This digest is intended to aggregate and distill 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, consortia and collaborations, foundations, and commercial organizations. We acknowledge that this scope yields an indicative, 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:
COMPASSIONATE USE/EXPANDED ACCESS
YOUNG PERSONS

Reflections on informed consent by children and adolescents for the provision of clinical healthcare services
Barcia M, Zunini C
Uruguayan Medical Journal, 2019; 35(2) pp 146-150

Abstract
The Convention on the Rights of the Child has established a change in the concept of childhood. Children become subjects of rights and protection instead of being objects of society. The health contexts, as a sphere for social processes needs to keep pace with this paradigm. It is necessary for children and adolescents to participate in the making of decisions affecting their health in the clinical context. The study aims to discuss the specific characteristics of informed consent in children and adolescents within the context of the provision of healthcare services from the paradigm proposed by the Convention of the Rights of the Child of 1989. Informed consent as an expression of will, needs to meet three requirements to be valid: competence to make autonomous decisions, information and freedom. The main challenge of the health team lies in defining the moment when a child and adolescent may grant a valid consent. This study will reflect on the characteristics of informed consent within the context of the provision of health care services. The health team must guarantee the participation of children and adolescents in the making of decisions, understanding autonomy is gradually acquired.

Editor’s note: This is a Spanish language publication.

How should assent to research be sought in low income settings? Perspectives from parents and children in Southern Malawi
Research Article
Helen Mangochi, Kate Gooding, Aisleen Bennett, Michael Parker, Nicola Desmond Susan Bull
BMC Medical Ethics, 14 May 2019; 20(32)

Abstract
Background
Paediatric research in low-income countries is essential to tackle high childhood mortality. As with all research, consent is an essential part of ethical practice for paediatric studies. Ethics guidelines recommend that parents or another proxy provide legal consent for children to participate, but that children should be involved in the decision through providing assent. However, there remain uncertainties about how to judge when children are ready to give assent and about appropriate assent processes. Malawi does not yet have detailed guidelines on assent. Understanding perspectives among children and their parents can assist in developing contextually-appropriate assent guidance.

Methods
Qualitative research was conducted with children and parents in three settings in Southern Malawi (low- and high-income urban and rural), to take account of any variations between socioeconomic and cultural contexts. In each setting, interviews were conducted with parents and their children who had participated in paediatric research to understand their experiences of assent and views on appropriate assent practice. Focus groups were also conducted with children and parents, to understand broader social perspectives.

Results
We found widespread support for involving children in decisions on research participation. Participants identified a range of factors that affect children’s capacity to give assent, including intellectual capacity, emotional development, life experience and cultural norms. Age was often mentioned as a consideration, but deemed an unreliable sole indicator of capacity to assent. In relation to appropriate assent processes, participants emphasised considerations such as supporting effective understanding and minimizing harms.
Views on how to achieve these aims varied; for example, there were different ideas about the appropriate order in which to approach children and parents, and about whose decision to respect in the event of disagreement.

Conclusions
Parents and children agreed about the value of involving children in decisions on research, and about the need to promote children’s decision-making capacity while respecting parents’ interests in children’s welfare. Developing practical guidance that meets these principles is challenging, particularly given the need for flexible approaches that suit different study types, children’s capacities and family environments. Further discussion within the Malawi research and ethics community will help develop contextually-appropriate guidelines.

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

COGNITIVE CHALLENGES

US State Regulation of Decisions for Pregnant Women Without Decisional Capacity
Research Letter
Erin S. DeMartino, Beau P. Sperry, Cavan K. Doyle, Julie Chor, Daniel B. Kramer, David M. Dudzinski, Paul S. Mueller
JAMA, 23 April 2019; 321(16) pp. 1629-1631
All US states have laws addressing decision making for individuals who cannot make their own medical decisions, including provisions for advance directives and processes authorizing relatives or interested persons to direct care as surrogate decision makers,1 although variation among state laws is increasingly recognized.2,3 However, the prevalence and content of state statutes and official advance directive documents addressing “treatment decisions for divisionally incapacitated pregnant women” is unknown.

Editor’s note: This article also appears under RIGHTS/LEGAL/LEGISLATIVE

TECHNOLOGY/OTHER MEDIATION

An Educational Video Improves Consent in Pediatric Lumbar Puncture: A Randomized Control Trial
Research Paper
Mary Dunbar, Gillian Paton, Ashutosh Singhal
Pediatric Neurology, 13 May 2019
Abstract
Background
Lumbar puncture is a low-risk procedure performed on pediatric patients for a variety of indications. Parents are consented to this procedure but are often left with concerns. There are no published studies on the nature of the concerns of parents in North America, and no studies examining a process to improve pediatric lumbar puncture consent.
Objective
Identify parent concerns with lumbar puncture and determine the utility of an adjunctive educational video.
Methods
Seventy-two patient-parent dyads were enrolled in a randomized control trial to receive standard consent with or without an educational video. A survey was provided to determine parent self-rated understanding of the procedure, their perception of its safety, their perception of the painfulness and their overall comfort
with their child undergoing lumbar puncture. In addition, demographic characteristics and qualitative information about parent concerns were collected.

Results
The video resulted in significantly greater parent understanding of the procedure (p=0.015) and perception of its safety (p=0.021) compared to controls. Parent comfort with the procedure increased after viewing the video (p = 0.002). Parents’ top three concerns were pain, infection, and neurologic injury.

Conclusions
Parent concerns in pediatric lumbar puncture include pain, infection and neurologic injury, and viewing an educational video improved parent perception of understanding and safety compared to controls. In addition, there was reduced variability of responses in those who viewed the video. Thus, a short educational video on a handheld device is an effective means to address parent concerns and standardize the process of pediatric lumbar puncture consent.

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BIOMEDICIAL RESEARCH

Evaluation of Legal Legislation Compliance and Readability of Clinical Trial Informed Consent Forms
Research Article
Buket Gungor, Mualla Aylin, Ayse Asena, Elif Inci Somuncuoglu, Nihan Burul Bozkurt, Serife Reyhan Ucku, Ayse Gelal
Therapeutic Innovation & Regulatory Science, 19 May 2019

Abstract
Background
The volunteers approached for participation in a clinical trial should be given detailed and understandable information about the study through an informed consent form (ICF) before enrollment. In this study, we evaluated clinical trial files submitted to the Turkish Medicines and Medical Devices Agency (TITCK) to investigate the compliance to legal legislation and readability of ICFs as well as the factors affecting them.

