This digest aggregates and distills key content around 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. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

*Informed Consent: A Monthly Review* is a service of the GE2P2 Global Foundation’s Center for Informed Consent Integrity, which 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 categories:
GENOMIC MEDICINE/GENE EDITING
YOUNG PERSONS
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COGNITIVE CHALLENGES

Issues of Informed Consent from Persons with Dementia When Employing Assistive Technologies [BOOK CHAPTER]
Peter Novitzky, Cynthia Chen, Alan F. Smeaton, Renaat Verbruggen, Bert Gordijn
Intelligent Assistive Technologies for Dementia, 14 October 2019; Chapter 10
Excerpt
Informed consent is one of the cornerstones and requirements sine qua non of modern medical research and clinical practice. It developed relatively quickly to gain great importance, despite initial setbacks. The requirement of informed consent applies to all subjects of medical research and therapy, including persons with dementia (PwDs), whose impaired competence to provide valid informed consent poses particular challenges...

Differing Understandings of Informed Consent Held by Research Institutions, People with Intellectual Disability, and Guardians: Implications for Inclusive, Ethical Research [BOOK CHAPTER]
Britteny Howell, Karrie Shogren
Research Involving Participants with Cognitive Disability and Differences: Ethics, Autonomy, Inclusion, and Innovation, 5 September 2019; Chapter 3
Excerpt
Approximately 1–3% of the world's population experiences an intellectual disability (ID)... Despite social and medical gains over the past several decades, people with ID are significantly more likely to experience poorer health and quality of life outcomes than people without... Research participation can play an important role in reducing such persistent disparities; however, people with ID remain under-represented in research for a variety of reasons, including the assumption that they are unable to provide informed consent for participation...

Using Ethnographic Methods to Determine Capacity to Consent amongst Individuals Diagnosed with Chronic Mental Illnesses [BOOK CHAPTER]
Saira A. Mehmood
Research Involving Participants with Cognitive Disability and Differences: Ethics, Autonomy, Inclusion, and Innovation, 5 September 2019; Chapter 14
Introduction
This chapter reports on an ethnographic research project conducted with people diagnosed with chronic mental illnesses and often economic and educational vulnerabilities as well. It focuses particularly on strategies for assessing capacity to consent...

Repurposing Ethnography to Assess Consent Capacity [BOOK CHAPTER]
Megan Wright
Research Involving Participants with Cognitive Disability and Differences: Ethics, Autonomy, Inclusion, and Innovation, 5 September 2019; Chapter 24
Introduction
Saira Mehmood illustrates how participant observation, an ethnographic method, can be applied to assess research consent capacity for persons with chronic mental illness who use mental health services at a non-
profit organization. Through observation of and interaction with prospective participants and organization staff members, Mehmood was able to get a sense of a mental health service user’s decisional capacity and vulnerability. While this is a novel and beneficial approach to assessing consent capacity, questions remain about its application, appropriateness, and usefulness in other contexts.

**Decisional capacity to consent to treatment and anaesthesia in patients over the age of 60 undergoing major orthopaedic surgery**

*Research Article*

Gabriele Mandarelli, Giovanna Parmigiani, Felice Carabellese, Silvia Codella, Paolo Roma, Domitilla Brancadoro, Andrea Ferretti, Lucio Alessandro, Giovanni Pinto, Stefano Ferracuti

*Medicine Science and the Law, 1 August 2019*

**Abstract**

Despite growing attention to the ability of patients to provide informed consent to treatment in different medical settings, few studies have dealt with the issue of informed consent to major orthopaedic surgery in those over the age of 60. This population is at risk of impaired decision-making capacity (DMC) because older age is often associated with a decline in cognitive function, and they often present with anxiety and depressive symptoms, which could also affect their capacity to consent to treatment. Consent to major orthopaedic surgery requires the patient to understand, retain and reason about complex procedures. This study was undertaken to extend the literature on decisional capacity to consent to surgery and anaesthesia of patients over the age of 60 undergoing major orthopaedic surgery. Recruited patients (N=83) were evaluated using the Aid to Capacity Evaluation, the Beck Depression Inventory, the State–Trait Anxiety Inventory Y, the Mini-Mental State Examination and a visual analogue scale for measuring pain symptomatology. Impairment of medical DMC was common in the overall sample, with about 50% of the recruited patients showing a doubtful ability, or overt inability, to provide informed consent. Poor cognitive functioning was associated with reduced medical DMC, although no association was found between decisional capacity and depressive, anxiety and pain symptoms. These findings underline the need of an in-depth assessment of capacity in older patients undergoing major orthopaedic surgery.

