants in the European Union (EU) fall under the scope of the General Data Protection Regulation (GDPR), which among others includes requirements for consent. These requirements are further specified by the Article 29 Working Party (WP29)—an EU advisory body currently known as the European Data Protection Board (EDPB). Unfortunately, their guidance is cause for some confusion. While the GDPR allows participants to give broad consent for research when specific research purposes are still unknown, the WP29 guidelines suggest that additional consent for specific uses should be obtained in addition to broad consent when this becomes applicable. This discrepancy elicits the question whether clinical biobanks can fail the requirement of consent if they obtain broad consent, but not a specific consent for each biomedical study. We analysed this discrepancy within the framework of contextual integrity, in order to describe the context-relative informational norms that govern information flows in clinical biobanks. However, our analysis demonstrates that there is no uniform set of norms that can be applied to all clinical biobanks. As such, neither the GDPR nor the WP29 guidance can act as a “one size fits all” approach to all clinical biobanks. Rather, differences between clinical biobanks—especially regarding the scientific aims and patient populations—make the case for context-relative norms that determine the appropriate type of consent.
CAPACITY TO CONSENT

Informed consent procedures for emergency interventional research in patients with traumatic brain injury and ischaemic stroke

Personal View

The Lancet Neurology, 21 October 2020

Summary
Health-care professionals and researchers have a legal and ethical responsibility to inform patients before carrying out diagnostic tests or treatment interventions as part of a clinical study. Interventional research in emergency situations can involve patients with some degree of acute cognitive impairment, as is regularly the case in traumatic brain injury and ischaemic stroke. These patients or their proxies are often unable to provide informed consent within narrow therapeutic time windows. International regulations and national laws are criticised for being inconclusive or restrictive in providing solutions. Currently accepted consent alternatives are deferred consent, exception from consent, or waiver of consent. However, these alternatives appear under-utilised despite being ethically permissible, socially acceptable, and regulatorily compliant. We anticipate that, when the requirements for medical urgency are properly balanced with legal and ethical conduct, the increased use of these alternatives has the potential to improve the efficiency and quality of future emergency interventional studies in patients with an inability to provide informed consent.

The Attitudes of Relatives of ICU Patients toward Informed Consent for Clinical Research

Research Article
Rania Mahafzah, Kareem H. Alzoubi, Omar F. Khabour

Critical Care Research and Practice, 9 October 2020

Open Access
Abstract
Background
Informed consent is a key ethical requirement for biomedical research that is implemented to ensure autonomy and voluntary participation. However, patients in the intensive care unit (ICU) may be unconscious or severely ill and thus lack the capacity for decisions about research participation. Thus, relatives or guardians are usually asked to provide informed consent prior to the inclusion of ICU patients in research.

Aims
This study aimed to assess the attitudes and preferences of relatives of ICU patients toward informed consent in biomedical research in Jordan.

Subjects and Methods
A sample of 184 relatives with a critically ill next of kin in the ICU was anonymously surveyed regarding their attitudes and preferences toward giving informed consent for biomedical research on behalf of their patients.

Results
The study showed that the majority of relatives had a positive attitude toward the informed consent process on behalf of their patients in the ICU (72.3%). The perception that participation in research would be directly beneficial to their patient was the most significant reason to provide informed consent among relatives. The degree of relatedness to the patient was significantly associated with the decision to provide informed consent on behalf of the patients in the ICU. Additionally, more than 70% of the relatives strongly agreed to take part in clinical research if they were to be unconscious patients in the ICU. Moreover, the majority of the respondents agreed that their first-degree relatives would give consent on their behalf.

Conclusion
Relatives with a critically ill next of kin in the ICU had positive attitudes toward providing informed consent on behalf of their patients. This was motivated by the direct benefit from the research to their patient.
Family perceptions of clinical research and the informed consent process in the ICU

Marie Labruyère, Nicolas Meunier-Beillard, Fiona Ecarnot, Audrey Large, François Aptel, Jean-Baptiste Roudaut, Pascal Andreu, Auguste Dargent, Jean-Philippe Rigaud, Jean-Pierre Quenot

Journal of Critical Care, 28 September 2020

Abstract
Purpose
We investigated experiences of families who provide consent for research on behalf of a loved-one hospitalized in intensive care (ICU).