Methods
This is a descriptive, cross-sectional study. We evaluated 160 ICFs in the phase II-IV clinical trial files submitted to TITCK in 2016 to determine their compliance to legislation (n = 160) and to assess their readability (n = 152) using Atesman formula. Overall compliance score was calculated. ICFs were also evaluated in terms of written format (font size, line spacing, section headings) and page count. Statistical analysis was performed with chi-square, Student’s t test, analysis of variance, Mann-Whitney U, and Kruskal Wallis analysis.

Results
Compliance to legislation and suitability of written format of international trial ICFs were significantly higher than those of national trial ICFs. Most of the national trials were investigator initiated. Readability was low in both national and international trial ICFs where the text was longer in the latter.

Conclusion
Results showed that researchers need easy-to-read ICF writing training that fits legal regulations.

Need for greater transparency in documenting informed consent
Commentary
Peter Tugwell, J. Andre Knottnerus
Journal of Clinical Epidemiology, May 2019; 109 pp v–vii

Abstract
Kotz et al. in a Commentary [1] call for a re-examination of patient consent in randomised clinical trials. Although informing potential participants about the aims and procedures of a trial is mandatory when seeking their consent, current practice in obtaining informed consent appears to have been shaped the legal duty of disclosure; consent is seen as an action, concluded by signing a form. In line with this administrative attitude toward informed consent, the procedure is standardly reported in a research article. However, there is evidence that the exact information that is given to potential participants is often not understood by them. This is unacceptable, so the authors argue that details about informed consent procedures of randomized controlled trials should be reported transparently with the essential features of the information for participants summarized in the methods section of a trial report and that the full, original participant information letter is published as supplementary material.

**Ethical tensions in the informed consent process for randomized clinical trials in emergency obstetric and newborn care in low and middle-income countries**

*Debate*

Dan K. Kaye, Gershom Chongwe, Nelson K. Sewankambo

*BMC Medical Ethics, 27 April 2019; 20(27)*

*Abstract*

**Background**

There is unanimous agreement regarding the need to ethically conduct research for improving therapy for patients admitted to hospital with acute conditions, including in emergency obstetric care. We present a conceptual analysis of ethical tensions inherent in the informed consent process for randomized clinical trials for emergency obstetric care and suggest ways in which these could be mitigated.

**Discussion**

A valid consenting process, leading to an informed consent, is a cornerstone of this aspect necessary for preservation and maintenance of respect for autonomy and dignity. In emergency obstetric care research, obtaining informed consent can be problematic, leading to ethical tension between different moral considerations. Potential participants may be vulnerable due to severity of disease, powerlessness or impaired decisional capacity. Time for the consent process is limited, and some interventions have a narrow therapeutic window. These factors create ethical tension in allowing potentially beneficial research while avoiding potential harms and maintaining respect for dignity, human rights, justice and autonomy of the participants.

**Conclusion**

Informed consent in emergency obstetric care in low- and middle-income countries poses numerous ethical challenges. Allowing research on vulnerable populations while maintaining respect for participant dignity and autonomy, protecting participants from potential harms and promoting justice underlie the ethical tensions in the research in emergency obstetric and newborn care. Those involved in research conduct or oversight have a duty of fair inclusion, to avoid denying participants the right to participate and to any potential research benefits.

**Reporting of ethical approval and informed consent in clinical research published in leading nursing journals: a bibliometric analysis**

Wu, Y, Howarth, ML, Zhou, C and Cong, W

*BMC Medical Ethics, 10 May 2019*

*Abstract*

**Background**

Ethical considerations play a prominent role in the protection of protect human subjects in clinical research. To date the disclosure of ethical protection in clinical research published in the international nursing journals has not been explored. Our research objective was to investigate the reporting of ethical approval and
informed consent in clinical research published in leading international nursing journals.

Methods
We used a research based on bibliometric analysis. All clinical research published in the five leading international nursing journals from the SCI Journal Citation Reports (2017 version) between 2015 and 2017 were retrieved to evaluate for evidence of ethical review.

Results
A total of 2041 citations have been identified from the contents of all the five leading nursing journals that were published between 2015 and 2017. Out of these, 1284 clinical studies have been included in the text to extract the data of ethical review. From these, a total of 87.5% of prospective clinical studies mentioned informed consent. Only 52.9% of those reported that written informed consent had been obtained; 3.6% reported oral consent, and 6.8% used other ways such as online consent or completion and return of data collection (such as surveys) to denote assent. Notably, 36.2% of those did not describe the method used to obtain informed consent and merely described that “consent was obtained from participants or participants agreed to join in the research”. Furthermore, whilst 93.7% of clinical studies mentioned ethical approval; 92.5% of those stated the name of ethical committee and interestingly, only 37.1% of those mentioned the ethical approval reference. The rates of reporting ethical approval were different between different study type, country, and whether mentioning financial support (all P<0.05). In addition, positive statistically significant correlations were found between reporting informed consent, reporting written informed consent, reporting ethical approval, naming of ethical committee, and reporting ethical approval reference number in the five leading international nursing journals (all P<0.01).

Conclusion
The reporting of ethics in leading international nursing journals demonstrates progress but improvement of the transparency and the standard of ethical reporting in nursing clinical research is required.

Comprehension and recall from the informed consent process by phase I healthy volunteers before dose administration
Research Article
Rami Tadros, Gillian E Caughey, Sally Johns, Sepehr Shakib
Clinical Trials, 28 February 2019; 16(3)
Abstract
Aims/Background
A fundamental part of all clinical trials is informed consent, reflecting the respect for the volunteer’s autonomy. Research participation is voluntary; therefore, certain aspects of the proposed study must be disclosed so that volunteers can make an informed decision. In this study, we aimed to examine the level of comprehension and recall of healthy volunteers from the informed consent process.

