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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

November 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 also monitor other research analysis and guidance beyond the journal literature globally. 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 (CICI), a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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

No new content identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
HUMANITARIAN CONTEXT

POLICY GUIDANCE/PROGRAM ACTION
TECHNOLOGY/OTHER MEDIATION

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

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COVID-19

Surgery during the COVID-19 pandemic: Are we obtaining informed consent?

Emily Robinson, Joseph Ayathamattam, Holly Harris, Malcolm McFall
British Journal of Surgery, 28 October 2021; 108(Supplement 7)
Abstract
Background
It was estimated that 1 in 4 inpatients with COVID-19 acquired the virus whilst admitted in December 2020. Surgical patients that contract COVID-19 have poor outcomes, with mortality rates as high as 24% and risk of pulmonary complications as high as 50%. The Royal College of Surgeons of England published COVID-19 consenting guidelines in June 2020.
Aims
To identify the proportion of surgical patients who were informed of the risk of acquiring COVID-19 during the consenting process at two District General Hospitals.
Methods
The consent forms of 220 surgical patients who had either elective or emergency surgery during the second COVID-19 lockdown were reviewed retrospectively (1/11/2020-20/11/2020). This included General Surgery, Trauma and Orthopaedics and Urology. Patients with incomplete notes or who lacked capacity were excluded.
Results
In total, 193 patients were included. We found that 41.5% of patients were consented for the risk of acquiring COVID-19 peri-operatively. This did not vary significantly between elective and non-elective patients.
Conclusions
Our study shows that current practice does not meet national recommendations. In order to provide informed consent, surgeons must engage in emerging research regarding the local prevalence of COVID-19 and the implications of infection during the peri-operative period. Only with this knowledge, will surgeons be able to balance the risks and benefits on a case by case basis, to provide the patient with necessary information for consent. We recommend that trusts adopt a COVID-19 consenting policy, as part of the pre-operative assessment.

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BIOMEDICAL RESEARCH

Characterization of Informed Consent Forms Posted on ClinicalTrials.gov

Research Letter
Tony Tse, Sarah White, Luke Gelinas, Walker Morrell, Barbara Bierer, Deborah A. Zarin
JAMA Network Open, 18 November 2021; 4(11)
Open Access

Introduction
Informed consent forms (hereinafter, forms), part of a larger consent process that serves multiple bioethical functions, are intended to provide potential research volunteers with sufficient written information about a clinical trial to help them decide about participation. Despite concerns about their overall quality, broadly generalizable samples of forms have been difficult to access for quality improvement. Since July 2017, ClinicalTrials.gov has allowed voluntary posting of forms for registered studies. Subsequently (January 21, 2019), the revised Common Rule form-posting requirement (45 CFR 46.116[h]) became effective (eAppendix in the Supplement). To explore how access to forms has increased on ClinicalTrials.gov after these initiatives, we sought to characterize registered trials with available forms and posting trends. We also assessed the frequency of form posting by funder type for trials initiated since the revised Common Rule compliance date…
Discussion
As of July 7, 2021, forms were publicly available on ClinicalTrials.gov for nearly 2100 US trials for a range of intervention types and conditions from across 600 mostly nonindustry sponsors. Many of these trials (1243 of 2088 [59.5%]) did not list funding by a US federal agency and, among those 1243 trials, some were initiated before the compliance date, suggesting that their forms were likely not required to be posted under the revised Common Rule. The absolute percentages of federally funded trials initiated since the Common Rule compliance date in set 2 remain relatively low, with fewer than 87 of 529 trials (16.5%) listing a key funder type of "NIH" or "other US federal agency" having posted forms. Although forms for a range of trials are now available on ClinicalTrials.gov, most appear to have been posted voluntarily. Limitations of this cross-sectional study include that retrieved trials were likely skewed toward those required by federal reporting requirements. Trials may have also been miscategorized because of errors or incomplete information in data self-reported by study sponsors. Further research is needed because it is likely too soon to assess the full impact of the revised Common Rule requirement.

Informed consent in pragmatic trials: results from a survey of trials published 2014-2019

Jennifer Zhe Zhang, Stuart G Nicholls, Kelly Carroll, Hayden Peter Nix, Cory E Goldstein, Spencer Phillips Hey, Jamie C Brehaut, Paul C McLean, Charles Weijer, Dean A Fergusson, Monica Taljaard
Journal of Medical Ethics, 15 November 2021
Abstract
Objectives
To describe reporting of informed consent in pragmatic trials, justifications for waivers of consent and reporting of alternative approaches to standard written consent. To identify factors associated with (1) not reporting and (2) not obtaining consent.
Methods
Survey of primary trial reports, published 2014-2019, identified using an electronic search filter for pragmatic trials implemented in MEDLINE, and registered in ClinicalTrials.gov.
Results
Among 1988 trials, 132 (6.6%) did not include a statement about participant consent, 1691 (85.0%) reported consent had been obtained, 139 (7.0%) reported a waiver and 26 (1.3%) reported consent for one aspect (eg, data collection) but a waiver for another (eg, intervention). Of the 165 trials reporting a waiver, 76 (46.1%) provided a justification. Few (53, 2.9%) explicitly reported use of alternative approaches to consent. In multivariable logistic regression analyses, lower journal impact factor ($p=0.001$) and cluster randomisation ($p<0.0001$) were significantly associated with not reporting on consent, while trial recency, cluster randomisation, higher-income country settings, health services research and explicit labelling as pragmatic were significantly associated with not obtaining consent (all $p<0.0001$).
Discussion
Not obtaining consent seems to be increasing and is associated with the use of cluster randomisation and pragmatic aims, but neither cluster randomisation nor pragmatism are currently accepted justifications for waivers of consent. Rather than considering either standard written informed consent or waivers of consent,

researchers and research ethics committees could consider alternative consent approaches that may facilitate the conduct of pragmatic trials while preserving patient autonomy and the public's trust in research.

Simplifying consent - Use of the novel integrated consent model in paediatric clinical research

Frances Yeung, Saoirse Cameron, Sepideh Taheri

Paediatrics & Child Health, 29 October 2021; 26(Supplement 1) pp e82–e84

Abstract

Background

Obtaining informed consent from patients to participate in clinical research has traditionally been a cumbersome process, often requiring lengthy documentation and the involvement of trained research staff. Moreover, this process can be a burden to the patient/family. As a result, progress in paediatric research and enabling continual improvement in care has been slow. In the last decade, research ethicists have proposed a new “integrated consent model” (ICM) for obtaining informed consent for pragmatic clinical trials that compare standard-of-care interventions, where there is clinical equipoise. In most cases of ICM, only a brief discussion with verbal consent is required, along with a handout on study purpose, risks, benefits, and procedures. This allows for a more condensed consent process, which maximizes clarity and minimizes information overload. ICM also allows the patient/family to maintain prospective autonomy and decision-making, as compared with deferred or waived consent. The ICM model allows staff in the circle of care to obtain consent, which minimizes the stress of meeting an additional person. To our knowledge, ICM has not yet been used in the paediatric population.

