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, 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:

**Editor**  
Paige Fitzsimmons, MA  
Editor & Associate Fellow  
paige.fitzsimmons@ge2p2global.org

**Publisher**  
David R. Curry  
President & CEO  
david.r.curry@ge2p2global.org

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

- YOUNG PERSONS  
- COGNITIVE CHALLENGES  
- TECHNOLOGY/OTHER MEDIATION  
- BIOMEDICAL RESEARCH  
- CULTURAL/COUNTRY CONTEXT  
- RIGHTS/LEGAL/LEGISLATIVE  
- GENERAL/OTHER  
- MEDICAL/SURGICAL  
- GENOMIC MEDICINES/GENE THERAPY

No new content identified for the following categories:  
BIOBANKING  
COMPASSIONATE USE/EXPANDED ACCESS
YOUNG PERSONS

Role of Informed Consent in Andrological Surgery in Adolescents and Adults
Mauro Silvani
Psychosexual Counseling in Andrological Surgery, 2 April 2019; pp 81-84
Abstract
Informed consent for andrological surgery, particularly during adolescence, is a delicate and strategic moment in the success of the patient’s therapeutic path. Informed consent must have certain characteristics:

- Clarity and simplicity of exposition to allow easy understanding by anyone who reads it, in addition to the patient, for example, his relatives, lawyers, doctors, and magistrates. The information must also be provided with particular delicacy to adolescent children who sometimes are confronting the hospital environment and surgery for the first time.
- Accompanied by a rich description that allows a better understanding.
- Must contain a part in which the signer declares that he has clearly understood the pathology that is affecting him and a distinct one from the previous part concerning the type of intervention that the patient will undergo, including a description of the relative complications. In this section of the consent form, other surgical procedures contemplated for the pathology in question should also be described.
- The collection of the consent form and a signature should always be by the surgeon before the operator, because, more than in any other surgery, this is a surgery in which the doctor-patient relationship of trust is particularly heard and developed.
- Attendance at the interview with a family member, of the partner if older, or parents if a minor. The signature on the informed consent form results from a clinical diagnostic path divided into multiple periods during which there is a two-way communication between the patient and family practitioner, surgeon, especially in the case of a minor patient, to develop a therapeutic alliance that is essential to a successful outcome.

Editor’s note: This article also appears under MEDICAL/SURGICAL

The Informed Consent in Pediatrics – A Child’s Right
Dana Elena Mindru, Mioara Calipsoana Matei, Aurica Rugina, Irina Mihaela Ciomaga, N. Nistor, Laura Florescu
The Medical-Surgical Journal, 29 March 2019; 123(1)
Abstract
Consent signifies the patient’s knowingly authorization of a medical intervention. Revealing the truth about the patient’s condition refers to the provision of information by the physician regarding the diagnosis and the treatment, as well as their understanding by the patient. His or her decision-making capacity refers to the ability of understanding the data that have been provided. The independent decision refers to the patient’s right to make a free decision regarding his or her treatment, without constraint or manipulation. Informed consent is one of the most sensitive issues of the physician-patient, researcher-subject relationship. Minors do not have the capacity of independent decision; therefore, the decision by substitution given by parents or legal representatives is required. The minor child’s consent to the medical treatment and pediatric scientific research expresses itself under the form of assent, which is valid starting with the age of 14. Doctors should ask for parental consent before medical interventions (except in cases of emergency, when parents cannot be contacted). From a practical standpoint, when it comes to obtaining a valid consent, it is useful to make a distinction between the problem-solving process and the decision-making process. The permission given by parents includes all standard elements of informed consent. In each case, the doctor has to make sure that
Informed Consent for Bedside Procedures in Pediatric and Neonatal ICUs: A Nationwide Survey
Arnolds, Marin M., Feltman, Dalia M.
Pediatric Critical Care Medicine, 5 April 2019
Abstract
Objectives
Primary objectives were to discover current practices of informed consent for bedside procedures in the PICU and neonatal ICU and how trainees learn to obtain consent. We also attempted to gauge if program directors felt that one method of consent was subjectively superior to another in the way it fulfilled established ethical criteria for informed consent.

Design
An online anonymous survey. Participants were asked about how and by whom informed consent is currently obtained, training practices for fellows, and attitudes about how different consent methods fulfill ethical criteria.

Setting
All U.S. fellowship programs for neonatology (n = 98) and pediatric critical care (n = 66) in the fall of 2017.

Subjects
Neonatal and pediatric critical care fellowship program directors.

Interventions
None.

Measurements and Main Results
The overall response rate was 50% (82 of 164). The most common method for obtaining consent in both ICU types was via a written, separate (procedure-specific) consent (63% neonatal ICUs, 83% PICUs); least common was verbal consent (8% neonatal ICUs and 6% PICUs). Fellows were reported as obtaining consent most often (91%), followed by mid-level practitioners (71%) and residents (66%). Residents were one-fifth as likely to obtain consent in the PICU as compared with the neonatal ICU. Sixty-three percent of fellowship directors rated their programs as “strong” or “very strong” in preparing trainees to obtain informed consent. Twenty-eight percent of fellowship directors reported no formal training on how to obtain informed consent.

Conclusions
Most respondents’ ICUs use separate procedure-specific written consents for common bedside procedures, although considerable variability exists. Trainees reportedly most often obtain informed consent for procedures. Although most fellowship directors report their program as strong in preparing trainees to obtain consent, this study reveals areas warranting improvement.