Methods
The study was carried out at a single phase I clinical trials unit. A questionnaire was administered to each volunteer to assess recall of important aspects of the study at the day-1 visit following the informed consent process. The questionnaire contained seven questions regarding study objectives, route, frequency and type of drug administration, adverse effects, number of subjects previously exposed and remuneration. One point was awarded for each correct answer.

Results
A total of 266 volunteers were administered the questionnaire. The mean total score (±standard deviation) for all volunteers was 4.5 ± 1.1 points out of 7, with a range of 0.8–6.7. For all 10 studies, 91% of volunteers responded correctly when answering about the route of administration, and 90% were able to accurately state the correct payment amount. Only 7% were able to repeat the aims of the study correctly.

Conclusion
The poor performance of our study volunteers raises concerns about recall of information prior to study drug administration. This has implications for the volunteer’s safety and ability to provide true informed consent. Interventions to improve recall prior to dosing should be undertaken.
Consent complexities, Ebola, and the fine line between collaboration and exploitation in research conducted during public health emergencies [KEYNOTE]
Nouvet, Elysée
Abstract
Background
There is significant and growing scholarship attending to the experiences and motivations of clinical Tx trial participants in Low and Middle Income Countries (LMICs). A smaller and newer body of research is emerging around perceptions and experiences of research conducted during public health emergencies. This presentation is based on one such Research on Research (RoR) study, the R2HC-funded qualitative study "Perceptions and moral experiences of research conducted during the 2014-16 West Africa Ebola outbreak."
Objective
This presentation takes West Africans’ first-hand accounts of decisions to support or enroll in EVD research as a point of departure for troubling normative parameters and markers of “consent to research”.
Methodology
Content for this presentation is based on team-based analysis of semi-structured interviews (N=99) with West African EVD study participants, members of research ethics boards, researchers, trial staff, and community leaders.
Findings
Our interviews revealed diverse motivations and aspirations or participating or supporting trials, as well as some frustrations around limited options for engagement and impact. A number of researchers with whom we spoke experienced their decisions to “collaborate” on trials as coerced. Others – participants and community leaders – evidently embraced opportunities to enroll in and/or support trials, but simultaneously connected their voluntariness to conviction of their participation’s impact on lives, to understandings of collective ownership over bio-samples, and/or to hopes for new political subjectivities. Mismatch between consent to trials (where consent includes both enrollment in or collaboration with) and the loaded significances of that consent for many with whom we spoke indicate a need for more localized and critical attention to the logics and significances of consent to research in particular humanitarian emergencies.
Conclusion
Upholding ideals of free and informed consent to research in contexts such as ETCs, where those approached for research are sick, distressed, and quarantined, is never going to be easy. What our research flags is that the complexities of consent during the West Africa EVD epidemic extended beyond the walls of the ETC and beyond infected patients. This in turn supports broadening what normally gets included in discussion of and strategies to uphold consent and voluntariness in humanitarian heath emergency research.

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CULTURAL/COUNTRY CONTEXT

Informed Consent in Africa – Integrating Individual and Collective Autonomy
Research Ethics Forum Series
Retha Visagie, Soné Beyers, J. S. Wessels
Social Science Research Ethics in Africa, 24 May 2019; 7 pp 165-179
Abstract
Free, prior informed consent is a universally acknowledged ethical requirement for research with human participants. In social sciences, informed consent guidelines are mostly critiqued for its inherent universalism and support of the individualised principlist notion of autonomy. Therefore, social science researchers
working with rural communities in Africa cannot ignore the values, concepts and theories relevant to collective autonomy. This chapter advocates for an integrated informed consent approach founded on Afro-communitarianism. We argue that the process of obtaining free, prior informed consent is deeply entrenched in cultural values. A one-size-fits-all approach to informed consent is in itself a form of disrespect for those concerned. The significant contribution of the chapter is a comparative analysis of individual and collective autonomy as it pertains to informed consent from two theoretical perspectives, namely principlism and Afro-communitarianism. We hope to encourage social researchers working in these settings to consider an African perspective on how to preserve participant autonomy.

**Challenges in informed consent decision-making in Korean clinical research: A participant perspective**

*Research Article*

Im-Soon Choi, Eun Young Choi, Iyn-Hyang Lee  
*PLOS ONE, 23 May 2019*

*Abstract*

*Objectives*

This study investigated how the essential elements of informed consent are realised during the consent process and examined the challenges in obtaining genuine informed consent in Korea.

*Methods*

Through purposive sampling, we recruited 21 subjects from those participating in anticancer drug research since 2013. We undertook 1:1 in-depth interviews and analysed the data by framework analysis.

*Results*

Themes raised throughout the interviews were categorised into ‘disclosure’ and ‘understanding’ of clinical information and ‘decision’. Provider-centred information, both verbal and written, was delivered to each participant. There were few tools that the research staff might evaluate study participants’ level of understanding of the provided information during the clinical trial. Although participants did not understand basic clinical trial concepts as much as desired, they may not seek to solve difficulties through communication with trial researchers. Doubts were raised about whether participants had sufficient capacity and free will to provide informed consent.

*Conclusion*

There is a concern that informed consent can fall short of genuine in Korea. To ensure informed consent meets the international standard, greater efforts should be made to establish an explicit standard operational protocol for obtaining informed consent.

**How should assent to research be sought in low income settings? Perspectives from parents and children in Southern Malawi**

*Research Article*

Helen Mangochi, Kate Gooding, Aisleen Bennett, Michael Parker, Nicola Desmond Susan Bull  
*BMC Medical Ethics, 14 May 2019; 20(32)*

*Abstract*

*Background*

Paediatric research in low-income countries is essential to tackle high childhood mortality. As with all research, consent is an essential part of ethical practice for paediatric studies. Ethics guidelines recommend that parents or another proxy provide legal consent for children to participate, but that children should be involved in the decision through providing assent. However, there remain uncertainties about how to judge when children are ready to give assent and about appropriate assent processes. Malawi does not yet have detailed guidelines on assent. Understanding perspectives among children and their parents can assist in developing contextually-appropriate assent guidance.

