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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

April 2021

This digest aggregates and distills key content addressing informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations.

Each month we monitor *Google Scholar* for the search terms "consent" and "informed consent" in title and available text. After careful consideration, a selection of these results appear in the digest. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

Informed Consent: A Monthly Review is a service of the Center for Informed Consent Integrity, a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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Editor's Note:

Informed consent for neonatal trials – Practical points to consider was the latest webinar in the Center's continuing series held on March 17th 2021. The invited speakers were Dr. Beate Aurich of the Institut National de la Santé et de la Recherche Médicale (INSERM) in Paris, France, and Dr. Eric Vermeulen of the Dutch Patient Association for Rare and Genetic Diseases (VSOP) in Soest, The Netherlands. The presentation was followed by a rich discussion with call participants regarding areas such as parental consent, assent and reconsent, and the role of patient and parent involvement in trials and the design of the informed consent process.

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

No new content identified for the following established categories:
BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION
YOUNG PERSONS

Please note that we maintain a glossary, tools for assessment, and guidance documents on our website.

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COVID-19

Informed consent and a risk-based approach to oncologic surgery in a cancer center during the COVID-19 pandemic

de Cássio Zequi S, Franca Silva ILA, Duprat JP, Coimbra FJF, Gross JL, Vartanian JG, Makdissi FBA, Leite FPM, Costa WHD, Yazbek G, Joaquim EHG, Bussolotti RM, Caruso P, de Ávila Lima MC, Nakagawa S, Aguiar S Jr, Baiocchi G, Lopes A, Kowalski LP

Journal of Surgical Oncology, 7 March 2021

Open Access

Abstract

Background

Cancer patients configure a risk group for complications or death by COVID-19. For many of them, postponing or replacing their surgical treatments is not recommended. During this pandemic, surgeons must discuss the risks and benefits of treatment, and patients should sign a specific comprehensive Informed consent (IC).

Objectives

To report an IC and an algorithm developed for oncologic surgery during the COVID-19 outbreak.

Methods

We developed an IC and a process flowchart containing a preoperative symptoms questionnaire and a PCR SARS-CoV-2 test and described all perioperative steps of this program.

Results

Patients with negative questionnaires and tests go to surgery, those with positive ones must wait 21 days and undergo a second test before surgery is scheduled. The IC focused both on risks and benefits inherent each surgery and on the risks of perioperative SARS-CoV-2 infections or related complications. Also, the IC discusses the possibility of sudden replacement of medical staff member(s) due to the pandemic; the possibility of unexpected complications demanding emergency procedures that cannot be specifically discussed in advance is addressed.

Conclusions

During the pandemic, specific tools must be developed to ensure safe experiences for surgical patients and prevent them from having misunderstandings concerning their care.

Waivers and Alterations of Research Informed Consent During the COVID-19 Pandemic

Ideas and Opinions

Emily A. Largent, Scott D. Halpern, Holly Fernandez Lynch

Annals of Internal Medicine, March 2021
Open Access
Excerpt
A foundational requirement of ethical research is that persons provide informed consent. Yet, there are exceptions that promote valuable research without unduly compromising participants' interests. Applicable regulations for federally funded research permit waiver or alteration of consent requirements when certain conditions are met, including that the research poses no more than minimal risk to participants and that it would be impracticable to do without waiver or alteration (1). Determining whether these regulatory standards are met has become increasingly challenging during the coronavirus disease 2019 (COVID-19) pandemic…

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BIOMEDICAL RESEARCH

Refusal rates and waivers of informed consent in pragmatic and comparative effectiveness RCTs: A systematic review

Lisa Y. Lin, Nicole Jochym, Jon F. Merz
Contemporary Clinical Trials, May 2021; 104
Abstract
Background
Pragmatic and comparative effectiveness randomized controlled trials (RCTs) aim to be highly generalizable studies, with broad applicability and flexibility in methods. These trials also address recruitment issues by minimizing exclusions. The trials may also appeal to potential subjects because of lower risk and lower burdens of participation. We sought to examine rates of refusal and uses of waivers of informed consent in pragmatic and comparative effectiveness RCTs.
Methods
A systematic review of pragmatic and comparative effectiveness RCTs performed wholely or in part in the United States and first published in 2014 and 2017.
Results
103 studies involving 105 discrete populations were included for review. Refusal data was collected for 71 RCTs. Overall, studies reported an average rate of 31.9% of potential subjects refused participation; on an individual basis, 38.4% of people asked to take part refused at some point during recruitment. 23 trials (22%) were performed, at least in part, with a waiver of informed consent, 7 (30%) of which provided any form of notice to subjects.
Conclusions
Overall refusal rates for pragmatic and comparative effectiveness RCTs appear roughly the same as other types of research, with studies reporting about a third of people solicited for participation refuse. Moreover, informed consent was waived in 22% (95% Binomial exact Confidence Interval 13.9–30.5%) of the trials, and further study is needed to understand when waivers are justified and when notice should be provided.