Methods
Multicentre, qualitative, descriptive study using semi-directive interviews in 3 ICUs. Eligible relatives were aged >18 years, and had provided informed consent for a clinical trial on behalf of a patient hospitalized in ICU. Interviews were conducted from 06/2018 to 06/2019 by a qualified sociologist, recorded and transcribed.

Results
Fifteen relatives were interviewed; average age 50.3 ± 15 years. All emphasized their interest in clinical research, seeing it as a duty. Involving their loved-one in research allowed them to find meaning in the events. Participants underlined that trust in caregivers and communication are determinant. The strict regulation of research was perceived as a guarantee of safety. Participants felt they lacked the intellectual capacity and knowledge to question explanations. The greatest fear was not that they might incur a risk for the patient, but rather, that they might deprive the patient of a chance at a cure.

Conclusion
Acceptance of research opportunities by relatives on behalf of decisionally-incapacitated patients is underpinned by trust in the physicians and the legislative framework. Communication and the quality of information provided by the caregivers are key.

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YOUNG PERSONS

Caregiver Perspectives on Informed Consent for a Pediatric Learning Healthcare System Model of Care

A. E. Pritchard, T. A. Zabel, L. A. Jacobson, E. Jones, C. Holingue, L. G. Kalb

AJOB Empirical Bioethics, 26 October 2020

Abstract
Background
Data is needed to provide insight into the issue of preference around consent for use of pediatric clinical data for research. This study evaluated caregivers’ preferences concerning use of their child’s clinical information.

Methods
Caregivers of children (n = 101; response rate 81.5% of n = 124) presenting for psychological evaluation at an urban medical center viewed a video regarding how the information contained in their child’s medical record could be used for research.

Results
An anonymous survey following the video indicated that: 1) >90% of caregivers felt comfortable with their child’s information being used; 2) >90% of caregivers felt their child’s privacy would be adequately protected; 3) 98% of caregivers reported themselves to be as or more likely to return to the institution after viewing the video; 4) 60% of caregivers felt no additional consent procedures beyond viewing the video were needed,
while 20% preferred an opt-out and 20% preferred a traditional consent procedure. Caregiver demographic variables were largely unrelated to consent preferences.

Discussion
Overall, caregivers reported strong support for use of their child’s clinical data for research purposes.

Issues of consent and assent in pediatric neurosurgery
Review Article
Rajeev D. Sen, Amy Lee, Samuel R. Browd, Richard G. Ellenbogen, Jason S. Hauptman
Child’s Nervous System, 17 October 2020
Abstract
Background
Consent and assent are important concepts to understand in the care of pediatric neurosurgery patients. Recently it has been recommended that although pediatric patients generally do not have the legal capacity to make medical decisions, they be encouraged to be involved in their own care. Given the paucity of information on this topic in the neurosurgery community, the objective is to provide pediatric neurosurgeons with recommendations on how to involve their patients in medical decision-making.

Methods
We review the essential elements and current guidelines of consent and assent for pediatric patients using illustrative neurosurgical case vignettes.

Results
The pediatric population ranges widely in cognitive and psychological development making the process of consent and assent quite complex. The role of the child or adolescent in medical decision-making, issues associated with obtaining assent or dissent, and informed refusal of treatment are considered.

Conclusion
The process of obtaining consent and assent represents a critical yet often overlooked aspect to care of pediatric neurosurgical patients. The pediatric neurosurgeon must be able to distill immensely complex and high-risk procedures into simple, understandable terms. Furthermore, they must recognize when the child’s dissent or refusal to treatment is acceptable. In general, allowing children to be involved in their neurosurgical care is empowering and gives them both identity and agency, which is the vital first step to a successful neurosurgical intervention.

