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, as well as other journals and sources. 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
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION

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

COVID-19

A literature review of consent declines and consent withdrawals in randomized controlled trials conducted during the COVID-19 pandemic

Original Article
NJ Gogtay, HJ Sheth, MR Maurya, MN Belhekar, UM Thatte
Journal of Postgraduate Medicine, 16 August 2021; 67(3) pp 134-138

Abstract
Objectives
We evaluated the extent of consent declines and consent withdrawals during the COVID-19 pandemic as seen in published randomized controlled trials (RCTs) and compared it with non-COVID-19 RCTs published at the same time and two historical controls.

Methods
PubMed/Medline only was searched using key-word “COVID-19” and “RCTs” separately, and filtered for COVID-19 RCTs and non-COVID-19 RCTs respectively, published during a nine-month period (1 Feb - 1 Nov 2020). Exclusions were study protocols, observational studies, interim analysis of RCT data and RCTs with missing data. Primary outcome measures were the proportion of consent declines and consent withdrawals as percentage of total participants screened and randomized respectively in COVID-19 RCTs. We compared consent declines and consent withdrawals of COVID-19 RCTs with non-COVID-19 RCTs and two earlier studies on the same topic that served as historical controls (non-pandemic setting).

Results
The search yielded a total of 111 COVID-19 RCTs and 49 non-COVID-19 RCTs. Of these, 39 (35.13%) COVID-19 RCTs and 11 (22.45%) non-COVID-19 RCTs were finally analysed. A total of 770/17759 (4.3%) consent declines and 100/7607 (1.31%) consent withdrawals were seen in 39 COVID-19 RCTs. A significant difference was observed in consent declines between COVID-19 vs non-COVID-19 RCTs [4.3% vs 11.9%, p < 0.0001] and between COVID-19 RCTs vs two historical controls [(4.3% vs 8.6%, p < 0.0001) and (4.3% vs 21.1%, p < 0.0001), respectively].

Conclusion
RCTs conducted during the COVID-19 pandemic appear to have significantly lower consent declines relative to non-COVID-19 RCTs during pandemic and RCTs conducted in non-pandemic settings.

Informed consent and informed intervention: SARS-CoV-2 vaccinations not just call for disclosure of newly emerging safety data but also for hypothesis generation and testing

Letter to the Editor
Abstract
Background
COVID-19 infection is a major threat to patients and health care providers around the world. One solution is the vaccination against SARS-CoV-2.

Methods
We performed a comprehensive query of the latest publications on the prevention of viral infections including the recent vaccination program and its side effects.

Results
The situation is evolving rapidly and there is no reasonable alternative to population-scale vaccination programs as currently enrolled.

Conclusion
Therefore, regulatory authorities should consider supplementing their conventional mandate of post-approval pharmacovigilance, which is based on the collection, assessment, and regulatory response to emerging safety findings.

\textbf{Anti-Coronavirus Disease 2019 Vaccines: Need for Informed Consent.} \\
Mazraani M, Barbari A \\
Experimental and Clinical Transplantation, 1 August 2021; 19(8) pp 753-762

Abstract
Vaccines are among some of the most efficacious medical and public health methods ever employed to contain a pandemic, in addition to providing protective and preventive measures. Evaluation of vaccine associated adverse events through experimentation and empirical evidence is an integral part of thoroughly assessing the safety of vaccines before authorization of their widespread use. History has highlighted the importance of continuous search for possible vaccine-related adverse effects and vaccine-induced immunogenicity long after licensure, suggesting that a primary concern with new vaccines is not only efficacy but also safety, particularly over the long term. Many of the various anti-COVID-19 vaccines have used different types of technology, with some being introduced for the first time or rushed shortly into testing, bypassing animal experimentations. They have been adopted for use through emergency use authorizations, leading to a less than optimal collection of broad data on safety, immunogenicity, effectiveness, and time span of protection, as well as short follow-up of few months, despite many infectious disease experts arguing that it takes 10 years to develop a vaccine. Given the valid concerns on well-recognized short-term and long-term safety issues, such as antibody-dependent enhancement and other processes like molecular mimicry and potential genomic transformation, the experimental nature of the vaccination process, the limited short term follow-up in the main trials, and the dismissal by law of pharma companies and health care providers from any medico-legal responsibilities, the application of an informed consent should become not only a necessity but also mandatory by law in accordance with all declarations on human rights. Such information should be provided to every potential recipient in the form of an official written digital consent prior to the registration for or the receipt of the vaccine.

Editor’s note: Experimental and Clinical Transplantation is the official journal of the Middle East Society for Organ Transplantation.
How Spanish Biobanks have Adapted the Informed Consent Process During the COVID-19 Pandemic
Pablo Enguer-Gosálbez, Jaime Fons-Martínez, Jacobo Martínez-Santamaría, Ana María Torres-Redondo, Cristina Villena-Portella, Aurora García-Robles, Javier Díez-Domingo
BioLaw Journal, 2021
Open Access
Abstract
Due to the situation caused by the Covid-19 pandemic, biobanks have adapted, among other processes, the obtaining of informed consents (IC). This paper details the most relevant elements of the applicable regulations, describes the adaptations done by some of the biobanks of the Spanish Biobank Network to manage the IC process, which have been approved by their Ethics Committees, and draws some conclusions from the results obtained from the survey carried out on these biobanks.

BIOMEDICAL RESEARCH

Are investigators’ access to trial data and rights to publish restricted and are potential trial participants informed about this? A comparison of trial protocols and informed consent materials
Research Article
Asger S. Paludan-Müller, Michelle C. Ogden, Mikkel Marquardsen, Karsten J. Jørgensen, Peter C. Gøtzsche
BMC Medical Ethics, 28 August 2021; 22(115)
Open Access
Abstract
Objectives
To determine to which degree industry partners in randomised clinical trials own the data and can constrain publication rights of academic investigators.
Methods
Cohort study of trial protocols, publication agreements and other documents obtained through Freedom of Information requests, for a sample of 42 trials with industry involvement approved by ethics committees in Denmark. The main outcome measures used were: proportion of trials where data was owned by the industry partner, where the investigators right to publish were constrained and if this was mentioned in informed consent documents, and where the industry partner could review data while the trial was ongoing and stop the trial early.
Results
The industry partner owned all data in 20 trials (48%) and in 16 trials (38%) it was unclear. Publication constraints were described for 30 trials (71%) and this was not communicated to trial participants in informed consent documents in any of the trials. In eight trials (19%) the industry partner could review data during the trial, for 20 trials (48%) it was unclear. The industry partner could stop the trial early without any specific reason in 23 trials (55%).
Conclusions
Publication constraints are common, and data is often owned by industry partners. This is rarely communicated to trial participants. Such constraints might contribute to problems with selective outcome reporting. Patients should be fully informed about these aspects of trial conduct.