*Methods*
Qualitative research was conducted with children and parents in three settings in Southern Malawi (low- and high-income urban and rural), to take account of any variations between socioeconomic and cultural contexts. In each setting, interviews were conducted with parents and their children who had participated in paediatric research to understand their experiences of assent and views on appropriate assent practice. Focus groups were also conducted with children and parents, to understand broader social perspectives.

Results
We found widespread support for involving children in decisions on research participation. Participants identified a range of factors that affect children’s capacity to give assent, including intellectual capacity, emotional development, life experience and cultural norms. Age was often mentioned as a consideration, but deemed an unreliable sole indicator of capacity to assent. In relation to appropriate assent processes, participants emphasised considerations such as supporting effective understanding and minimizing harms. Views on how to achieve these aims varied; for example, there were different ideas about the appropriate order in which to approach children and parents, and about whose decision to respect in the event of disagreement.

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

A Critical Review of Thyroidectomy Consent in the UK
Original Research
C.McIntyre, N.Tolley
International Journal of Surgery, 2 May 2019

Abstract
Background
In 2015-16, the National Health Service (NHS) Litigation Authority received 10,965 claims for clinical negligence with Surgery having the highest number of claims. Currently a sum amounting to 25% of the annual NHS budget has been ring-fenced to meet extant claims. Claims made on a basis of inadequate informed consent are increasingly seen with many achieving a successful plaintiff outcome. There are presently no UK guidelines for thyroidectomy consent.

Method
A prospective study was performed to investigate current consent practice among the British Association of Endocrine and Thyroid Surgeons (BAETS) membership and patients having previously undergone thyroidectomy. For surgeons, the Bolam legal test applied where surgeons declared what risks and complications they routinely consented for during their practice. A study was also undertaken in patients who had previously undergone thyroidectomy for cancer applying the rule of Montgomery.

Results
Consent practice from 193 surgeons and data from 415 patients was analysed. In total thyroidectomy for cancer, 95% of surgeons consent for Recurrent Laryngeal Nerve (RLN) injury and temporary or permanent voice change. 70% specifically consent for External Laryngeal Nerve (ELN) injury, 50% for tracheostomy and 55% for general anaesthetic associated complications. Analysis of patient data showed they would like to be consented for far more risks than they are presently informed about in general medical practice. There was significant variation in the consenting practice in BAETS surgeons.

Conclusion
A BAETS approved consensus guideline to standardise UK consent practice would be appropriate. This may reduce complaints, litigation claims and guide expert witnesses.
Unique characteristics of informed consent in clinical genetics and genetic counselling
Havlovicová M, Curtisová V, Šubrt I
Journal of Czech Physicians, 2019 Spring; 158(1) pp 38-43
Abstract
Rapid development of clinical genetics was enabled by the advances of molecular genetic laboratory
diagnostics. Genetic laboratory testing has unique characteristics, and results of germinal genome testing has
consequences not only for the patient but also for his relatives. Genetic laboratory testing in the Czech
Republic is governed by the act no. 373/2011, which explicitly states that the testing requires the completion
of a written informed consent. This article explains in detail the process of obtaining an informed consent
within a broader framework of genetic counselling. An informed consent with genetic laboratory testing not
only informs the patient (this being its primary purpose), but can also serve as a lead for physicians of other
clinical specialties intending to order genetic laboratory tests.

Implementation of Immunization Program: Does it Need Informed Consent?
Rani Tiyas Budiyanti, Ayun Sriatmi, Nikie Astorina Yunita Dewanti
Indian Journal of Health & Medical Law, 2018; 1(2) pp 51-54
Abstract
Immunization program is important to prevent children from getting diseases that can be prevented by
immunization. However, in the implementation of this program there were some controversies and
rejections related to adverse events following immunization (AEFI), belief, and halal factor. This study aims to
determine whether informed consent regarding immunization programs needs to be done considering the
importance of immunization for children’s health. This research is a normative research with statue and
comparative approach. The data comes from law, journal, proceedings, and articles about health law. In
many countries, informed consent was needed in immunization program. But there is, any exception
according to belief, philosophy, culture, and religion. In Indonesia, implementation of government program
not needs informed consent. But it is not consistent with other regulation about implementation of
immunization program. Indonesia needs to review the regulations regarding immunization and synchronize
between regulations, so that in the implementation there are no conflicting regulations and overlapping with
each other.

RIGHTS/LEGAL/LEGISLATIVE

GDPR: Patient consent and the law
Suzanne Lurie
Practice Management, 8 May 2019; 29 (5) Legal
Abstract
This article examines the lawful bases for processing data under GDPR (general data protection regulation),
why consent is not an appropriate lawful basis and which lawful basis a clinician should rely on for the
processing of personal data.

Declaration of the Rights of People Affected by Tuberculosis
STOP TB Partnership, TB People
Article 12. Right to informed consent, May 2019; pp 15-16
Excerpt
Every person affected by tuberculosis has the right to informed consent.

This means respecting a person’s autonomy, self determination and dignity through voluntary health services delivery. It includes the right to informed consent—verbal or written, depending on the situation—to all forms of testing, treatment and medical research associated with tuberculosis, with information provided in an age and gender appropriate, culturally sensitive manner, imparted in a non-technical, comprehensible manner in a language understood by the person receiving the information. For children affected by tuberculosis who lack capacity to give informed consent, all decisions made by their parents or legal guardians with respect to testing, treatment or medical research associated with tuberculosis must be made in the best interests of the child, based on accurate medical evidence.

The right to informed consent includes the right to refuse health care for tuberculosis, in accordance with Chapter 15 of the World Health Organization’s Ethics Guidance for the Implementation of the End TB Strategy. The Ethics Guidance establishes that it is never appropriate to force treatment of people with tuberculosis because, among other things, it amounts to an invasion of bodily integrity and may put health care workers at risk...

Editor’s note: Full text of the declaration is available at the title link above.