COGNITIVE CHALLENGES

Competence to Consent and Its Relationship With Cognitive Function in Patients With Schizophrenia
Norio Sugawara, Norio Yasui-Furukori, Tomiki Sumiyoshi
Frontiers of Psychiatry, 12 April 2019
Abstract
Decisional capacity to consent is an emerging ethical and legal concept, and is closely related to self-determination of patients facing important medical decisions or research participations. Recently, the
MacArthur Competence Assessment Tool (MacCAT), a semi-structured interview consisting of four dimensions (Understanding, Appreciation, Reasoning, and Expression of a Choice), was developed to assess the decisional capacity. Decision-making capacity in a group of patients with schizophrenia, as measured by the MacCAT, has been shown to be impaired in comparison with healthy control people. However, this does not necessarily mean the presence of impaired decisional capacity in all cases. Considering the real-world practice of obtaining informed consent from patients with schizophrenia, it is important to evaluate the relationship between psychopathological features and decisional capacity of the illness. Negative symptoms of schizophrenia have been demonstrated to be related to the ability to understand information relevant to the decision, reason rationally, and appreciate a situation and its consequences. On the other hand, positive symptoms, such as delusions and hallucinations have been an inconsistent correlate of poor capacity. Furthermore, some studies indicate that impairment of cognitive function, a core symptom of schizophrenia, could be more largely associated with decisional capacity than positive and negative symptoms. Therefore, it is reasonable to assume cognitive enhancement would enlarge the capacity to consent and promote autonomy in medical treatment and research participation in patients with schizophrenia. Further studies are warranted to elucidate this and related issues.

Editor’s note: More information regarding the MacArthur Competence Assessment Tool (MacCAT) noted in the abstract is available here.

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.

TECHNOLOGY/OTHER MEDIATION

Annals Graphic Medicine - Patient-Informed Consent
Anna Brand, MD; Linde Gao, MD; Alexandra Hamann; Sophia Martineck; Verena Stangl, MD

Annals of Internal Medicine, 9 April 2019

Information
Medical graphic narratives to improve patient comprehension and periprocedural anxiety before coronary angiography and percutaneous coronary intervention: a randomized trial.

Editor’s note: The full graphic is available via open access at the link above. Below you will find a small excerpt.
Medical Graphic Narratives to Improve Patient Comprehension and Periprocedural Anxiety Before Coronary Angiography and Percutaneous Coronary Intervention: A Randomized Trial
Anna Brand, Linde Gao, Alexandra Hamann, Claudia Crayen, Hannah Brand, Susan M. Squier, Karl Stangl, Friederike Kendel, Verena Stangl
Annals of Internal Medicine, 16 April 2019

Background
Written informed consent (IC) before such interventions as coronary angiography may not ensure that patients understand the rationale, procedural details, and potential risks involved. Barriers include patient anxiety, literacy, and differences in clinicians' communication skills. Medical graphic narratives (“comics”) may communicate complex health information more clearly.

Objective
To assess whether supplementing standard IC (ICstandard) with a comic (ICcomic) improves patient comprehension, anxiety, and satisfaction.

Methods
From October 2016 to January 2018, a total of 135 consecutive hospitalized patients who were having coronary angiography at Charité – Universitätsmedizin Berlin, Campus Mitte, were screened for enrollment. Of these patients, 121 were randomly assigned to ICstandard (official consent form and conversation with physician) with or without ICcomic (graphic illustrations of central IC aspects based on the official consent form [available at www.annals.org/aim/article/doi/10.7326/G19-0008]); the same physician explained the procedure to all participants. After all participants completed ICstandard, the ICcomic group additionally received the patient comic...

Attitudes of postnatal women and maternity staff towards audio recording of consent discussions
Ivermee C, Yentis SM
Anaesthesia, 11 April 2019

Abstract
Audio recording consent discussions, and giving a copy of the recording to the patient to keep, might improve the consent process and reduce the risk of misunderstandings, complaints or medicolegal claims. However, there may be concerns over confidentiality and how being recorded could affect the consent discussion. We ascertained the views of 50 postnatal women and 100 maternity staff (25 anaesthetists, 25 obstetricians and 50 midwives) on making audio recordings of consent discussions. There was a wide range of opinions, with women and staff similarly supportive of audio recording overall, but the women were more supportive of recording than the staff when asked if they were against it, or whether they would support...
Consent Plus: Improving the Consent Process in Elective Lower Limb Arthroplasty
P. Lee, A. P. Chandratreya
Orthopsedic Proceedings, 4 April 2019; 101B(3)

Abstract

Background of study
Following the Montgomery ruling, consent is now a matter of law. The medical professionals have to show proof that risks and implications and material risks are explained to the patient and that they have accepted to go ahead with surgery.

Materials and Methods
We devised a free web based programme (www.consentplus.com) which introduces a documented checkpoint to the consent process in hip and knee replacement surgery. It enables reproducible high-quality bite-sized information delivery to patients and their families in an optimal environment. It utilises the flip classroom principle to facilitate dialogue between doctors and patients. It generates physical documentation to show patients’ knowledge and understanding of the risks; to produce a truly informed consent.

Results
1567 users completed the Consent PLUS process over 28 hospitals across the UK. 98.1% of users were satisfied with Consent PLUS in terms of quality of service and information delivered. Users’ self-rated knowledge increased by 29%, independent of age group, prior knowledge or check-point scores. Supportive documentation for 100% of the users, which facilitated the consent process but did not replace the consultation.

60% of users accessed the system via desktop computers, 23% via tablet and 17% via mobile phone. 55 consultant surgeons and 28 hospitals have been registered into the system by the users. 96.9% of users found Consent PLUS useful and 96.3% would recommend it to their friends. 92.6% would use it again.

Conclusion
Consent PLUS can facilitate information delivery and improve patients’ understanding of the risks of surgery and its implications subjectively and objectively. Consent PLUS is a tool designed to enhance and facilitate the consent process, not to replace the current consent forms.