An evaluation of the process of informed consent: views from research participants and staff
Research
Lydia O’ Sullivan, Laura Feeney, Rachel K. Crowley, Prasanth Sukumar, Eilish McAuliffe, Peter Doran
Trials, 18 August 2021; 22(544)
Open Access
Abstract
Background
The process of informed consent for enrolment to a clinical research study can be complex for both participants and research staff. Challenges include respecting the potential participant’s autonomy and information needs while simultaneously providing adequate information to enable an informed decision. Qualitative research with small sample sizes has added to our understanding of these challenges. However, there is value in garnering the perspectives of research participants and staff across larger samples to explore the impact of contextual factors (time spent, the timing of the discussion and the setting), on the informed consent process.
Methods
Research staff and research participants from Ireland and the UK were invited to complete an anonymous survey by post or online (research participants) and online (research staff). The surveys aimed to quantify the perceptions of research participants and staff regarding some contextual factors about the process of informed consent. The survey, which contained 14 and 16 multiple choice questions for research participants and staff respectively, was analysed using descriptive statistics. Both surveys included one optional, open-ended question, which were analysed thematically.
Results
Research participants (169) and research staff (115) completed the survey. Research participants were predominantly positive about the informed consent process but highlighted the importance of having sufficient time and the value of providing follow-up once the study concludes, e.g. providing results to participants. Most staff (74.4%) staff reported that they felt very confident or confident facilitating informed consent discussions, but 63% felt information leaflets were too long and/or complicated, 56% were concerned about whether participants had understood complex information and 40% felt that time constraints were a barrier. A dominant theme from the open-ended responses to the staff survey was the importance of adequate time and resources.
Conclusions
Research participants in this study were overwhelmingly positive about their experience of the informed consent process. However, research staff expressed concern about how much participants have understood and studies of patient comprehension of research study information would seem to confirm these fears. This study highlights the importance of allocating adequate time to informed consent discussions, and research staff could consider using Teach Back techniques.

Rethinking informed consent in the age of behavioural sciences and relational autonomy
Original Article
P. Sylvestre, N. Orr Gaucher, T. Perez, O. Drouin
Ethics, Medicine and Public Health, December 2021; 19
Summary
Background and objectives
Informed consent is one of the cornerstones of modern medicine, clinical ethics, and biomedical research. However, emerging evidence in behavioural sciences and relational accounts of autonomy in clinical ethics have highlighted biases and constructs that may challenge informed consent. In this paper, we examine these findings and explore ways forward to ensure the integrity of informed medical decision making.
Method
Cognitive biases affecting patients and clinicians were reviewed in relation to their influence on the cognitive abilities traditionally considered fundamental to informed decision making required for consent: understanding, appreciation and reasoning. The way these findings resonate with criticisms advanced by proponents of relational autonomy was explored.
Results
For patients and clinicians alike, perceiving risks, interpreting probabilities and projecting oneself into the future are influenced by many biases, including loss aversion, underweighting of small probabilities and optimistic bias. These biases directly impact informed decision making by affecting the cognitive processes of understanding, appreciation, and reasoning. In clinical ethics, growing interest in relational accounts of autonomy have highlighted how people are socially embedded, and how patients’ identities and preferences are forged through important social and relational influences. In all, evidence from the behavioural sciences offers support for relational accounts of autonomy and ways forward to improve current practices of informed consent.

Conclusion
Integrating the empirical evidence from behavioural sciences and theoretical elements of relational autonomy compels us to adapt current practices of informed consent. To ensure the integrity of informed medical decision making, the process must further consider the inherent contextual and relational elements that shape how persons consider risks and make decisions.

Personalized and long-term electronic informed consent in clinical research: stakeholder views
Research
Evelien De Sutter, Pascal Borry, David Geerts, Isabelle Huys
BMC Medical Ethics, 31 July 2021; 22(108)
Open Access
Abstract
Background
The landscape of clinical research has evolved over the past decade. With technological advances, the practice of using electronic informed consent (eIC) has emerged. However, a number of challenges hinder the successful and widespread deployment of eIC in clinical research. Therefore, we aimed to investigate the views of various stakeholders on the potential advantages and challenges of eIC.

Methods
Semi-structured interviews were conducted with 39 participants from 5 stakeholder groups from across 11 European countries. The stakeholder groups included physicians, patient organization representatives, regulator representatives, ethics committee members, and pharmaceutical industry representatives, and all were involved in clinical research. Interviews were analyzed using the framework method.

Results
Interviewees identified that a powerful feature of eIC is its personalized approach as it may increase participant empowerment. However, they identified several ethical and practical challenges, such as ensuring research participants are not overloaded with information and offering the same options to research participants who would prefer a paper-based informed consent rather than eIC. According to the interviewees, eIC has the potential to establish efficient long-term interactions between the research participants and the research team in order to keep the participants informed during and after the study. Interviewees emphasized that a personal interaction with the research team is of utmost importance and this cannot be replaced by an electronic platform. In addition, interviewees across the stakeholder groups supported the idea of having a harmonized eIC approach across the European Member States.

Conclusions
Interviewees reported a range of design and implementation challenges which needs to be overcome to foster innovation in informing research participants and obtaining their consent electronically. It was considered important that the implementation of eIC runs alongside the face-to-face contact between research participants and the research team. Moreover, interviewees expect that eIC could offer the opportunity to enable a personalized approach and to strengthen continuous communication over time. If successfully implemented, eIC may facilitate the engagement of research participants in clinical research.
**Social Science Research**

**Integration of Social Media With Targeted Emails And In-Person Outreach For Exception From Informed Consent Community Consultation**

Cindy H. Hsu, Jennifer Fowler, James A. Cranford, Michael P. Thomas, Robert W. Neumar

*Academic Emergency Medicine, 20 August 2021*

**Abstract**

**Background**

Exception from informed consent (EFIC) enables the enrollment of research subjects with emergent conditions to clinical trials without prior consent. EFIC study approval requires community consultation and public disclosure. We hypothesized that the integration of social media with targeted emails and in-person outreach is an effective community consultation strategy.

**Methods**

We utilized social media with targeted emails and in-person outreach for the community consultation of the ACCESS cardiac arrest trial. Study advertisements were disseminated using Facebook and Instagram, and targeted emails were sent to emergency medicine, prehospital and cardiology providers. We also interviewed at-risk individuals with cardiac conditions, their caretakers, and patient advocacy groups. Participants were asked to complete a survey about their opinions about the study.

**Results**

We collected 559 surveys over an 8-week period, and 70.5% of the surveys were obtained using social media. The mean age of survey respondents was 45 years; 89.9% were white and 60.1% were women. 91.3% believed ACCESS was an important study. Compared to the in-person group, more from social media (81.8% vs 63.3%, \( p < 0.05 \)) and targeted email (77.4% vs 63.3%, \( p < 0.05 \)) groups said they would include their loved ones in the study. More from the in-person group believed that their opinion would be considered seriously compared to the social media (75.9% vs 62.6%, \( p < 0.05 \)) and targeted email (75.9% vs 54.5%, \( p < 0.05 \)) groups. The incorporation of social media and targeted emails for community consultation reduced the cost per survey by 4-fold compared to an in-person only strategy.

**Conclusions**

The integration of social media with targeted emails and in-person outreach was a feasible and cost-saving approach for EFIC community consultation. Future work is necessary to determine the perception and best utilization of social media for community consultation.

**“A question of trust” and “a leap of faith”: A qualitative study of participants’ perspectives on consent, privacy and trust in smart home research**

Mari-Rose Kennedy, Richard Huxtable, Giles M Birchley, Jonathan C S Ives, Ian J Craddock

*JMI R mHealth and uHealth, 1 August 2021*

**Abstract**

**Background**

‘Ubiquitous’, ‘smart’ computing technology has the potential to assist humans in numerous ways, including health and social care. Covid-19 has notably hastened the move to remote delivery of many health services. Development of technology involves a variety of stakeholders in the process of testing, refinement, and evaluation. Where stakeholders are research participants, this poses practical and ethical challenges, particularly if the research is situated in people’s homes. Researchers must observe prima facie ethical obligations linked to participants’ interests in having their autonomy and privacy respected.