**The Patients Have a Story to Tell: Informed Consent for People who use Illicit Opiates in a Qualitative Research Project**

Jane McCall, J. Craig Phillips, Andrew Estefan

*Canadian Society of Addiction Medicine, November 2018*

**Open Access**

**Abstract**

This paper discusses the ethical issues that arise when seeking informed consent from people who use illicit opiates. There is a significant discourse in the literature that opines that people who use illicit opiates are unable to provide informed consent due to withdrawal symptoms and cognitive impairment as a result of opioid use. This paper outlines the ethical issues that have been discussed in relation to this issue, reviews the findings of a study in which staff were asked their opinions about their patients’ ability to provide informed consent and discusses the issues that arise when patients are not allowed to consent to research.

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Consent for mobile phone surveys of non-communicable disease risk factors in low-resource settings: an exploratory qualitative study in Uganda

Original Article
Erisa Mwaka, Janet Nakigudde, Joseph Ali, Joseph Ochieng, Kristina Hallez, Raymond Tweheyo, Alain Labrique, Dustin G. Gibson, Elizeus Rutebemberwa, George Pariyo
mHealth, 5 July 2019; 5(26)
Open Access
Abstract
Background
Lack of data for timely decision-making around the prevention and control of non-communicable diseases (NCDs) presents special challenges for policy makers, especially in resource-limited settings. New data collection methods, including pre-recorded Interactive Voice Response (IVR) phone surveys, are being developed to support rapid compilation of population-level disease risk factor information in such settings. We aimed to identify information that could be used to optimize consent approaches for future mobile phone surveys (MPS) employed in Uganda and, possibly, similar contexts.

Methods
We conducted an in-depth qualitative study with key stakeholders in Uganda about consent approaches, and potential challenges, for pre-recorded IVR NCD risk factor surveys. Semi-structured interviews were conducted with 14 key informants. A contextualized thematic approach was used to interpret the results supported by representative quotes.

Results
Several potential challenges in designing consent approaches for MPS were identified, including low literacy and the lack of appropriate ways of assessing comprehension and documenting consent. Communication with potential respondents prior to the MPS and providing options for callbacks were suggested as possible strategies for improving comprehension within the consent process. “Opt-in” forms of authorization were preferred over “opt-out”. There was particular concern about data security and confidentiality and how matters relating to this would be communicated to MPS respondents.

Conclusions
These local insights provide important information to support optimization of consent for MPS, whose use is increasing globally to advance public health surveillance and research in constructive ways.

Editor’s note: mHealth covers “clinical telemedicine practice, advances in health technology, health services research, highlights of emerging products, public health implications of health technology, health policy and regulation and management of health care systems and other related fields”

Usability Inspection of Multipurpose Scalable Informed Consent Platform
Finkelstein J, Robins D, Liu J
Studies in health technology and informatics, 4 July 2019
Abstract
We developed a multipurpose scalable electronic informed consent platform (E-Consent) which is reusable for any informed consent in a multitude of settings. The platform allows research staff to easily upload multimedia information about a research protocol with an approved informed consent into the system, which delivers this content interactively for prospective study candidates in a user-friendly way. Consistent with user-centered design, E-Consent underwent usability inspection via cognitive walkthroughs accompanied by surveys that captured task complexity on a 5-point Likert-type scale. The System Usability Scale (SUS) provided a standardized reference for usability and satisfaction. Overall, the E-Consent framework was considered by participants to be easy-to-use, satisfying, and timely, while delivering complex information such as that on a consent form. E-Consent ranked in the top 10th percentile for usability as
measured by SUS. This extensible framework successfully delivered complex information and recorded user consents, all in an easy-to-understand and highly usable fashion.

**Digitizing the Informed Consent: the Challenges to Design for Practices [CONFERENCE PAPER]**
Michela Assale, Erica Barbero, Federico Cabitza
2019 IEEE 32nd International Symposium on Computer-Based Medical Systems, 5-7 June 2019; Spain

Abstract
This paper reports a user study performed to assess the usability of a Web-based electronic informed consent application called DICE, which is aimed at supporting patients in the process of reading, understanding and using the informed consent as a trigger for further interaction with the team of caregivers. In particular, we performed a questionnaire-based study and a series of individual semi-structured interviews to understand whether the application is usable and can be used in real-world settings, respectively. We found that patients could appreciate the availability of interactive tools like DICE, but health professionals believe that its actual adoption in current workflows and practices could be hampered by the chronic lack of time and health operators who could timely address the licit requests that such a tool could bring to light.