Patients Acceptance and Comprehension to Written and Verbal Consent (PAC-VC)

Research Article
Rabia Kashur, Justin Ezekowitz, Shane Kimber, Robert Welsh
BMC Medical Ethics, 2 March 2021
Open Access
Abstract
Background

Acute myocardial infarction (AMI) research is challenging as it requires enrollment of acutely ill patients. Patients are generally in a suboptimal state for providing informed consent. Patients' understanding to verbal assents have not been previously examined in AMI research. Patients Acceptance and Comprehension to Written and Verbal Consent (PAC-VC) compared patients' understanding and attitudes to verbal and written consents in AMI RCTs.

Methods

PAC-VC recruited patients from 3 AMI trials using both verbal N=12 and written N=6 consents. We compared patients' understanding using two survey questionnaires. The first questionnaire used open ended questions with multiple choice answers. The second questionnaire used a 5-point Likert scale to measure patients understanding and attitudes to the consent process. Overall answers average scores were categorized into three groups: Adequate understanding (71-100) %, Partial understanding (41-70)% and Inadequate understanding (0-40)%.

Results

Responses showed patients with verbal assent had adequate understanding to most components of informed consent, close to those of written consent. Most patients did not read written information entirely and believed that it is not important to make a final decision. Patients favoured to have written information be part of the consent but not necessarily presented during the initial consent process. Patients felt less pressured in the verbal assent arm than those of written consent.

Conclusion

Patients had adequate understanding to most components of verbal assent and comparable to those of written consent. Utilizing verbal assents in the acute care setting should be further assessed in larger trials.

Distinctive aspects of consent in pilot and feasibility studies

Original Paper

Julius Sim

Journal of Evaluation in Clinical Practice, 24 February 2021

Open Access

Abstract

Prior to a main randomized clinical trial, investigators often carry out a pilot or feasibility study in order to test certain trial processes or estimate key statistical parameters, so as to optimize the design of the main trial and/or determine whether it can feasibly be run. Pilot studies reflect the design of the intended main trial, whereas feasibility studies may not do so, and may not involve allocation to different treatments. Testing relative clinical effectiveness is not considered an appropriate aim of pilot or feasibility studies. However, consent is no less important than in a main trial as a means of morally legitimizing the investigator's actions. Two misperceptions are central to consent in clinical studies—therapeutic misconception (a tendency to conflate research and therapy) and therapeutic misestimation (a tendency to overestimate possible benefits and/or underestimate possible harms associated with participation). These phenomena may take a distinctive form in pilot and feasibility studies, owing to potential participants' likely prior unfamiliarity with the nature and purposes of such studies. Thus, participants may confuse the aims of a pilot or feasibility study (developing or optimizing trial design and processes) with those of a main trial (testing treatment effectiveness) and base consent on this misconstrual. Similarly, a misunderstanding of the ability of pilot and feasibility studies to provide information that will inform clinical care, or the underdeveloped nature of interventions included in such studies, may lead to inaccurate assessments of the objective possibility of benefit, and weaken the epistemic basis of consent accordingly. Equipoise may also be particularly challenging to grasp in the context of a pilot study. The consent process in pilot and feasibility studies requires a particular focus, and careful communication, if it is to carry the appropriate moral weight. There are corresponding implications for the process of ethical approval.

Model Operational Procedures for the Implementation and Review of NIH Sponsored Multicenter Clinical Trials with Exception from Informed Consent (EFIC) for Emergency Research

SIREN Clinical Coordinating Center

Version 1, January 2021

Open Access

Introduction

The purpose of this document is to provide a model process and procedures that can be used as starting point for implementation of clinical trials using Exception from Informed Consent for Emergency Research (EFIC) in NIH funded multicenter clinical trials. The process and procedures described can and must be adapted to the specific needs and details of any future trials. The materials provided were developed and informed by both thorough review of the accumulated scholarship related to EFIC, and other lessons learned through practical shared experiences of prior NIH funded emergency care researchers.

This document is intended to be a useful, practical, and tested peer-to-peer tool for future investigators in this field. It is not intended to be a definitive guideline for application of the EFIC regulations, and should NOT be interpreted as any form of regulatory guidance. Regulatory guidance is available from FDA. This document does not represent the only way to implement Exception from Informed Consent, and may not be applicable or optimal for EFIC studies that differ from those for which this document was created. This document is intended to be open access, and shared through a Creative Commons Attribution-NonCommercial (CC BY-NC) license that lets others adapt, and build upon the work non-commercially. New works must acknowledge the source materials and the NIH and be non-commercial. The derivative works do not have be licensed on the same terms.

Nano-drug Clinical Trials: Informed Consent and Risk Management Through Blockchain

Yousef Haik, Ilias Bantekas

Pittsburgh Journal of Technology Law & Policy, 2021

Open Access

Abstract

Drug bearing nano-shells that can be utilized for targeted drug delivery have been shown to enhance the therapeutic index by increasing the drug concentration in diseased tissue and reducing the toxicity in normal tissue. The controllability of the drug bearing shell size provides predictability measure for the amount of drug payload per shell which improves the administration of the therapeutic dose. The FDA approved different formulations for clinical use in metastatic and recurrent breast cancer, among other diseases. At the moment, some of these formulations are the subject of international clinical trials. Informed consent is legally mandated in administering drug bearing nano-shells. The risks of the new formulations, as with all new technologies, are not well known and continue to be a subject of intensive research, thus exacerbating the existing informed consent legal issues, thus exacerbating the existing informed consent legal issues. This short essay focuses on proposing a framework to mitigate liabilities administering a new formulation on nano-enabled drug carriers particularly when uncertainties of the benefits and damages are not fully known.