**Objective**

This research explores ethical considerations around consent, privacy, anonymisation and data-sharing with participants involved in SPHERE, a project developing smart technology for monitoring people’s health behaviours at home. Their unique insights from being part of this unusual experiment offers valuable perspectives on how to properly approach informed consent for similar smart home research in the future.
Methods
Semi-structured qualitative interviews (with adults and children) were conducted with 7 households/16 participants recruited from SPHERE. Purposive sampling was used to invite participants from a range of household types and ages. Interviews were conducted in participants’ homes or on-site at the University of Bristol. Interviews were digitally recorded, transcribed verbatim and analysed using an inductive thematic approach.

Results
Four themes were identified: (1) motivations for participating; (2) transparency, understanding and consent; (3) privacy, anonymity, and data use; and (4) trust in research. Motivations to participate in SPHERE stemmed from an altruistic desire to support research directed towards the public good. Participants were satisfied with the SPHERE consent process despite reporting some difficulties: recalling and understanding information received; the timing and amount of information provision; and sometimes finding the information to be abstract. Participants were also satisfied that privacy was assured and judged that reasons for conducting the research compensated for threats to privacy. Participants trusted the project and the team. Factors relevant to developing and maintaining this trust were the trustworthiness of the research team, provision of necessary information, the control participants had over participation, and positive prior experiences of research involvement.

Conclusions
This small study offers valuable insights into the perspectives of participants in smart home research on important ethical considerations around consent and privacy. The findings might have practical implications for future research regarding the types of information researchers should convey, the extent to which anonymity can be assured, and the long-term duty of care owed to participants who place trust in researchers not only on the basis of this information, but also because of their institutional affiliation. This study highlights important ethical implications: although autonomy matters, trust appears to matter most. Researchers should therefore be alert to the need to foster and maintain trust, particularly as failing to do so might have deleterious effects on future research.

GENOMIC MEDICINE/GENE EDITING

Parents’ experiences of decision making for rapid genomic sequencing in intensive care
Fiona Lynch, Amy Nisselle, Zornitza Stark, Clara L. Gaff, Belinda McLaren
European Journal of Human Genetics, 23 August 2021

Abstract
The clinical utility of rapid genomic sequencing (rGS) for critically unwell infants and children has been well demonstrated. Parental capacity for informed consent has been questioned, yet limited empirical data exists to guide clinical service delivery. In an Australian nationwide clinical implementation project offering rGS for critically unwell infants and children, parents made a decision about testing in under a day on average. This study reports parents’ experiences of decision making for rGS within this rapid timeframe to inform pre-test counselling procedures for future practice. A nationwide sample of 30 parents, whose children were amongst the first to receive rGS, were interviewed. We found that framing and delivery of rGS require careful consideration to support autonomous decision making and avoid implicit coercion in a stressful intensive care setting. Many parents described feeling ‘special’ and ‘lucky’ that they were receiving access to expensive and typically time-consuming genomic sequencing. Thematic analysis revealed a spectrum of complexity for decision making about rGS. Some parents consented quickly and were resistant to pre-test counselling. Others had a range of concerns and described deliberating about their decision, which they felt rushed to make. This research identifies tensions between the medical imperative of rGS and parents’ decision making, which need to be addressed as rGS becomes routine clinical care.
BIOBANKING

The value of consent for biobanking
News & Views
Elizabeth Bromley, Dmitry Khodyakov
Nature Human Behaviour, 23 August 2021
Excerpt
Biobanks facilitate large-scale tests of hypotheses that may advance health, but whether biobanking participants adequately comprehend the potential uses of their data should concern researchers and the public. Consent matters because it provides a singular safeguard and a participatory mechanism to influence science’s production of new forms of power...

Communicating With Diverse Patients About Participating in a Biobank: A Randomized Multisite Study Comparing Electronic and Face-to-Face Informed Consent Processes
Research Article
Christian M. Simon, Kai Wang, Laura A. Shinkunas, Daniel T. Stein, Paul Meissner, Maureen Smith, Rebecca Pentz, David W. Klein
Journal of Empirical Research on Human Research Ethics, 19 August 2021
Abstract
Some individuals’ understanding of informed consent (IC) information may improve with electronic delivery, but others may benefit from face-to-face (F2F). This randomized, multisite study explores how individuals from diverse backgrounds understand electronic IC documents versus F2F, their confidence in understanding, and enrollment in research. A total of 501 patients at two U.S. biobanks with diverse populations participated. There were no overall differences between electronic and F2F understanding, but F2F predicted higher confidence in understanding and enrollment. Ethnicity and a higher educational level predicted higher understanding and confidence. Study findings suggest that electronic consent may lead to better understanding for non-Hispanic patients of higher socioeconomic status. F2F processes may lead to better understanding and higher enrollment of patients from Hispanic and lower socioeconomic levels. Researchers should carefully consider how they implement electronic IC processes and whether to maintain an F2F process to better address the needs and limitations of some populations.

Vulnerabilities of Cancer Patients and Their Effects on Informed Consent for Biobanking
Mason Kyle, Diana Cortez, Blaze Carbonell, Edgar Masmila, Alfredo Molinolo, and Sharmeela Kaushal
Biopreservation and Biobanking, 4 August 2021
Introduction
The biorepository (BR) at the Moores Cancer Center (MCC) of the University of California, San Diego is a College of American Pathologists (CAP)-accredited biobanking core that performs informed patient consent, tissue collection, characterisation, storage, and distribution under Institutional Review Board (IRB)-approved protocol. The informed consent process is the key element that allows the BR to procure and distribute human biospecimens and associated patient information for research...
Rebooting consent in the digital age: a governance framework for health data exchange

Analysis
Nivedita Saksena, Rahul Matthan, Anant Bhan, Satchit Balsari
BMJ Global Health, 22 July 2021; 6(5)

Abstract
In August 2020, India announced its vision for the National Digital Health Mission (NDHM), a federated national digital health exchange where digitised data generated by healthcare providers will be exported via application programme interfaces to the patient’s electronic personal health record. The NDHM architecture is initially expected to be a claims platform for the national health insurance programme ‘Ayushman Bharat’ that serves 500 million people. Such large-scale digitisation and mobility of health data will have significant ramifications on care delivery, population health planning, as well as on the rights and privacy of individuals. Traditional mechanisms that seek to protect individual autonomy through patient consent will be inadequate in a digitised ecosystem where processed data can travel near instantaneously across various nodes in the system and be combined, aggregated, or even re-identified.

In this paper we explore the limitations of ‘informed’ consent that is sought either when data are collected or when they are ported across the system. We examine the merits and limitations of proposed alternatives like the fiduciary framework that imposes accountability on those that use the data; privacy by design principles that rely on technological safeguards against abuse; or regulations. Our recommendations combine complementary approaches in light of the evolving jurisprudence in India and provide a generalisable framework for health data exchange that balances individual rights with advances in data science.