Medicolegal Importance of Consent in Medical Practice: A Study in Tertiary Medical Centre of Barabanki U.P.
Singh Amit Kumar, Singh Anju, Singh DK
Indian Journal of Forensic Medicine & Toxicology, 7 May 2019; 13(2) pp 26-29

Abstract
Introduction
The Term consent means voluntary agreement, compliance or permission. section 13 of the Indian Contract Act lays down that two or more persons are said to consent when they agree upon the same thing in the same sense(meeting of the minds). From the times immemorial, medical practitioners played paternalistic role and were trusted with the responsibility of deciding the best treatment for their patients. With time, doctor patient relationship has changed from paternalistic to service provider and consumer type relationship. Patient being the consumer of services provided by the medical practitioner, have the right to full information concerning their diagnosis, treatment options, prognosis and possible complication. Informed Consent is the back of Patient's Autonomy. The advancement in medical technology has further increased its importance. In the developing countries including India, general physicians play a vital role in providing health care to the patients but unfortunately majority of them are unaware about the ethical aspects of Medical Practice.

Method
Objective: To determine the level of awareness about consent among faculty members in Tertiary Medical centre of Barabanki U.P.

Period of study
2Month.

Material and method
A questionnaire exploring the awareness about consent was offered to the faculty member of MIMS, Barabanki U.P.

Results
The survey revealed that 12 questionnaire were given to RMP of MIMS, out of 12 questions in 7 questions more than 50% of RMP were aware of correct response and in 5 questions more than 50% of RMP were unaware of requirement/procedure obtaining consent in various clinical situations.

Conclusions
They were aware of only those situations which are discussed and debated at various forums.
US State Regulation of Decisions for Pregnant Women Without Decisional Capacity

Research Letter
Erin S. DeMartino, Beau P. Sperry, Cavan K. Doyle, Julie Chor, Daniel B. Kramer, David M. Dudzinski, Paul S. Mueller
JAMA, 23 April 2019; 321(16) pp. 1629-1631
All US states have laws addressing decision making for individuals who cannot make their own medical decisions, including provisions for advance directives and processes authorizing relatives or interested persons to direct care as surrogate decision makers, although variation among state laws is increasingly recognized. However, the prevalence and content of state statutes and official advance directive documents addressing “treatment decisions for divisionally incapacitated pregnant women” is unknown.

Editor’s note: This article also appears under COGNITIVE CHALLENGES

BIOBANKING

Can dynamic consent facilitate the protection of biomedical big data in biobanking in Malaysia?

Original Paper
Mohammad Firdaus Abdul Aziz, Aimi Nadia Mohd Yusof
Abstract
As with many other countries, Malaysia is also developing and promoting biomedical research to increase the understanding of human diseases and possible interventions. To facilitate this development, there is a significant growth of biobanks in the country to ensure continuous collection of biological samples for future research, which contain extremely important personal information and health data of the participants involved. Given the vast amount of samples and data accumulated by biobanks, they can be considered as reservoirs of precious biomedical big data. It is therefore imperative for biobanks to have in place regulatory measures to ensure ethical use of the biomedical big data. Malaysia has yet to introduce specific legislation for the field of biobanking. However, it can be argued that its existing Personal Data Protection Act 2010 (PDPA) has laid down legal principles that can be enforced to protect biomedical big data generated by the biobanks. Consent is a mechanism to enable data subjects to exercise their autonomy by determining how their data can be used and ensure compliance with legal principles. However, there are two main concerns surrounding the current practice of consent in biomedical big data in Malaysia. First, it is uncertain that the current practice would be able to respect the underlying notion of autonomy, and second, it is not in accordance with the legal principles of the PDPA. Scholars have deliberated on different strategies of informed consent, and a more interactive approach has recently been introduced: dynamic consent. It is argued that a dynamic consent approach would be able to address these concerns.

Biobanking and the consent problem [BOOK CHAPTER]
Timothy Caulfield, Blake Murdoch
Abstract
From a research perspective, interest in biobanking continues to intensify. Governments and industry have invested heavily in biobanks, as exemplified by initiatives such as the UK Biobank and the United States’ Precision Medicine Initiative. But despite this enthusiasm, many profound legal and ethical challenges remain unresolved. Indeed, there continue to be disagreements about how best to obtain consent and the degree and nature of control that research participants retain over donated samples and health information.
Emerging social trends - including concerns about commercialization and perceived rights of continuing control ("biorights") - seem likely to intensify these issues.

**Dynamic Consent and biobanking: a means of fostering sustainability? [BOOK CHAPTER]**
Jane Kaye, Megan Prictor
*Law 2019 - Chapter 7, 26 April 2019; pp 117-129*

**Abstract**
Biobanks are rich repositories of biological materials (such as DNA) and other health and demographic data, often collected over a long period, that can be used for a variety of research purposes to improve the health of individuals and populations. It is important that the value of biobanks is maximized, but at this point in time, there are a number of challenges to achieving this. There are continued debates over the most appropriate mode of gaining consent from people who contribute tissue samples and data to biobanks, that will uphold high ethical standards and enable autonomous decisionmaking. As in other fields, there are changing legal and regulatory frameworks that can have significant implications for biobank management. There are also increasing concerns as to whether biobanks are achieving maximum usage and what the longer-term sustainability plans of maintaining these repositories should be. In this chapter, we outline some of the risks facing biobanks, using examples drawn from a range of international settings. We suggest that the concept of “Dynamic Consent,” a digital platform for engaging research participants, has the capacity to ensure a more engaged and informed cohort of participants, that might in turn address many of the legal and sustainability challenges currently facing biobanks. In this chapter, current uses of Dynamic Consent platforms in biobanking research in the UK, continental Europe, and the USA, and outline considerations for future application and evaluation of this tool to help enhance the relevance, ethical operation, sustainability, and interoperability of biobanks, are examined.

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**GENOMIC MEDICINES/GENE THERAPY**

**Consent and Autonomy in the Genomics Era**
*Review*
Rachel Horton, Anneke Lucassen
*Current Genetic Medicine Reports, 2 May 2019; Cancer Genomics, pp 1–7*

**Abstract**

*Purpose of Review*
Genomic tests offer increased opportunity for diagnosis, but their outputs are often uncertain and complex; results may need to be revised and/or may not be relevant until some future time. We discuss the challenges that this presents for consent and autonomy.