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SOCIAL SCIENCE RESEARCH

"Why didn't we do it"? Reproductive loss and the problem of post-mortem consent

Kate Reed, Maria Teresa Ferazzoli, Elspeth Whitby

Social Science & Medicine, 12 March 2021

Abstract

Informed consent has been a much debated topic within the social sciences. It often forms a central feature of discussions on research in medical settings and in social research methods more broadly. While sympathetic to its' underlying principles of autonomy and choice, social scientists have tended to argue that these are seldom enacted in research or clinical practice. Rather, such principles are often circumscribed by wider social structures and by a culture of medical dominance. Drawing on data from a qualitative study on perinatal post-mortem, this paper explores informed consent in the emotionally charged clinical arena of perinatal pathology. Our in-depth analysis will provide fresh insight into post-mortem decision-making in the sensitive arena of baby loss. Our findings show how parents often found it difficult to give consent for post-mortem, and also for professionals to take consent from parents. It was also not uncommon for parents to experience regret over non-consent later on. One of our key findings, however, related to the sense of emotional and diagnostic closure often afforded by post-mortem when consent had been given. We conclude by arguing that, although we cannot resolve the tension between the principles of consent and their enactment in practice, we can develop a reflexive approach with which to navigate the process. In doing so, the paper contributes to wider sociological discussions on the meaning and use of informed consent in various settings beyond medical contexts.

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GENOMIC MEDICINE/GENE EDITING

Mainstreaming informed consent for genomic sequencing: A call for action

Current Perspective

Eline M. Bunnik, Wybo J. Dondorp, Annelien L. Bredenoord, Guido de Wert, Martina C. Corneld

European Journal of Cancer, May 2021; 148 pp 405-410

Abstract

The wider availability of genomic sequencing, notably gene panels, in cancer care allows for personalised medicine or the tailoring of clinical management to the genetic characteristics of tumours. While the primary aim of mainstream genomic sequencing of cancer patients is therapy-focussed, genomic testing may yield three types of results beyond the answer to the clinical question: suspected germline mutations, variants of uncertain significance (VUS), and unsolicited findings pertaining to other conditions. Ideally, patients should be prepared beforehand for the clinical and psychosocial consequences of such findings, for themselves and for their family members, and be given the opportunity to autonomously decide whether or not to receive such unsolicited genomic information. When genomic tests are mainstreamed into cancer care, so should accompanying informed consent practices. This paper outlines what mainstream oncologists may learn from the ethical tradition of informed consent for genomic sequencing, as developed within clinical genetics. It argues that mainstream informed consent practices should focus on preparing patients for three types of unsolicited outcomes, briefly and effectively. Also, it argues that when the chance of unsolicited findings is very low, opt-out options need not be actively offered. The use of a layered approach – integrated in information systems – should render informed consent feasible for non-geneticist clinicians in mainstream settings. (Inter) national guidelines for mainstreaming informed consent for genomic sequencing must be developed.

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HEALTH DATA

The use of personal health information outside the circle of care: consent preferences of patients from an academic health care institution

Research Article

Sarah Tosoni, Indu Voruganti, Katherine Lajkosz, Flavio Habal, Patricia Murphy, Rebecca K. S. Wong, Donald Willison, Carl Virtanen, Ann Heesters, Fei-Fei Liu

BMC Medical Ethics, 24 March 2011; 22(29)

Open Access

Abstract

Background

Immense volumes of personal health information (PHI) are required to realize the anticipated benefits of artificial intelligence in clinical medicine. To maintain public trust in medical research, consent policies must evolve to reflect contemporary patient preferences.

Methods

Patients were invited to complete a 27-item survey focusing on: (a) broad versus specific consent; (b) opt-in versus opt-out approaches; (c) comfort level sharing with different recipients; (d) attitudes towards commercialization; and (e) options to track PHI use and study results.

Results

222 participants were included in the analysis; 83% were comfortable sharing PHI with researchers at their own hospital, although younger patients (≤ 49 years) were more uncomfortable than older patients (50 + years; 13% versus 2% uncomfortable, $p < 0.05$). While 56% of patients preferred broad consent, 38% preferred specific consent; 6% preferred not sharing at all. The majority of patients (63%) preferred to be asked for permission before entry into a contact pool. Again, this trend was more pronounced for younger patients (≤ 49 years: 76%). Approximately half of patients were uncomfortable sharing PHI with commercial enterprises (51% uncomfortable, 27% comfortable, 22% neutral). Most patients preferred to track PHI usage (61%), with the highest proportion once again reported by the youngest patients (≤ 49 years: 71%). A majority of patients also wished to be notified regarding study results (70%).

Conclusions

While most patients were willing to share their PHI with researchers within their own institution, many preferred a transparent and reciprocal consent process. These data also suggest a generational shift, wherein younger patients preferred more specific consent options. Modernizing consent policies to reflect increased autonomy is crucial in fostering sustained public engagement with medical research.