CAPACITY TO CONSENT

Divergent Human Rights Approaches to Capacity and Consent [BOOK CHAPTER]
Gerald Neuman
Mental Health, Legal Capacity, and Human Rights, 2021 [Cambridge University Press]

Abstract
The institutional dialogue among the Committee on the Rights of Persons with Disabilities and other human rights tribunals has led to greater protection of rights. But not all courts and treaty bodies have accepted the Committee’s absolutist position on legal capacity. The chapter illustrates the multiple human rights-based approaches to capacity and decision-making, and describes how the Committee’s absolutism endangers many of the people living with moderate or severe dementia whom it supposedly benefits.

TECHNOLOGY/OTHER MEDIATION

Impact of animation-supported consent on complaints and serious incidents due to failure to inform
D S Wald, L Arrol
QJM: An International Journal of Medicine, 17 August 2021

Summary
Background
Introduction of digital animations to explain medical procedures before consent to treatment (animation-supported consent) has been shown to improve patient-reported understanding of a procedure’s benefits, risks and alternatives.

Aim
We examined whether introduction of animation-supported consent is associated with a change in the incidence of complaints and serious incidents due to failure to inform.

Methods
Multi-language animations explaining 10 cardiac procedures, in coronary intervention, electrophysiology and cardiac surgery, (www.explainmyprocedure.com) were introduced at a London cardiac centre from April 2019. Complaints and serious incidents due to failure to inform were identified from the hospital Datix database for the two years before introducing animation-supported consent (no animation group) and the two years afterwards (animation group), together with the total number of procedures and major complications recorded during these periods. We compared the incidence of complaints and serious incidents, expressed as a proportion of the number of major complications, recorded during each period.

Results
There were 580 complications among 21,855 procedures performed in the no animation group and 411 complications among 18,254 procedures in the animation group. There were 14 complaints or serious incidents due to failure to inform in the no animation group and 3 in the animation group; rates of 2.41% (14/580) and 0.73% (3/411), respectively (P < 0.001 for difference).

Conclusion
In this observational comparison, introduction of animation-supported consent was associated with a 70% reduction in complaints or serious incidents due to failure to inform before consent. This has significant quality and cost implications for improving consent pathways in clinical practice.

Graphic narrative based informed consent for bronchoscopy improves satisfaction in patients after lung-transplantation: A randomized controlled trial
Benjamin Seeliger, Moritz Z. Kayser, Nora Drick, Jan Fuge, Christina Valtin, Mark Greer, Jens Gottlieb
Patient Education and Counseling, 13 August 2021

Abstract

Objective
This study investigated the effects of supplementing standard informed consent (IC) with a graphic narrative on patient satisfaction, periprocedural anxiety and experience.

Methods
Patients due to undergo first conscious surveillance bronchoscopy following lung transplantation were randomized to receive IC with (intervention group) or without (control group) a graphic narrative illustrating the procedure. The primary endpoint was overall patient satisfaction with the IC. Key secondary endpoints were change in state anxiety level, as measured by State Trait Anxiety Inventory, and a questionnaire assessing satisfaction with IC and adverse experience during bronchoscopy (judged by patient and examiners).

Results
Sixty patients were randomized, and 59 patients were included in the analysis (30 intervention-group; 29 control-group). Overall patient satisfaction was higher in the intervention group 9.5 (25Q–75Q: 8.6–9.8) vs. 8.6 (25Q–75Q: 8.1–9.2), p = 0.028). Change in state anxiety level (before vs after informed consent) was similar between the groups. There were no significant differences in adverse experience during bronchoscopy.

Conclusion
Addition of a graphic narrative illustrating bronchoscopy improved patient satisfaction with IC but did not influence anxiety before and adverse experience during the procedure.
Practice implications
Supplementing the IC process with a procedure-specific graphic narrative may be a simple tool to improve patient satisfaction.

YOUNG PERSONS

Transparent reporting of recruitment and informed consent approaches in clinical trials recruiting children with minor parents in sub-Saharan Africa: a secondary analysis based on a systematic review
Research Article
Angela De Pretto-Lazarova, Domnita Oana Brancati-Badarau, Christian Burri
BMC Public Health, 28 July 2021; 21(1473)
Open Access
Abstract
Background
Standardised checklists of items to be addressed in clinical study protocols and publications are promoting transparency in research. However, particular specifications for exceptional cases, such as children with minor parents are missing. This study aimed to examine the level of transparency regarding recruitment and informed consent approaches in publications of clinical trials recruiting children with minor parents in sub-Saharan Africa. We thereby focused particularly on the transparency about consenting persons (i.e. proxy decision-makers) and assessed the need to expand reporting guidelines for such exceptional cases.

Methods
We conducted a secondary analysis of clinical trial publications previously identified through a systematic review. Multiple scientific databases were searched up to March 2019. Clinical trial publications addressing consent and potentially recruiting children with minor parents in sub-Saharan Africa were included. 44 of the in total 4382 screened articles met our inclusion criteria. A descriptive analysis was performed.

Results
None of the included articles provided full evidence on whether any recruited children had minor parents and how consent was obtained for them. Four proxy decision-maker types were identified (parents; parents or guardians; guardians; or caregivers), with further descriptions provided rarely and mostly in referenced clinical trial registrations or protocols. Also, terminology describing proxy decision-makers was often used inconsistently.

Conclusions
Reporting the minimum maternal age alongside maternal data provided in baseline demographics can increase transparency on the recruitment of children with minor mothers. The CONSORT checklist should require clinical trial publications to state or reference exceptional informed consent procedures applied for special population groups. A standardized definition of proxy decision-maker types in international clinical trial guidelines would facilitate correct and transparent informed consent for children and children with minor parents.

Age-of-Consent Policies and HIV Among Adolescents in SubSahara Africa [DISSERTATION]
Suzanne Marie King
Walden University, 2021
Open Access
Abstract
Age of consent policies have recently been identified as a barrier to HIV testing among adolescents in HIV endemic Sub-Saharan Africa. Grounded in the modified social ecological model, the purpose of this study was to determine if these policies were related to HIV testing rates and prevalence. In this quantitative research secondary data sets from the Demographic Health Survey were used. This study included all sexually active respondents aged 18 years or below (N=37,015) and then was further limited by respondents that had HIV test results (N=25,107). Binary logistic regression showed that respondents with lower age of consent had higher rates of HIV testing. Compared to respondents with an age of consent of 18 years, respondents with age of consent of 16 were 3 times more likely to have been tested (p<0.001, OR 2.876, 95% CI [2.697, 3.067]), age of consent of 15 were 1.5 times more likely to be tested, age of consent of 14 were 0.5 times less likely to be tested, age of consent of 13 were 5 times more likely to be tested, age of consent of 12 were 3 times more likely to be tested, and age of consent of 11 were 2 times more likely to have been tested. Age of consent was also related to HIV prevalence. For each year decrease in age of consent, odds of being HIV positive increased by 1.2%. The outcomes of this study showed further relationships between HIV testing and age of consent policies. This research can be used to inform updated age of consent policies to ensure that all adolescents can access HIV testing. This research could shed light on the importance of HIV testing for adolescents, their families, and their communities leading to positive social change.