**BIOMEDICAL RESEARCH**

**Model consent clauses for rare disease research**

Research Article
Minh Thu Nguyen, Jack Goldblatt, Rosario Isasi, Marlene Jagut, Anneliene Hechtelt Jonker, Petra Kaufmann, Laetitia Ouillade, Fruszina Molnar-Gabor, Mahsa Shabani, Eric Sid, Anne Marie Tassé, Durhane Wong-Rieger, Bartha Maria Knoppers

BMC Medical Ethics, 1 August 2019; 20(55)

Open Access

Abstract

Background
Rare Disease research has seen tremendous advancements over the last decades, with the development of new technologies, various global collaborative efforts and improved data sharing. To maximize the impact of and to further build on these developments, there is a need for model consent clauses for rare diseases research, in order to improve data interoperability, to meet the informational needs of participants, and to ensure proper ethical and legal use of data sources and participants’ overall protection.

Methods
A global Task Force was set up to develop model consent clauses specific to rare diseases research, that are comprehensive, harmonized, readily accessible, and internationally applicable, facilitating the recruitment and consent of rare disease research participants around the world. Existing consent forms and notices of consent were analyzed and classified under different consent themes, which were used as background to develop the model consent clauses.

Results
The IRDIRC-GA4GH MCC Task Force met in September 2018, to discuss and design model consent clauses. Based on analyzed consent forms, they listed generic core elements and designed the following rare disease research specific core elements; Rare Disease Research Introductory Clause, Familial Participation, Audio/Visual Imaging, Collecting, storing, sharing of rare disease data, Recontact for matching, Data Linkage, Return of Results to Family Members, Incapacity/Death, and Benefits.

Conclusion
The model consent clauses presented in this article have been drafted to highlight consent elements that bear in mind the trends in rare disease research, while providing a tool to help foster harmonization and collaborative efforts.

**An Important Gap in Informed Consent Documents for Oncology Clinical Trials: Lack of Quantitative Details About Expected Treatment Outcomes**

*Viewpoint*

Charles A. Schiffer

*JAMA Oncology, 22 August 2019*

*Excerpt*

Written informed consent must be obtained in addition to the discussions that physicians have with patients considering participation in clinical trials. Implicit in this requirement is the assumption that these dialogues with the caregivers are insufficient, requiring supplementation by written documents to reinforce what had been presented and/or to provide details that may not have been mentioned. The consents should be written in lay language with clear explanations of scientific and medical terms.1 Over the years, consent forms have become longer and more detailed and there is an extensive literature about how much information is actually retained by the patient after reading about Health Insurance Portability and Accountability regulations, handling of biologic specimens, long lists of potential adverse effects, the nature of randomization, etc.2 There are concerns that this litany of details distracts attention from the most critical features, including the aims of the study and the extra requirements and inconveniences compared with standard care.

**A survey of informed consents from FDA’s center for devices and radiological health**

Fabienne Santel, Isatu Bah, Katherine Kim, Ja-An Lin, Jack McCracken, Adaeze Teme

*Contemporary Clinical Trials, 21 August 2019*

*Abstract*

Legally effective informed consent has been a long-standing requirement for FDA-regulated clinical studies. However, informed consent forms (ICFs) are often thought to be too long, too complex, and too difficult for participants to understand. In this article, investigators from the FDA’s Center for Devices and Radiological Health (CDRH) surveyed 399 ICFs from approved investigational device exemption (IDE) applications for fiscal years 2015 and 2016 to evaluate the readability of ICFs.

The investigators collected data from the ICFs, using variables related to structure, readability, and comprehension.

The investigators found that the mean grade-reading levels of the ICFs ranged from 10th grade to college level (Table 2), higher than the recommended 6th to 8th grade level [1], when measured by major readability evaluation tools (the SMOG readability grade level formula, the Flesch-Kincaid Index Grade Level Readability Formula, the Flesch Reading Ease test, and the Dale-Chall readability formula).

Overall, the ICFs and informed consent (IC) processes, as described in the IDE application, lacked components that enhanced participants’ comprehension, such as short sentences (e.g., no more than 8 to 10 words) and the use of pictures, tables, and diagrams.