14-Year-Old Schoolchildren Can Consent to Get Vaccinated in Tyrol, Austria: What Do They Know about Diseases and Vaccinations?
Peter Kreidl, Maria-Magdalena Breitwieser, Reinhard Würzner, Wegene Borena
Vaccines, 15 October 2020
Open Access
Abstract
In Austria, consent to receiving vaccines is regulated at the federal state level and in Tyrol, children aged 14 years are allowed to consent to receiving vaccination. In August 2017, we investigated determinants associated with vaccine hesitancy, having been vaccinated against measles and human papillomavirus (HPV) and the intention to vaccinate among schoolchildren born in 2002 and 2003. Those who consider measles and HPV a severe disease had a significantly higher intention to be vaccinated (prevalence ratio (PR) of 3.5 (95% CI 1.97–6.32) for measles and a PR of 3.2 (95% CI 1.62–6.35) for HPV). One-third of the participants (32.4%; 95% CI 27.8–37.4) were not aware that they are allowed to consent to receiving vaccines. The most common trusted source reported by respondents (n = 311) was the medical doctor (80.7%; 95% CI 75.7–84.7). The main finding related to the aim of the study was that the proportion of objectors is below 4% and therefore it should still be possible to reach measles
elimination for which a 95% uptake is necessary. Although the proportion of objectors is not higher compared to adults, we recommend to intensify health education to increase health literacy.

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

Who Are We Missing? The Impact of Requiring Parental or Guardian Consent on Research With Lesbian, Gay, Bisexual, Trans, Two-Spirit, Queer/Questioning Youth

Adolescent Health Brief
Eli Cwinn, Courtney Cadieux, Claire V. Crooks

Journal of Adolescent Health, 13 October 2020
Open Access

Abstract

Purpose
The purpose was to examine whether a requirement for parental or guardian consent systematically limits which lesbian, gay, bisexual, trans, two-spirit, queer/questioning (LGBT2Q+) youth participate in research.

Methods
A total of 60 LGBT2Q+ youth (aged 14–18 years) completed measures assessing gender and sexual minority identity, depression and anxiety, help-seeking intentions, and social support.

Results
A substantial proportion (37.6%) of youth reported that they would not have participated in the research if parental or guardian consent was required. Those who would not have participated had more negative attitudes about their sexual and gender identity, less family support, lower levels of help-seeking intentions, and higher levels of negative affect.

Conclusions
The results suggest that requiring parental or guardian consent may exclude the most at-risk youth. Policy and practice decisions regarding the health and mental health outcomes of LGBT2Q+ youth might be based on incomplete and unrepresentative data.

How acceptable is adolescent self-consent for the HPV vaccination: Findings from a qualitative study in south-west England

Suzanne Audrey, Michelle Farr, Marion Roderick, Karen Evans, Harriet Fisher

Vaccine, 9 October 2020
Open Access

Abstract

Background
Human Papillomavirus (HPV) vaccination programmes have the potential to reduce the incidence of cervical cancer. The preferred age for HPV vaccination is 12–13 years for optimal benefit. The legal framework in England allows adolescents to be vaccinated without parental consent if they are assessed as competent. A ‘South West Template Pathway on Self Consent for School Aged Immunisations’ was developed to improve uptake of immunisations in south-west England.

Study aim
To examine how acceptable the new procedures are to the young women, parents and carers, school staff and immunisation nurses involved.

Methods
The research was undertaken in two local authorities in south-west England during the 2017/18 and 2018/19 programme years. Semi-structured digitally recorded interviews were undertaken with 53 participants: one health service manager, three immunisation nurses, five staff at alternative education providers, three staff at mainstream schools, 19 young women and 22 parents. All recordings were transcribed verbatim and thematic analysis was undertaken, assisted by NVivo software.
Results
Most participants were not fully aware of the legal framework that enables a young person to self-consent to vaccination. There was a strong presumption that parents should make decisions affecting the health of their children. The preferred age at which the HPV vaccination is administered (12–13 years) contributed to reluctance in endorsing self-consent which was thought to have the potential to break down trust between parents and school staff, and within families. In practice, formal self-consent was rare.