RIGHTS/LEGAL/LEGISLATIVE

The Rise of the French Doctrine of Informed Consent: Criminal Responsibility for an Unauthorised Medical Experiment – The Case of the Antiquaille Hospital and Subsequent Notable Judgments
Anatoliy A. Lytvynenko
Athens Journal of Law, 2021; 7 pp 1-14
Open Access

Abstract
The French doctrine regarding a patient’s informed consent has a long and very rich history, dating back at least to the mid-nineteenth century. Medical malpractice had become a frequent subject of criminal trials and civil litigation against physicians and surgeons in the nineteenth and early twentieth centuries, resulting in French medical case law and its academic scholarship becoming one of the most prominent throughout all the civil law jurisdictions. Simultaneously, medical malpractice lawsuits were not rare in civil or common law jurisdictions. The uniqueness of French jurisprudence lies in the development of a robust body of case law, which formed the basis for patients’ rights, and specifically informed consent and the right to medical data confidentiality. The right to informed consent is a reflection of the patient’s right to their own bodily integrity, which may not be violated for the purpose of treatment, except in an emergency. Moreover, the rule of consent is even stricter if physicians are administering experimental treatment (which is not generally banned, as it may benefit the patient), or conducting certain methods of treatment for purely scientific purposes – as was in the case of the Antiquaille Hospital in Lyon, where a dangerous and experimental method of treatment was used to treat a ten-year-old minor suffering from dermatophytosis, which was not authorised by his guardians. The case, which was adjudicated by the criminal court of Lyon, is historically one of the first legal cases to deal with unconsented treatment conducted for the purpose of a scientific experiment. Over the twentieth century, similar legal cases became more frequent in France.
FREE PRIOR INFORMED CONSENT (FPIC)

Renewable energy development on the Indigenous Estate: Free, prior and informed consent and best practice in agreement-making in Australia
Lily O’Neill, Kathryn Thorburn, Bradley Riley, Ganur Maynard, Esmé Shirlow, Janet Hunt
Energy Research & Social Science, November 2021; 81

Abstract
In Australia, large-scale renewable energy projects are being developed or proposed on lands over which First Nations hold rights and interests. Our review of the literature on renewable energy and First Nations peoples globally indicates that renewable energy projects are likely to present risks in the distribution of socio-economic and environmental impacts, as well as significant opportunities for First Nation benefit. This paper explores the conditions under which First Nations people with communal property rights and interests in their traditional land are likely to derive benefit from large scale renewable energy projects.

We examine ‘free, prior and informed consent’ (FPIC), a widely-recognised international human rights standard that sets out a consent, information and consultation framework for proposed developments on First Nation land. In calling for the just economic inclusion and participation of First Nation people in large-scale renewable energy projects we propose that ‘free, prior and informed consent’ offers a suitable framework for approaching the development of these projects. Furthermore, we detail what is best, and worst, practice in agreement making, based on previous First Nations agreement making experience, predominately with the resource extraction sector.

Engaging Free, Prior and Informed Consent for Mutual Benefit
Rudolph C. Rÿser
Fourth World Journal, Summer 2021; 21(1) pp 98-143

Abstract
The Center for World Indigenous Studies, prompted by inquiries and urgings by leaders of indigenous nations, sponsored the planning, organization and convening of a Congress of Nations and States—the process that began in the summer of 2019. In this article we discuss the Congress as a new international mechanism to facilitate engagement by indigenous nations and states on an equal political plain in pursuit of comity and establishment of cooperative measures for mutual benefit. This article discusses the consequences of the failure of decolonization advanced by the United Nations in 1945 that resulted up to 1.9 billion people from indigenous nations left without their consent inside the boundaries of existing states contributing to social, economic, political and security conflicts demanding relief. More than 5000 nations occupy territories and political space inside states with the states’ claiming those territories and competing for political space by asserting state sovereignty. The article presses forward by emphasizing the importance of the principle of free, prior and informed consent responding to the long list of principles and commitments in the policy areas of economics, environment, culture & society, political governance, security, and justice made by nations and states since 1977. I suggest that existing agreements on principles and commitments if implemented by nations and states may resolve most of the current conflicts. Specific principles and commitments are discussed and sourced to treaties, conventions, declarations, and outcome documents issued by nations and states from 1977 forward.

Editor’s note: The Fourth World Journal is published by the Center for World Indigenous Studies.

CULTURAL/COUNTRY CONTEXT

Legal and Ethical Challenges in the Construction of China's Biobanks
Jiajv Chen, Jiayu Huang, Xuekai Xie
Biotechnology Law Report, 26 August 2021

Abstract
China has no special legislation on biobanks, and it regulates these banks by several different laws and regulations. In the past 15 years, China's biobanks have collected a large number of biological samples. The law gives many institutions the right to store and use biological samples; however, due to the absence of government regulation, lack of ethical norms, and unclear legal provisions, the risks related to biosafety are rising. In terms of informed consent, China's current legislation clearly defines the scope and standard of “informed consent,” but the corresponding boundaries are still vague, and there are loopholes in practical operation. In terms of privacy and confidentiality, Chinese laws do not specify the ownership of genetic information. In the event of genetic risk, Chinese doctors often tell the family members of patients about genetic information. In terms of cross-border supervision of biological samples, the Chinese government not only regulates the entry of biological samples, but also controls the exit of biological samples. In recent years, the corresponding law enforcement and punishment efforts have increased. In terms of trust, China's biobanks often rely on hospitals. Against the background of tense doctor-patient relationships, biological sample donors do not trust hospitals, which is unfortunate because biological sample donors often donate out of their trust in doctors. In terms of benefit sharing, China's legal system still lacks clear provisions, and there are disputes about the mode and subject of benefit sharing. In China's future legislative revision(s), the above aspects should be improved, the ethical traditions of China’s “patriarchal system” should be considered, and a biobanking system in line with China's national conditions should be formulated.

Family Refusal to Consent Donation: Retrospective Quantitative Analysis of Its Increasing Tendency and the Associated Factors Over the Last Decade at a Spanish Hospital
José Manuel Viñuela-Prieto, María Carmen Escarpa Falcón, Francisco Javier Candel, Alonso Mateos Rodríguez, Juan Ignacio Torres González, Francisco del Río Gallegos

Transplantation Proceedings, 19 August 2021

Open Access

Abstract

Background
Organ and tissue recovery remains limited by several factors. This study retrospectively analyzes the factors associated with family refusal to consent to donation at a high-donor-volume Spanish hospital.

Methods
Data regarding the annual number of potential donors and family refusal rates at hospital and regional levels were retrieved from 2008 to 2017. Descriptive, bivariate, and multivariate analyses were performed to detect those factors independently associated with family refusal. Results were cross-validated using the data from years 2018 and 2019 as the validation group. To explore potential inter-relations between factors a Multiple Correspondence Analysis was performed.

Results
A total of 601 family interviews for petition of consent were conducted between 2008 and 2017, 531 (88.4%) resulted in acceptance and 70 (11.6%) resulted in refusal of the donation. Lesser experience of the interviewers (odds ratio [OR], 2.980; P = .001), donation after brain death (OR, 2.485; P = .013), number of interviews conducted per family (OR, 1.892; P < .001), age of the main decision maker (OR, 1.025; P = .045), and high or middle attributed cultural levels (OR, 0.142; P < .001 and OR, 0.199; P < .001 respectively) were observed to be independently associated with the family final decision. The logistic regression model displayed good predictive power for both derivation and validation cohorts, with an overall predictive accuracy of 80.9% (95% confidence interval, 0.747-0.870; P < .001) and 74.4% (95% confidence interval, 0.635-0.854; P = .001), respectively.

