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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

July 2023 :: Issue 55

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.

In preparing this digest, we monitor *Google Scholar* using the search terms "consent", "informed consent", and "assent" in title and available text. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic 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 this digest using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. We lead each edition with a spotlight section highlighting articles which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
GENOMIC MEDICINE/GENE EDITING
HUMANITARIAN CONTEXT
POLICY/GUIDANCE/CODES/PROGRAM ACTION

Please note that while we strive to identify the primary subject area for the categorization of the monthly digest we also recognize that many articles are relevant across other subject areas. We encourage readers to review the entire digest and to utilize the search function on our website where articles are cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the website.

SPOTLIGHT ARTICLES

This month our spotlight section focuses on strategies to strengthen informed consent for persons with disabilities. The first article is by Boie et al., publishing in *Investigative Ophthalmology & Visual Science* – **Adaptations to the administration of informed consent when conducting research with older adults that are deafblind. The authors** investigate ways that new technologies can be used to overcome barriers faced by people living with "deafblindness". They propose easy-to-implement adaptations of IC content to alternative and adapted formats for the administration of informed consent/assent helping protect patient autonomy and dignity, as well as confidentiality.

ASL Consent in the Digital Informed Consent Process by Kosa et al., appears in the *Journal on Technology & Persons with Disabilities.* In this article, the authors propose to use machine learning technologies in an app which enables consent transactions via American Sign Language. This innovation – which they coin as "ASL consent" – helps to overcome existing text/spoken language barriers to help reach patient populations who may be otherwise excluded from research.

Adaptations to the administration of informed consent when conducting research with older adults that are deafblind

Norman Robert Boie, Atul Jaiswal, Walter Wittich

Investigative Ophthalmology & Visual Science, June 2023

Abstract

Purpose

Multiple access barriers exist for persons with deafblindness that want to participate in research. The process of informed written consent is not easily accessible for persons with deafblindness, and its administration is often regulated by institutional review boards that have little or no experience accommodating this process. The purpose of this study was to explore alternative and adapted formats for the administration of informed consent/assent in research with older adults living with reduced or absent functional vision and hearing.

Methods

Within the context of a larger project on deafblindness and health service access during the COVID-19 pandemic, we recruited 32 persons (Age 59 to 91, M = 77) with deafblindness, through rehabilitation centres in Canada. The research assistant systematically tracked communication formats and accessibility requirements and coordinated with the rehabilitation centres to adjust the consent process according to the requirements and preferences of each participant. He took systematic field notes and compiled all adaptations, which were later analyzed using qualitative description.

Results
We converted our approved consent text into free-format electronic versions or paper-format without logos, line boxes, or bullet points, to facilitate easy access through scanners or screen readers. For participants who communicated through interpreters, we adapted the process to make interpretation into sign language easier. Verbal consent could be recorded for individuals where paper signatures posed a barrier. For the administration of demographic questionnaires, we eliminated check boxes and accepted verbal or signed response formats that could be more easily recorded. The main outcome of these adaptations was to allow our research participants with deafblindness to access and complete their informed consent process as independently as possible. Not only did these adaptations protect confidentiality and dignity, but their implementation facilitated the subsequent qualitative interviews in the most autonomous way possible.
Conclusions
These adaptations contributed to the experience of our participants and increased the capacity of our team by developing skills centered around flexibility, patience, respect and trust. This improved communication and empathy, while facilitating equity, diversity and inclusion in research through accessibility.