Conclusion
Unresolved issues in relation to adolescent self-consent include public and professional perceptions of young people’s rights and abilities to take responsibility for decisions affecting their health, and concerns about the impact of self-consent on relationships both within families and between professionals and the families they serve.

Adolescent Barriers to HIV Prevention Research: Are Parental Consent Requirements the Biggest Obstacle?
Original Article
Seema K. Shah, Zaynab Essack, Katherine Byron, Catherine Slack, Daniel Reirden, Heidi van Rooyen, Nathan R. Jones, David S. Wendler
Journal of Adolescent Health, 1 October 2020; 67(4) pp 495-501
Abstract
Purpose
One third of people newly living with HIV/AIDS are adolescents. Research on adolescent HIV prevention is critical owing to differences between adolescents and adults. Parental permission requirements are often considered a barrier to adolescent enrollment in research, but whether adolescents view this barrier as the most important one is unclear.

Methods
Adolescents were approached in schools in KwaZulu-Natal, South Africa, and at a sexually transmitted infection clinic at the Children’s Hospital of Aurora, Colorado. Surveys with a hypothetical vignette about participation in a pre-exposure prophylaxis trial were conducted on smartphones or tablets with 75 adolescents at each site. We calculated descriptive statistics for all variables, using 2-sample tests for equality of proportions with continuity correction. Statistical significance was calculated at p < 0.05. Multivariate analyses were also conducted.

Results
Most adolescents thought side effects (77%) and parental consent requirements (69%) were very important barriers to research participation. When asked to rank barriers, adolescents did not agree on a single barrier as most important, but the largest group of adolescents ranked parental consent requirements as most important (29.5%). Parental consent was seen as more of a barrier for adolescents in South Africa than in the United States. Concerns about being experimented on or researchers’ mandatory reporting to authorities were ranked much lower. Finally, most (71%, n = 106) adolescents said they would want to extra support from another adult if parental permission was not required.

Conclusion
Adolescents consider both parental permission requirements and side effects important barriers to their enrollment in HIV prevention research. Legal reform and better communication strategies may help address these barriers.
Informed Consent and Health: A Global Analysis, Thierry Vansweevelt and Nicola Glover-Thomas (eds) [BOOK REVIEW]
Craig Purhouse
Medical Law Review, 28 October 2020

Excerpt
The English law of ‘informed consent’, which regulates what information doctors should provide to patients, has been influenced by, and influenced, other jurisdictions. In Sidaway v Bethlem Royal Hospital, Lord Scarman (in the minority) referred to the ‘transatlantic doctrine of informed consent’ and endorsed the prudent patient test as the determinant of information disclosure. The majority of the House of Lords, however, rejected the patient-friendly approach prevalent in the USA and Canada and, instead, adopted the Bolam standard of disclosure, whereby doctors would escape liability provided they complied with peer opinion regarding what information should be disclosed to patients. The High Court of Australia chose a different path...

CULTURAL/COUNTRY CONTEXT

14-Year-Old Schoolchildren Can Consent to Get Vaccinated in Tyrol, Austria: What Do They Know about Diseases and Vaccinations?
Peter Kreidl, Maria-Magdalena Breitwieser, Reinhard Würzner, Wegene Borena
Vaccines, 15 October 2020

Open Access

Abstract
In Austria, consent to receiving vaccines is regulated at the federal state level and in Tyrol, children aged 14 years are allowed to consent to receiving vaccination. In August 2017, we investigated determinants associated with vaccine hesitancy, having been vaccinated against measles and human papillomavirus (HPV) and the intention to vaccinate among schoolchildren born in 2002 and 2003. Those who consider measles and HPV a severe disease had a significantly higher intention to be vaccinated (prevalence ratio (PR) of 3.5 (95% CI 1.97–6.32) for measles and a PR of 3.2 (95% CI 1.62–6.35) for HPV). One-third of the participants (32.4%; 95% CI 27.8–37.4) were not aware that they are allowed to consent to receiving vaccines. The most common trusted source reported by respondents (n = 311) was the medical doctor (80.7%; 95% CI 75.7–84.7). The main finding related to the aim of the study was that the proportion of objectors is below 4% and therefore it should still be possible to reach measles elimination for which a 95% uptake is necessary. Although the proportion of objectors is not higher compared to adults, we recommend to intensify health education to increase health literacy.