Conclusions
Transplant coordination team members having a thorough knowledge of the family decision mechanisms may be a key factor in donation process optimization.
South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities: a cross-cultural qualitative study

Research Article
Francis Akpa-Inyang, Sylvestre C. Chima

BMC Medical Ethics volume, 14 August 20121; 22(111)

Open Access

Abstract

Background

The Western-European concept of libertarian rights-based autonomy, which advocates respect for individual rights, may conflict with African cultural values and norms. African communitarian ethics focuses on the interests of the collective whole or community, rather than rugged individualism. Hence collective decision-making processes take precedence over individual autonomy or consent. This apparent conflict may impact informed consent practice during biomedical research in African communities and may hinder ethical principlism in African bioethics. This study explored African biomedical researchers' perspectives regarding informed consent and potential limitations to the principle of respect for autonomy in African communities.

Methods

We conducted a qualitative study based on in-depth interviews with 12 biomedical researchers, five females and seven males aged 34 to 74 years, currently working at an African university. Interviews lasted 35–40 min each and involved semi-structured open-ended interviews, which allowed participants to offer information about their perceptions and feelings regarding respect for autonomy and informed consent as practised in Africa. Empirical data from the interviews were recorded, transcribed, and analysed using thematic content analysis, together with an interrogation of relevant scientific literature about African communitarian ethics, making evaluations and drawing inferences consistent with the empirical bioethics approach.

Results

Based on these interviews and analysis of relevant literature, we found that informed consent is difficult to apply in an African context because it derives from a Western conception of libertarian rights-based autonomy. Most respondents pointed out that it was challenging to implement informed consent in the African setting. Furthermore, communalism, customary beliefs, spirituality, and relational autonomy are predominant in most African communities, as exemplified by the African moral philosophies of Ubuntu/Botho and Ukama, which emphasize communitarianism over individual rights. We also found that language, education, poverty, and cultural beliefs are barriers to obtaining proper informed consent in African communities.

Conclusions

We conclude that there are limitations to applying the principle of respect for autonomy and informed consent in African communities, especially in the context of human biomedical research. We recommend using a more relational approach, such as Ross's prima facie duties, to implement informed consent in African communities.

Motivation to participate and experiences of the informed consent process for randomized clinical trials in emergency obstetric care in Uganda

Research Article
Dan Kabonge Kaye

BMC Medical Ethics, 28 July 2021; 22(104)

Open Access

Abstract

Background

Informed consent, whose goal is to assure that participants enter research voluntarily after disclosure of potential risks and benefits, may be impossible or impractical in emergency research. In low resource settings, there is limited information on the experiences of the informed consent process for randomized
clinical trials in the emergency care context. The objective of this study was to explore the experiences of the informed consent process and factors that motivated participation in two obstetrics and newborn care randomized clinical trials (RCTs).

**Methods**
This was a qualitative study conducted among former participants of RCTs in the emergency obstetric care context, conducted at Kawempe National Referral Hospital, Uganda. It employed 30 in-depth interviews conducted from June 1, 2019 to August 30, 2019. Issues explored included attitudes about research, the purpose of the research in which they participated, motivations to take part in the study, factors that influenced enrolment decisions, and experiences of the informed consent process.

**Results**
Respondents felt that research was necessary to investigate the cause, prevention or complications of illness. The decisions to participate were influenced by hope for material or therapeutic benefit, trust in the healthcare system and influence of friends and family members. Many were satisfied with the informed consent process, though they did not understand some aspects of the research.

**Conclusion**
Respondents valued participation in RCTs in emergency obstetric and newborn care. Hope for benefit, altruism, desire to further scientific knowledge and trust in the investigators featured prominently in the motivation to participate. Both intrinsic and extrinsic factors were motivators for RCT participation.

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**Informed consent and responses of surgical patients: A study in North India**
Aman Dev Singh, Ritu Rochwani, Simmi Oberoi
National Journal of Physiology Pharmacy and Pharmacology, 9 July 2021; 11(8) pp 925-929

**Open Access**

**Abstract**

**Background**
A patient’s decision about his or her treatment without being pressurized by their health-care provider is his right and termed as autonomy. Informed consent means that a patient is not merely signing a paper but the whole process in which he is imparted knowledge regarding his disease, diagnostic options, and details regarding intervention modalities for his/her condition. As informed consent is patient’s right and key to trust/relationship between doctor and patient, it is imperative that consent is in layman’s language and the process is completely understood and appropriately documented. In India, there are very less studies conducted for the informed consent.

**Aims and Objectives**
With this background, the present study was conducted in a tertiary care hospital at Patiala, Punjab, with the objectives – (1) to determine levels of awareness and understanding regarding contents of informed consent and (2) to analyze the patient’s perspective of the process of informed consent in a tertiary care hospital setting.

**Materials and Methods**
A cross-sectional survey was carried out among the patients who had undergone elective or emergency surgery in the surgical departments of general surgery, obstetrics and gynecology, orthopedics, otolaryngology, ophthalmology, urology, and plastic surgery at a tertiary care teaching hospital at Patiala, Punjab, during October–December 2013. Around 400 post-operative randomly selected patients were interviewed using pre-structured questionnaires. Permission was obtained from the Institutional Ethics Committee.

**Results**
A total of 400 post-operative patients were randomly selected for this study. Patients himself/herself responded in 60.5% of cases. Only 255 (69.29%) knew about proposed procedure, while 122 (33.15%) were informed about alternate treatment. Almost half (n = 170, 46.19) of them received information about type of anesthesia and only 51 (13.48%) were informed about its complications. In 32 (8%) cases, patients perceived that no informed consent was taken although record was available of the same.
Conclusion
Informed consent enjoys an irrefutable position in clinical practice as a safeguard of patient’s rights. It also minimizes the chances of legal action against the treating physician if a complication arises from the proposed therapy. There is a dire need to alert the doctors and health-care providers.

The Role of the Nurse in Informed Consent to Treatments: An Observational-Descriptive Study in the Padua Hospital
Veronica Strini, Roberta Schiavolin, Angela Prendin
Clinics and Practice, 2021; 11(3) pp 472-483
Open Access
Abstract
Background
The process to obtain valid informed consent in healthcare reflects many aspects. Healthcare professionals that take care of the patient must provide him all the necessary information and verify his understanding, considering individual characteristics. Nurses are one of the main participants in this process.
Objective
This study assesses nurses’ perceptions of their role in the informed consent process. Material and Methods
An observational study involving 300 nurses operating in 13 wards of the Padua Hospital, through the submitting of a questionnaire in the period November–December 2018.
Results
The final sample is made up of 206 nurses—27 males (13.11%) and 179 females (86.89%). Work experience, on average 15 years, is significant in determining the answers to questions about opinions and experiences. Age is significant in determining how often nurses provide information to the patient’s family members about the actions to be taken after discharge. The ward was decisive in the responses related to information provided to patients on the nursing care level and the actions to be taken after discharge, and the definition of the nurse’s duties.
Conclusions
The data collected show the need for interventions to reduce the causes of difficult that the nurse has in informing patients.