ASL Consent in the Digital Informed Consent Process

Ben S. Kosa, Ai Minakawa, Patrick Boudreault, Christian Vogler, Poorna Kushalnagar, Raja Kushalnagar
Journal on Technology & Persons with Disabilities, 2023
Abstract
There is an estimated 500,000 people in the U.S. who are deaf and who use ASL and live in the U.S. Compared to the general population, deaf people are at greater risk of having chronic health problems and experience significant health disparities and inequities (Sanfacon, Leffers, Miller, Stabbe, DeWindt, Wagner, & Kushalnagar, 2020; Kushalnagar, Reesman, Holcomb, & Ryan, 2019; Kushalnagar & Miller, 2019). Much of the disparities are explained by the barriers in the environment, such as the unavailability of materials in ASL and lack of healthcare professionals who know how to provide deaf patient-centered care. Intersecting social determinants of health (e.g., intrinsic - low education; and extrinsic - barrier to healthcare services) create a mutually constituted vulnerability for healthdisparities when a person is deaf (Kushalnagar & Miller, 2019; Lesch, Brucher, Chapple, R., & Chapple, K., 2019; Smith & Chin, 2012). Moreover, the longstanding history of inequitable access to language and education, and a lack of printed information and materials, leave people who are deaf and use ASL unaware of opportunities to participate in cutting-edge research/clinical trials. An unintended consequence, therefore, is that PIs neglect to include people who are deaf and use ASL in their subject sample pools, and this marginalized population continues to be at disparity for health outcomes and also clinical research participation. One barrier is the unavailability of informed consent materials that are accessible in ASL. The current research study conducted by our team at the Center for Deaf Health Equity at Gallaudet University attempts to address the language barrier to the consent process through a careful reconsideration of its traditional English format and the development of an American Sign Language (ASL) informed consent app. This team successfully leveraged existing machine learning methods to develop a way to navigate and signature an informed consent process using ASL. We call this new method of navigation and signature "ASL consent." In our findings, we found that deaf people who are primarily college educated were more likely to agree that the process for obtaining ASL consent through an accessible app is comparable to traditional English consent.

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BIOMEDICAL RESEARCH

Informed consent practices in clinical research: present and future

Natasha A Jawa, J Gordon Boyd, David M Maslove, Stephen H Scott, Samuel A Silver
Postgraduate Medical Journal, 2 June 2023

Abstract
Clinical research must balance the need for ambitious recruitment with protecting participants' autonomy; a requirement of which is informed consent. Despite efforts to improve the informed consent process, participants are seldom provided sufficient information regarding research, hindering their ability to make informed decisions. These issues are particularly pervasive among patients experiencing acute illness or neurological impairment, both of which may impede their capacity to provide consent. There is a critical need to understand the components, requirements, and methods of obtaining true informed consent to achieve the vast numbers required for meaningful research. This paper provides a comprehensive review of the tenets underlying informed consent in research, including the assessment of capacity to consent, considerations for patients unable to consent, when to seek consent from substitute decision-makers, and consent under special circumstances. Various methods for obtaining informed consent are addressed, along with strategies for balancing recruitment and consent.

Trusting relationships between patients with non-curative cancer and healthcare professionals create ethical obstacles for informed consent in clinical trials: a grounded theory study

Mary Murphy, Eilis McCaughan, Gareth Thompson, Matthew A. Carson, Jeffrey R Hanna, Monica Donovan, Richard Wilson, Donna Fitzsimons

BMC Palliative Care, 21 June 2023

Abstract
Background
Clinical trial participation for patients with non-curative cancer is unlikely to present personal clinical benefit, which raises the bar for informed consent. Previous work demonstrates that decisions by patients in this setting are made within a 'trusting relationship' with healthcare professionals. The current study aimed to further illuminate the nuances of this relationship from both the patients' and healthcare professionals' perspectives.
Methods
Face-to-face interviews using a grounded theory approach were conducted at a regional Cancer Centre in the United Kingdom. Interviews were performed with 34 participants (patients with non-curative cancer, number (n) = 16; healthcare professionals involved in the consent process, n = 18). Data analysis was performed after each interview using open, selective, and theoretical coding.
Results
The 'Trusting relationship' with healthcare professionals underpinned patient motivation to participate, with many patients 'feeling lucky' and articulating an unrealistic hope that a clinical trial could provide a cure. Patients adopted the attitude of 'What the doctor thinks is best' and placed significant trust in healthcare professionals, focusing on mainly positive aspects of the information provided. Healthcare professionals recognised that trial information was not received neutrally by patients, with some expressing concerns that patients would consent to 'please' them. This raises the question: Within the trusting relationship between patients and healthcare professionals, 'Is it possible to provide balanced information?'. The theoretical model identified in this study is central to understanding how the trusting professional-patient relationship influences the decision-making process.
Conclusion
The significant trust placed on healthcare professionals by patients presented an obstacle to delivering balanced trial information, with patients sometimes participating to please the 'experts'. In this high-stakes scenario, it may be pertinent to consider strategies, such as separation of the clinician-researcher roles and enabling patients to articulate their care priorities and preferences within the informed consent process. Further research is needed to expand on these ethical conundrums and ensure patient choice and autonomy in trial participation are prioritised, particularly when the patient's life is limited.