*Recent Findings*
Popular discourse around genomic testing tends to be strongly deterministic and optimistic, yet many findings from genomic tests are uncertain or unclear. Clinical conversations need to anticipate and potentially challenge unrealistic expectations of what a genomic test can deliver in order to enhance autonomy and ensure that consent to genomic testing is valid.

*Summary*
We conclude that ‘fully informed’ consent is often not possible in the context of genomic testing, but that an open-ended approach is appropriate. We consider that such broad consent can only work if located within systems or organisations that are trustworthy and that have measures in place to ensure that such open-ended agreements are not abused. We suggest that a relational concept of autonomy has benefits in encouraging focus on the networks and relationships that allow decision making to flourish.
NGS-Based genetic testing for heritable cardiovascular diseases. Specific requirements for obtaining informed consent
Jörg Schmidtke, Kathrin Wittkowski, Ralf Glaubitz
Molecular and Cellular Probes, 3 May 2019
Abstract
Clinical genetic testing in cardiovascular genetic medicine has undergone rapid changes. Next generation sequencing allows simultaneous testing of all genes associated with any cardiovascular phenotype, and molecular genetic testing for multiple genes has become the standard of practice for cardiovascular medicine. While technical and clinical advantages of multigenic approaches are evident, informed consent procedures have become more complex and challenging to the physician ordering such a test, particularly due to the increased potential for unsolicited findings. Based on the EuroGentest “Guidelines for diagnostic next-generation sequencing” we here propose a set of disease-specific requirements for obtaining informed consent for NGS-based genetic testing in a cardiogenetic clinic. We can show that it is often not feasible to obtain informed consent for every detail and suggest, in such cases, to reach general consent beforehand and discuss specific implications of unsolicited findings after the test results are available.

Informed consent and community engagement in genomic research [PhD THESIS]
Ogunrin, O. A.
University of Liverpool, 2019
Abstract
The introduction of genomic research to, and emergence of biobanks in, sub-Saharan African countries raise ethical issues that require urgent attention. Firstly, there are concerns about whether individuals and communities would agree to participate in this type of research especially considering how communitarianism may affect their decision-making process. Secondly, there are controversies over whether the informed consent process as it is applied to other biomedical researches would be appropriate for genomic research in sub-Saharan Africa. And thirdly, the components of engagement of culturally distinct communities in genomic research are not yet clarified... There was consensus between the adult research participants and the biomedical researchers on the appropriateness of blanket consent type for genomic research but the community leaders, health workers and the youths prefer either reconsenting or delegated consent...

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GENERAL/OTHER

The concise argument: the importance of consent and choice
The concise argument
John McMillan
BMJ Journal of Medical Ethics, 13 May 2019; 45 pp 285-286
When Beauchamp and Childress articulated the necessary and sufficient conditions for informed consent, they might have thought that would be the final word on what informed consent is.1 It’s emphasis in the Belmont Report,2 the Nuremberg Code,3 the Helsinki Declaration4 and numerous codes of professional ethics seems more than sufficient for emphasising its importance. Nonetheless, its place as the central issue for medical ethics appears undiminished and Pubmed lists 6192 publications with ‘Informed Consent’ in the title since 1979. One view of this is that medical ethics has channelled too much intellectual effort into consent, perhaps at the expense of other important ethical issues. Papers in this issue of the Journal of Medical Ethics suggest that the discussion of consent continues because of the need to consider what it means in new contexts, how
it can be a challenge in some contexts, how it is related to tough theoretical issues about the value of choice and autonomy and how it can blend into other debates…

**The notion of free will and its ethical relevance for decision-making capacity**

Tobias Zürcher, Bernice Elger, Manuel Trachsel

*BMC Medical Ethics, 8 May 2019; 20(31)*

*Abstract*

**Background**

Obtaining informed consent from patients is a moral and legal duty and, thus, a key legitimation for medical treatment. The pivotal prerequisite for valid informed consent is decision-making capacity of the patient. Related to the question of whether and when consent should be morally and legally valid, there has been a long-lasting philosophical debate about freedom of will and the connection of freedom and responsibility.

**Main text**

The scholarly discussion on decision-making capacity and its clinical evaluation does not sufficiently take into account this fundamental debate. It is contended that the notion of free will must be reflected when evaluating decision-making capacity. Namely, it should be included as a part of the appreciation-criterion for decision-making capacity. The argumentation is mainly drawn on the compatibilism of Harry Frankfurt.

**Conclusions**

A solution is proposed which at the same time takes the notion of free will seriously and enriches the traditional understanding of decision-making capacity, strengthening its justificatory force while remaining clinically applicable.

**Consent in pregnancy: a qualitative study of the views and experiences of women and their healthcare professionals**

Jacqueline Nicholls, Anna L David, Joseph Iskaros, Anne Lanceley

*European Journal of Obstetrics & Gynecology and Reproductive Biology, 11 May 2019*

*Abstract*

**Objective**

Consent in antenatal settings is contentious, poorly understood and recognised as problematic for pregnant women. This study aimed to investigate participants’ views and experiences of the consent process.

**Design**

Qualitative research performed in a large urban teaching hospital in London. Sixteen pregnant women and fifteen healthcare professionals (obstetricians and midwives) participated. Consent consultations were observed and in-depth interviews carried out with healthcare professionals and pregnant women using semi-structured interview guides. Data were collectively analysed to identify themes in the experiences of the consent process.

**Results**

Four themes were identified: 1) Choice and shared decision-making. Pregnant women do not always experience consent in a choice-making way and often do not understand information provided to them. 2) Contextualising information disclosure. What is important to women is not only the information but the relational context in which consent is obtained. 3) Quality of HCP-woman relationship. Trust in their healthcare professional sometimes makes women seek less information and conversely. Individualised information is desired by women but professionals found it difficult to ensure that women receive this in practice. 4) Law and professional practice. Doctors are more aware of legal developments in consent related to the Montgomery case than their midwifery colleagues, but they are not always certain of the implications.

**Conclusion**

Results suggest that an effective antenatal consent process which empowers pregnant women requires their understanding of provided information to be elicited. There is a delicate balance to be struck between the trust of a patient in their professional and information-based consent, rather than a simple focus on
improving information provision. Whilst recognising women’s desire for bespoke consent professionals acknowledged the difficulty of ensuring this in practice. If consent is to remain the legal yardstick of autonomous choice-making, women’s understanding and that shared with their healthcare professional needs to be more explicitly addressed.