Objectives

The objective of this abstract is to report on the utility of ICM in a non-randomized clinical trial carried out in the inpatient setting of a tertiary children’s hospital.

Design/Methods

We compared two widely accepted standards of care for maintaining peripheral intravenous catheter patency in a cohort of children, namely continuous infusion (“to keep the vein open” or TKVO) versus saline lock (SL). The ICM process was reviewed and approved by REB. Nurses in the circle of care received a study package that included an REB approved “consent script” to be read to the patient/family, a single page information sheet, and instructions on documenting the obtained verbal consent in the patient’s chart (Graphic 1).

Results

With ICM, 79% of participants were recruited into the trial by a nurse. Patient recruitment was completed 4 months ahead of the predicted schedule (Figure 1). Nursing, research, and medical staff were satisfied with ICM and found it easy to administer. ICM occurred smoothly and quickly for patients/families, with no interference with their medical care and practically no disruption to their daily schedule.

Conclusion

ICM is a practical alternative to laborious traditional consent models, is associated with higher patient recruitment rates, and is less burdensome for the patient/family. Paediatricians should be aware of the utility of this novel consent model.

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SOCIAL SCIENCE RESEARCH

Informed consent in psychotherapy: a survey on attitudes among psychotherapists in Switzerland

Research

Klara Eberle, Martin grosse Holtforth, Marc Inderbinen, Jens Gaab, Yvonne Nestoriuc, Manuel Trachsel

BMC Medical Ethics, 12 November 2021; 22(150)

Open Access

Abstract

Background

The legal and ethical guidelines of psychological professional associations stipulate that informed consent by patients is an essential prerequisite for psychotherapy. Despite this awareness of the importance of informed consent, there is little empirical evidence on what psychotherapists' attitudes towards informed consent are and how informed consent is implemented in psychotherapeutic practice.

Methods

155 psychotherapists in Switzerland completed an online survey assessing their attitudes regarding informed consent.

Results

Among the surveyed psychotherapists, there was a high consensus on important information that should be communicated to patients in the context of informed consent. Almost all psychotherapists rated confidentiality and its exemptions (95%) and self-determined decision-making (97%) as important. The importance to disclose information regarding fees and the empirical effectiveness of the provided treatment, were both seen as important by more than 80% of participants. The disclosure of personal information about the therapist was rated as important by 60%. Other aspects, which are not direct components of informed consent but rather overarching goals, were also evaluated rather homogeneously: self-determined decision making of the patient was rated as important by almost all of the surveyed psychotherapists (97%). The following components were also judged as important by a majority of the participants: promotion of hope (80%) and discussion of treatment goals (93%). Most psychotherapists described the implementation of informed consent as an ongoing process, rather than a one-time event during the first session of therapy. Therapists' age, postgraduate training, treated patient group, and setting influenced attitudes towards informed consent.

Conclusions

The present study shows that informed consent is perceived by psychotherapists as both a challenge and a resource. The implementation of informed consent in psychotherapy requires further research from a clinical and ethical perspective.

From Shadow Profiles to Contact Tracing: Qualitative Research into Consent and Privacy

Sacha Molitorisz, James Meese, Jennifer Hagedorn

Law, Technology and Humans, 8 November 2021; 3(2)

Abstract

For many privacy scholars, consent is on life support, if not dead. In July 2020, we held six focus groups in Australia to test this claim by gauging attitudes to consent and privacy, with a spotlight on smartphones. These focus groups included discussion of four case studies: 'shadow profiles', eavesdropping by companies on smartphone users, non-consensual government surveillance of its citizens and contact tracing apps developed to combat COVID-19. Our participants expressed concerns about these practices and said they valued individual consent and saw it as a key element of privacy protection. However, they saw the limits of individual consent, saying that the law and the design of digital services also have key roles to play. Building on these findings, we argue for a blend of good law, good design and an appreciation that individual consent is still valued and must be fixed rather than discarded - ideally in ways that are also collective. In other words, consent is dead; long live consent.

"A Question of Trust" and "a Leap of Faith"—Study Participants' Perspectives on Consent, Privacy, and Trust in Smart Home Research: Qualitative Study

Mari-Rose Kennedy, Richard Huxtable, Giles Birchley, Jonathan Ives, Ian Craddock

JMIR Mhealth Uhealth, November 2021; 9(11)

Abstract
Background
Ubiquitous, smart technology has the potential to assist humans in numerous ways, including with health and social care. COVID-19 has notably hastened the move to remotely delivering many health services. A variety of stakeholders are involved in the process of developing technology. Where stakeholders are research participants, this poses practical and ethical challenges, particularly if the research is conducted in people's homes. Researchers must observe prima facie ethical obligations linked to participants' interests in having their autonomy and privacy respected.
Objective
This study aims to explore the ethical considerations around consent, privacy, anonymization, and data sharing with participants involved in SPHERE (Sensor Platform for Healthcare in a Residential Environment), a project for developing smart technology for monitoring health behaviors at home. Participants' unique insights from being part of this unusual experiment offer valuable perspectives on how to properly approach informed consent for similar smart home research in the future.
Methods
Semistructured qualitative interviews were conducted with 7 households (16 individual participants) recruited from SPHERE. Purposive sampling was used to invite participants from a range of household types and ages. Interviews were conducted in participants' homes or on-site at the University of Bristol. Interviews were digitally recorded, transcribed verbatim, and analyzed using an inductive thematic approach.
Results
Four themes were identified—motivation for participating; transparency, understanding, and consent; privacy, anonymity, and data use; and trust in research. Motivations to participate in SPHERE stemmed from an altruistic desire to support research directed toward the public good. Participants were satisfied with the consent process despite reporting some difficulties—recalling and understanding the information received, the timing and amount of information provision, and sometimes finding the information to be abstract. Participants were satisfied that privacy was assured and judged that the goals of the research compensated for threats to privacy. Participants trusted SPHERE. The factors that were relevant to developing and maintaining this trust were the trustworthiness of the research team, the provision of necessary information, participants' control over their participation, and positive prior experiences of research involvement.
Conclusions
This study offers valuable insights into the perspectives of participants in smart home research on important ethical considerations around consent and privacy. The findings may have practical implications for future research regarding the types of information researchers should convey, the extent to which anonymity can be assured, and the long-term duty of care owed to the participants who place trust in researchers not only on the basis of this information but also because of their institutional affiliation. This study highlights important ethical implications. Although autonomy matters, trust appears to matter the most. Therefore, researchers should be alert to the need to foster and maintain trust, particularly as failing to do so might have deleterious effects on future research.

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GENOMIC MEDICINE/GENE EDITING

A Blockchain-Based Dynamic Consent Architecture to Support Clinical Genomic Data Sharing (ConsentChain): Proof-of-Concept Study

Faisal Albalwy, Andrew Brass, Angela Davies
JMIR Medical Informatics, 3 November 2021; 9(11)
Abstract
Background

In clinical genomics, sharing of rare genetic disease information between genetic databases and laboratories is essential to determine the pathogenic significance of variants to enable the diagnosis of rare genetic diseases. Significant concerns regarding data governance and security have reduced this sharing in practice. Blockchain could provide a secure method for sharing genomic data between involved parties and thus help overcome some of these issues.