Editor’s Note: The mission statement of Consent PLUS as taken from the website on 17 April 2019 is as follows: “Consent PLUS has enabled the healthcare team to improve patient experience, save consultant time and standardise information delivery processes. Using Consent PLUS at the hospital in an access-controlled manner has enabled competent clinicians to give individual patients and their carers much more quality information about the procedure, including the material risks and benefit involved for that individual. From the healthcare provider point of view, it saves a considerable amount of time, checklist and videos help standardised the information delivery, rather than the clinician having to repeat them. The form is stored on the server and can be scanned back into the system once signed.”

BIOMEDCIAL RESEARCH

When Is It Ethical for Physician-Investigators to Seek Consent From Their Own Patients?
Stephanie R. Morain, Steven Joffe, Emily A. Largent
The American Journal of Bioethics, 17 April 2019; 19(4) pp 11-18

Abstract
Classic statements of research ethics advise against permitting physician-investigators to obtain consent for research participation from patients with whom they have preexisting treatment relationships. Reluctance about “dual-role” consent reflects the view that distinct normative commitments govern physician–patient and investigator–participant relationships, and that blurring the research–care boundary could lead to ethical transgressions. However, several features of contemporary research demand reconsideration of the ethics of dual-role consent. Here, we examine three arguments advanced against dual-role consent: that it creates role conflict for the physician-investigator; that it can compromise the voluntariness of the patient-participant’s consent; and that it promotes therapeutic misconceptions. Although these concerns have merit in some circumstances, they are not dispositive in all cases. Rather, their force—and the ethical acceptability of dual-role consent—varies with features of the particular study. As research participation more closely approximates usual care, it becomes increasingly acceptable, or even preferable, for physicians to seek consent for research from their own patients. It is time for a more nuanced approach to dual-role consent.

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

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.

*Editor’s note: The authors mentions sub-Sharan Africa as an example of the LMICs they are referring to in this article.*

**Informed Consent in IBD Trials: Where We Are and Where We Need to Go**

Michael Kurin, Jeffry Katz, Eric Kodish, Bret Lashner

*Inflammatory Bowel Diseases, 16 April 2019*

**Abstract**

Patient enrollment is increasingly recognized as a major limiting factor to inflammatory bowel disease (IBD) clinical trial completion. Many IBD trials will fail to enroll enough patients to adequately power their study. This has led to a renewed multifaceted effort to encourage more patients to enroll in clinical trials. Although
this is of clear importance, it is also important to ensure that all efforts to enroll patients in clinical trials do not compromise the quality and validity of the patient's/study participant's informed consent. Informed consent has 4 components: disclosure, voluntariness, understanding, and capacity. The application of informed consent to IBD clinical trials for biologic agents has not been previously studied. Yet the nature of clinical trials for biologics in IBD creates certain challenges to properly fulfilling the requirements of informed consent in the recruitment process that should be examined. In the following commentary, the components of informed consent are reviewed, challenges to their fulfillment in IBD trials are reviewed, and practical advice is offered.

**Will Shorter Informed Consent Forms with Visual Aids Improve Understanding of the Document in Adult and Elderly Populations of Clinical Trials?**
Bloswick, Agata, Skowron, Agnieszka
*Ethics & Medicine, Spring 2019; 35(1) pp 43-44*

**Abstract**
The informed consent form (ICF) is a critical document for ensuring patients are properly informed about participation in clinical trials, yet there are no regulations that govern the length and format of the document, for the texts reach an average length of 18 pages. The aim of the present study is to conduct a readability assessment, comparing a standard version ICF of 18 pages and a modified (shortened to 11 pages and illustrated) version ICF, using the methodology for the approval of patient information leaflets for marketed medications mandated in Poland and assessing two age groups—adults aged 18-65 and elderly >65. Ten adult and 10 elderly participants were included in the study.

The long and short versions of the ICF resulted in different reading speeds in the adult group; the long version was read 75% faster than the short one on a words-per-minute basis, suggesting a less-thorough reading of the longer text. The difference in information retention, measured by a follow-up questionnaire, was over 20% better recall of risks, procedures, and benefits by the adult group readers of the short ICF.

In the elderly group of participants, the retention and understanding of the documents was significantly lower overall (50% fewer correct answers in comparison to the adult group). In contrast to the adult group, the words-per-minute reading speed for the shorter version was 50% greater than for the longer. The elderly readers appeared to have reviewed the longer document more thoroughly while skipping the tabularized elements of the shortened document that were intended to simplify key information. A detailed analysis shows that the documents with visual aids were less effective for the elderly than plain text.

Based on the information retention observed in this study, significant improvements in readability and design are needed for informed consent forms to fulfill their intended purpose.

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**CULTURAL/COUNTRY CONTEXT**

**Preference and Values of Stroke Interventions, Kingdom of Saudi Arabia**
Reem Alamri, Adel Alhazzani, Saeed A. Alqahtani, Hayfa Al-Alfard, ShahadMukhtar, Khadejah Alshahrany, Faisal Asiri
*Neurology Research International, 1 April 2019*

**Background**
Acute ischemic stroke (AIS) occurs when there is a sudden occlusion of the arterial blood supply to part of the brain resulting in sudden focal neurological deficits. Recent major clinical trials of reperfusion therapy had proved the efficacy of timely stroke intervention to restore blood flow. Development of acute stroke protocols waiving the informed consent to obtain necessarily brain images or provide thrombolytic therapy is important to streamline and organize efforts to achieve the goal of early intervention and better functional outcome.
**Objective**
This study aims to identify the preference and values of acute stroke interventions standard of care therapy without informed consent in the absence of surrogate decision-makers.

**Methods**
A cross-sectional survey was conducted in the Kingdom of Saudi Arabia using an electronic questionnaire. The questionnaire addressed the patients' preference of acute stroke protocol waiving the informed consent for hyperacute brain images and delivering thrombolytic therapy or mechanical thrombectomy in absence of surrogate. All Saudi population aging from 18 to 65 years were invited to participate.