Xenotransplantation and Informed Consent

Book Chapter

Daniel J. Hurst

Xenotransplantation, 22 June 2023 [Springer]

Abstract

Xenotransplantation (XTx; particularly, pig-to-human transplant) clinical trials of solid organs are likely on the horizon. There is a rich literature noting ethical issues that are particular to XTx clinical trials. Because of these ethical particularities and peculiarities, the informed consent process for XTx has been seen by some commentators as a very challenging endeavor. While organ transplant appears to be on the verge of a wave of XTx clinical trials, it can be surprising that more recent standardized guidance on proper informed consent for these trials is largely missing from the literature. This chapter provides an overview of where the major debates in XTx informed consent lay and attempts to provide some clarity for a way forward.

Who owns your consent? How REBs give away participants' agency

Janice Aurini, Vanessa Iafolla

Research Ethics, 14 June 2023

Abstract

We draw on three illustrative vignettes to examine how REBs manage participants' agency in the context of qualitative research. We ask: Who owns a participant's consent? Central to informed consent is the principle of Respect for Persons, which privileges the autonomy of individuals to make decisions about what happens (or not) to them. Yet, REBs sometimes require researchers to get permission from organizations to conduct research on their current and former members, even when the research is not about those organizations. Our aim is to raise awareness about the inherent contradictions of this practice and to consider guidelines for determining the appropriateness of involving organizations that may be tangentially connected to the research objectives or potential participants.

Editor's note: REB in the abstract above refers to a research ethics board.

Reshaping consent so we might improve participant choice (II) – helping people decide

Research Article

Hugh Davies, Rosie Munday, Maeve O'Reilly, Catriona Gilmour Hamilton, Arzhang Ardahan, Simon E Kolstoe, Katie Gillies

Research Ethics, 12 June 2023

Open Access

Abstract

Research consent processes must provide potential participants with the necessary information to help them decide if they wish to join a study. On the Oxford 'A' Research Ethics Committee we've found that current research proposals mostly provide adequate detail (even if not in an easily comprehensible format), but often fail to support decision making, a view supported by published evidence. In a previous paper, we described how consent might be structured, and here we develop the concept of an Information and Decision Aid (IDA) that can support decision making and be used to guide the dialogue between researcher and potential participant. Our proposal requires limited changes to current processes or paperwork and would provide an easily accessible document for others that the potential participant might approach for advice. It could later be integrated with the Informed Consent Form to ensure all matters of concern to the individual participant have been addressed before consent is formally signed off.

Parental perceptions of informed consent in neonatal emergency research

Susanne Tippmann, Janine Schäfer, Christine Arnold, Julia Winter, Norbert Paul, Eva Mildenberger, André Kidszun

Z Geburtshilfe Neonatol, 2023; 227(03)

Abstract

Background and Objective

Obtaining informed consent in neonatal emergency research is challenging. The aim of this study was to assess parental perceptions of informed consent following participation in a clinical trial in neonatal emergency care.

Methods

This was a supplementary analysis of a randomised controlled trial comparing video and direct laryngoscopy for neonatal intubation. After obtaining informed consent for the clinical trial, parents were asked to answer a series of self-administered questions about their perceptions of the consent process. Informed consent had been given either before birth, after birth but before inclusion in the trial, or after inclusion in the trial.

Results

Of the 63 preterm and term infants who participated in the study, we received responses from 33 mothers and 27 fathers (n = 60). Fifty-four (91.5%, n = 59) parents agreed that infants should participate in clinical trials. Fifty-one (85%) parents agreed that parents should be asked for their consent to participate in research studies involving their children. A minority of six (10%) parents would prefer not to be asked to consent to their infant participating in the study. Fifty-three (89.8%, n = 59) parents felt that their infant's participation in this particular trial would be beneficial. Twelve (20%) parents thought that infants who take part in clinical trials generally get better treatment. Almost all parents (56 (93.3%)) felt well informed about the purpose of the trial. Fifty-two (86.7%) parents felt that the informed consent process was satisfactory. One parent (100%, n=1) approached before birth, 23 parents (82.1%, n=28) approached after birth but before enrolment and 26 (83.9%, n=31) parents approached after enrolment were satisfied with the timing of the consent process. Eight (13.3%) parents felt pressured to agree to participate in the study. Of these, two (25%) were approached before enrolment and six (75%) were approached after enrolment. When asked about the best time to discuss consent with parents in clinical trials in neonatal emergency care, 20 (33%) parents said it was before birth, while 40 (67%) parents said it was after birth.