Objective

This study aims to contribute to the growing knowledge of the potential role of blockchain technology in supporting the sharing of clinical genomic data by describing blockchain-based dynamic consent architecture to support clinical genomic data sharing and provide a proof-of-concept implementation, called ConsentChain, for the architecture to explore its performance.

Methods

The ConsentChain requirements were captured from a patient forum to identify security and consent concerns. The ConsentChain was developed on the Ethereum platform, in which smart contracts were used to model the actions of patients, who may provide or withdraw consent to share their data; the data creator, who collects and stores patient data; and the data requester, who needs to query and access the patient data. A detailed analysis was undertaken of the ConsentChain performance as a function of the number of transactions processed by the system.

Results

We describe ConsentChain, a blockchain-based system that provides a web portal interface to support clinical genomic sharing. ConsentChain allows patients to grant or withdraw data requester access and allows data requesters to query and submit access to data stored in a secure off-chain database. We also developed an ontology model to represent patient consent elements into machine-readable codes to automate the consent and data access processes.

Conclusions

Blockchains and smart contracts can provide an efficient and scalable mechanism to support dynamic consent functionality and address some of the barriers that inhibit genomic data sharing. However, they are not a complete answer, and a number of issues still need to be addressed before such systems can be deployed in practice, particularly in relation to verifying user credentials.

Improving patient informed consent for haemophilia gene therapy: the case for change

Review Article

Laurence Woollard, Richard Gorman, Dakota J. Rosenfelt

Therapeutic Advances in Rare Disease, 26 September 2021

Abstract

Adeno-associated virus-based gene therapy points to a coming transformation in the treatment of people living with haemophilia, promising sustained bleed control and potential improvement in quality of life. Nevertheless, the consequences of introducing new genetic material are not trivial. The perceived benefits should not minimise the challenges facing patients in understanding the long-term risks and providing a valid and meaningful informed consent, whether in a research or clinical setting. Informed consent is a fundamentally important doctrine in both medical ethics and health law, upholding an individual's right to define their personal goals and make their own autonomous choices. Patients should be enabled to recognise their clinical situation, understand the implications of treatment and integrate every facet of their life into their decision. This review describes informed consent processes for haemophilia gene therapy clinical trials, factors affecting patients' decision making and the availability of patient-centred decision support interventions, to ensure that patients' interests are being protected. Regulatory guidance has been published for physicians and manufacturers in haemophilia on informed consent, including for gene therapy, while best-practice recommendations for patient–physician discussions are available. In all settings, however, communicating and presenting highly technical and complex therapeutic information is challenging, especially where multiple barriers to scientific knowledge and health literacy exist. We propose several evidence-informed strategies to enhance the consent procedure, such as utilising validated literacy and

knowledge assessment tools as well as participatory learning environments over an extended period, to ensure that patients are fully cognisant of the consent they give or deny. Further research is needed to define new, creative approaches for patient education and the upholding of ethical values in the informed consent process for gene therapy. The lessons learnt and approaches developed within haemophilia could set the gold standard for good practice in ensuring ethical preparedness amidst advances in genetic therapies.

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HEALTH DATA

Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road

Scientific Contribution

Eugenijus Gefenas, J. Lekstutiene, V. Lukaseviciene, M. Hartlev, M. Mourby, K.Ó Cathaoir

Medicine, Health Care and Philosophy, 17 November 2021

Abstract

This paper explores some key discrepancies between two sets of normative requirements applicable to the research use of personal data and human biological materials: (a) the data protection regime which follows the application of the European Union General Data Protection Regulation (GDPR), and (b) the Declaration of Helsinki, CIOMS guidelines and other research ethics regulations. One source of this controversy is that the GDPR requires consent to process personal data to be clear, concise, specific and granular, freely given and revocable and therefore has challenged the concept of 'broad consent', which has been widely applied in the context of biobanking. Another source of controversy is the interplay between regulations of research ethics and protection of personal data related to the secondary use of personal data and biological materials. In this case, the GDPR 'research condition' provides an alternative to re-consent for the use of previously collected personal data and biological materials. Although the mentioned controversies have been raised in the legal literature, they have not been explicitly addressed from the research ethics perspective. Should consent be regarded as a priority legal basis for personal data processing in health data research? Can broad consent still be a suitable legal ground for biobanking? What should be the role of research ethics provisions that differ from the GDPR standards, and what should be the role and function of research ethics committees in the changing environment of health data research? These are the ongoing controversies to be explored in the paper.

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CAPACITY TO CONSENT

Supported Decision-Making in Persons With Dementia: Development of an Enhanced Consent Procedure for Lumbar Puncture

Original Article

Theresa S. Wied, Julia Haberstroh, Jakov Gather, Tarik Karakaya, Frank Oswald, Mishal Qubad, Matthé Scholten, Jochen Vollmann, Johannes Pantel, the ENSURE Consortium

Frontiers in Psychiatry, 16 November 2021

Abstract

The right to make autonomous decisions is enshrined in law. However, the question how persons with cognitive deficits can be enabled to make autonomous decisions has not been satisfactorily addressed. In particular, the concept of supported decision-making and its implementation into practice has been poorly explored for persons with dementia (PwD).This article describes the empirical development and

implementation of support tools to enhance informed consent processes (so called enhanced consent procedures/ECP) for PwD on whether to undergo lumbar puncture. In the end of the process of pilot testing and further development of the tools, the following tools were defined: (1) Standardized Interview Structure, (2) Elaborated Plain Language, (3) Ambience and Room Design, (4) Keyword Lists, (5) Priority Cards, (6) Visualization, and (7) Simplified Written Informed Consent (Patient Information), as well as the general attitude (8) Person-Centered Attitude of the facilitator. As the development, implementation and evaluation of ECP tools is one objective of the transnational ENSURE project, we also include an overview of future empirical procedures. So far, our findings can serve as a selection of possibilities to support PwD in decision-making and help practitioners achieve an appropriate balance between the autonomy and protection of PwD in complex decision-making situation. Future studies should address the question if the proposed set of tools is effective to enhance informed consent processes in PwD.