**Results**
The study included 2004 participants with ages ranging from 18 to 65 years with mean age of 30.1 years. About 66% of the participants were females and 95% were Saudi. Overall, 90.5% of the participants agreed on performing computed tomography angiography (CTA) by the medical staff for the acute strokes without consenting followed by 79% for thrombolytic therapy, 70.8% for mechanical thrombectomy, and only 49.3% for acute lifesaving surgical intervention.

**Conclusion**
Researchers found that the high percentage of participants had favorable response and positive perception toward providing acute stroke intervention and mechanical thrombectomy without informed consent. However, the study showed skeptical acceptance among participants regarding invasive surgical measures.

**Informed Consent in Medical Decision Making In India**
Rateesh Sareen; Consultant, Department of Pathology & Transfusion Medicine, Santokba Durlabhji Memorial Hospital and Research Center, Jaipur, Rajasthan, India, Akanksha Dutt; Consultant Anesthesiology, Department of Anesthesia, Bhagwan Mahaveer Cancer Hospital and Research Center, Jaipur, Rajasthan, India
*Journal of Counselling and Family Therapy, April 2019; 1(1)*

**Abstract**
Consent is one of the key elements for protection of welfare of patients or research participants. The physician has a legal and ethical responsibility to provide adequate information to the patient so that he or she is able to process the information and make appropriate decisions. The patient's consent must be voluntary and competent. In order to meet the requirements for effective, informed decision making, a physician must disclose material facts, which are relevant to decision making, including the patient's diagnosis, proposed treatment, risks and benefits of the treatment, alternative treatments along with their risks and benefits, and the risks of refusal. A physician must answer truthfully about the number of similar procedures or cases performed, and disclose success rates, and any financial conflict(s) of interest. The physician must advise patients of all personnel involved in their care and their respective roles, including residents, students, and equipment representatives.

*Editor's note: The vision of the Journal of Counselling and Family Therapy is to provide opportunities to bring fore new knowledge and concepts from various inter-linked subjects concerned with the study of mental health, disorders and related issues.*

**Consent in current psychiatric practice and research: An Indian perspective**
Furkhan Ali, Gopi Gajera, Guru S Gowda, Preeti Srinivasa, Mahesh Gowda
*Indian Journal of Psychiatry, 8 April 2019; 61(10) pp 667-675*

**Abstract**
Consent is a process that allows for free expression of an informed choice, by a competent individual. The consent is considered as one of the important components of health-care delivery and biomedical research today. Informed consent involves clinical, ethical, and legal dimensions and is believed to uphold an individual's autonomy and the right to choose. It is very important in Indian mental health care as the Mental Healthcare Act (MHCA) 2017 mandates informed consent in admission, treatment, discharge planning, and research intervention/procedures. In 2017, the Indian Council of Medical Research laid down the National...
Ethical Guidelines for BioMedical and Health Research involving Human Participants for research protocols, which the MHCA advocates. This article gives an overview on the evaluation of consent in clinical practice and also highlights the approach and challenge in psychiatric practice in India.

Editor’s note: For reference the National Ethical Guidelines for BioMedical and Health Research involving Human Participants noted in the abstract is available here.

**The public debate on organ donation and presumed consent in Denmark: Are the right issues being addressed?**
Anja M. B. Jensen, Johanne Bjørg Larsen
*Scandinavian Journal of Public Health, 11 April 2019*

**Abstract**
The legal framework for organ donation in Denmark is informed consent. But due to the unsatisfactory number of organ donors, Denmark is considering changing legislation to presumed consent. This article discusses the public debate on organ donation and presumed consent in Denmark, and asks whether the right issues are being addressed in the quest towards more available organs and better donor rates? Basing our considerations on the various arguments in the debate and on scientific findings, we question the potential benefits of presumed consent and challenge some of the assumptions and rationalizations that characterize the discussions in Denmark regarding public support, public trust and the role of the family in donation decisions.

**Dematerialisation of patient’s informed consent in radiology: insights on current status and radiologists’ opinion from an Italian online survey**
Francesca Coppola, Lorenzo Faggioni, Roberto Grassi, Corrado Bibbolino, Agatina Rizzo, Nicoletta Gandolfo, Antonella Calvisi, Carlo Alberto Cametti, Giorgio Benea, Andrea Giovagnoni, Carmelo Privitera, Daniele Regge
*La radiologia medica, 2 April 2019; pp 1–8*

**Abstract**

**Purpose**
To assess the current status of patient’s informed consent (PIC) management at radiological centres and the overall opinion of radiologist active members of the Italian Society of Medical Radiology (SIRM) about PIC dematerialisation through an online survey.

**Methods and materials**
All members were invited to join the survey as an initiative by the Imaging Informatics Chapter of SIRM. The survey consisted of 11 multiple-choice questions about participants’ demographics, current local modalities of PIC acquisition and storage, perceived advantages and disadvantages of PIC dematerialisation over conventional paper-based PIC, and overall opinion about PIC dematerialisation.

**Results**
A total of 1791 radiologists (amounting to 17.4% of active SIRM members for the year 2016) joined the survey. Perceived advantages of PIC dematerialisation were easier and faster PIC recovery (96.5%), safer storage and conservation (94.5%), and reduced costs (90.7%). Conversely, the need to create dedicated areas for PIC acquisition inside each radiological unit (64.0%) and to gain preliminary approval for the use of advanced digital signature tools from patients (51.8%) were seen as potential disadvantages. Overall, 94.5% of respondents had a positive opinion about PIC dematerialisation.