CDRH investigators believe that information about ICFs’ readability, comprehension, and structure will help support current and future efforts to improve the IC process. The intent of the article is to demonstrate that improvements are needed in the IC process and to encourage clinical trial stakeholders to consider implementing those approaches that optimize patient comprehension in the development of their IC processes.
Informed consent at stake? Language barriers in medical interactions with immigrant anaesthetists: a conversation analytical study
Damaris Borowski, Uwe Koreik, Udo Ohm, Claudia Riemer, Niels Rahe-Meyer
BMC Health Services Research, 23 August 2019; 19(597)
Open Access
Abstract
Background
Language barriers in doctor-patient interactions are still an understudied phenomenon. This is particularly true concerning interactions with immigrant physicians who are learners of the patient’s language; there is a lack of research even though labour migration is increasing internationally. This conversation analytical study focusses on language errors in one specific type of doctor-patient interaction, namely pre-anaesthesia evaluations with immigrant anaesthetists.
Methods
The study combines the research field of language acquisition with that of medical interaction. It is a qualitative study with an ethnomethodological framework which addresses the following research question: How do language errors, produced by immigrant anaesthetists, impact pre-anaesthesia evaluations? The primary data comes from naturally occurring pre-anaesthesia evaluations carried out by immigrant anaesthetists. The analysis method is a combination of conversation and error analysis.
Results
The study shows that the anaesthetists produced a considerable number of unintelligible utterances, due to various language errors. Despite the lack of understanding, hardly any negotiation of meaning occurred and both sides (anaesthetists and patients) claimed to be satisfied.
Conclusions
The findings appear to be contradictory. An explanation for this can be found in the effect of the roles and scripts that are given in pre-anaesthesia evaluations. Since no negotiation of meaning is initiated during the interactions, the anaesthetists’ insufficient language competence leads to a considerable impairment of informed consent, which is the main goal of the pre-anaesthesia evaluations. Based on these findings, the study reveals an urgent need for action regarding immigrant anaesthetists’ language skills.

Paternal consent in prenatal research: ethical aspects
Mats Johansson, Göran Hermerén, Nils-Eric Sahlin
Medicine, Health Care and Philosophy, 10 August 2019; pp 1–7
Open Access
Abstract
The role of mothers in prenatal research has been discussed extensively. Significantly less work has been done on the father’s role. In this article, focusing on ethical issues, we seek to redress this imbalance. Examining the father’s position in research conducted on pregnant women, we ask whether or not paternal consent ought to be required in addition to that of the pregnant woman. Having distinguished between different concepts of father and mother, we proceed by giving an overview of the reasons for requiring consent of the woman who is carrying the child. We then examine which of these reasons apply to the biological father, and show that some of them are relevant to the father. The case, roughly speaking, revolves around privacy issues, the father’s future legal responsibilities, and the likelihood that he will care about the health and wellbeing of his future child. These factors in the decision problem should all be recognized, as should the fact that they can in principle be trumped by other considerations.
BIOBANKING

Researchers’ Perspectives on Informed Consent and Ethical Review of Biobank Research in South Africa: A Cross-Sectional Study

Research Article

Erisa Mwaka, Lyn Horn

Journal of Empirical Research on Human Research Ethics, 5 August 2019

Abstract

There is limited literature on the opinions and perspectives of researchers on the ethical issues in biobank research in South Africa. This study aimed to explore researchers’ perspectives on informed consent and ethical review of biobank research in South Africa. An online survey was conducted among researchers and scientists at Stellenbosch University and the University of Kwazulu-Natal. The majority of researchers opined that broad consent is appropriate for biobank research. However, there was no consensus on the necessity for re-consent. Researchers were also in agreement that issues concerning informed consent and future use of samples require thorough discussions during the ethical review process. Overall, the attitude of researchers on informed consent and ethical review of biobank research was positive and ethically informed.

CULTURAL/COUNTRY CONTEXT

Exploring the Role of Shared Decision Making in the Consent Process for Pediatric Genomics Research in Cameroon, Tanzania, and Ghana

Daima Bukini, Jantina deVries, Marsha Treadwell, Kofi Anie, Jemima Dennis-Antwi, Karene Kengne Kamga, Sheryl McCurdy, Kwaku Ohene-Frempong, Julie Makani, Ambroise Wonkam

American Journal of Bioethics Empirical Bioethics, 5 August 2019; pp 182-189

Abstract

Background

It is customarily perceived that in Africa, decisions around research participation may be based not only on individual reflection but also on discussions with others. Some authors have argued that such decision making is reflective of a more traditional communitarian African worldview; one critique of such a perspective is that it is lacking an empirical grounding. In this study, we explore decision making around enrollment in sickle cell genomics research in three countries in Africa, namely, Ghana, Cameroon, and Tanzania. Particularly, we focus on exploring the role of shared decision making with regard to participating in genomic studies.