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YOUNG PERSONS

The Narrative Approach to Informed Consent: Empowering Young Children's Rights and Meaningful Participation

Practial Guide
Fiona Mayne, Christine Howitt
Routledge, 2022
Open Access
Excerpt
The Narrative Approach to Informed Consent: Empowering Young Children's Rights and Meaningful Participation is a practical guide for researchers who want to engage young children in rights-based, participatory research. This book presents the Narrative Approach, an original and innovative method to help children understand their participation in research. This approach moves away from traditional paper-based consent to tailor the informed consent process to the specific needs of young children. Through the Informing Story, which employs a combination of interaction, information and narrative, this method enables children to comprehend concepts through storytelling. Researchers are stepped through the development of an Informing Story so that they can deliver accurate information to young children about what their participation in research is likely to involve. To further inform practice, the book documents the implementation of the Narrative Approach in four case studies demonstrating the variety of settings in which the method can be applied…

Deferred Consent in Pediatric Drug Trials: Moving from Why to How

Commentary
Martin Offringa, Terry P. Klassen
Pediatric Drugs, 28 October 2021; 23 pp 533–535
Excerpt
Medical care of critically ill and injured infants and children globally should be based on best research evidence to ensure safe and effective treatment. There is an ongoing need for clinical trials investigating emergency drug treatments of children with life-threatening conditions as there are still relatively few clinical trials in this setting and severely ill children are under-represented in research. A main challenge of such trials is seeking parents' consent for including their critically ill child in a research study. The reasons are obvious: there is not always someone with parental responsibility present when a child enters a hospital's emergency department, newly delivered mothers may be unable to give consent to emergency investigations or treatment of their baby because of general anesthetic or post-delivery sedation, or parents may be highly

stressed in an emergency and struggle to make an informed decision about research in the limited time available…

Consent, privacy and confidentiality: Babies, children and young people's experience of healthcare

Review

National Guideline Alliance (UK)

NICE Evidence Reviews Collection, August 2021

Excerpt

Babies, children and young people accessing healthcare have the right to consent to treatment, and rights to privacy and confidentiality. These rights are outlined both in the United Nations Convention on the Rights of the Child (UNCRC) and the NHS Constitution, and this review did not aim to assess the validity of these rights.

The provision of consent is covered by professional frameworks and international human rights laws, and young people over 16 have the right to consent to their own treatment. Those under the age of 16 can consent if they have the competence to do so, otherwise someone with parental responsibility can consent on their behalf.

The right to privacy includes privacy and dignity during discussions, examination, treatment and care, and the right to confidentiality includes the restricted use and sharing of personal and identifiable data and access to health records.

The aim of this review was to determine how children and young people, and the parents or carers of babies and young children prefer discussions about their privacy and confidentiality to be addressed by healthcare services and healthcare providers, as well as their views and preferences on discussions about consent…

Consent and confidentiality: exploring the ethical challenges of working with young people [CONFERENCE PAPER]

Zoe Morris, Nicholas Gamble

International School Psychology Association Annual Conference 2021, 13-16 July 2021

Abstract

Working with young people, particularly within schools, is complex work for psychologists and counsellors, both ethically and legally. Little is known about the process by which psychologists and counsellors determine the capacity for young people to provide their own consent for services - yet this process is undertaken everyday by school psychologists. This paper aimed to explore role that context and client characteristics may play in assessing a young person's capacity. This paper presents findings from a study of 108 practitioners working in Australia. Participants responded to questions related to how they undertake an assessment of capacity in a young person and what factors are considered to support or negate capacity to consent. Responses provided insight into practitioner reasoning and decision-making processes when facing ethical dilemmas with young people as clients. This paper will explore current practice, highlight common challenges for school psychologists, and integrate with current guidelines and policy.

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RIGHTS/LEGAL/LEGISLATIVE

Understanding the legal considerations of consent in nursing practice

Iwan Dowie

Nursing Standard, 22 November 2021

Abstract

Consent to treatment is a common, albeit complex, aspect of nursing practice. Over the past few years, laws have been strengthened to provide increased recognition of patient autonomy. This has meant that there is a greater onus placed on nurses to understand how consent is obtained from patients, the elements required to ensure any consent is valid, and how to proceed when it has been determined that a patient does not have the mental capacity to consent to treatment. This article explores some of the legal considerations that nurses should keep in mind when seeking consent from a patient.

Obtaining informed consent from patients hospitalized in the surgical wards as a major legal challenge

Seyed Khosro Ghasempouri, Masoud Shayesteh Azar, Mohammad Hosein Kariminasab, Zakaria Zakariaei, Mohammad Khademloo, Hesamoddin Raeeis Danaei, Ashkan Zakariaei

Annals of Medicine and Surgery, 17 November 2021

Open Access

Abstract

Background and objectives

Informed consent (IC) is the process of establishing communication between the physician and the patient or an alternative decision that leads to the agreement or rejection of the patient and/or their legal representative to perform specific medical procedures. In this study, we evaluated the level of awareness and patient participation in IC in the surgical wards of the general hospital in northern Iran in the 2019–2020 years.

Patients and methods

This study is cross-sectional research that was performed during the 2019–2020 years. The statistical population includes patients admitted to the surgical wards of the general hospital in northern Iran in 2019–2020. The Cochran's formula was used to determine the sample size and the statistical sample size was 385 patients. The sampling method is stratified random. The method of data collection was through questionnaire tools. The software used was SPSS 21 with an independent t-test and one-way ANOVA.

Results

Our data showed that the frequency of men was significantly higher ($P < 0.001$). Individuals with a higher education group have a significantly higher level of awareness ($P < 0.001$). The Pearson's Correlation (PC) test showed that there was no significant correlation between age and patients' awareness score ($PC = -0.007$, $P = 0.887$).

Conclusion

The current study showed that individuals with higher education had a significantly higher level of awareness, and there was no significant correlation between age and patients' awareness score. Therefore, senior university administrators are suggested to improve IC processes in accordance with the patients' rights charter and internationally accredited standards, and assist health care providers with legal implications in the courts.

Informed consent: Legalities, perspectives of physicians and patients, and practices in OECD/non-OECD countries

Original Article

Amrita Shenoy, Gopinath N. Shenoy, Gayatri G. Shenoy

Médecine Palliative, 30 October 2021

Summary

In the medico-legal context, obtaining informed consent is described as the process in which the doctor apraises the patient of the intricacies of the proposed treatment, its alternatives, benefits and risks presented, therein, the right to refuse or withdraw consent at any point, and the risks of not undergoing

treatment at all. As segments of disciplined inquiry, we, hereby, present a synthesis of the legalities, perspectives of physicians and patients, and practices in two cohorts of countries. We, specifically, analyze the above segments in the context of formative informed consent codes prevalent in France, United States, United Kingdom, Brazil, and India. In this process, we place focus on landmark judgments that conceived the frameworks of informed consent to its present stage. The present study, additionally, elaborates on the past practice of modulating the volume/intensity of medical details conveyed to the patient or, in other words, how informed the informed consent should be. We illustrate the above concept with an example of the once conservative English medical approach that has now shifted to a collaborative American one. An eminent Scottish judgment ruled in 2017 was instrumental in enacting the same. Conclusively, we explore how illiterate or semi-literate, financially constrained patients are withdrawn and passive in medical decision-making. The process of obtaining informed consent from the above stratum of poverty-stricken fiscally restrained patients is known to be potentially cumbersome. In this context, we, nevertheless, propose to expand on the ways of obtaining informed consent contextual to the above patient qualities.

Should we criminalize a deliberate failure to obtain properly informed consent?

Clark Hobson, José Miola

Medical Law International, 25 October 2021

Open Access

Abstract

This paper takes the form of a polemic and thought experiment. The starting point is that, if medical law's claims to place autonomy at the heart of the enterprise are to be taken seriously, then autonomy either needs to be considered a recoverable harm, or the most egregious infringements should be subject to the criminal law. This might particularly be the case where a doctor deliberately attempts to modify the patient's decision by failing to disclose information that they know that the patient would find significant. The article considers medical law's relationship with autonomy, before applying the criminal law – in the form of the analogous situation of defendants who deliberately fail to disclose HIV+status to their sexual partners. What we find is a distinct difference in the way that autonomy is seen by medical and criminal law, although both are equally unsatisfactory.