**Conclusion**
Radiologists were mostly favourable to PIC dematerialisation. However, concerns were raised that its practical implementation might face hurdles due to its complexity in current real life working conditions.
Determine the Influence of Social Demography and Access to Information on Giving Consent of Medical Action Toward an Understanding of Informed Consent in Public Hospital With Class C at Pekanbaru [Indonesia]
Tri Purnama sari, Doni Jepisah
Journal of Economic Info, 18 February 2019; 6(1)
Abstract
Informed consent is approval of medical action which is given by the patient or his immediate family after obtaining a complete explanation about medical or dentist action that will be performed on that patient. This study aims to determine the influence of social demography and access to information on giving consent of medical action toward an understanding of informed consent in Public hospital with class C at Pekanbaru. This study employs quantitative method with cross sectional analytic design. The population in this study were all Patient or Families of patient who had received medical treatments in inpatient room for three days before the return of patient as much 267 respondent where the total sample of this research are 194 respondents. The sampling technique is Proportional Random Sampling. Data analysis was carried out in three stages: univariate, bivariate, and multivariate analysis. Based on the result of study found that there was a significant relationship between Education variable (p value 0.007 POR 2,368), work variable (p value 0.042 POR 1,937), age (p value 0.017 POR 2,158), Completeness Information (p value 0.001 POR 2,857), Language Delivery (p value 0.002 POR 2,871) with an understanding of the approval of medical action. Based on the results of multivariate test, it was found that education, completeness of information and language of delivery were the most influential factors. The submission of information must be adjusted to the characteristics of consent provider, especially those related to education, completeness of information and language delivery, so that, if things happen that are not desirable after surgery, the patient or family is expected to receive it because before the surgery is done, the doctor has given an explanation to the patient.

Rights/Legal/Legislative
Legal review of the civil, criminal, and administrative consequences of informed consent violation in medical practice
Vallejo-Jiménez, Geovana A.a; Nanclares-Márquez, Julianab
Colombian Journal of Anesthesiology, April-June 2019; 47(2) pp 107–112
Abstract
Introduction
The informed consent (IC) ensures respect of the patient's rights to information, freedom, and autonomy. However, when the physician neglects the obligation to inform, legal consequences may follow, including the award of damages or even imprisonment.
Objective
To analyze the legal implications for a medical practitioner who fails to obtain the patient's IC.
Methodology
Based on the relevant jurisprudence and legal decisions. With regards to the former, the decisions and legal precedents of the Colombian High Courts with regards to IC and medical practice were studied, emphasizing the rulings of the State Council and the Supreme Court of Justice (civil and penal chambers). With regards to the legal decisions, the analysis enabled the review, systematization and interpretation of the discussions generated around the topic of interest, pursuant to the doctrine or research on civil administrative, and criminal law.
Results
There is consensus in the Colombian jurisprudence about the liability of the healthcare professional and of the state when the IC or any of its component parts is missing in the doctor–patient relationship.
Nevertheless, there are different standpoints, particularly in the criminal arena, where a lack of unanimity exists with regards to this issue.

**Conclusion**

Any violation of the IC or the lack of an IC, could give rise to the practitioner's civil liability and disciplinary actions, in addition to the administrative liability of the State, but there should be no criminal liability for the physician.

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**The Italian law on informed consent and advance directives: its impact on intensive care units and the European legal framework**

Giuseppe R. Gristina, Lucia Busatta, Mariassunta Piccinni

*Minerva Anestesiologica, 2019 April; 85(4) pp 401-11*

**Abstract**

The Italian Parliament has recently approved a law on informed consent, advance directives and advance care planning. The law also deals with health care proxy and health care decisions for minors and adults who are not able to give consent. The Italian law arrived quite late in comparison with other European countries. After several years of debate on the need to approve such a law, the focus has now shifted to the assessment of the legislative provisions and their impact on clinical practice. In this article, the authors firstly offer an overview of the findings from the empirical research regarding the use of the different legal tools in the field of intensive care medicine; secondly, they present the tools now provided by law no. 219/2017 particularly with regard to the decision-making processes in the Intensive Care Unit (ICU); thirdly, the authors offer a comparison between the new Italian law and other European legal orders, with special reference to France, Spain, Germany and England. The aim of the article is to assess the degree of innovation of the law vis-à-vis the previous framework.

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**Informed Consent and Advance Care Directives: Cornerstones and Outstanding Issues in the Newly Enacted Italian Legislation**

Gianluca Montanari Vergallo, Antonio G. Spagnolo

*The Linacre Quarterly, 29 March 2019*

**Abstract**

This article’s authors delve into, and comment on, some of the key provisions within law no. 219, passed in 2017, which came into full effect in 2018. The legislation presents several innovative aspects: (a) communication time is equated to care; (b) patients may turn down lifesaving treatments, yet doctors must put in place all suitable support processes, from a psychological standpoint as well, in order to make sure that patients make informed decisions in full awareness; (c) refusal to treatment may be expressed prior to the onset of the disease making the patient incapable, as long as the advance directive is laid out by a mentally capable adult who has been provided with all relevant medical information available as to the consequence of a refusal to undergo a given treatment; (d) artificial nutrition and hydration are tantamount to treatment; thus, they may not be carried out and kept in place in absence of valid consent; (e) patients may appoint a healthcare proxy holder, tasked with interacting with doctors and caregivers and expressing consent or refusal; (f) patient will, whether current or advance, must be complied with even under emergency or urgency conditions, provided that clinical conditions and circumstances make it possible to acquire it; (g) doctors may disregard advance directives only when specifically provided for by the law; (h) patients may not demand treatment deemed to be illegal or running counter to ethical codes or scientific evidence. The new legislation, therefore, is meant to uphold the right to exercise self-determination as well as the patient’s quality of life, yet ensuring that doctors remain fully capable of making the decisions that they are best positioned to.
GENERAL/OTHER

**Ethics of crisis sedation: questions of performance and consent**  
Nathan Emmerich, Bert Gordijn  
*Journal of Medical Ethics, 20 April 2019*  
*Abstract*  
This paper focuses on the practice of injecting patients who are dying with a relatively high dose of sedatives in response to a catastrophic event that will shortly precipitate death, something that we term ‘crisis sedation.’ We first present a confabulated case that illustrates the kind of events we have in mind, before offering a more detailed account of the practice. We then comment on some of the ethical issues that crisis sedation might raise. We identify the primary value of crisis sedation as allowing healthcare professionals to provide some degree of reassurance to patients, their families and the professionals who are caring for them. Next we focus on the issue of informed consent. Finally, we ask whether continuous deep sedation might be preferable to crisis sedation in scenarios where potential catastrophic events can be anticipated.