Results

We involved 64 participants in 15 individual interviews or in 49 focus-group discussions with research participants in rural and urban Tanzania (n = 20), Ghana (n = 30), and Cameroon (n = 14). We used a vignette to explore decision making around enrollment of children in sickle cell genomics research. Data were imported in NVivo11 and analyzed using thematic content analysis. Our findings indicate that the majority of the participants from both rural and urban settings prefer to make their own individual decisions and not consult with extended family or community leaders. Shared decision making was only considered necessary for individuals who were perceived to be in some way vulnerable.

Conclusion

We found very limited support for shared decision making as the primary process for decision making about research participation. While consultation was considered important to support individual decision making, particularly when parents were perceived as vulnerable, there was no suggestion in our data that shared decision making would be a more important or valuable means of seeking consent for research participation in the African research context.
A Formative Qualitative Study on the Acceptability of Deferred Consent in Adult Emergency Care Research in Malawi

Research Article
Lucinda Manda-Taylor, Fanuel Meckson Bickton, Kate Gooding, Jamie Rylance

Journal of Empirical Research on Human Research Ethics, 8 August 2019
Open Access

Abstract
Research in emergency medical care is challenging due to a limited therapeutic window for intervention, which may compromise informed consent. “Deferred consent” allows initiation of study procedures before full consent is recorded. We conducted a formative qualitative study exploring perspectives on deferred consent in Malawi among research ethics committee members, health care professionals, and lay representatives. Participants identified several advantages of deferred consent including scientific value and potential health benefits to the study subjects and wider population. Participants also had concerns, including regulatory barriers and the risk of abuse and malpractice. Conditions affecting acceptability are related to the role of proxies, the nature of the research, the availability of robust regulatory oversight, and the need for community engagement. Our findings show deferred consent would be acceptable in Malawi, provided that a clear case can be made to advance medical knowledge and that adequate regulatory and ethical protections are in place.

Consent Challenges and Psychosocial Distress in the Scale-up of Voluntary Medical Male Circumcision Among Adolescents in Western Kenya

Original Paper
Winnie K. Luseno, Samuel H. Field, Bonita J. Iritani, Stuart Rennie, Adam Gilbertson, Fredrick S. Odongo, Daniel Kwaro, Barrack Ongili, Denise D. Hallfors

AIDS and Behavior, 2 August 2019; pp 1-11

Abstract
In priority sub-Saharan African countries, on the ground observations suggest that the success of voluntary medical male circumcision (VMMC) programs should not be based solely on numbers of males circumcised. We identify gaps in the consent process and poor psychosocial outcomes among a key target group: male adolescents. We assessed compliance with consent and assent requirements for VMMC in western Kenya among males aged 15–19 (N = 1939). We also examined differences in quality of life, depression, and anticipated HIV stigma between uncircumcised and circumcised adolescents. A substantial proportion reported receiving VMMC services as minors without parent/guardian consent. In addition, uncircumcised males were significantly more likely than their circumcised peers to have poor quality of life and symptoms of depression. Careful monitoring of male adolescents’ well-being is needed in large-scale VMMC programs. There is also urgent need for research to identify effective strategies to address gaps in the delivery of VMMC services.

Knowledge and Attitudes of Mental Health Professionals Regarding Informed Consent and Patient Confidentiality in Clinical Practice and Research in Udupi District

Vidyashree S.V., Kumar Naveen, Kamath Rajesh, D'Souza Brayal, Ashok Lena, Kamath Sagarika

Indian Journals, 8 August 2019; 19(2) pp 180-184

Abstract
The control of patient information regarding mental illness is a challenging issue in mental health care. Patients have the right to control and know all information concerning their health. In India, an individual's identity is intimately connected to his or her family's; family is integral to one's self. This study was conducted to increase awareness among mental health professionals regarding informed consent and patient's confidentiality protection in clinical practice and research. The findings of this study can help
hospitals frame policies. The objectives of the study were to assess the knowledge (K) and attitudes (A) of mental health professionals regarding ‘informed consent’ and confidentiality protection in clinical practice and research. The study was conducted in three different phases. In phase one, a questionnaire was formulated, validated and distributed among the mental health professionals to analyze K&A regarding informed consent and confidentiality protection in clinical practice and research. In phase two, an education module was developed and distributed among healthcare professionals. In phase three, the participants were reassessed on their K&A using the same questionnaire. The results show no significant difference in the mean values (mean=7.46, SD=1.22) in both confidentiality and consent during phase one. However, after administering the education module, the mean score of knowledge and attitude towards consent and confidentiality has increased (mean=9.86, SD=0.40) compared to the pretest. It was concluded that the delivery of the education module incorporating the updated information on acts and amendments related to the mental health profession has been effective.