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FREE PRIOR INFORMED CONSENT (FPIC)

Indigenous agency through normative contestation: Defining the scope of free, prior and informed consent in the Russian North [BOOK CHAPTER]

Marina Peeters Goloviznina

Indigenous Peoples, Natural Resources and Governance, 2021 [Routledge]

Abstract

This chapter explores how obshchiny, the most numerous grassroots Indigenous peoples' organizations in contemporary Russia, deal with the challenge of exercising their right to free, prior and informed consent (FPIC). The study nuances our understanding of the agency of obshchiny, drawing much-needed attention to their practices of making a difference in the governance of extractive activities at the local level through FPIC. The analysis explores normative contestation practices of a family-based obshchina in the Sakha Republic (Yakutia), focusing on their members' efforts to enhance their rights to FPIC in relations with a gold mining company. Despite the obshchina's inferior position in asymmetrical power relations with the mining company, the study shows that assistance from the Ombudsman for Indigenous Peoples' Rights can increase the obshchina's chances of maximizing the benefits of negotiations with the company.

Can free, prior and informed consent support reconciliation between indigienous peoples and the state in multicultural societies [THESIS]

A Beales

City University of London Doctoral Thesis, 2021

Abstract

The United Nations Declaration on the Rights of Indigenous Peoples has been hailed as a 'framework for reconciliation' on which states and indigenous peoples can build harmonious relationships. However, during the negotiations of UNDRIP's text, some argued that its impact would be constrained by the adoption of a cultural rights framework over an unambiguous recognition of the right to self-determination.

This thesis investigates the implementation of a key provision of UNDRIP: the requirement on states to consult with indigenous peoples in order to obtain their consent before approving measures or policies that would impact on indigenous rights, asking whether weak interpretations of indigenous self-determination under a multicultural model of rights are constraining the reconciliatory potential of prior consultation. It provides a theoretical analysis of prior consultation, drawing from indigenous critiques of human rights based multiculturalism and western theories of dispute resolution, and applying a decolonial theoretical framework. The theoretical analysis is grounded in case studies that illustrate how prior consultation is being implemented in Peru and Canada.

This thesis concludes that two different conceptualisations of FPIC have emerged: the 'general rule' approach, which is based on the right to self-determination and generally favoured by indigenous peoples; and the 'multiculturalist approach', which views FPIC as a facet of multicultural democracy. This latter approach is generally favoured by states, whose practice in this regard will shape the future development of FPIC as an international legal norm. However, this 'multiculturalist approach' is unlikely to lead to reconciliation because it constrains indigenous self-determination within a colonial imbalance of epistemic, political and economic power that overwhelmingly benefits the state.

In contrast, this thesis puts forward a dispute resolution approach which reimagines prior consultation as a duty to forge consensus. Such an approach, based on mutual respect and collaboration between peoples, may be more likely to contribute to reconciliation because it sidesteps commonly-held concerns that indigenous consent will be wielded as a unilateral right of veto, and recognises indigenous self-determination more fully. Viewing prior consultation through the lens of dispute resolution also suggests that mediation may offer a range of tools to counterbalance structural disadvantages that indigenous peoples face within the prior consultation process and encourage a more genuine intercultural dialogue.

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CULTURAL/COUNTRY CONTEXT

Cross-Cultural and Religious Critiques of Informed Consent [BOOK]

Joseph Tham, Alberto García Gómez, Mirko Daniel Garasic

Routledge, 29 November 2021

Open Access

Summary

This book explores the challenges of informed consent in medical intervention and research ethics, considering the global reality of multiculturalism and religious diversity. Even though informed consent is a gold standard in research ethics, its theoretical foundation is based on the conception of individual subjects making autonomous decisions. There is a need to reconsider autonomy as relational—where family members, community and religious leaders can play an important part in the consent process. The volume re-evaluates informed consent in multicultural contexts and features perspectives from Buddhism, Confucianism, Hinduism, Christianity, Judaism and Islam. It is valuable reading for scholars interested in

bioethics, healthcare ethics, research ethics, comparative religions, theology, human rights, law and sociology.

Exception from Informed Consent for Biomedical Research in Emergency Settings: A Study from Jordan

Samah F. Al-Shatnawi, Karem H. Alzoubi, Rawand A. Khasawneh, Omar F. Khabour, Basima A. Almomani
Heliyon, 23 November 2021
Open Access
Abstract
Background
Research conduction in emergency settings is of paramount importance to promote knowledge and experiences related to treating acutely ill patients. However, the complexity of situations creates a considerable ethical challenge facing researchers who basically deal with emergent cases. This study aimed to determine attitudes of healthcare providers (HCPs) towards exception from informed consent (EFIC) and enrollment willingness in emergency research in Jordan.
Methods
A quantitative research with face-to-face questionnaire was conducted by an interviewer during 6-month period in 2019. Survey measures included items related to EFIC policy and overall willingness of HCPs to participate or support their family members' participation in emergency research.
Results
A total of 151 HCPs in the emergency departments (EDs) in Jordan was recruited. Positive attitude toward emergency research dominated among participants; about 21.9% of participants reported previous experience in the conduction of emergency research and 12.3% had related publications. Regarding EFIC policy, there was a general consensus of disagreement to most of the examined items. There was a trend to lower support of EFIC policy when questioned about the enrollment of family members or public in emergency research, however, the application of EFIC was accepted for self-enrollment of respondents in emergency research. No significant differences (P = 0.37), among participants from different disciplines, were reported regarding the attitudes towards EFIC items or willingness to enroll in emergency research.
Conclusions
Generally, HCPs reported an overall positive support to emergency research despite a consensus of disagreement related to EFIC terms. Therefore, it is recommended to pursue future studies to compare well informed subjects; recruited from well-developed institutions in regard to emergency research potentials; with the present basic attitudinal surveillance in order to dissipate the effect of such confounder and to get better insight of the actual attitudes related to emergency research and EFIC. In addition, efficient multidisciplinary communication channels between researchers and policy makers can lather the way to collaborative research with simultaneous innovative delivery of quality emergency care.

An Approach to Reviewing Local Context for Exception from Informed Consent Trials Using a Single IRB

Ann R. Johnson, Lisa M. Rigtrup, John VanBuren, Erin Rothwell, J. Michael Dean
Ethics & Human Research, 9 November 2021
Abstract
In the context of emergency research, researchers can ask the institutional review board (IRB) to waive the regulatory requirement that individuals provide informed consent when enrolling in research studies. A requirement of the waiver of informed consent is that the reviewing IRB must review and approve a community consultation and public disclosure plan. It is critical that an IRB serving as the single IRB (sIRB) for multisite research be thoroughly versed in the local context concerns for each participating site to determine whether the site's community is being adequately consulted about the research in which individuals will be enrolled under an exception to the informed consent requirement. We designed an sIRB review model for

evaluating site-specific community consultation plans that included a local evaluation and feedback step, and we piloted the model with a four-site, pediatric exception from informed consent (EFIC) clinical trial. We identified three key roles for the model: the sIRB, the investigators, and the representative of the institution's human research protection program (HRPP). We successfully collected the information and local input needed to evaluate each site's community consultation plan and applied the information to a thorough IRB review, despite the geographic distance between the study site and the sIRB.