**Ethics and Breast Cancer**  
Amtul R. Carmichael, Kerstin Sandelin  
*Surgical Ethics, 27 March 2019; pp 257-264*  
*Abstract*  
Enabling, empowering and educating a woman to make the right choice between breast-conserving surgery and mastectomy are aligned with the fundamental principle of bioethics, that is, respect for patient autonomy. A clear understanding of the contemporary ethical and social issues related to genetic testing for breast cancer is necessary to develop a practical approach for counselling, testing and treating patients with genetic disposition to breast cancer. Ethnic inequities, disparities, opportunity and timeliness to treatment and its prognostic significance on breast cancer mortality have been studied in several populations worldwide. While the underutilisation of screening mammography can be attributed to socioeconomic and cultural and geographic barriers, ethical principles must be taken into account. The debate regarding no intervention for low-grade ductal carcinoma in situ and the issue of overdiagnosis are further ethical issues that raise concerns in the informed decision process and the ethical concepts of no harm and autonomy.

MEDICAL/SURGICAL

**Informed Consent For Anaesthesia: Are Our Patients Well Informed?**  
H Y Embu, M G Yilkudi, S I Nuhu  
*Journal of Biomendical Research & Clinical Practice, 4 April 2019; 2(1)*  
*Abstract*  
Patients have the right to be properly informed about procedures to be undertaken on them so that they could make informed decisions. This study was done at the Jos University Teaching Hospital and the University of Abuja Teaching Hospital. Questionnaires on informed consent were administered postoperatively on patients who had undergone elective surgeries under various forms of anaesthesia. The questionnaires sought to find out how much information patients were given about their anaesthesia and how satisfied they were with the information given. 148 patients were interviewed. The mean age was 34.8±13.8 years and the male: female ratio was 1:1.8. Ninety-eight (66.22%) of the procedures were done under general anaesthesia and 50(33.78%) under regional anaesthesia. 104 (70.27%) were told about the
type of anaesthesia to be used. Thirty-eight (25.68%) were not told of the possible side effects. Eighty-six (58.1%) understood the information given. 131(88.51%) believed it was necessary to be given information about the anaesthesia. Postoperative pain management was discussed with 10 (6.76%) of respondents. 104 (70.27%) expressed satisfaction with the information given. Information about anaesthesia was given by residents in anaesthesia in 62.16% of cases, by consultant anaesthetists in 8.78% cases, by surgeons in 10.81% of cases and by house officers and nurses in 14.19% of cases. Majority of patients would like information about their anaesthesia procedures but were inadequately informed. Consent for anaesthesia is often obtained by junior residents who have had little training in this aspect. Training on informed consent should be part of the residency program.

Barriers and pathways to informed consent for ionising radiation imaging examinations: A qualitative study
C.W.E.Younger, S.Moran, C.Douglas, H.Warren-Forward
Radiography, 2 April 2019
Abstract
Introduction
Informed consent for ionising radiation medical imaging examinations represents a recent change to medical imaging practice. This practice has not had a definitive and authoritative integration into clinical practice, and lack of direction has caused many health care professionals to be unsure of an appropriate consent methodology. Consent practices have been undertaken inconsistently and sometimes poorly. This research sought to investigate what barriers exist to meaningful informed consent, and what pathways are suggested to overcome these barriers. These views are then discussed in the context of practical health care consent practices.
Methods
A semi-structured interview explored the views of radiographers and radiologists on the practice of disclosing the ionising radiation risk of a clinical medical imaging examination. Qualitative data was analysed using a nominal method of quantitative transformation. Responses were reviewed, and a set of definitive themes constructed. Participants considered the influences, logistics and barriers to the informed consent process. Participants were then asked what pathways might be developed that would improve the process.
Results
Twenty-one (21) radiographer participants and nine (9) radiologists were interviewed. The barriers to consent identified issues of time constraints, lack of a unified message, and patient presentations. Pathways suggested included limiting the scope of the consent practice, sharing the consent responsibility, and formulation of definitive consent guidelines.
Conclusion
A unified, definitive series of guidelines for informed consent for ionising radiation examinations would alleviate many of the identified barriers. Having the consent process consistently begin with the referring doctor would facilitate more meaningful consent.

Role of Informed Consent in Andrological Surgery in Adolescents and Adults
Mauro Silvani
Psychosexual Counseling in Andrological Surgery, 2 April 2019; pp 81-84
Abstract
Informed consent for andrological surgery, particularly during adolescence, is a delicate and strategic moment in the success of the patient’s therapeutic path. Informed consent must have certain characteristics:

- Clarity and simplicity of exposition to allow easy understanding by anyone who reads it, in addition to the patient, for example, his relatives, lawyers, doctors, and magistrates. The information must also be provided with particular delicacy to adolescent children who sometimes are confronting the hospital environment and surgery for the first time.
• Accompanied by a rich description that allows a better understanding.
• Must contain a part in which the signer declares that he has clearly understood the pathology that is affecting him and a distinct one from the previous part concerning the type of intervention that the patient will undergo, including a description of the relative complications. In this section of the consent form, other surgical procedures contemplated for the pathology in question should also be described.
• The collection of the consent form and a signature should always be by the surgeon before the operator, because, more than in any other surgery, this is a surgery in which the doctor-patient relationship of trust is particularly heard and developed.
• Attendance at the interview with a family member, of the partner if older, or parents if a minor. The signature on the informed consent form results from a clinical diagnostic path divided into multiple periods during which there is a two-way communication between the patient and family practitioner surgeon, especially in the case of a minor patient, to develop a therapeutic alliance that is essential to a successful outcome.