**The Prior Consultation of Indigenous Peoples in Latin America: Inside the Implementation Gap**

[BOOK]
Claire Wright, Alexandra Tomaselli
Routledge, 22 August 2019

*Summary*
This book delves into the reasons behind and the consequences of the implementation gap regarding the right to prior consultation and the Free, Prior and Informed Consent (FPIC) of Indigenous Peoples in Latin America...

**RIGHTS/LEGAL/LEGISLATIVE**

H. Russell Searight
Ethical Challenges in Multi-Cultural Patient Care, 14 August 2019; pp 29-44

*Abstract*
While patients’ and family preferences for nondisclosure of life-threatening illness found among contemporary Native Americans and Asian Americans may seem to be a cultural anomaly, a brief review of physician practices and legal rulings in the 20th century suggests that disclosure of this information to patients is a relatively recent practice.

**Consent is everybody’s business; Why banks need to act on free, prior and informed consent**

Shona Hawkes
Oxfam Library, August 2019

*Open Access*

*Summary*
A community’s choice to give, or withhold, their free, prior and informed consent (FPIC) to a project or activity planned to take place on their land is a recognized right of Indigenous peoples under international law. It is also a best practice principle that applies to all communities affected by projects or activities on the land, water and forests that they rely on. Free, prior and informed consent has additional benefits for banks involved in such projects, and their clients, in helping to avoid a diverse array of potential risks...

*Editor’s note: This paper is published by Oxfam International as a “part of a series of papers written to inform public debate on development and humanitarian policy issues.”*
Getting youth PrEPared: adolescent consent laws and implications for the availability of PrEP among youth in countries outside of the United States
Taggart T, Bond KT, Ritchwood TD, Smith JC
Journal of the International AIDS Society, July 2019; 22(7)
Open Access
Abstract
Introduction
Youth under the age of 25 are at high risk for HIV infection. While pre-exposure prophylaxis (PrEP) has the potential to curb new infections within this population, it is unclear how country-specific laws and policies that govern youth access to sexual and reproductive health (SRH) services impact access to PrEP. The purpose of this review was to analyse laws and policies concerning PrEP implementation and SRH services available to youth in countries with a high HIV incidence. To the best of our knowledge this is the first systematic assessment of country-level policies that impact the availability of PrEP to adolescent populations.
Methods
We conducted a review of national policies published on or before 12 June 2018 that could impact adolescents' access to PrEP, SRH services and ability to consent to medical intervention. Countries were included if: (1) there was a high incidence of HIV; (2) they had active PrEP trials or PrEP was available for distribution; (3) information regarding PrEP guidelines were publicly available. We also included a selected number of countries with lower adolescent HIV incidence. Internet and legal database searches were used to identify policies relevant to adolescent PrEP (e.g. age of consent to HIV testing).
Results and Discussion
Fifteen countries were selected for inclusion in this review. Countries varied considerably in their respective laws and policies governing adolescents’ access to PrEP, HIV testing and SRH services. Six countries had specific polices around the provision of PrEP to youth under the age of 18. Five countries required people to be 18 years or older to access HIV testing, and six countries had specific laws addressing adolescent consent for- and access to- contraceptives.
Conclusion
Adolescents' access to PrEP without parental consent remains limited or uncertain in many countries where this biomedical intervention is needed. Observational and qualitative studies are needed to determine if and how adolescent consent laws are followed in relation to adolescent PrEP provisions. Intensified efforts to amend laws that limit adolescent access to PrEP and restrict the establishment of national guidelines supporting adolescent PrEP are also needed to address the epidemic in this group.

A Professional Standard for Informed Consent for Stem Cell Therapies
Viewpoint
Jeremy Sugarman, Roger A. Barker, R. Alta Charo
JAMA, 12 August 2019
Open Access
Excerpt
In November 2018, the US Food and Drug Administration (FDA) issued a press release that stated: “The potential health benefits of regenerative medicine have spurred major progress in stem-cell biology over the past several decades. But we continue to see bad actors exploit the scientific promise of this field to mislead vulnerable patients into believing they’re being given safe, effective treatments; when instead these stem
cell producers are leveraging the field’s hype to push unapproved, unproven, illegal, and potentially unsafe products."