Consent to minimally invasive tissue sampling procedures in children in Mozambique: A mixed-methods study

Research Article

Khátia Munguambe, Maria Maixenchs, Rui Anselmo, John Blevins, Jaume Ordi, Inácio Mandomando, Robert F. Breiman, Quique Bassat, Clara Menéndez

PLoS One, 8 November 2021

Open Access

Abstract

Background

Minimally invasive tissue sampling (MITS), also named minimally invasive autopsy is a post-mortem method shown to be an acceptable proxy of the complete diagnostic autopsy. MITS improves the knowledge of causes of death (CoD) in resource-limited settings. Its implementation requires understanding the components of acceptability, including facilitators and barriers in real-case scenarios.

Methods

We undertook a mixed-methods analysis comparing anticipated (hypothetical scenario) and experienced (real-case scenario) acceptability of MITS among relatives of deceased children in Mozambique. Anticipated acceptability information was obtained from 15 interviews with relatives of deceased children. The interview focus was on whether and why they would allow the procedure on their dead child in a hypothetical scenario. Experienced acceptability data were obtained from outcomes of consent requested to relatives of 114 deceased children during MITS implementation, recorded through observations, clinical records abstraction and follow-up informal conversations with health care professionals and semi-structured interviews with relatives.

Results

Ninety-three percent of relatives indicated that they would hypothetically accept MITS on their deceased child. A key reason was knowing the CoD to take preventive actions; whereas the need to conform with the norm of immediate child burial, the secrecy of perinatal deaths, the decision-making complexity, the misalignment between MITS' purpose and traditional values, lack of a credible reason to investigate CoD, and the impotency to resuscitate the deceased were identified as potential points of hesitancy for acceptance. The only refusing respondent linked MITS to a perception that sharing results would constitute a breach of confidentiality and the lack of value attached to CoD determination. Experienced acceptability revealed four different components: actual acceptance, health professionals' hesitancy, relatives' hesitancy and actual refusal, which resulted in 82% of approached relatives to agree with MITS and 79% of cases to undergo MITS. Barriers to acceptability included, among others, health professionals' and facilities' unpreparedness to perform MITS, the threat of not burying the child immediately, financial burden of delays, decision-making complexities and misalignment of MITS' objectives with family values.

Conclusions

MITS showed high anticipated and experienced acceptability driven by the opportunity to prevent further deaths. Anticipated acceptability identified secrecy, confidentiality and complex decision-making processes as barriers, while experienced acceptability revealed family- and health facility-level logistics and practical aspects as barriers. Health-system and logistical impediments must also be considered before MITS implementation. Additionally, the multiple components of acceptability must be taken into account to make it more consistent and transferrable.

Perceptions of Singaporeans towards informed consent: a cross-sectional survey

Mehek Gupta, Sudharsan Madhavan, Felicia Siok Ying Teo, Jee Keem Low, Vishal G Shelat

Singapore Medical Journal, 31 October 2021

Abstract

Introduction

In a patient-centric health system, it is essential to know patients' views about informed consent. The objective of this study was to understand the perceptions of the local population regarding informed consent.

Methods

Spanning across six weeks from January 2016 to March 2016, a cross-sectional survey of adults attending General Surgery outpatient clinics at Tan Tock Seng Hospital was performed. Sociodemographic data, lifestyle and health-related information, perception and purpose of consent forms, and decision-making preferences were studied.

Results

445 adults participated in the survey. Most participants were below 40 years old (n = 265, 60.1%), female (n = 309, 70.1%) and degree holders (n = 196, 44.4%). 56.9% of participants wanted to know every possible risk, while 28.3% wanted to know common and serious risks. On multivariate analysis, age (age 61-74 years: odds ratio [OR] 11.1, 95% confidence interval [CI] 2.2-56.1, p = 0.004; age > 75 years: OR 22.2, 95% CI 1.8-279.1, p = 0.017) was a predictor of not wanting to know any risks. Age also predicted risk of disclosure for death (age 61-74 years: OR 13.4, 95% CI 4.2-42.6, p < 0.001; age > 75 years: OR 32.0, 95% CI 4.5-228.0, p = 0.001). Most participants (48.1%) preferred making shared decisions with doctors, and an important predictor was employment status (OR = 4.8, 95% CI 1.9-12.2, p = 0.001).

Conclusion

Sociodemographic factors and educational level influence decision-making, and therefore, the informed consent process should be tailored for each patient.

Compliance with the Informed Consent to Blood Transfusion: Constraints and Physic for the Developing Africa

Joseph Aondowase Orkuma, George N. Ayia, Mernan Roselynda Ikwue, Joseph Ojobi, Gomerep Samuel Simji

Asian Journal of Medicine and Health, 9 July 2021; 19(7) pp 78-91

Abstract

The informed consent to blood transfusion is a patient centered care where the health care provider is ethically obliged and legally compelled to disclose the details, alternatives and consequences of a procedure such as blood donation or transfusion and obtain from the patient a prior consent before it is carried out. However, this newly evolving practice is largely constrained in many developing countries of Africa and this study sought to identify constraints and advance remedies. Literature search on PubMed, PubMed Central, Google Scholar, and African Journal on Line (AJOL) as well as print material literatures where applicable was used to retrieve 66 publications whose contents met the criteria for inclusion into the study. Constraints range from nondisclosure or defective disclosure, knowledge gaps of health care providers and non-comprehension of consent-based information by patients, illiteracy, religious and cultural practices, poor funding and administrative bottlenecks like non provision of consent forms or consent-based information materials as well as weak structures of effective oversight for compliance of health institutions by governmental regulating agencies. Physic like deployment of contentious professional development (CPD) activities for different professionals, focused training on consent-related guidelines, public awareness and education on prevailing social, religious and cultural impediments, research and localization of institution specific challenges. Additionally, proactive economic policies like the deployment of insurance indemnity covers for healthcare workers with negligent liabilities in order to dissuade health care providers from practicing defensive medicine which is inimical to quality health care delivery. There is a need for more

researches on constraints prevalent in each developing country in Africa for a more appreciable advancement of the practice.

Editor's note: We recognize some of the variable sentence structure in the abstract above.

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MEDICAL/SURGICAL

The Urine Drug Screen in the Emergency Department: Overuse, Technical Pitfalls, and a Call for Informed Consent

Megan Yu, Charles Desmond Donohoe

International Journal of Health Systems and Translational Medicine, 2022

Abstract

Urine drug screens (UDSs) are often performed in the emergency department (ED) as part of a standard ED order set in patients with significant altered mental status, trauma, or seizures usually without the patient's knowledge or specified informed consent. In the ED the UDS has been included in the standard consent to treatment for routine testing along with blood studies, EKG, urinalysis and radiology. Many technical factors are known to effect UDS results.There is a lack of education among physicians regarding the clinical pitfalls of UDS interpretation. This article discusses the current state and issues associated with the UDS, and presents three clinical vignettes that illustrate the impact of false-positive UDS results on patient care and the potential for a patient becoming unknowingly and unfairly stigmatized. The article also offers suggestions including a requirement for either formal informed consent or an "opt out" screening process, as recommended by the CDC in HIV testing, designed to protect patient autonomy and confidentiality.