Conclusion

Parents valued their infant's participation in a clinical trial in neonatal emergency care and considered it important to be asked for consent. Timing seemed to be less important. Deferred consent appears to be a feasible approach to obtaining informed consent for clinical trials in neonatal emergency care. However, future studies need to investigate whether parents feel more pressured to give consent in this way.

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SOCIAL SCIENCE RESEARCH

Parents' perceptions of parental consent procedures for social science research in the school context

Thabo J van Woudenberg, Esther Rozendaal, Moniek Buijzen

International Journal of Social Research Methodology, 21 June 2023

Abstract

Typically, parents or other legal guardians are asked for an active declaration that the participation of their child in scientific research is informed and voluntary. However, asking for active parental consent leads to lower quality studies and passive parental consent might be preferable. In this study, we used an online survey in which parents (N = 156) watched video vignettes of multiple types of research in the classroom and asked them to rate the appropriateness of using active and passive parental consent. The results indicated that parents perceived active consent procedures as more appropriate in most types of research. However, particularly for secondary school children passive consent was rated as comparably appropriate for several types of research (e.g. observation and questionnaire studies). Other aspects of providing consent are

displayed in a supplementary online dashboard. We conclude with recommendations for parental consent procedures for social science research in the school context.

Transplant Recipient Preferences Regarding Organ Donor Research: Their Role in Consent and use of Their Data

Research Article

Amanda Lucas, Patricia H. Strachan, Frederick D'Aragon, Aimee J. Sarti, Maureen O. Meade

Journal of Empirical Research on Human Research Ethics, 12 June 2023

Abstract

Research on deceased organ donors has been hindered by concerns related to seeking research consent from transplant recipients. We undertook this qualitative study to elucidate solid organ transplant recipients views on organ donor research, their role in the consent for such research, and their preferences related to providing their data. We conducted interviews with 18 participants and three themes emerged from the data. The first centered around participant research literacy. The second described practical preferences of participating in research, and the third related to the connection between donor and recipient. We concluded that previously held views about the requirement for transplant recipients to have a consenting role in donor research is not always suitable.

Challenges in Obtaining Informed Consent in Qualitative Research and Suggestions to Improve It-A Descriptive Qualitative Study

National Journal of Community Medicine, June 2023; 14(06) pp 386-390

R. Sindhuri, Amol Dongre

Abstract

Introduction

The dynamic and flexible nature of qualitative studies is expected to impose new challenges upon the researchers in obtaining informed consent. The study objectives were to explore the challenges perceived by the researchers in obtaining informed consent in qualitative research and their suggestions to improve it.

Material and Methods

It was a descriptive qualitative study in which In-depth interviews were conducted among ten qualitative researchers purposively selected from one medical college in Puducherry. Transcripts prepared from the audio recordings were thematically analyzed manually.

Results

The challenges identified were inadequate knowledge of the researcher in designing qualitative consent form, reluctance to sign consent document by participant, ensuring confidentiality and risk benefit communication. The main suggestions provided by the participants were to use of multimedia tools to improve their understanding and creating a rapport to enhance their trust to participate in the study.

Conclusions

Since most of the challenges were related to the reluctance of participants to provide consent due to various reasons and lack of adequate knowledge of the researcher, creating a good rapport with the participants and providing simple information through multimedia approaches and ethical training of qualitative researchers will aid us to overcome majority of these challenges.

'It's All Public Anyway': A Collaborative Navigation of Anonymity and Informed Consent in a Study with Identifiable Parent Carers

Pam Joseph

Ethics and Social Welfare, 30 May 2023

Abstract

For qualitative researchers seeking the perspectives of people with unusual characteristics or circumstances, compliance with expectations about participant anonymity can be difficult, if not impossible. In the age of internet communications and emerging research methodologies, traditional strategies require ongoing re-examination to ensure cohesion between a project's ethical framework and its research practice. This paper reflects on the approach to informed consent used in a study with parent carers whose children had high-level support needs. A two-step process of written consent was developed in response to concerns about the possible re-identification of these parents as a result of their highly individual circumstances. This approach acknowledged the potential for identification, and maximised participants' agency in choosing the level of risk that they were comfortable to accommodate. The paper discusses the researcher's and participants' responses to the adapted consent process and recommends that researchers and ethics review committees remain open to the development of collaborative and innovative approaches that are also culturally and contextually relevant, to enable people to contribute perspectives that might otherwise be silenced by the very ethical frameworks that purport to protect their interests.