Over the last decade, there has been an increase in the number of “clinics” (570 in the United States alone according to a recent estimate) offering what is portrayed as “stem cell therapy” for conditions ranging from orthopedic injuries to Alzheimer disease. The unproven nature of these interventions suggests that patients who received them were, at a minimum, misled. At worst, they were severely injured, as in the case of at least 3 women who were left legally blind after intravitreal injections of platelet-rich plasma derived from tissue obtained through liposuction...

**Mapping HIV laws and policies**
*Press Release*
UNAIDS
Lawsandpolicies.unaids.org, 31 July 2019

*Excerpt*
A new website that enables people to identify national laws and policies related to the AIDS response has been launched by UNAIDS.

Covering areas as diverse as a country’s ability to diagnose HIV among young babies, the existence of laws that discriminate against transgender people and whether people are prosecuted for carrying condoms, the Laws and Policies Analytics website aims to give a full overview of a country’s laws and policies related to the HIV response. It also allows to view policy data jointly with other data on the HIV epidemic and response.

“We must better understand legal and policy environments to drive effective responses to the HIV epidemic. This new tool will provide access to data on national laws and policies and allow for joint analysis with data on the epidemic and response, so that we can drive more deeply-informed decision-making,” said Shannon Hader, UNAIDS Deputy Executive Director, Programme...

*Editor’s note:* In addition to surveying the literature we continue to monitor for other resources such as this web based, non-bibliographic resource.

**Informed consent, shared-decision making and a reasonable patient’s wishes based on a cross-sectional, national survey in the USA using a hypothetical scenario**
*Research*
John T James, Darwin Jay Eakins, Robert R Scully
BMJ, 30 July 2019; 9(7)

*Open Access*

*Abstract*

**Objective**
In approximately half the states in the USA, and more recently in the UK, informed consent is legally defined as what a reasonable patient would wish to know. Our objective was to discern the information needs of a hospitalised, ‘reasonable patient’ during the informed-consent process.

**Design**
We performed a cross-sectional study to develop a survey instrument and better define ‘reasonable person’ in relation to informed consent in a hypothetical scenario where an invasive procedure may be an option.

**Setting**
A 10-question survey was administered from April 19 through 22 October 2018 to three groups: student nurses (n=76), health professions educators (n=63) and a US national population (n=1067).

**Primary and secondary outcome measures**
The primary outcome measure was the average intensity, on a 5-point scale, by which survey groups wished to have each of 10 questions answered. The secondary outcome was to discern relationships between survey demographics and the intensity by which participants wanted an answer.

**Results**
Despite substantial demographic differences in the nursing-student group and health-professions-educator group, the average intensity scores were within 0.2 units on nine of 10 questions. The national survey revealed a strong desire to have an answer to each question (range 3.98–4.60 units). It showed that women desired answers more than men and older adults desired answers more than younger adults.

Conclusions
Based on responses to 10 survey questions regarding wishes of people in a situation where an invasive procedure may be necessary, the vast majority want an answer to each question. They wanted to know about all treatment options, risky drugs, decision aids, who will perform the procedure, and the cost. They wanted their advocate present, periodic review of their medical record, a full day to review documents and expected outcomes and restrictions after the procedure.

MEDICAL/SURGICAL

Say what? Patients have poor immediate memory of major risks of interscalene block disclosed during the informed consent discussion

Original Article
Johnny Wei Bai, Faraj W W Abdallah, Melanie Cohn, Stephanie Ladowski, Poorna Madhusudan, Richard Brull
Regional Anesthesia & Pain Medicine, 23 August 2019

Abstract
Background
Poor memory of disclosed risks can undermine informed consent and create medicolegal challenges. The extent to which patients remember the risks of peripheral nerve blockade following the informed consent discussion is unknown. This prospective cohort study evaluated patients’ immediate memory of risks related to interscalene block (ISB) that were disclosed during the preoperative informed consent discussion.

Methods
Using a standardized script, patients scheduled for arthroscopic shoulder surgery were informed of the risks of ISB by an anesthesiologist in the preoperative assessment clinic. Immediately thereafter, consenting participants were asked to identify the risks of ISB from a printed list of nine true risks (four major and five minor) and nine ‘distractor’ items, which were unrelated adverse events and not disclosed. The primary outcome was the proportion of participants who remembered all four major risks of ISB. The mean number of major risks remembered was 2±1 out of 4. Fifteen (12%) participants remembered all nine true risks. The mean number of true risks remembered was 6±2 out of 9. Multivariable analysis revealed that participants’ self-rated assessment of their memory was not associated with actual recall.