Problems between the theory and practice of informed consent in Dentistry in South America

Investigation Article

Paola Luciani Reynoso, Aldo Calzolari

Vital Dentistry, December 2021

Summary

Introduction

Ethical and legal aspects play a preponderant role in the dentist-patient relationship.

Aim

Analyze the relevant criteria necessary for informed consent in dentistry and evaluate its incorporation into models in use by professionals.

Methods

81 theoretical documents and informed consent models from South American countries were analyzed, extracted from the Internet, in a selection for convenience. The theoretical data were contrasted with the models applied in professional practice. After cleaning the 81 materials found to eliminate theoretical documents with very similar texts, 17 theoretical documents and 12 models of informed consent remained.

Results

The 17 documents coincide in pointing to 10 criteria as the most relevant. On the contrary, none of the 12 models contemplate these 10 criteria. Seven of the informed consent models contained 6 or fewer relevant criteria, while some only contemplated 4, those referring to basic patient identification data, treatment, and understanding of what they were signing.

Conclusion

There is a lack of relationship between the relevant theoretical criteria accepted as important for informed consent in Dentistry and the models in use by professionals.

Assessment of Informed Consent and the Impact of Simulation on Anesthesia Trainees

Original Article

Muhammad Adeel Bashir, Asma A. Khan, Sanaa A. Khan

Cureus, 21 November 2021

Abstract

Introduction

Over the years, the process of obtaining informed consent has evolved and now places an emphasis on the concept that patients should play a major role in medical decision making. Failure to adequately involve patients in making decisions regarding their health can lead to medicolegal consequences. Therefore, taking informed consent is a fundamental component of anaesthesia training. Simulation, for training, is an excellent tool that is being utilised widely in the training of medical professionals. The use of simulated training for teaching the process of informed consent is an innovative initiative that can provide improved results.

Material and methods

After approval from the institutional review board, a prospective clinical study was conducted at Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore, from August 2019 to September 2020. Sixteen anaesthesia trainees were randomly selected for the study. The study was divided into pre-interventional, interventional and post interventional phases. For data collection, a predesigned checklist was used. Data collected was analysed using SPSS version 23 (IBM Inc., Armonk, New York). The McNemar test was deployed to assess the difference between the baseline assessment and post-simulated training assessment; p-value < 0.05 was taken to be significant.

Results

Of the 16 participants, the majority were males (n= 13). A positive impact was observed in terms of improvement of the outcome of the following study components i.e., description of benefits of the procedure (p=0.01), disclosure of associated minor risks (p=0.005), disclosure of major risks (p=0.01), discussion of alternatives (p=0.001), teach back (p=0.001), documentation of patients' verbal agreement (p=0.01), and communication skills involving utilising the process of connecting, introduction, communication, permission, response, and exit (p = 0.01).

Conclusion

Simulated training had a positive impact in improving outcomes in the following study components: description of benefits of the procedure, disclosure of associated risks, discussion of alternatives, teach back, documentation of patients' verbal agreement, and utilisation of the process of connecting, introduction, communication, permission, responding, and exiting.

Patient and proxies' attitudes towards deferred consent in randomised trials of acute treatment for stroke: A qualitative survey

Research Article

Noa van den Bos, Sophie A van den Berg, Catalina MM Caupain, Jeannette AJ Pols, Tessa van Middelaar, Vicky Chalos, Diederik WJ Dippel, Yvo BWEM Roos, Manon Kappelhof, Paul J Nederkoorn

European Stroke Journal, 13 November 2021

Open Access

Abstract

Introduction

Deferral of consent for participation in a clinical study is a relatively novel procedure, in which informed consent is obtained after randomisation and study treatment. Deferred consent can be used in emergency situations, where small therapeutic time windows limit possibilities for patients to provide informed consent. We aimed to investigate patients' or their proxies' experiences and opinions regarding deferred consent in acute stroke randomised trials.

Patients and methods

For this qualitative study, Dutch Collaboration for New Treatments of Acute Stroke (CONTRAST) trial participants were selected. Study participants were either patients or their proxies who provided consent and were selected with theoretical sampling based on patient characteristics. Semi-structured interviews were conducted face-to-face or by telephone. Themes and subthemes were iteratively defined.

Results

Twenty of the 23 interviewed participants (16 patients and 7 proxies) considered deferred consent acceptable. The received study treatment and consent conversation were remembered by 18 participations, although the concept of randomisation and treatment comparison were generally not well understood. Sixteen participants felt capable of overseeing the decision to give deferred consent. Distress in the first days after stroke, lack of understanding and neurological deficits were reasons for feeling incapable of providing consent. Four participants would have preferred a different timing of the consent conversation, of whom two prior to treatment.

Conclusion

Our study found that deferred consent was considered acceptable by most study participants who provided consent for acute stroke randomised trials. Though they felt capable, the recall and comprehension of consent were overall limited.

Informed Written Consent for Orthopaedic Trauma in the Emergency Setting at a Tertiary Referral Centre: A Closed-Loop Audit

Original Article

Martin S. Davey, Matthew G. Davey, Kunal Mohan, Conor S. O'Driscoll, Colin G. Murphy

Cureus, 11 November 2021; 13(11)

Abstract

Introduction

The purpose of this investigation was to perform an audit of the standards of consent forms in which patients sign prior to operative intervention for orthopaedic trauma in an emergency setting in our institution, with comparison to the 'Orthopaedic Surgical Consent' standards, as set by the American Association of Orthopaedic Surgeons (AAOS). If required, the investigator aimed to close the loop in this audit by educating orthopaedic surgeons on the necessary standards of obtaining written consent for orthopaedic trauma.

Methods

Following being granted approval by our institutional audit committee, a pre-intervention cycle was performed to assess the quality of consent obtained in written format using electronic patient records in consecutive patients over a four-week period. Following the analysis of this data, an education session was provided for all orthopaedic doctors responsible for obtaining informed written consent from patients who are planned to undergo operative management of a soft tissue or bony injury by the trauma and orthopaedic service in the emergency setting. Thereafter, a post-intervention cycle was performed with subsequent descriptive analysis using the GraphPad software.

Results

In the pre-intervention audit cycle, all included (n = 107) consent forms (100%) correctly included the patient's name, date of birth (DOB) and institutional board number (BN). However, only 79 consent forms (74.5%) were completed without using abbreviations or acronyms of any kind, whilst 81 consent forms (76.4%) were completed without correctly stating the side or site of the planned intervention. In the post-intervention cycle, all included (n = 40) consent forms (100%) correctly included the patient's name, DOB and institutional BN. Additionally, a total of 37 consent forms (92.5%) were correctly completed without using abbreviations or acronyms of any kind (74.5% versus 92.5%, p = 0.02). Furthermore, a total of 39 consent forms (97.5%) were completed correctly stating the side or site of the planned intervention (76.4% versus 97.5%, p = 0.0015).