MEDICAL/SURGICAL

Practice variation in the informed consent procedure for thrombolysis in acute ischemic stroke: a survey among neurologists and neurology residents
Valentijn J. Zonjee, Jos P. L. Slenders, Frank de Beer, Marieke C. Visser, Bastiaan C. ter Meulen, Renske M. Van den Berg-Vos, Sander M. van Schaik
BMC Medical Ethics, 25 August 2021; 22(114)
Open Access
Abstract
Background
Obtaining informed consent for intravenous thrombolysis in acute ischemic stroke can be challenging, and little is known about if and how the informed consent procedure is performed by neurologists in clinical practice. This study examines the procedure of informed consent for intravenous thrombolysis in acute ischemic stroke in high-volume stroke centers in the Netherlands.
Methods
In four high volume stroke centers, neurology residents and attending neurologists received an online questionnaire concerning informed consent for thrombolysis with tissue-type plasminogen activator (tPA). The respondents were asked to report their usual informed consent practice for tPA treatment and their considerations on whether informed consent should be obtained.

Results
From the 203 invited clinicians, 50% (n = 101) completed the questionnaire. One-third of the neurology residents (n = 21) and 21% of the neurologists (n = 8) reported that they always obtain informed consent for tPA treatment. If a patient is not capable of providing informed consent, 30% of the residents (n = 19) reported that they start tPA treatment without informed consent. In these circumstances, 53% of the neurologists (n = 20) reported that the resident under their supervision would start tPA treatment without informed consent. Most neurologists (n = 21; 55%) and neurology residents (n = 45; 72%) obtained informed consent within one minute. None of the respondents used more than five minutes for informed consent. Important themes regarding obtaining informed consent for treatment were patients’ capacity, and medical, ethical and legal considerations.

Conclusion
The current practice of informed consent for thrombolysis in acute ischemic stroke varies among neurologists and neurology residents. If informed consent is obtained, most clinicians stated to obtain informed consent within one minute. In the future, a shortened information provision process may be applied, making a shift from informed consent to informed refusal, while still considering the patient’s capacity, stroke severity, and possible treatment delays.

Research Article
J. Blake Hotchkiss, Judy Thompson
Journal of the Association for Vascular Access, 18 August 2021
Abstract
Background
Vascular access device insertion is one of the most performed procedures in healthcare today. With different device types available to provide infusion therapy, there are many different variables to consider, including the process of obtaining informed consent from patients. This literature review aims to discuss common themes present in current evidence-based practice and point out critical areas of variability that exist.

Methods
A literature review was conducted searching Cochrane Library, Joanna Briggs Institute for Evidence-Based Practice, Cumulative Index to Nursing and Allied Health Literature, PubMed, and Google Scholar databases for recently published articles in the English language and those written in English. Articles were screened to include those that describe informed consent within the context of vascular access or other invasive procedures. There were 35 articles and 5 systematic reviews identified that met criteria for inclusion in this literature review.

Discussion
The topics of ethics, legal responsibility, who provided consent, and how education about procedures was performed demonstrated clear insight into how to improve the consent process. Some areas in current evidence lack clear direction and create variability in the informed consent procedure. These included who should obtain consent from the patient and which vascular access devices required a written consent. Who obtains consent was found to be more related to current legal precedence and not the clinician inserting the device like that found when a nonphysician clinician performed the procedure. Vascular access device related variability in requiring written versus verbal consent was found to be rooted in the degree of complexity of the procedure, need for specialized training, and the inherent risk to the patient.

Conclusion
These two areas of variability described in current clinical practice require more research and consensus agreement to standardize the practice of obtaining informed consent in vascular access device insertion.

**Does radiology require informed consent for radiation risk?**

*Commentary*
Elizabeth M Davies, Andrew J Bridges, Emma ML Chung
*The British Institute of Radiology, 6 August 2021*

*Abstract*
Recent trends in medical decision-making have moved from paternalistic doctor-patient relations to shared decision-making. Informed consent is fundamental to this process and to ensuring patients’ ongoing trust in the health-care profession. It cannot be assumed that patients consent to the risk associated with medical exposures, unless they have been provided with the information to make that decision. This position is supported by both the legal and ethical framework around Radiation Protection detailed in this commentary.

**Are patients truly informed? A retrospective chart review of the documentation of informed consent in laparoscopic cholecystectomy**

Erin Williams, Raj Selvam, Wilma Hopman, Sulaiman Nanji
*Canadian Journal of Surgery, 29 July 2021; 64(4)*

*Abstract*
*Background*
Research on informed consent (IC) has traditionally focused on the documentation of the discussion with patients of potential complications. We sought to examine the completeness of documentation for all elements of IC for laparoscopic cholecystectomy (LC): potential complications, alternatives to LC and details of the procedure. Differences in the documentation of IC for elective and emergent LC were examined.

*Methods*
A retrospective chart review of patients undergoing LC at our institution between 2015 and 2017 was performed. Completeness of documentation was defined as documentation of all 3 elements of IC in the clinic note, the operating room note or the consent form itself. Data were analyzed descriptively. We compared documentation for emergent and elective cases as well as documentation by residents and attending physicians using t tests.

*Results*
A total of 270 patients were included in the analysis. Only 5 (2%) had complete documentation of all elements of IC. Documentation of potential complications was noted in 232 cases (86%), of which 58 (25%) were elective and 174 (75%) were emergent. Details were noted in 28 (10%) cases, of which 21 (75%) were elective and 7 (25%) were emergent. Alternatives were documented the least frequently: they were documented in 23 cases (9%), of which 20 (87%) were elective and 3 (13%) were emergent. Residents performed better than attending physicians in documenting IC discussions in clinic notes and on consent forms, but not in operating room notes.

*Conclusion*
Documentation of the elements of IC for LC was poor. Potential complications were the most frequently documented element of IC; alternatives and details were often omitted. Future studies comparing audiotaped IC conversations with the documentation of IC are warranted. The use of procedure-specific consent forms for LC may facilitate documentation.

**Soft Tissue Filler Therapy and Informed Consent – A Canadian Review**

*Review Article*
John P. Arlette, Andrea L. Froese, Jaspreet K. Singh
Journal of Cutaneous Medicine and Surgery, 26 July 2021

Abstract
Soft Tissue Filler (STF) Therapy for cosmetic facial rejuvenation is associated with known complications. The manifestation of these known complications can lead to patients commencing civil litigation actions or making complaints to provincial regulatory authorities and alleging that the practitioner failed to obtain the patient’s informed consent to the therapy. Data provided by the Canadian Medical Protective Association (CMPA) on medical-legal cases arising from the provision of STF therapy between 2005 and 2019 are presented. Select reported case law decisions from Canadian courts and regulatory bodies addressing the concept of informed consent are reviewed. Insights about the risk factors pertaining to the process of obtaining informed consent for STF therapy are presented to increase an understanding of the elements of communication and documentation needed to ensure patients are aware of the consequences of this treatment.

An Evaluation of the Comprehensibility Levels of Ophthalmology Surgical Consent Forms

Original Article
Ibrahim Ethem Ay, Mustafa Doğan
Cureus, 26 July 2021

Abstract
Background/Aim
This study aimed to evaluate the comprehensibility of the consent forms used for interventional procedures in the ophthalmology clinic of a university hospital and to determine which texts could be read according to patient age and education level.

Materials and methods
Forty separate consent forms used as the standard for various interventional procedures in the ophthalmology department of a university hospital were evaluated. The comprehensibility formulas used were developed for the Turkish language by Ateşman and Bezirci-Yilmaz.