Conclusion
Patients have poor immediate memory of the major risks related to ISB disclosed during the informed consent discussion. Under the present study conditions, the validity of the informed consent process for patients undergoing ISB may be undermined.

Obtaining consent for obstetric procedures

Katrina Henderson, Siân Griffiths
Anaesthesia & Intensive Care Medicine, 19 August 2019

Abstract
Consent is a process that involves information disclosure of a proposed treatment or intervention. It includes a discussion of the risks relevant to that particular patient as well as the benefits and alternative options. The
process must be clearly documented to provide a legal justification for treatment. Obtaining informed consent can be a challenge when a labouring woman is in severe pain or under the influence of strong analgesics. High-risk women should be encouraged to attend pre-assessment clinics to enable adequate time to process the information discussed. Pregnant women are presumed competent and are entitled to refuse treatment even if this risks their life or the life of their fetus. Rarely, if a woman is not considered competent to make decisions for herself, clinicians should take into account the underlying reasons and consider proceeding in their best interests under the doctrine of necessity or apply to the courts for approval of an intervention. This article summarizes current guidelines in relation to consent that have been updated to reflect recent case law.

**Deferred consent for delivery room studies: the providers’ perspective**
*Original Article*
Maria C den Boer, Mirjam Houtlosser, Elizabeth E Foglia, Enrico Lopriore, Martine Charlotte de Vries, Dirk P Engberts, Arjan B te Pas
*Archives of Disease in Childhood: Fetal & Neonatal, 19 August 2019*

**Abstract**

**Objective**
To gain insight into neonatal care providers’ perceptions of deferred consent for delivery room (DR) studies in actual scenarios.

**Methods**
We conducted semistructured interviews with 46 neonatal intensive care unit (NICU) staff members of the Leiden University Medical Center (the Netherlands) and the Hospital of the University of Pennsylvania (USA). At the time interviews were conducted, both NICUs conducted the same DR studies, but differed in their consent approaches. Interviews were audio-recorded, transcribed and analysed using the qualitative data analysis software Atlas.ti V.7.0.

**Results**
Although providers reported to regard the prospective consent approach as the most preferable consent approach, they acknowledged that a deferred consent approach is needed for high-quality DR management. However, providers reported concerns about parental autonomy, approaching parents for consent and ethical review of study protocols that include a deferred consent approach. Providers furthermore differed in perceived appropriateness of a deferred consent approach for the studies that were being conducted at their NICUs. Providers with first-hand experience with deferred consent reported positive experiences that they attributed to appropriate communication and timing of approaching parents for consent.

**Conclusion**
Insight into providers’ perceptions of deferred consent for DR studies in actual scenarios suggests that a deferred consent approach is considered acceptable, but that actual usage of the approach for DR studies can be improved on.

**Attitudes, Beliefs, and Practices of Aesthetic Plastic Surgeons Regarding Informed Consent**
*Accepted Manuscript*
Chelsea O Hagopian, Teresa B Ades, Thomas M Hagopian, Erik M Wolfswinkel, W Grant Stevens
*Aesthetic Surgery Journal, 30 July 2019*

**Abstract**

**Background**
Best practice for informed consent in aesthetic plastic surgery is a process of shared decision-making (SDM), yet evidence strongly suggests this is not commonly reflected in practice nor is it supported by traditional informed consent documents (ICD). Falsely held beliefs by clinicians about SDM may contribute to its lack of adoption.

**Objective**
To understand the baseline attitudes, beliefs, and practices of informed consent among board-certified plastic surgeons with a primarily aesthetics practice.

Methods
A 15-question online survey was emailed to active members of the American Society for Aesthetic Plastic Society (ASAPS). Items included: demographics, Likert scales, free-text, acceptability, and one question seeking consensus on general information all patients must understand before any surgery.

Results
This survey appreciated a 13% response rate with a 52% completion rate across 10 countries and 31 U.S. states. 69% are very-extremely confident that ICD contain evidence-based information. 63% are not at all-not so confident in ICD effectiveness of prompting patients to teach-back essential information. 51% believe surgical ICD should be reviewed annually. 86% report assistance with patient education during informed consent. “ASAPS members” should be a source of evidence for content (free-text). 63% were somewhat-very satisfied with the survey and 84% will probably-definitely yes participate in future surveys.

Conclusions
Findings echo concerns in the literature that ICD are focused on disclosure not patient understanding. There is notable concern regarding information overload and retention, but less regarding the quality and completeness of information. Current culture suggests key clinician stakeholders are amenable to change.