Get this thing out of my body! Factors determining consent for translational oncology research: a qualitative research

Research

Després Caroline, Mamzer Marie-France

Journal of Translational Medicine volume, 21 May 2023; 21(336)

Open Access

Abstract

Background

Depending on the needs of scientific research at a given time, biobanks make biological samples and data available to researchers. In this article, we aim to describe the reasons and underlying logic that determine the decision to grant or deny consent to the conservation of tumour samples in a biological resource platform for research purposes. We make use of the CARPEM biological resource platform model, where broad consent is required.

Methods

The results are based on semi-structured interviews, conducted between 2019 and 2021, with 25 individuals having various profiles.

Results

All the people interviewed readily accepted the principle of conserving a tumour sample for research purposes. They explained their decision by citing the desire to participate in research dedicated to improving therapeutic medicine. Their trust in research institutions or in doctors was an important factor in their consent. The tumorous nature of the samples also played an important role, as did the absence of constraints. Finally, the high level of consent was also based on the difficulty they had in conceiving what the future risks might be once the sample had been taken, whereas the fact that they did not know the nature or purpose of the research to be carried out when they signed the consent form posed some problems. These results stem from a lack of a culture of ethics among the people interviewed.

Conclusion

The information provided in the context of consent at the CARPEM tumour bank seems inadequate for consent to be considered 'informed', given the low level of knowledge that people have of the risks and issues. Information is missing even though we feel it would not change consent or only marginally. This raises questions, since part of the act of granting consent is based on the implicit trust French people have in the hospital that collects the data and in research practices in general. In the minds of those who participate, transparency is the ground on which trust rests. Lack of transparency could be deleterious for future research practices. However, it is not by striving to improve information leaflets that the consent-related information will improve but, rather, by more effectively helping future patients to assimilate that information.

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COVID-19

COVID-19 Vaccination and the Role of Informed Consent: England as a Case Study

Caterina Milo

European Journal of Health Law, 22 May 2023

Abstract

Informed consent (IC), following the Supreme Court judgment in Montgomery v Lanarkshire Health Board, [2015] UKSC 11, constitutes a key patients' right. There is a vast literature exploring the significance of this right, while an analysis of the role that this has played in England during the COVID-19 vaccine distribution has been under-explored. Using England as a case study, this paper argues that IC has received limited protection in the COVID-19 vaccination context of the adult population, upholding at its best only a minimalistic approach where mere 'consent' has been safeguarded. It suggests that new approaches should be brainstormed so as to more properly safeguard IC in a Montgomery-compliant-approach, namely in a way that enhances patients' autonomy and medical partnership, and also to better prepare and respond to future pandemics.

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CAPACITY TO CONSENT

Psychedelic treatments for mental health conditions pose challenges for informed consent

Comment

Carolina Seybert, Gonçalo Cotovio, Luís Madeira, Miguel Ricou, Ana Matos Pires, Albino J. Oliveira-Maia

Nature Medicine, 14 June 2023

Excerpt

Enhanced informed consent procedures are needed for patients treated with psychedelics such as psilocybin and MDMA, due to effects that include an altered state of consciousness and vulnerability to suggestion.

In past years, clinical trials with psychedelic substances have been conducted to find alternative treatments for hard-to-treat mental health conditions such as treatment-resistant depression1, cancer-related depression and anxiety symptoms2 and post-traumatic stress disorder3. Clinical research has advanced under the regulation of national ethical and medication authorities for clinical trials, much as for any study testing a new intervention. Indeed, recent research on psychedelics has been conducted under the protected conditions of clinical trials, following international guidelines. However, psychedelic treatments present unique ethical and regulatory challenges that may not have been fully addressed within the traditional structures of clinical trial regulation4. These challenges need to be addressed before these substances are approved for use in general clinical practice…

Informed consent and compulsory treatment on individuals with severe eating disorders. A bio-ethical and juridical problem

F. M. Damato, P. Ricci, R. Rinaldi

Clinica Terapeutica, 2023; 174(4) pp 211-215

Abstract

Background

The problem concerning the activation of the measure of Compulsory Health Treatment (CHT) for subjects suffering from Eating Disorders (ED) represents a legal paradox that places health professionals in the position of frequently doubting the real usefulness of the measure within the hospital context. This issue is mainly related to anorexia nervosa, which puts the subject in a higher life-threatening situation than other EDs.