A survey on the current status and future perspective of informed consent management in the MIRACUM consortium of the German Medical Informatics Initiative

Research

Christopher Hampf, Martin Bialke, Lars Geidel, Albert Vass, Thomas Bahls, Romina Blasini, Arne Blumentritt, Martin Boeker, Christian Bruns, Burkhard Jandrig, Maximilian Fünfgeld, Philipp Heinrich, Torsten Leddig, Achim Michel-Backofen, Anna Pirkl, Michael Rautenberg, Fabian Simons, Dana Stahl, Hans-Ulrich Prokosch, Wolfgang Hoffmann

Translational Medicine Communications, 8 March 2021; 6(7)

Open Access

Abstract

Background

The consent management is an essential component for supporting the implementation of consents and withdrawals and thus, the realisation of patient's rights. In MIRACUM, one of the four consortia of the Medical Informatics Initiative (MII), ten university hospitals intend to integrate the generic Informed Consent Service® (gICS) in their Data Integration Center (DIC). To provide a tool that supports the local workflows of the MIRACUM sites, the gICS should be improved.

Methods

We used three standardised questionnaires with 46 questions to elicit requirements from the ten sites. Each site answered the questions from the current and the desired future perspective. This made it possible to understand the individual processes at each site and it was possible to identify features and improvements that were generally necessary.

Results

The results of the survey were classified according to their impact on the gICS. Feature requests of new functionalities, improvements of already implemented functionalities and conceptual support for implementing processes were identified. This is the basis for an improved gICS release to support the ten sites' individual consent management processes.

Conclusions

A release plan for the feature requests and improvements was coordinated with all sites. All sites have confirmed that the implementation of these features and enhancements will support their software-based consent management processes.

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TECHNOLOGY/OTHER MEDIATION

Assessing Patient Satisfaction and Confidence After Use of Educational Video to Augment Surgical Consent for Thyroid Surgery

Michelle Schafer, Katie Holland, Alexander Duffy, Kelley Yuan, Marisa Wu, Raphael Banoub, Elizabeth Cottrill

Translational Medical Research Commons, February 2021

Abstract

Introduction

Informed consent is a crucial aspect of ethical patient care, yet the increase in surgical complexity presents a challenge in achieve this properly. This study explores the use of an educational video to help standardize the consent process, increase patient retention of information, and promote patient understanding by allowing patients to replay the information remotely as often as needed.

Methods

This is a prospective, survey-based study of adult patients undergoing thyroid surgery. A novel video detailing thyroid surgery containing the standard contents of informed consent was shown to patients after traditional informed consent followed by a survey on their level of comfort of the information before and after the video. Data on patient age, education level, previous surgical experience was collected.

Results

Preliminary data shows that there is an increase in confidence, benefits, and knowledge of risk of the patients' operation. We expect to find that with the addition of an educational video to the thyroid surgery consent process, patients will report a higher level of satisfaction as well as confidence in regards to their surgery.

Discussion

The process of informed consent has not evolved with the complexity of procedures. The use of multimedia has been demonstrated as a valuable teaching tool in addition to traditional informed. Our study reinforces that there is a place for multimedia, specifically educational videos in informed consent for thyroid surgery as it may help patients better understand their procedure. Future aims of this study include evaluating patient comprehension with the addition of an educational video to informed consent, as well as the creation of more educational videos for head and neck surgery consent.

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CAPACITY TO CONSENT

Competence and informed consent

Adam Doležal, Tomáš Doležal

Vnitřní lékařství, Winter 2021; 67(1) pp 49-55

Abstract

The issue of a patient´s competence is often solved in practice without a major theoretical concept. Such an approach, focused only on the basis of intuitions and experiences of physicians, however, may lead in some cases to an inadequate assessment of competence of a particular patient. Ultimately, it can happen that the decision of an incompetent person will be respected or that the decision of the competent person will be disrespected. Both possibilities can have ethical as well as legal consequences. This article addresses both theoretical and practical issues of competence in adult patients.

Editor's note: Internal Medicine is the official journal of the Czech Internal Medicine Society.

Psychological, ethical and legal aspects of neurosurgical procedures in conscious patients with judgment consent

Zygmunt Siedlecki, Agnieszka Gutkowska, Karol Nowak, Sheeba Shaik, Maciej Śniegocki

Psychology and Education, 2021; 58(2) pp 7179-7183

Open Access

Abstract

Neurosurgical procedures are often performed on patients with brain diseases, making them mentally dysfunctional. These patients may be unconscious, and the surgery is emergency and life-saving then. Its execution from a legal point of view is performed with implied consent. Another problem, both ethically and legally, are the conscious patients who, however, has mental limitations and disturbed criticism, are fully conscious and who do not agree to pronounced treatment. Judgment approval is necessary in these cases. A certain dilemma is the implementation of treatment during the consistently emphasized refusal of treatment. It is difficult for physician, especially since he has contact with this patient every day. We present our own experience in the treatment of such patients. We share our comments and observations. We describe cases of patients treated for brain tumors, hydrocephalus and chronic subdural hematomas. We present the daily ethical, legal and organizational aspects of treating such patients. We suggest that empathy and conversation with such patients is of key importance.

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RIGHTS/LEGAL/LEGISLATIVE

An Extended Doctrine of Implied Consent – A Digital Mediator?