Revamping the Privacy Policy: A Study on Informed Consent and User Interactions [PhD THESIS]
Denton Wood
Baylor University, Department of Computer Science, May 2019
Abstract
Privacy is an abstract concept that has very real repercussions for users of technology in the twenty-first century. Recent large-scale controversies such as the Facebook and Cambridge Analytica scandal bring into question users’ understandings of what companies are allowed to do with their data. The primary method of communicating privacy rights to users is the privacy policy; however, these policies are not always effective at gaining users’ informed consent regarding their rights. This thesis will attempt to show the effectiveness of privacy policies at gaining informed consent through an experiment showing the impact of different display factors on users’ understanding.

MEDICAL/SURGICAL

Getting the Gist Across Is Enough for Informed Consent for Acute Stroke Thrombolytics
Comments and Opinions
Skolarus LE, O’Brien A, Meurer WJ, Zikmund Fisher BJ
Stroke, 14 May 2019
Acute stroke thrombolytics greatly reduce poststroke disability, both in clinical trails and in clinical practice. Too few patients, however, take advantage of these life-improving and cost-saving treatments. In fact, in the United States, up to 7.5% of tPA (tissue-type plasminogen activator) eligible patients refuse this time limited stroke treatment, and even among stroke patients who receive tPA, up to 20% experience delayed treatment due to patient and family consent...

Assessing adequacy of informed consent for elective surgery by student-administered interview
Original Article
Clement L. K. Chia, Kai Siang Chan, Marcus J. M. Ng, Anil D. Rao, Reyaz Singaporewalla
ANZ Journal of Surgery, 14 May 2019
Abstract
Background
Studies show that patients often sign consent documents without fully comprehending the risks, benefits and potential complications. There is currently no Asian study performed analysing adequacy of informed consent. This study aims to assess adequacy of informed consent by evaluating patient understanding and retention of key information and complications pertaining to surgery via medical student-administered interview.
Methods
A prospective study was performed on 48 patients undergoing groin hernia surgery, laparoscopic cholecystectomy and total thyroidectomy from 2017 to 2018 in a teaching hospital. Standardized assessment forms including major common complications and key details of the surgery were prepared. Structured one-to-one interviews between students and patients were performed and recorded on the morning of surgery.
Results
Although 93.8% of the patients claimed to have understood the information regarding their surgery, only 19.4%, 44.4% and 62.5% of the patients could actually recall the serious complications of groin hernia surgery, laparoscopic cholecystectomy and thyroidectomy, respectively. Elderly patients (>65 years) had poorer understanding of surgical procedure compared to the young (80% versus 100%, respectively, P = 0.008) with 26.7% of elderly patients claiming that they did not understand the indication for surgery. High satisfaction rates with this preoperative interview were reported by both patients and students (95.8% and 97.9%, respectively). Time interval from informed consent to surgery did not make any difference.

**Conclusion**

Understanding of information and key complications was generally low, especially in the elderly population. The structured preoperative interview achieved the dual goal of reinforcing patient gaps in knowledge and improving student communication skills.

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**Assessment of Use, Specificity, and Readability of Written Clinical Informed Consent Forms for Patients With Cancer Undergoing Radiotherapy**

*Original Investigation*

Subha Perni, Michael K. Rooney, David P. Horowitz, Daniel W. Golden, Anne R. McCall, Andrew J. Einstein, Reshma Jagsi

**JAMA Oncology, 2 May 2019**

**Abstract**

**Importance**

Appropriate informed consent processes are crucial to preservation of patient autonomy and shared decision making. Although half of patients with cancer receive radiotherapy, it is unknown whether current consent practices are comprehensible for patients.

**Objective**

To characterize use, specificity, and readability of clinical informed consent forms for radiotherapy, hypothesizing that forms would be higher than the recommended sixth- to eighth-grade readability level.

**Design, Setting, and Participants**

This nationwide cross-sectional survey study and readability analysis was conducted from 2016 to 2018 and included 89 academic radiation oncology departments that were part of the 2016 Electronic Residency Application Service. Department leaders (clinical directors, chairs, and personal contacts of study authors) at academic radiation oncology departments were contacted via email.

**Main Outcomes and Measures**

Readability levels were measured by 7 validated readability indices, including the Ford, Caylor, Sticht (FORCAST) index for nonnarrative texts. Difficult words were identified using The Living Word Vocabulary, which describes the readability grade levels of 40,000 common words.

**Results**

Of 89 departments, 67 (75%) responded to questions and 57 (64%) provided 113 forms for analysis. Departments providing forms did not differ substantially from others in terms of region, residency size, research output, rural vs urban location, or public vs private institution status. All departments obtained patient written informed consent before radiotherapy; 38 (57%) used body site–specific forms. Using the most conservative (low-score) estimate, mean form readability ranged from grade level 10.6 to 14.2. By 7 distinct indices, only 9 (8%) of 113 forms met the recommended eighth-grade readability level, and 4 (4%) forms met a sixth-grade level. Not a single form met either recommendation based on the FORCAST index. Forms used an average of 7.2 difficult words. Body site–specific forms had considerably better readability than general consent forms.

**Conclusions and Relevance**

This nationwide study of informed consent practices for cancer treatment with radiotherapy demonstrates that while all US academic radiotherapy departments use written consent forms, it is rare for templates to meet the recommended readability levels for patient materials. These data suggest the need for reevaluation
and modification of the approach to radiotherapy consent, ideally with guidance and templates designed by national professional organizations.