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

Spanish online survey on informed consent for the performance of paracentesis. Do we have it? Do we use it?
Javier Jiménez Sánchez, Lidia Serrano Díaz, Diana Chuni Jiménez, Miguel Ruiz Moreno, Blanca Gallego Pérez, Carmen María Marín Bernabé, María Gómez Lozano, Daniel García Belmonte, Rosa Gómez Espín, Isabel Nicolás de Prado, José Enrique Hernández Ortuño, Esperanza Egea Simón, Juan José Martínez Crespo
Revista Española de Enfermedades Digestivas, 15 October 2020

Abstract

Introduction
informed consent is necessary for invasive procedures as a document that guarantees the ethical health relationship and patient safety.

**Aims**
to analyze whether we have and use informed consent documents for paracentesis in our hospitals and to obtain data on the technique.

**Methods**
a descriptive observational study was performed during December 2019, via a cross-sectional survey disseminated through social networks, aimed at specialists and residents of gastroenterology.

**Results**
two hundred and three anonymous surveys were included (55.2 % gastroenterologist and 44.8 % residents) from 74 hospitals in 34 Spanish provinces. Ninety respondents (44.3 %) stated that they had the document in their centers. Of these, 29 (32.2 %) always provided it, 31 (34.4 %) provided it sometimes and 21 (23.3 %) never. Seventy-two professionals (35.5 %) answered that they did not have it and 41 (20.5 %) selected "unknown". Of these, 77 (68.1 %) considered it was necessary to create this document, 31 (27.4 %) did not think it was necessary and five (4.4 %) did not answer. With regards to the technique, 173 (85.2 %) performed paracentesis under direct visualization and 30 (14.8 %) were eco-guided on most occasions. One hundred and nine (53.7 %) always applied local anesthetic, 80 (39.4 %) sometimes and 14 (6.9 %) did not. One hundred and sixty-seven respondents (82.3 %) considered it to be a simple technique versus 36 (17.7 %) who thought that it was of intermediate complexity. In terms of risk, 150 (73.5 %) considered it was low and 52 (25.6 %), medium. Ninety-nine (48.8 %) experienced minor complications and 37 (18.2 %) experienced major complications.

**Conclusions**
paracentesis is a common technique in digestive services and could be associated with complications, even though it is considered to be simple and safe. Due to the important intra- and inter-hospital variability that this technique presents, we consider standardized training in this technique is necessary, as well as the creation, spread and use of informed consents.

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**Approach to Informed Consent in Telepsychiatric Service: Indian Perspective**
Guru S Gowda, Arun Enara, Furkhan Ali, Mahesh R Gowda, Chethan Basavarajappa, Channaveerachari
Naveen Kumar, Suresh Bada Math

*Indian Journal of Psychological Medicine, 14 October 2020*

**Open Access**

**Abstract**
Consent is an essential and important medico-legal prerequisite for a patient’s treatment. This necessitates the service provider to participate in the informed consent process and discuss the risk-benefit of the proposed treatment, the best available treatment, engage in shared decision-making process, opportunity to convey their view and thereby limit chances of legal liability for all parties. The clinician should have ample knowledge and skill pertaining to the informed consent process and also have adequate understanding of medical ethics and law. This article provides an overview on informed consent pertaining to telepsychiatric services in India.