Georgia Jenkins

International Review of Intellectual Property and Competition Law, 23 March 2021

Open Access

Abstract

This article explores whether an extended doctrine of implied consent can better balance copyright interests in the digital environment, particularly users' access to digital content. Implied licences are analysed from a variety of jurisdictions including the United Kingdom, the European Union, Germany, the United States and Australia to submit that the role of implied consent emerges as a fundamental legal principle in both common and civil law jurisdictions. Given the significance of consent within the doctrine of exhaustion, the article also evaluates its application in the digital environment and the extent to which this could impact the proposal for an extended doctrine of implied consent. The boundaries of the extended doctrine along with its

practical impact will be assessed through an example illustrating users' access and interaction with digital content. It then becomes clear from the discussion that follows, that an extended doctrine of implied consent has the potential to balance copyright interests in the digital environment due to its status as a fundamental legal principle and inherent flexibility to consider a range of factors regarding users' subsequent use of digital content.

Deceased by default: Consent systems and organ-patient mortality

Research Article

Bart H. H. Golsteyn, Annelore M. C. Verhagen

Plos One, 17 March 2021

Abstract

Previous research shows that countries with opt-out consent systems for organ donation conduct significantly more deceased-donor organ transplantations than those with opt-in systems. This paper investigates whether the higher transplantation rates in opt-out systems translate into equally lower death rates among organ patients registered on a waiting list (i.e., organ-patient mortality rates). We show that the difference between consent systems regarding kidney- and liver-patient mortality rates is significantly smaller than the difference in deceased-donor transplantation rates. This is likely due to different incentives between the consent systems. We find empirical evidence that opt-out systems reduce incentives for living donations, which explains our findings for kidneys. The results imply that focusing on deceased-donor transplantation rates alone paints an incomplete picture of opt-out systems' benefits, and that there are important differences between organs in this respect.

A Step in the Wrong Direction: Florida Lawmakers' Interference with Informed Consent for Pelvic Examinations

Commentary

David Alfandre, Cynthia Geppert, Jennifer Goedken, Toby Schonfeld

Women's Health Issues, 11 March 2021

Excerpt

Over the last two decades, several states have passed laws regulating informed consent for pelvic examinations. Much of the change has been positive, reflecting bipartisan state-supported legislation enforcing stringent informed consent requirements when health professions students perform pelvic examinations while a patient is under anesthesia. These stronger laws have helped to ensure that patients are included in, and make decisions about, any additional pelvic examinations performed for a student's educational benefit rather than for the patient's care (Friesen, 2018; Greene, 2020).

More recently, however, the state of Florida passed a strict consent law that requires a patient's written consent before any pelvic examination, not just for those performed while under anesthesia. This law signals an ethically concerning trend in women's health care that would create a more burdensome and unnecessary written consent processes for a broader range of low-risk interventions. In this commentary, we describe the ethical concerns the law raises and discuss more productive ways to empower patients while maintaining strong informed consent practices…

Deemed consent for organ donation: a comparison of the English and Scottish approaches

Jordan A. Parsons

Journal of Law and the Biosciences, 4 March 2021

Open Access

Abstract

Deemed consent for organ donation has long been discussed as a potential solution to the shortage of organs for transplantation, with several countries having implemented it. In Great Britain, Wales was the first nation to introduce such a system, having done so in 2015. Now, the other two nations are following suit. In this paper, I compare the approaches of England and Scotland in moving to systems of deemed consent for organ donation. After outlining both sets of legislation, I focus on three points on which the two nations differ. First, the role of those close to the deceased in the consent process and the extent to which clinicians are required to consult them ahead of consent being deemed. Second, the role of government ministers in ensuring widespread public awareness. Third, the ways in which the two nations responded to the challenge of the COVID-19 pandemic in relation to the implementation of deemed consent. I conclude that on all three points, the Scottish approach is preferable.

Heterogeneity of national legislation and practice on clinical trials with vulnerable patients based on the EU Clinical Trials Directive by the example of adults permanently incapable of giving informed consent

Research Article

Janna K. Schweim, Michael Nonnemacher, Karl-Heinz Jöckel

German Medical Science, 2 March 2021; 19

Open Access

Abstract

In principle, persons wishing to participate in a clinical trial must give informed consent in advance after comprehensive information has been provided. Under certain conditions, it is possible to deviate from this requirement in the European Union (EU) in order to enable the participation of so-called vulnerable persons who are incapable of giving their informed consent. Kuthning et al. [1] have already dealt with general and specific aspects of vulnerable patients and the principle of informed consent in clinical trials. One group of vulnerable persons, for example, are adults temporarily or permanently incapable of giving consent due to their state of health. For a long period of time, no systematic and uniform legal basis for clinical trials existed in the EU as a whole. The Clinical Trials Directive (CTD) [2], adopted in 2001, aimed to change this by harmonizing all legal regulations on clinical trials applicable in the EU, but nevertheless allowing national deviations in implementation into national laws through opening clauses and aspects that were left unregulated. In view of the Clinical Trials Regulation (CTR) [3] which, according to the current status, will with high probability be applied from 2022 on, and which in future will be the legal basis for clinical trials with medicinal products in humans, applied directly in all EU member states, the necessity to take stock of the effects of the CTD was evident.