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

Does using anatomical models improve patient satisfaction in orthopaedic consenting? Single-blinded randomised controlled trial
K.Sugand, H.H.Malik, S.Newmana, D.Spicer, P.Reilly, C.M.Gupte
The Surgeon, 1 April 2019

Background
Patient satisfaction in consenting is a major pillar of clinical governance and healthcare quality assessment. The purpose was to observe the effect of using 3D anatomical models of knee and shoulder joints on patient satisfaction during informed consent in the largest single-blinded randomised controlled trial in this field.

Methods
52 patients undergoing elective knee or shoulder surgery were randomised into two groups when being consented. The intervention group (n = 26) was shown an anatomical model of the knee/shoulder joint while the control group (n = 26) was given only a verbal explanation without a model. Patients rated their satisfaction on the validated Medical Interview Satisfaction Scale (MISS-26) questionnaire. Semi-structured interviews were analysed for specific themes to determine key factors that influenced patient satisfaction. The mean score ±SD were calculated with significance set at p < 0.05.

Results
There was a significant difference in the overall satisfaction between the control and intervention cohorts (MISS-26 score 4.33 [86.6%] ± 0.646 vs 4.70 [94.0%] ± 0.335 respectively, 7.4% improvement, 8.5% difference, p = 0.01). Behavioural criteria showed a 13% increase in satisfaction (p = 0.02). Semi-structured interviews determined that the factors influencing satisfaction included the surgeon’s interpersonal manner, the use of the visual aid and seeing the consultant surgeon in clinic. All patients in the intervention cohort identified factors contributing to their satisfaction, whereas a fifth of the control cohort claimed nothing at all made them feel satisfied.

Conclusion
Anatomical models as visual aids significantly increased patient satisfaction during the consenting process and played an integral part of the surgeon’s explanation. Patients exposed to anatomical models also claimed to be more satisfied with the surgeon’s inter-personal skills. This study recommends the use of anatomical models, which are both cost-effective and easily implementable, during explanation and consent for orthopaedic procedures.

Incorporating fetal archival tissues into undergraduate medical education
Kaylin Jeanne Beiter, Sophie Elise Fourniquet, Jason C Mussell
Federation of American Societies for Experimental Biology, 1 April 2019; 33(1)
Abstract

Purpose

A great deal of time is spent in undergraduate medical education preparing students for death and also the importance of informed consent. Missing from these preparations are the differences students may feel when encountering the death of an elderly individual versus the death of an infant and how the different informed consent processes came to be. Purposeful incorporation of fetal specimens in at various time points throughout the first year may be able to help solve these problems simultaneously.

Methods

The Louisiana State University Health Sciences Center at New Orleans (LSUHSC-NO) has in its possession a large repository of fetal specimens, many of which were collected prior to the era of IRB protocols, preventing informed consent from being secured for their use. These fetal specimens are used in anatomy education at LSUHSC-NO annually. We identified appropriate time points throughout the first year of training to insert discussions of informed consent and to examine emotions coincident with dealing with fetal and neonatal death and how they might contrast to student emotions about their cadavers, i.e. adult death, as well as how these feelings evolve over the year. Thematic analyses of self-reflections were used to assess differences in student emotions when confronting death. They will also be used to examine changes in student attitudes regarding death during the entire first year.

Results

Using archival material as the centerpiece for principled discourse challenges students to contextualize the practice of medical ethics socially and historically, heightening awareness of their own cultural and social biases. This experience also provided an outlet for students to share their thoughts on the ethical principles that will guide their future practice and to share their emotional reactions to the fetal specimens. Preliminary results showed themes of anxiety and reverence predominating before students entered the adult cadaver lab while sadness, informed consent, and impropriety predominated student reflections before exposure to fetal specimens.

Conclusions

Providing medical students with an example thought process allows students to begin developing their own methods of incorporating respectful pragmatism into their own careers. Incorporation of fetal collections and discussions of their origins enables undergraduate medical students to think critically and examine their own ethical mores in addition to mastering high volumes of content knowledge.

Informed consent in spinal surgery

N. V. Todd, N. C. Birch

The Bone & Joint Journal, 31 March 2019; 101B(4) pp 355-360

Abstract

Informed consent is a very important part of surgical treatment. In this paper, we report a number of legal judgements in spinal surgery where there was no criticism of the surgical procedure itself. The fault that was identified was a failure to inform the patient of alternatives to, and material risks of, surgery, or overemphasizing the benefits of surgery. In one case, there was a promise that a specific surgeon was to perform the operation, which did not ensue. All of the faults in these cases were faults purely of the consenting process. In many cases, the surgeon claimed to have explained certain risks to the patient but was unable to provide proof of doing so. We propose a checklist that, if followed, would ensure that the surgeon would take their patients through the relevant matters but also, crucially, would act as strong evidence in any future court proceedings that the appropriate discussions had taken place. Although this article focuses on spinal surgery, the principles and messages are applicable to the whole of orthopaedic surgery.
**Informed Consent and Disclosure of Surgeon Experience**
Sabha Ganai
*Surgical Ethics, 27 March 2019; pp 217-229*

**Abstract**
This chapter reviews ethical issues and legal precedent relevant to informed consent for surgical procedures using a shared decision-making framework. The process of informed consent is examined in a systematic fashion, including reviewing ways to improve doctor-patient communication and important considerations for documentation of the consent process. Disclosure of surgical experience will also be explored, including the complexities of dealing with statistics from surgeon-specific reports. Ethical principles including respect for patient autonomy, beneficence, and distributive justice and duty to tell the truth will be explored as relevant to the doctrine of informed consent.