**What is in a Name? Parent, Professional and Policy-Maker Conceptions of Consent-Related Language in the Context of Newborn Screening**
Stuart G Nicholls, Holly Etchegary, Laure Tessier, Charlene Simmonds, Beth K Potter, Jamie C Brehaut, Daryl Pullman, Robin Z Hayeems, Sari Zelenietz, Monica Lamoureux, Jennifer Milburn, Lesley Turner, Pranesh Chakraborty, Brenda J Wilson
Public Health Ethics, 4 May 2019

**Abstract**
Newborn bloodspot screening programs are some of the longest running population screening programs internationally. Debate continues regarding the need for parents to give consent to having their child screened. Little attention has been paid to how meanings of consent-related terminology vary among stakeholders and the implications of this for practice. We undertook semi-structured interviews with parents (n = 32), healthcare professionals (n = 19) and policy decision makers (n = 17) in two Canadian provinces. Conceptions of consent-related terms revolved around seven factors within two broad domains, decision-making and information attainment. Decision-making comprised: parent decision authority; voluntariness; parent engagement with decision-making; and the process of enacting choice. Information ascertainment comprised: professional responsibilities (including disclosure of information and time to review); parent responsibilities; and the need for discussion and understanding prior to a decision. Our findings indicate that consent-related terms are variously understood, with substantive implications for practice. We suggest that consent procedures should be explained descriptively, regardless of approach, so there are clear indications of what is expected of parents and healthcare professionals. Support systems are required both to meet the educational needs of parents and families and to support healthcare professionals in delivering information in a manner in keeping with parent needs.

**The quality of informed consent obtained for orthopedic surgeries-elective versus trauma: A prospective interview-based study**
Journal of Orthopaedic Surgery (Hong Kong), 1 May 2019; 27(2)

**Abstract**
Background
Orthopedic surgeons routinely obtain informed consent prior to surgery. Legally adequate informed consent necessitates a thorough discussion of treatment options and risks and proper documentation. However, the quality of informed consent in orthopedic trauma patients is an under-researched area.

**Purpose**
To assess the quality of the informed consent process in trauma compared with elective orthopedic patients and to assess patients' emotional state at the time of signing consent form.

**Methods**
Sixty-two consecutive patients undergoing either elective total joint arthroplasty (N = 32) or orthopedic trauma surgery (N = 30) were included. The data were collected through personal interviews using a proposed informed consent score. The interviews were held after obtaining the informed consent and before the index procedure. Patients were asked to describe their diagnosis, the surgical procedure, its' benefits, and risks as well as alternative treatments.

**Results**
Mean age differed significantly between elective and trauma group patients (66.1 vs. 51.6, respectively, p < 0.01), while gender and education level were comparable (p = 0.075, p = 0.55, respectively). The quality of consent was significantly better for patients with post-high-school education compared to elementary education level (consent score: 16.9 ± 4.1 vs. 12.2 ± 5.5, p = 0.021). Patients in the elective group showed an
overall higher quality of consent, as reflected by a mean score of 17.03 ± 4.2 versus a mean score of only 13.73 ± 4.7 in the trauma group (p = 0.005, 95% CI: 1.02-5.57). Specifically, trauma patients demonstrated a lower comprehension of the diagnosis, the benefits of surgical treatment, the possible complications, and the expected postoperative course.

Conclusion
Patients undergoing trauma surgery are significantly more likely to have an inadequate understanding of the proposed treatment. These findings raise questions concerning the validity of consent from trauma patients.

**Partnering with Patients and Families during Childbirth: Confirming Knowledge for Informed Consent**
Simpson, Kathleen Rice
The American Journal of Maternal/Child Nursing, May/June 2019; 44(3) pp 180

**Abstract**
There are many opportunities during hospitalization for childbirth to offer information to the woman and her family about various options and choices for clinical care and treatment. Women should be provided information at their appropriate literacy level and language to make decisions about their care in partnership with the health care team. While events of labor and births may seem routine to clinicians, they are usually not for patients. Therefore, shared decision-making approaches and patient consent are essential throughout the childbirth hospitalization.

**Informed Consents or Consent of Information? Assessing Quality of Informed Consents for Scheduled Cesarean Section [9]**
Janelle Jackman, Carolina Martinez, Erroll Byer, Kimen Balhotra
Obstetrics & Gynecology, May 2019; 133 pp 97S–98S

**Abstract**

**Introduction**
Informed consents of patients undergoing procedures are important not only for ethical and legal reasons but also for the quality of care. Patients' understanding allows for better cooperation, improves results and satisfaction and also helps prevent errors. Providers must ensure that the patient understands the nature of their condition, the risks and benefits of the procedure, the alternatives and agrees voluntarily. Although consents are a well-established practice, it often fails to meet its purpose. Providers must realize that signing a consent form is not equivalent to receiving informed consent.

**Methods**
A cross sectional survey of patients admitted for scheduled cesarean section. The anonymous questionnaires were administered within 30 minutes to 48 hours of having the consent explained. The questions focused on patient's recall of information about the explanation of the procedure, risks and alternatives, preferences about the decision process and overall satisfaction with the manner in which the consent was obtained.

**Results**
Only 9% of the patients didn't receive explanations about risks but 42% didn't have discussions of alternative options. Most patients (70%) weren't asked to repeat the explanation. Expectations about decision varied, with 65% favoring shared decision and nearly 26% preferring autonomous decision. Satisfaction was rated as good or very good by 94% of patients.

**Conclusion**
In conclusion, most patients do not remember receiving explanations about alternatives for procedures nor are they asked to repeat explanations. We recommend that the quality of consents be regularly assessed, to ensure informed consent is being obtained.
Informed consent in gynecologic surgery
Patricia Overcarsh, Cynthia Arvizo, Lara Harvey
Current Opinion in Obstetrics and Gynecology, 30 April 2019

Abstract

Purpose of review
Informed consent is frequently used interchangeably with obtaining a signature on a form. This oversimplification shifts the value from the process of informed consent to the documentation. This review focuses on the recommended components of the consent process, barriers encountered, factors influencing patient satisfaction, attempts to improve the consent practice, and considerations in special populations.

Recent findings
The process of informed consent is key to promoting shared decision-making and patient autonomy. Several barriers exist to providing optimal consent including time constraints as well as educational, cultural, and language barriers. Innovative approaches such as audiovisual aids show promise in overcoming barriers and improving the consent process.

Summary
Patients seek expertise and knowledge to aid in making decisions that align with their care goals. Providers have an obligation to provide individualized and accessible counseling. Ongoing research is needed to optimize this process.