The national deviations with regard to the participation of patients incapable of giving informed consent were investigated qualitatively and quantitatively by means of a systematic analysis of legislation in 16 EU countries and a retrospective database analysis of a European clinical trial registry over a ten-year observation period. Although the analysis initially showed a predominantly homogeneous picture, the differences between the EU member states became apparent in a detailed examination. The database analysis yielded a clear result, since in some countries the majority of clinical trials are carried out. The clearest difference was found between the legal analysis and the results of the evaluated clinical trials concerning adults who are permanently incapable of giving informed consent. A presumed association between the “degree of liberality” of the national law and the frequency of clinical trials conducted in the respective country could not be confirmed. In the past, the selection of countries for conducting a clinical trial was based less on legal requirements and more on experience and financial considerations.

Security and Privacy Requirements for Electronic Consent: A Systematic Literature Review

Research Article

Stef Verreydt, Koen Yskout, Wouter Joosen

ACM Transactions on Computing for Healthcare, March 2021; 2(2)

Abstract
Electronic consent (e-consent) has the potential to solve many paper-based consent approaches. Existing approaches, however, face challenges regarding privacy and security. This literature review aims to provide an overview of privacy and security challenges and requirements proposed by papers discussing e-consent implementations, as well as the manner in which state-of-the-art solutions address them. We conducted a systematic literature search using ACM Digital Library, IEEE Xplore, and PubMed Central. We included papers providing comprehensive discussions of one or more technical aspects of e-consent systems. Thirty-one papers met our inclusion criteria. Two distinct topics were identified, the first being discussions of e-consent representations and the second being implementations of e-consent in data sharing systems. The main challenge for e-consent representations is gathering the requirements for a "valid" consent. For the implementation papers, many provided some requirements but none provided a comprehensive overview. Blockchain is identified as a solution to transparency and trust issues in traditional client-server systems, but several challenges hinder it from being applied in practice. E-consent has the potential to grant data subjects control over their data. However, there is no agreed-upon set of security and privacy requirements that must be addressed by an e-consent platform. Therefore, security- and privacy-by-design techniques should be an essential part of the development lifecycle for such a platform.

A Modern History of Informed Consent and the Role of Key Information

Lydia A. Bazzano, Jaquail Durant, Paula Rhode Brantley
Ochsner Journal, March 2021; 21 pp 81–85
Open Access
Abstract
Background
The concept of informed consent has evolved significantly with regard to both the practice of medicine and research conducted with human volunteers. Yet the process of informed consent used in clinical research and the lengthy consent documents that are difficult to comprehend have been criticized.
Methods
We review the history of informed consent as a legal and regulatory concept and the intended impact of the new key information section, a requirement that was introduced in the 2017 revisions to the Common Rule.
Results
The key information section is intended to be a concise and focused presentation at the beginning of the informed consent document that facilitates potential participants' comprehension of the research. However, the lack of regulatory guidance regarding content and length has been problematic. To avoid the risk of noncompliance, many institutions have sought safe harbor by following the limited format guidelines included in the preamble to the revisions to the Common Rule.
Conclusion
Research examining formats for the key information section and aids to increasing potential participants' understanding of a research project should be conducted to ensure that the new regulations achieve the original intent rather than simply lengthening an already lengthy paper document. In addition, the human research protections community should evaluate whether the key information section increases research participants' understanding of what they will be undertaking in a particular study.

Editor's note: The Ochsner Journal is a peer-reviewed quarterly medical journal published by the Academic Division of Ochsner Clinic Foundation.

Comparison of notice requirements for consent between ISO/IEC 29184:2020 and General Data Protection Regulation

Harshvardhan J. Pandit, Georg Philip Krog
Journal of Data Protection & Privacy, Spring 2021; 4(2)
Abstract

This paper analyses the ISO/IEC 29184:2020 standard and compares its requirements for notice and consent with those specified by the General Data Protection Regulation (GDPR). More specifically, it considers the extent to which the ISO/IEC 29184 standard can be applied to demonstrate compliance with the requirements of the GDPR and to identify the additional requirements in areas where it is not sufficient. The paper concludes with remarks on the potential role of ISO/IEC 29184 as a certification mechanism under the GDPR for consent and notice.

Informed Consent of Minors with a Special Focus on the Czech Legal Regulation

Tomáš Doležal

The Lawyer Quarterly, January 2021; 11(1) pp 126-140

Open Access

Abstract

This article is focused on the examination of the law concerning medical treatment of minors, that is, persons under the age of 18. The first part of this article brings a short overview of the international documents regulating the rights of the child and specifically children's rights within the area of health care provision. This article analyzes the issue of the maturity and competence of children and discusses whether persons under the age of 18 may be regarded as being capable of consenting to medical treatment. Furthermore this article brings a short comparative overview of the laws concerning medical treatment of minors in different countries and tries to extract the common features of the regulations in the different countries. Finally, the last and longest part of this article analyzes the issue of the capacity of minors to consent to medical treatment in the territory of the Czech Republic from the historical perspective and brings a structured overview of this issue under the current Czech laws.