Method and materials

To outline the current state of the art, the most recent national and international scientific publications concerning informed consent and CHT in EDs were searched. In addition, Italian rulings in various degrees of judgement were evaluated with the suggestion of a possible resolution of these issues.

Results

The analysis of the literature showed that although a multitude of psychometric instruments has been created to identify the ability to give informed consent, there are still not all the elements necessary to identify the actual degree of disease awareness of ED subjects. An important factor could be the exploration of the person's interception, which has been seen to be very high in individuals with AN who are known not to experience the sensation of hunger. At present, reviews of the bibliography and judgments have shown that the measurement of CHT remains crucial if it is intended as a lifesaving treatment. However, it is evident that in terms of BMI, CHT is not a definitive intervention and therefore the adoption of this practice is necessary with extreme caution taking into account the person's actual ability to consent.

Conclusions

Future studies will have the task of determining the psychic factors necessary to better understand the state of the person in his or her physical and mental wholeness, giving due weight to these characteristics and orienting knowledge in a practical sense to more profitable direct treatment for individuals with ED.

Editor's note: This is an Italian language publication.

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HEALTH DATA/DATA

Withdrawal of consent for processing personal data in biomedical research

Marcu Florea

International Data Privacy Law, 15 June 2023

Open Access

Excerpt

In the context of biomedical research, consent is both a ground for the lawful processing of personal data and a bioethical requirement for participation in scientific research projects. While the conditions for obtaining valid consent are extensively discussed in legal and bioethical literature, withdrawal of consent has received considerably less attention. According to the EU General Data Protection Regulation (GDPR), that data subjects have the right to withdraw their consent at any time, but the duties of the entities processing personal data are not clearly defined in the text of the Regulation. Pursuant to Article 7 GDPR, withdrawal 'shall not affect the lawfulness of processing based on consent before its withdrawal', but there is no clear specification of the rules governing what happens after this moment…

Obtaining Informed Consent for Future Reuse of Patient Data

Kelly FitzGerald

Applied Clinical Trials, 8 June 2023; 32(6)

Excerpt

…One of the first national policies regarding this was the National Institutes of Health (NIH) Genomic Data Sharing Policy enacted in 2014, which established the expectation of broad and responsible sharing of genomic research data. During the public comment period and subsequent publication of the final policy, the

issue of adequate informed consent for this kind of far-reaching research was raised. This resulted in NIH recommending that investigators seek the broadest consent possible when first obtaining consent from participants. However, NIH recognized that in some cases, limits will still be required, and it allows for use of controlled access databases as a way to mitigate concerns.

The policy requires that participants provide consent for sharing their data, even after it is de-identified, in order for the data to be deposited in an accessible database. The policy also requires that institutions, usually by way of their institutional review boards (IRBs), confirm the data sharing is consistent with the informed consent of study participants, and that consideration was given to the risks to individual participants and their families as well as groups or populations associated with the data…

Massive Omission of Consent (MOOC): Ethical Research in Educational Big Data Studies

Eamon Costello, James Brunton, Richard Bolger, Tiziana Soverino, Clément Juillerac

Online Learning Journal, 1 June 2023

Abstract

Ethical reviews of research plans function as a cornerstone of good research practice in order that no harm should come to participants. Ethical concerns have taken on a new salience in a digital world where data can be generated at scale. Big data research has grown rapidly, raising increased ethical concerns. Several intersecting areas of big data research exist within educational research, such as learning analytics, artificial intelligence (AI), and Massive Open Online Courses (MOOCs). In the current study, an investigation was made of peer-reviewed papers on MOOC teaching and learning to determine if they explicitly refer to (a) ethical considerations in their studies, and (b) obtaining formal ethical approval for their research. This investigation was accomplished through a review of MOOC-related, English-language papers available in Scopus database, over the course of a year. The review produced a total of 1,249 articles, of which, 826 articles related to empirical studies involving human participants where full text of the articles could be obtained. The string "ethic" was searched for within these articles, and resulting articles analyzed, which found that a small fraction, 42 articles (5.08%), mention ethics in relation to the study presented in the article, and only 13 articles (1.57%) explicitly mention obtaining formal ethical approval for the research. The findings show a lack of transparency in reporting on and/or engagement with ethical considerations in MOOC teaching and learning research. These findings indicate the need for further stakeholder engagement and sectoral dialogue in relation to ethics education and training for researchers; consideration of ethics in big data studies in education; and norms/policies in academic publishing for authors to report how ethical issues have been considered.