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**MEDICAL/SURGICAL**

**The value of communities and their consent: A communitarian justification of community consent in medical research**

*Original Article*
Pepijn Al
Bioethics, 20 October 2020

Abstract
Community engagement is increasingly defended as an ethical requirement for biomedical research. Some forms of community engagement involve asking the consent of community leaders prior to seeking informed consent from community members. Although community consent does not replace individual consent, it could problematically restrict the autonomy of community members by precluding them from research when community leaders withhold their permission. Community consent is therefore at odds with one of the central principles of bioethics: respecting autonomy. This raises the question as to how community consent can be justified or even required. This paper aims to provide an answer to this question by arguing, based on the work of Taylor and Kymlicka, that community practices are important for the identity and autonomy of community members. When these practices are incompatible with a solitary focus on individual informed consent, they need to be protected by making these decision-making practices (including asking permission to community authorities) part of the consent process. Since these decision-making practices are important for the autonomy of community members, community consent with the goal of protecting these practices is not necessarily in conflict with autonomy.

Identification of Informed Consent in Patient Videos on Social Media: Prospective Study

Original Paper
Jane O'Sullivan, Cathleen McCarrick, Paul Tierney, Donal B O'Connor, Jack Collins, Robert Franklin

JMIR Medical Education, 13 October 2020; 6(2)

Open Access

Abstract

Background
The American Medical Association Code of Medical Ethics states that any clinical image taken for public education forms part of the patient’s records. Hence, a patient’s informed consent is required to collect, share, and distribute their image. Patients must be informed of the intended use of the clinical image and the intended audience as part of the informed consent.

Objective
This paper aimed to determine whether a random selection of instructional videos containing footage of central venous catheter insertion on real patients on YouTube (Google LLC) would mention the presence of informed consent to post the video on social media.

Methods
We performed a prospective evaluation by 2 separate researchers of the first 125 videos on YouTube with the search term “central line insertion.” After duplicates were deleted and exclusion criteria applied, 41 videos of patients undergoing central line insertion were searched for reference to patient consent. In the case of videos of indeterminate consent status, the posters were contacted privately through YouTube to clarify the status of consent to both film and disseminate the video on social media. A period of 2 months was provided to respond to initial contact. Furthermore, YouTube was contacted to clarify company policy. The primary outcome was to determine if videos on YouTube were amended to include details of consent at 2 months postcontact. The secondary outcome was a response to the initial email at 2 months.

Results
The researchers compiled 143 videos. Of 41 videos that contained footage of patient procedures, 41 were of indeterminate consent status and 23 contained identifiable patient footage. From the 41 posters that were contacted, 3 responded to initial contact and none amended the video to document consent status. Response from YouTube is pending.

Conclusions
There are instructional videos for clinicians on social media that contain footage of patients undergoing medical procedures and do not have any verification of informed consent. While this study investigated a small sample of available videos, the problem appears ubiquitous and should be studied more extensively.
**Patients’ Experiences of Informed Consent and Preoperative Education**

*Research Article*

Elif Akyüz, Yurdagül Erdem

*Clinical Nursing Research, 7 October 2020*

**Abstract**

The aim of this descriptive cross-sectional study was to determine adult surgery patients’ experiences of informed consent and preoperative education. Research was conducted between September 2018 and February 2019. The sample consisted of 201 adult patients of a university hospital in Turkey. Data were collected using a 48-item questionnaire developed by the researchers based on literature. More than half of the participants (54.2%) were fully informed while 36.8% were partially informed about their surgery process and 61.2% were informed by physicians. Overall, 33.3% had unanswered questions about surgery, with questions relating mostly to the type of surgery (26.8%) and its effect on their body (25.4%). Participants were least informed about preoperative deep breathing and cough exercises (47.8%). More than half (58.4%) of participants expected healthcare professionals to avoid using medical terminology when informing them. Physicians and nurses perform invasive interventions on patients and, therefore, should be sensitive about informing patients.