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CULTURAL/COUNTRY CONTEXT

Towards building a culturally informed consent process in Central Asia

Research Article

Christopher M. Whitsel, Martha C. Merrill

Central Asian Survey, 26 March 2021

Abstract

Researchers working in Central Asia often report difficulty obtaining Western-style signed informed consent statements. The principles underlying informed consent were developed in cultures characterized by low-power distance and individualism, low context communication and a rules basis, whereas many Central Asian cultures emphasize high-power distance, collectivism, high-context communication and relationships. Yet, consent is an important principle. We interviewed scholars who grew up in Central Asia, but completed graduate work in the United States, Canada or the UK, to ask their recommendations for developing a culturally appropriate consent process. The common themes that arose include working within a network, building relationships of trust with potential participants and not utilizing legal-type documentation as a basis for consent.

Providing emergency medical care without consent: How the 'emergency principle' in Australian law protects against claims of trespass

Sam Boyle, Nikola Stepanov

Emergency Medicine Australasia, 24 March 2021

Abstract

In a medical emergency, the usual requirement to obtain consent before giving treatment does not apply. This exception to the general rule on consent to medical treatment is known as the 'emergency principle'. By considering a case scenario, and by adjusting the facts to this scenario, we explain the circumstances in which the emergency principle will protect practitioners from an action in trespass. Although the fundamentals of this principle are uncontroversial, there are a number of uncertainties and inconsistencies in this law in relation to certain parameters. For example, whether a practitioner would ever be obliged to seek consent from a substitute decision-maker before providing emergency treatment is not clearly or consistently explained. We suggest the law should be clarified.

Informed Consent in the Health Care System: An Overview from a Dental Perspective in Saudi Arabia

Review Article

Nassar A.A., Demyati A.K.

Saudi Journal of Health Systems Research, March 2021; 1 pp 11–15

Open Access

Abstract

Background

Patient autonomy in the health care system is achieved by the vital principle of providing informed consent. Throughout history, informed consent gained recognition and improved to include more aids and steps to formalize and standardize the process of obtaining proper consent in medical and dental practice. Regardless of the type of informed consent obtained before the treatment, it should include an adequate understandable description of nature and diagnosis of the disease, treatment plan, proper alternatives, risks, and limitations.

Summary

There is limited information in the ethics literature covering critical concepts related to different dental procedures in Saudi Arabia. In Saudi Arabia, informed consent in dentistry is not well-documented. As everything is evolving and changing in Saudi society, litigation has progressed and impacted dentistry. This overview will help in addressing aspects related to informed consent and closing the gaps in the dental health care system in Saudi Arabia, managing complex ethical issues associated with dental patients. In addition, providing recommendations and shedding some light on the importance of informed consent will improve the situation of the informed consent process in Saudi Arabia.

Key Messages

Informed consent allows patients to be part of the decision-making process, and it provides legal protection for the practitioners from practice lawsuit cases. Dentists should take extra care in documenting the consent process and patient's choice regarding their treatment to avoid unfavorable consequences. In Saudi Arabia, attention should be drawn toward the crucial role of informed consent, and more studies should be published in order to enrich the knowledge and to improve the health care system.

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MEDICAL/SURGICAL

Understanding Exception from Informed Consent in Planned Emergency Research

Understanding Research

CourtneyEdwards, Kimberly D. Johnson

Journal of Emergency Nursing, 11 March 2021

Abstract

Many of the current accepted treatment practices provided to patients in the first critical hour after a traumatic injury, stroke, or cardiac arrest have not been rigorously tested in clinical research trials. The

inability to obtain informed consent is often a barrier to research in emergency, time-sensitive situations in which the patient is not able to provide informed consent nor is their family member immediately available to provide consent on behalf of the patient. Planned emergency research, often with exception from informed consent, is a type of research study that involves a patient with a life-threatening medical condition that requires urgent interventions, wherein the current treatments may be unproven or suboptimal, and who, because of their current condition, is unable to provide informed consent. This article summarizes the necessary components for using exception from informed consent in planned emergency research. Understanding the research design, particularly research processes specific to time-critical emergency situations, will ensure that the care provided by stretcher-side emergency nurses will result in optimal patient outcomes and is an integral aspect of emergency nursing practice.

Are we undermining the value of palliative care through advanced cancer clinical trial consent language?

Commentary

Puja J. Umaretiya, Jennifer P. Rubin, Jennifer M. Snaman, Christina Ullrich, Angela M. Feraco, Veronica Dussel, Joanne Wolfe, Elisha Waldman

Cancer, 10 March 2021

Abstract

Informed consents for advanced cancer trials contain language that misrepresents palliative care as an alternative to trial participation. This language should be revised to highlight that palliative care is appropriate at any point in the illness trajectory and alongside disease-directed therapy.