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YOUNG PERSONS

Consent, assent and randomised evaluations

Discussion

Michael Sanders, Jack Summers, Vanessa Hirneis, Susannah Hume, Gabrielle McGannon

Policy Press, 9 June 2023

Abstract

Background

Randomised trials have been on the rise in social policy over the last decade and a half, particularly in areas working with young people and vulnerable adults. Informed consent is an important principle for ethics committees governing research conducted by universities.

Aims and objectives

We consider the arguments for and against opt-in consent by parents, and opt-out assent, when it comes to trials taking place, particularly in schools.

Methods
We review what is known about this from a methodological standpoint.
Findings
We find that extant evidence suggests that requiring opt-in consent, rather than assent, to participation, risks reducing the ethical standards of trials by minimising participation; and by potentially risking disclosure of sensitive information about a child's life to their parents. Moreover, there are important equity considerations, with more vulnerable groups likely to be excluded from research findings under an opt-in framework.
Discussion and conclusion
We conclude that the ethical argument for assent rather than consent is compelling under some circumstances, and should be considered on a case-by-case basis. Precautions must always be taken to safeguard participants.

Editor's note: Policy Press is a product of Bristol University.

Lowering the age of consent: Legal, ethical, and clinical implications of adolescent-directed therapy

Special Feature
Kathleen McNamara
Family Court Review, 8 June 2023
Abstract
This article discusses a recently enacted Colorado law that aims to reduce the youth suicide rate by lowering the age of consent for psychotherapy from age 15 to age 12. The author discusses the challenges therapists face when young adolescents seek therapy without parental consent in cases involving interparental conflict. Suggestions for managing adolescent-directed therapy are offered.

Consent in minors: the differential treatment of acceptance and refusal. Part 1 Autonomy and children's rights

Tim Hawkins, Martin Curtice, Tom Adams
BJPsych Advances, 5 June 2023
Summary
This is the first of two articles reviewing consent in those under the age of 18 (also referred to as 'minors' in UK law). This can be a complex issue in clinical practice because the law endows competent/capacitated minors with the absolute right to accept treatment, but a limited right to refuse. This first article summarises recent cases of refusal of treatment in minors. It uses them to ask two central questions: how do we, as clinicians, think about autonomous self-determination in minors and to what extent does the rights agenda support minors' autonomous self-determination? Autonomy as one of the principles of biomedical ethics is explored. How the minors' rights agenda supports the development of autonomy is considered. The amount of weight given in the domestic courts to the rights of minors with reference to the Human Rights Act 1998 and the United Nations Convention on the Rights of the Child is described. These considerations demonstrate the way that the courts are giving the views of the minor greater weight in decision-making in keeping with age and maturity. This article introduces the second article, which comprehensively reviews decision-making in minors, explores competence and capacity in minors and examines the differential treatment of acceptance and refusal.

Editor's note: BJPsych Advances distils current, peer-reviewed, clinical knowledge dealing with physical and biological aspects of treatment, psychological and sociological interventions, management issues and treatments specific to the different psychiatric subspecialties.

Consent in minors: the differential treatment of acceptance and refusal. Part 2 Minors' decision-making and the reach of their capacity

Tim Hawkins, Martin Curtice

BJPsych Advances, 5 June 2023

Summary

This is the second of a pair of articles reviewing the topic of consent in minors. Both articles have a particular emphasis, drawing on theory and case law, on the differential treatment of acceptance and refusal in minors. This article considers the concept of capacity in young people (aged 16 and over) and competence in children (under the age of 16) by reviewing underpinning statute and case law with particular reference to England and Wales. This provides a platform for consideration of the reach of capacity in minors with regard to acceptance and refusal of treatment. In doing so the article explores the key, but still elusive, ingredient of maturity, which has significance to the process. Fictitious vignettes allow consideration of the application of the concepts of maturity and autonomy in clinical practice. The article also considers the potential for the UK's Parliament to make changes to current statute regarding consent in minors.

Research ethics committee members' perspectives on paediatric research: a qualitative interview study

Kajsa Norberg Wieslander, Anna T Höglund, Sara Frygner-Holm, Tove Godskesen

Research Ethics, 2023

Abstract

Research ethics committees (RECs) have a crucial role in protecting children in research. However, studies on REC members' perspectives on paediatric research are scarce. We conducted a qualitative study to explore Swedish scientific REC members' perspectives on ethical aspects in applications involving children with severe health conditions. The REC members considered promoting participation, protecting children and regulatory adherence to be central aspects. The results underscored the importance of not neglecting ill children's rights to adapted information and participation. REC members supported a contextual and holistic approach to vulnerability and risk, which considers the child's and parents' psychological wellbeing and the child's integrity, both short and long term. The ethical complexity of paediatric research requires continuous ethical competence development within RECs.