**Consent for spine surgery: an observational study**

*Original Article*

Angela Li Ching Ng, Lucinda S. McRobb, Sarah J. White, John A. Cartmill, Allan M. Cyna, Kevin See

*ANZ Journal of Surgery, 5 October 2020*

**Abstract**

**Background**

The tension between the ideal of informed consent and the reality of the process is under-investigated in spine surgery. Guidelines around consent imply a logical, plain-speaking process with a clear endpoint, agreement and signature yet surgeons' surveys and patient interviews suggest that surgeons' explanation is anecdotally variable and patient understanding remains poor. To obtain a more authentic reflection of practice, spine surgeons obtaining ‘informed consent’ for non-instrumented spine surgery were studied via video recording and risk/benefit discussions were analysed.

**Methods**

A prospective observational study was conducted at a single neurosurgical institution. Twelve video recordings involving six surgeons obtaining an informed consent for non-instrumented spine surgery were transcribed verbatim and blindly analysed using descriptive quantification and linguistic ethnography.

**Results**

Ten (83%) consultations discussed surgical benefit but less than half (41%) quantified the likelihood of benefit from surgery. The most discussed risks were nerve damage or paralysis (92%), bleeding (92%), infection (92%), cerebrospinal fluid leak (83%) and bowel and bladder dysfunction (75%). Surgeons commonly used a quantitative statement of risk (58%) but only half of the risks were explained in words patients were likely to understand.

**Conclusions**

This study highlights inconsistencies in the way spine surgeons explain risks and obtain informed consent for ‘simple’ spine procedures in a real-world setting. There are wide disparities in the provision of informed consent, which may be encountered in other surgical fields. Direct observation and qualitative analysis can provide insights into the limitations of current informed consent practice and help guide future practice.
Are We Meeting the Current Standards of Consent for Anesthesia? An International Survey of Clinical Practice
Tomas Jovaisa, Ieva Norkiene, Juri Karjagin, Iveta Golubovska, Lukas Gambickas, Migle Kalinauskaite, Evaldas Kauzonas, Dhuleep Wijayatilake
Medical Science Monitor, 5 October 2020
Open Access
Abstract
Background
International application of existing guidelines and recommendations on anesthesia-specific informed consent is limited by differences in healthcare and legal systems. Understanding national and regional variations is necessary to determine future guidelines.
Material and Methods
Anonymous paper surveys on their practices regarding anesthesia-specific patient informed consent were sent to anesthesiologists in Estonia, Latvia, and Lithuania.
Results
A total of 233 responses were received, representing 36%, 26%, and 24% of the practicing anesthesiologists in Lithuania, Latvia, and Estonia, respectively. Although 85% of responders in Lithuania reported using separate forms to secure patient informed consent for anesthesia, 54.5% of responders in Estonia and 50% in Latvia reported using joint forms to secure patient informed consent for surgery and anesthesia. Incident rates were understated by 14.2% of responders and overstated by 66.4% (P<0.001), with the latter frequently quoting incident rates that are several to tens of times higher than those published internationally. Physicians obtaining consent in the outpatient setting were more satisfied with the process than those obtaining consent on the day of surgery, with 62.5% and 42.6%, respectively, agreeing that the informed consent forms provided a satisfactory description of complications (P=0.03). Patients were significantly less likely to read consent information when signing forms on the day of surgery than at earlier times (8.5% vs. 67.5%, P<0.001). Only 46.2% of respondents felt legally protected by the current consent process.
Conclusions
Anesthesia-specific informed patient consent practices differ significantly in the 3 Baltic states, with these practices often falling short of legal requirements. Efforts should be made to improving information accuracy, patient autonomy, and compliance with existing legal standards.