[Expert consensus on informed consent for vaccination (part two)]

Zhonghua Liu Xing Bing Xue Za Zhi

Chinese Preventive Medicine Association, 1 March 2021; 42(3) pp 369-399

Abstract

The Vaccine Administration Law of the People's Republic of China and other relevant laws require that vaccine recipients or their guardians be educated about vaccines and how they work, and described in general the methods and contents of such vaccination education. With the new law and "Standard Operational Procedures for Immunization" as foundation documents, and in consultation with experts at home and abroad, the Chinese Preventive Medicine Association developed a consensus statement about informed consent for vaccination. This consensus statement is written for disease control and prevention health care personnel in vaccination services and describes the educational content of informed consent, a theoretical framework for immunization and immunization knowledge, the informed consent processes, principles of planning for vaccination, and an informed consent form. Part Two of the consensus includes influenza vaccine, pneumococcal vaccine, haemophilus influenzae type b containing vaccine, enterovirus type 71 inactivated vaccine, rotavirus vaccine, varicella attenuated live vaccine, herpes-zoster vaccine, human papillomavirus vaccine, rabies vaccine, hemorrhagic fever with renal syndrome vaccine, leptospira vaccine, anthrax vaccine, hepatitis E vaccine, cholera vaccine, typhoid vaccine, and tick-borne encephalitis vaccine.

Editor's Note: This is a Chinese language publication

The advantages of nurse-led consent for dialysis in improving shared decision-making and obtaining legal consent

Jo-Anne Moodie, Elaine Sanders, Brett Sobey, Jade Ryan, Jayne Amy, Jenny Beavis, Adele Montgomery, Stephen G Holt

Renal Society of Australasia Journal, March 2021; 17(1) pp 4-9

Abstract

The treatment/medical consent procedure has generally been performed by doctors. Despite the recognised importance of the consent process, formal initial consent for maintenance dialysis was poorly performed at in our service and rarely performed thereafter. As a large renal unit with a commitment to excellence in patient care, we felt this was out of keeping with our remit and sought to change the process to ensure we delivered useful information to allow our patients to have a meaningful discussion around consent issues. We trained senior nurses to perform the reconsent process, and took the opportunity to reassess patients' decision-making competence, discuss advance care planning, blood consent and personal data privacy issues. We demonstrated a large improvement in the number of patients having a valid dialysis consent form, and realised the potential of this procedure to improve the care we give to our patient group. We recommend the benefits of nurse-led consent for dialysis to other services.

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GENERAL/OTHER

Online Extremism and Terrorism Research Ethics: Researcher Safety, Informed Consent, and the Need for Tailored Guidelines

Maura Conway

Terrorism and Political Warfare, 24 March 2021; 33(2) pp 367-380

Abstract

This article reflects on two core issues of human subjects' research ethics and how they play out for online extremism and terrorism researchers. Medical research ethics, on which social science research ethics are based, centers the protection of research subjects, but what of the protection of researchers? Greater attention to researcher safety, including online security and privacy and mental and emotional wellbeing, is called for herein. Researching hostile or dangerous communities does not, on the other hand, exempt us from our responsibilities to protect our research subjects, which is generally ensured via informed consent. This is complicated in data-intensive research settings, especially with the former type of communities, however. Also grappled with in this article therefore are the pros and cons of waived consent and deception and the allied issue of prevention of harm to subjects in online extremism and terrorism research. The best path forward it is argued—besides talking through the diversity of ethical issues arising in online extremism and terrorism research and committing our thinking and decision-making around them to paper to a much greater extent than we have done to-date—may be development of ethics guidelines tailored to our sub-field.

Written Informed Consent-Translating into Plain Language. A Pilot Study

Agnieszka Zimmermann, Anna Pilarska, Aleksandra Gaworska-Krzemińska, Jerzy Jankau, Marsha N Cohen

Healthcare, 20 February 2021; 9(2)

Open Access

Abstract

Background

Informed consent is important in clinical practice, as a person's written consent is required prior to many medical interventions. Many informed consent forms fail to communicate simply and clearly. The aim of our study was to create an easy-to-understand form.

Methods

Our assessment of a Polish-language plastic surgery informed consent form used the Polish-language comprehension analysis program (jasnopis.pl, SWPS University) to assess the readability of texts written for people of various education levels; and this enabled us to modify the form by shortening sentences and

simplifying words. The form was re-assessed with the same software and subsequently given to 160 adult volunteers to assess the revised form's degree of difficulty or readability.

Results

The first software analysis found the language was suitable for people with a university degree or higher education, and after revision and re-assessment became suitable for persons with 4-6 years of primary school education and above. Most study participants also assessed the form as completely comprehensible.

Conclusions

There are significant benefits possible for patients and practitioners by improving the comprehensibility of written informed consent forms.

The Case for Consent Pluralism

Jessica Keiser

Journal of Ethics and Social Philosophy, 2021

Abstract

A longstanding debate regarding the nature of consent has marked a tri-fold division among philosophical and legal theorists according to whether they take consent to be a type of mental state, a form of behaviour, or some hybrid of the two. Theorists on all sides acknowledge that ordinary language cannot serve as a guide to resolving this ontological question, given the polysemy of the word “consent” in ordinary language. Similar observations have been noted about the function of consent in the law and use of the word “consent” in legal contexts. This paper makes a parallel argument regarding consent’s characteristic normative role: roughly, to transform moral prohibitions into permissions. This role is neither unique nor essential to any one particular kind of thing, be it a mental state, form of behaviour, or hybrid of the two—rather, it is played by mental states and behaviour in independent and context-sensitive ways. The upshot is that insofar as we are interested in its normative implications, we ought to adopt a pluralistic approach to consent which gives independent weight to the moral contributions of facts about mental states and facts about behaviour relative to a context.

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