**The Surgical Informed Consent Process: Myth or Reality?**
Miguel A. Caínzos, Salustiano Gonzalez-Vinagre
*Surgical Ethics, 27 March 2019; pp 203-216*

**Abstract**
Informed consent is currently considered to be a highly important factor which is becoming a critical component of surgical practice. It is a complex process and not just an event or a single encounter. In the twenty-first century, it is accepted that the traditional paternalist relationship between the patient and physician has been replaced by a new type of relationship in which the patient detents a very active and crucial role. For patients who need a surgical procedure, the informed consent process represents the honing of this link between the surgeon and his or her patient. The legal principle emphasizes the fact that the patient is an independent adult who has the capacity to authorize what is going to be done to his or her body. This is a process with significant ethical and legal aspects where both the surgeon and the patient play a major role.

The components which make up the informed consent process are the preconditions, the information provided to the patient, and the consent itself. The most complex step of the informed consent process for the surgeon is providing correct, truthful, unbiased, and accurate information to the patient while keeping hope in him or her. The physician disclosure has three stages: the disclosure of information, the patient understanding, and the patient decision-making. It is necessary to adapt the information to each patient in a language they can always understand. The physician must provide information about the surgical procedure, the benefits, the associated risks, potential complications, and alternative procedures, if any. Surgeons must use all the available tools to adequately inform the patient and the relatives and improve his or her understanding: information leaflets, multimedia interventions, decision aids, the Internet, and government and professional organization guidelines. New tools as surgical risk calculators which estimate patient-specific postoperative complications for different procedures are now available.

The ultimate goal of the informed consent process should be fostering the patient’s trust in his or her surgeon.

*Editor’s note: The ultimate goal of informed consent as stated here is the author’s view and does not represent the views of this digest.*

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**GENOMIC MEDICINES/GENE THERAPY**

**Post-Hong Kong: Human Genome Editing’s Brave New World [VIDEO; 1:33:17]**
Wednesday, March 27, 2019 2:00 pm - 3:30 pm; CSIS Headquarters, 2nd Floor

*Summary*
A firestorm followed Professor He Jiankui's disturbing announcement last fall in Hong Kong that he had made heritable genetic changes in human embryos that resulted in the birth of twin girls. Critics pointed to the lack of oversight and transparency, the inadequacy of the informed consent process, the lack of a compelling medical rationale, potential unknown future harms to the edited babies, and the lack of a clear consensus about the actual use of new, powerful gene editing technologies. This historic incident has stirred an intense debate over both the promise of these technologies to cure devastating diseases, such as Huntington’s Disease, and alarm over the idea that these same technologies might be used to create “designer babies.” The U.S. National Academy of Sciences and National Academy of Medicine, together with other international academies, have led vital international discussions over next steps.

On Wednesday, March 27, 2:00-3:30 pm, the National Academy of Medicine and the CSIS Commission on Strengthening America’s Health Security [hosted] a conversation on the unfolding debate as to whether human germline genome editing should be permitted, the types of applications which might be appropriate, the standards and criteria that should be followed, and what regulatory or governance framework is needed.

Editor’s Note: In the context of the hour long broadcast by CSIS an audience question related to informed consent and relating to this digest was posed. It was answered by Jeffrey Kahn; Andreas C. Dracopoulos Director, Johns Hopkins Berman Institute of Bioethics, an excerpt of which has been transcribed below. Readers can find this exchange at around 1:20:45 in the broadcast.

Excerpt

Q – audience member:
Can you talk about some of the therapies that [Editas Medicine] is developing and walk through the informed consent process that would happen in, say for example, childhood blindness? How does that work?

A – Jeffrey Kahn; Andreas C. Dracopoulos Director, Johns Hopkins Berman Institute of Bioethics:
I served on the recombinant DNA advisory committee, the so called RAC as Victor mentioned, when the drug that became the Spark Therapeutics drug for treatment of genetic inherited forms of blindness was being considered in its early phase. So that’s the body that reviews gene transfer, so called gene therapy, research in humans. You must get approval from that body advisory to the NIH before you can go forward.

What was really interesting about that particular story which was and is for children, was that the parents of those children, first of all there are no other treatments, there are no alternatives, it was very promising in animal studies and so this is the first time in humans it is being offered. They showed a video I remember very clearly of a child walking through a maze, which was how they set up and assess levels of vision before and after one eye being treated. It was remarkable to watch this child stumble into the obstacles in the before film and then navigate it very easily after.

The question wasn’t so much about whether it should go forward as a clinical trial but whether parents should be permitted to give consent to having both eyes of their children injected at the same time. So the question was, do we know enough about this very novel first in human use of a therapy to say we’re willing to let you risk your child’s vision, because we don’t know the long term effects of this and whether the child’s restored vision would last or plummet and go away after a few weeks.

And the parents said let us make the decision about preserving whatever vision our child may have. The sooner you treat these kids the more vision you preserve it turns out.

What I learned from that was that is not consent in the sense that we really wish for. There aren’t good alternatives and these parents are willing to do anything for their children to preserve or restore their vision, understandably.

Consent doesn’t work in the way that I think we hope it will in some of these first in human devastating diseases, no other therapy, contexts. People will do anything effectively, so it’s an insufficient tool for doing the ethics work that I think your question implies. I don’t have a good alternative but in lived experience it’s really challenging.
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