Results
As a result of the evaluation of the consent forms in this study, a mean of 55.6±5.73 points was obtained according to the Ateşman comprehensibility index, and this value was found to correspond to being understood by eleventh and twelfth-grade school students. According to the Bezirci-Yilmaz comprehensibility index, the mean points of the consent forms were 10.05±2, which corresponded to a level that could be understood by 10th and 11th-grade students.

Conclusion
The comprehensibility level of the consent forms given to patients was found to be low in this study, which was similar to the findings of previous studies in the literature. When preparing informed consent forms, the education level of the country must be taken into consideration.

GENERAL/OTHER

Does the General Medical Council’s 2020 guidance on consent advance on its 2008 guidance?

Clinical Ethics
Abeezar I Sarela
Journal of Medical Ethics, 23 August 2021

Abstract
The General Medical Council renewed its guidance on consent in 2020. In this essay, I argue that the 2020 guidance does not advance on the earlier, 2008 guidance in regard to treatments that doctors are obliged to
offer to patients. In both, doctors are instructed to not provide treatments that are not in the overall benefit, or clinical interests, of the patient; although, patients are absolutely entitled to decline treatment. As such, consent has two aspects, and different standards apply to each aspect. To explore this paradigm, I propose the reconceptualisation of consent as a person’s freedom to achieve treatment, using Amartya Sen’s approach. Sen explains that freedom has two aspects: process and opportunity. Accordingly, a patient’s freedom to achieve treatment would comprise a process for the identification of proper treatment, followed by an opportunity for the patient to accept or decline this treatment. As per Sen, the opportunity aspect is to be assessed by the standard of public reason, whereas the standard for the process aspect is variable and contingent on the task at hand. I then use this reconceptualised view of consent to analyse case law. I show that senior judges have conceived the patient’s opportunity to be encompassed in information, which is to be decided by public reason. On the other hand, the process aspect relies on the private reason of medical professionals. Given the nature of professionalism, this reliance is inescapable, and it is maintained in the case law that is cited in both guidances.

**Consent is an organizational behavior issue**
Vanessa K.Bohns, RachelSchlund
Research in Organizational Behavior, 18 August 2021

*Abstract*
Consent is central to many organizational interactions and obligations. Employees consent to various terms of employment, both formal (contractual obligations) and informal (extra-role responsibilities, interpersonal requests). Yet consent has traditionally been considered a legal matter, unrelated to organizational behavior. In this article, we make a case for why, and how, organizational behavior scholars should undertake the study of consent. We first review scholarship on the legal understanding of consent. We argue that the traditional legal understanding is an incomplete way to think about consent in organizations, and we call for a more nuanced understanding that incorporates psychological and philosophical insights about consent—particularly consent in employer-employee relationships. We then connect this understanding of consent to traditional organizational behavior topics (autonomy, fairness, and trust) and examine these connections within three organizational domains (employee surveillance, excessive work demands, and sexual harassment). We conclude with future directions for research on consent in organizations.

**ICME: an informed consent management engine for conformance in smart building environments**

*CONFERENCE PAPER*
Chehara Pathmabandu, John Grundy, Mohan Baruwal Chhetri, Zubair Baig

*Open Access*

*Abstract*
Smart buildings can reveal highly sensitive insights about their inhabitants and expose them to new privacy threats and vulnerabilities. Yet, convenience overrides privacy concerns and most people remain ignorant about this issue. We propose a novel Informed Consent Management Engine (ICME) that aims to: (a) increase users’ awareness about privacy issues and data collection practices in their smart building environments, (b) provide fine-grained visibility into privacy conformance and infringement by these devices, (c) recommend and visualise corrective user actions through “digital nudging”, and (d) support the monitoring and management of personal data disclosure in a shared space. We present a reference architecture for ICME that can be used by software engineers to implement diverse end-user consent management solutions for smart buildings. We also provide a proof-of-concept prototype to demonstrate how the ICME approach works in a shared smart workplace. Demo: <a>https://youtu.be/5y6CdyWAdgY</a>
Communication and Libertarianism [BOOK]
Pavel Slutskiy
Springer, 3 August 2021
Editor’s note: In Communication and libertarianism, which covers a range of themes, the four chapters below were relevant to consent.

Communicating Consent
Abstract
The libertarian non-aggression principle rests on two concepts: the concept of property rights, which defines the borders of individual autonomy, and the concept of consent, which defines unwarranted intrusion. Both concepts depend on communication—borders of property need to be publicly manifested on the one hand, and consent needs to be expressed in order to exist in the reality of human action on the other. Unless consent is manifested, it remains hypothetical, and hypothetical consent is never valid. Even if an action based on hypothetical consent coincides with the preferences of the consent-giver, it happens to be so only by coincidence. Counting on such hypothetical consent is risky, and the actor who takes the risk bears full responsibility for potential mistakes which may lead to uninvited interference. Hypothetical consent needs to be separated from tacit and implied consent, both of which can be valid. Internal “mental” aspects of consent may be important felicity conditions for consent, but they are not enough for a successful performance of the act of consenting. It is “external” or expressive aspects of consenting which are crucial for making the preferences of the consent-giver identifiable to another agent, thus changing the status of his actions. Only communicated consent is capable of performing the “magic” of making actions permissible, and only communicated consent can be used by actors to defend against potential accusations in rights violation.

Communication Ethics: Consent as the Foundation of Non-aggression
Abstract
One of the major challenges for political philosophy is the postulated impossibility of building a sound theory without a solid foundation in ethics. Ethical questions of what is good and what is bad arise within the context of social interactions—in relation to actions unto other people. But judgements on what is good and what is bad are necessarily subjective. This, however, does not mean that this subjective judgement is not true. Man’s opinion about what is a bad action unto him is a correct evaluation of the action in question. For an acting agent, the opinion of the action’s recipient is thus the source of the correct ethical assessment of the action. This assessment can only become known to the acting agent by the means of communication. Communicating a subjective value judgement on what is good and what is bad gives the other agent knowledge about the ethical value of the intended action. Acting unto another man against his consent thus implies wrongdoing.

Manipulation of Consent
Abstract
This chapter examines several criticisms of non-fraudulent commercial speech. According to critics, even if business propaganda does not constitute fraud by intentionally misleading consumers, it still may be illegitimate for other reasons. Advertising is accused of coercion through manipulative persuasion, exaggeration and puffery. Other charges include accusations of promoting products and services that are harmful for consumers who therefore later regret purchasing them, and this regret invalidates the consent given at the moment of making the purchase. These accusations are examined from the property rights perspective as well from the communication perspective.

The Role of Property Rights in the Ethics of Consent
Abstract
Consent is what allows us to tell others whether their actions unto us are acceptable from our point of view. Proceeding with an action without our consent, or after consent has been refused, would constitute a moral
wrongdoing. However, consent is only required for giving moral evaluation to actions that are directed towards other actors and affect them. An action can be considered as intended towards another person if it interferes with this person’s “zones of control”—borders of physical objects with which one creates a particular relationship. This relationship is ownership—it assumes that any hindrance to the use of the object without the consent of the owner is a wrongdoing. Ownership comes from the direct control of bodies, and original appropriation of external objects and voluntary transfers forms the foundation of property rights—violation against property is a violation against the owner. A legal system based on the idea that property rights violations constitute an offence recognises the validity of the non-aggression principle. The non-aggression principle prohibits the initiation of force, which is understood as an action of border crossing without the owner’s consent. The concept of consent and the concept of borders are ontologically based on communication, which means that communication is the basis of the non-aggression principle.

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