Conclusion

This closed-loop audit found that the quality of informed consent obtained by orthopaedic surgeons in the emergency setting might potentially be significantly improved with at least one virtual education session.

Such simple education sessions may potentially improve the documentation of the planned potential operative intervention by orthopaedic surgeons for cases of orthopaedic trauma to ensure patient safety is optimised. As the turnover of non-consultant hospital doctors is high in university teaching hospitals, regular education sessions on such topics may introduce a cultural shift in maintaining high standards when marking and consenting patients in the emergency setting.

Implicit Surgeon Perceptions of Patient Personas: a Framework for Surgical Informed Consent Design

Jasmine Panton, Jayson S. Marwaha, Gabriel Brat

Journal of the American College of Surgeons, 1 November 2021; 233(5)

Open Access

Abstract

Introduction

Surgeons communicate risk with patients in different ways based on patient and contextual factors. To optimize risk communication for surgeons, there has to be a detailed understanding of how surgeons think about using risk in preoperative conversations with patients. In this study, we sought to identify personas leveraged by surgeons to facilitate risk communication during informed consent.

Methods

We conducted interviews with 13 surgeons regarding strategies for discussing patient-specific risk, and completed a narrative review on risk communication across surgical contexts. With these data, we created a framework to characterize the implicit patient personas used by surgeons during informed consent to appropriately communicate risk.

Results

In our analysis, we identified 7 key elements implicitly evaluated by surgeons during preoperative consent. These included the patients' health profile, acuity of illness, health literacy, perception of and receptiveness to risk, clinical and procedural context, and encounter scenario. By accounting for these, we found that additional outputs beyond perioperative complications, such as postoperative quality-of-life complications and pain, are needed to provide personalized risk to lower acuity patients.

Conclusion

Understanding the implicit heuristic used by surgeons during informed consent has the potential to significantly inform efforts to improve preoperative consent. Tools using risk data to facilitate shared decision-making may benefit from patient personas to improve generalizability across patient populations. Because surgeons' communication strategies and priorities are driven by key components of the patient's persona, next-generation shared decision-making tools should use personas to optimize surgeon risk communication in the context of patient needs.

Please Sign Here: Evaluating Differences Between Resident and Attending Informed Consent for Cholecystectomy

Kathleen E. Singer, Jennifer E. Baker, Nora C. Elson, Taylor E. Wallen, Ann E. Salvator, Ralph Quillin, Jeffrey J. Sussman, Amy T. Makley, Michael D. Goodman

Journal of the American College of Surgeons, 1 November 2021; 233(5)

Open Access

Abstract

Introduction

There is considerable variability in surgeons' approach to write and obtain informed consent for surgery, particularly among resident trainees. We analyzed differences in procedures and complications described in surgical consents for cholecystectomy between residents and attendings. We hypothesized that attending consents would list more comprehensive procedures and complications than those done by residents.

Methods

A retrospective analysis of 334 patients who underwent cholecystectomy at an academic tertiary care center was conducted. Charts were queried for demographics, surgical approach, whether the consent was completed electronically, and which provider completed the consent. Specifically, consents were evaluated for inclusion of possible conversion to open procedure, intraoperative cholangiogram, bile duct injury, injury to nearby structures, reoperation, bile leak, as well as if the consent matched the actual procedure performed.

Results

Of all consents analyzed, 46% included possible intraoperative cholangiogram, 47% included bile duct injury, 24% included injury to nearby structures, 7% included reoperation, and 20% included bile leak. In comparing residents and attendings, residents were more likely to consent for more possible complications and additional procedures, except for possible conversion to open and consenting for the complete procedure (Table 1). Junior residents were more likely than senior residents to include injury to nearby structures but senior residents were more likely to include reoperation.

Conclusion

Significant variation exists between resident and attending cholecystectomy consents, with residents including more complications than attendings on their consent forms. These data suggest that experience alone does not predict content of written consents, particularly for common ambulatory procedures.

Breast Core Biopsy Information and Consent: Do we Prepare or do we Scare?

Research Article

Jennifer Pollard, Heather Rose, Russell Mullen, Nick Abbott

Journal of Patient Experience, 28 October 2021

Open Access

Abstract

Informed consent has important ethical considerations for invasive procedures. Anecdotal evidence suggests an informed consent policy could heighten anxiety. We evaluated whether detailed information about breast biopsy prior to appointment negatively impacted patient experiences. Phase 1 surveyed patients receiving a standard appointment letter who underwent core biopsy (group A). Phase 2 surveyed two groups receiving standard letter plus biopsy leaflets: those who underwent core biopsy (group B) and those who did not (group C). The analysis included descriptive statistics and qualitative thematic analysis. Hundred percent of group A felt they were given enough information prior to biopsy and 72% felt it would not be helpful having information to read in the clinic beforehand. Hundred percent of group B and 94.1% of group C found it helpful to receive information with their letter. Common themes were good service, verbal explanation, and appreciation of written information. Despite concerns that too much information would heighten anxiety, this has not resulted in negative clinic experiences. Most patients found detailed information included with their appointment letter helpful, regardless of whether they had a biopsy or not.

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GENERAL/OTHER

Applying utilitarianism to the presumed consent system for organ donation to consider the moral pros and cons

Jelena Morris, Janet Holt

British Journal of Nursing, 1 November 2021; 30(19)

Abstract

In May 2020, England adopted an opt-out approach for organ donation, also referred to as the deemed consent system, with the aim of alleviating the demand for organs in the UK. This system dictates that those

who have not opted out will have their organs donated following their death, with the exception of those meeting certain criteria. This article applies the philosophical theory of utilitarianism to the deemed consent system for organ donation, focusing particularly on topics such as that of informed consent and family refusal. Utilitarianism is a consequentialist theory that attempts to determine whether an action is morally right or wrong based on whether or not it maximises the preferences of the greatest number of people, with each person's satisfaction being considered as equal to another's.

Respondent understanding of data linkage consent

Joseph Sakshaug, Alexandra Schmucker, Frauke Kreuter, Mick P Couper, Leonie Holtmann

JournalSurvey Methods: Insights from the Field, 1 October 2021

Abstract

Across survey organizations around the world, there is increasing pressure to augment survey data with administrative data. In many settings, obtaining informed consent from respondents is required before administrative data can be linked. A key question is whether respondents understand the linkage consent request and if consent is correlated with respondent understanding. In the present study, we investigate these issues in separate telephone and Web surveys, where respondents were presented with follow-up knowledge questions to assess their understanding of the linkage consent request. Overall, we find that understanding of the linkage request is relatively high among respondents who consent to linkage and rather poor among those who do not consent, with some variation in the understanding of specific aspects of the linkage request, including data protection. Additional correlates of understanding were also identified, including demographic characteristics, privacy attitudes, and the framing and placement of the linkage consent questions. Practical implications of these results are provided along with suggestions for future research.

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