Readability of foot and ankle consent forms in Queensland
Original Article
Giuseppe Pastore, Philip M. Frazer, Andrew Mclean, Tom P. Walsh, Simon Platt
ANZ Journal of Surgery, 5 October 2020
Abstract
Background
The aim of this study was to conduct a readability analysis on both patient take-home information and consent forms for common foot and ankle procedures. Our hypothesis was that the objective reading skills required to read and comprehend the documentation currently in use would exceed the recommendations in place by both national and international bodies.
Methods
The current Queensland Health consent forms are divided into specific subsections. The readability of consent form subsections C and G (sections containing detailed information on risks of the procedure and pertaining to informed patient consent specifically) and patient take-home information (provided as take-home leaflet from the consent form which is procedure specific) was assessed by an online readability software program using five validated methods calculated by application of the algorithms for (i) Flesch–Kincaid grade level, (ii) the SMOG (Simple Measure of Gobbledygook), (iii) Coleman–Liau index, (iv) automated readability index and the (v) Linsear Wriste formula.
Results
The mean ± standard deviation reading grade level of risk (section C), grade level of patient consent (section G) and grade level for procedure-specific take-home patient information were 8.7 ± 0.9, 11.6 ± 1.2 and 7.5 ± 0.2, respectively.

Conclusion
The readability of sections C and G of the Queensland Health consent form exceeds the recommendations by national and international bodies, but the patient take-home information appears suitable. Consideration should be given to lower the reading grade level of patient consent forms to better reflect the reading grade of the Australian population.

‘Hobson’s choice’: a qualitative study of consent in acute surgery
Anthony Howard, Jonathan Webster, Naomi Quinton, Peter V Giannoudis
BMJ Open, 25 August 2020; 10
Open Access
Abstract
Objectives
The study aimed to understand through qualitative research what patients considered material in their decision to consent to an acute surgical intervention.

Participants, setting and intervention
The patients selected aged between 18 and 90, having been admitted to a major trauma centre to undergo an acute surgical intervention within 14 days of injury, where English was their first language. Data saturation point was reached after 21 patients had been recruited. Data collection and analysis were conducted simultaneously, through interviews undertaken immediately prior to surgery. The data were coded using NVIVO V.12 software.

Results
The key theme that originated from the data analysis was patients were unable to identify any individual risk that would modify their decision-making process around giving consent. The patient’s previous experience and the experience of others around them were a further theme. Patients sensed that there were no nonoperative options for their injuries.

Conclusion
This is the first study investigating what patient considered a material risk in the consent process. Patients in this study did attribute significance to past experiences of friends and family as material, prompting us to suggest that the surgeon asks about these experiences as part of the consent process. Concern about functional recovery was important to patients but insufficient to stop them from consenting to surgery, thus could not be classified as material risk.

GENERAL/OTHER

What Do you Mean by “Informed Consent”? Ethics in Economic Development Research
Featured Article
Anna Josephson, Melinda Smale
Applied Economic Perspectives and Policy, 27 October 2020
Open Access
Abstract
The ethical conduct of research requires the informed consent and voluntary participation of research participants. Institutional Review Boards (IRBs) work to ensure that these ethical standards are met. However, incongruities in perspective and practice exist across regions. In this article, we focus on informed
consent as practiced by agricultural and applied economists, with emphasis on research conducted in low income and/or developing countries. IRB regulations are clear but heterogeneous, emphasizing process rather than outcome. The lack of IRBs and institutional reviews in some contexts and the particulars of the principles employed in others may fail to adequately protect research participants.

Philosophical and Cognitive Elements of Risk Communication in Informed Consent [BOOK CHAPTER]
Daniele Chiffi

Clinical Reasoning: Knowledge, Uncertainty, and Values in Health Care, 2 October 2020; pp 145-157

Abstract
There is growing scientific interest in studying the multidisciplinary aspects of risk. Still, no universally accepted definition of risk has been agreed upon. When dealing with the sector of health-related risk, there should be an essential interplay between risk perception and risk communication. The present chapter argues that the effectiveness of risk communication in the health domain can be considerably improved by taking into consideration the cognitive and emotional biases along with all the factors affecting risk perception. I contend that risk communication is effective when based on the negotiation of meanings and therapeutic options in the clinical encounter, which is essential in the context of informed consent and in a person-centred and humanistic perspective in health care.

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