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TECHNOLOGY/OTHER MEDIATION

Applications of Extended Reality (XR) in obtaining informed consent: A narrative review

Research Article

Michelle Lai, Rob (Hongbo) Chen, Andrew Evanyshyn, Zeina Shaltout, Myrtede Alfred

Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care, 7 June 2023

Abstract

Informed consent in healthcare requires patients to have a sufficient understanding of their upcoming procedure before deciding to proceed. Unfortunately, education prior to a surgical procedure is constrained by barriers including poor health literacy, language barriers, one-sided dialogue during consultations, anxiety, and knowledge retention. Extended reality (XR), which includes virtual reality (VR), augmented reality (AR), and mixed reality (MR) has the potential to improve informed consent processes by creating an immersive, interactive, and multimodal sensory experience that supports patient education. The purpose of the study was to review the extant literature on the effectiveness of XR technology in improving patient education, a vital component of informed consent. We screened fifty-two articles and ten relevant papers from PubMed,

Scopus, and Compendex, which were included in the review based on our eligibility criteria. We found that VR and AR proved effective in enhancing patient education in eight studies, and thus improving informed consent processes. MR was not utilized in the studies reviewed. The studies were conducted in several countries and positives findings were reported from a broad range of clinical settings and procedures. Though further investigation is needed, this is a promising finding that may encourage health systems to implement similar interventions prior to procedures. The review also provided an overview of the existing XR technology utilized for patient education such as a downloadable mobile application with a virtual chatbot character, and an environment designed to simulate the MRI patient's perspective. These applications provide immersive and interactive experiences when paired with a head mounted headset such as Google VR Cardboard. The findings also revealed that XR tools are customizable and can be tailored to specific surgical procedures, which makes the potential of implementation applicable to a broader range of settings.

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CULTURAL/COUNTRY CONTEXT

Beyond translations, perspectives for researchers to consider to enhance comprehension during consent processes for health research in sub-saharan Africa: a scoping review

Nkosi Busisiwe, Janet Seeley, Ann Strode, Michael Parker

BMC Medical Ethics, 21 June 2023; 24(1) pp 1-16

Open Access

Abstract

Background

Literature on issues relating to comprehension during the process of obtaining informed consent (IC) has largely focused on the challenges potential participants can face in understanding the IC documents, and the strategies used to enhance comprehension of those documents. In this review, we set out to describe the factors that have an impact on comprehension and the strategies used to enhance the IC process in sub-Saharan African countries.

Methods

From November 2021 to January 2022, we conducted a literature search using a PRISMA tool. We searched electronic databases (PubMed, EMBASE, EBSCOHOST) to identify relevant peer reviewed studies. We then reviewed the references of these articles to find additional literature that might have been missed through the initial search. We were particularly interested in full text articles in English that focused on the IC process in SSA published between 2006 and 2020. We included systematic reviews, and studies from Western and Asian countries that included data about SSA. We excluded articles that focused on medical interventions and studies that did not require IC.

Results

Out of the 50 studies included most were multi-country (n = 13) followed by single country studies in South Africa (n = 12); Kenya, Tanzania, Uganda (n = 5) each; Gambia, Ghana and Nigeria (n = 2)each ; and one each for Botswana, Malawi, Mali, Mozambique. We identified three areas of focus: (1) socio-cultural factors affecting IC; (2) gaps in the ethical and legal frameworks guiding the IC process; and (3) strategies used to improve participants' understanding of IC.

Conclusion

Our review showed wide recognition that the process of achieving IC in SSA is inherently challenging, and there are limitations in the strategies aimed at improving comprehension in IC. We suggest that there is a need for greater flexibility and negotiation with communities to ensure that the approach to IC is suited to the diverse socio-cultural contexts. We propose moving beyond the literal translations and technical language to understanding IC comprehension from the participants' perspectives and the researchers' views, while examining contextual factors that impact the IC process.

A survey on current practice of informed consent process in surgical specialties of a Portuguese tertiary teaching hospital center: What is the state of play?

Original Article

A.L. Vieira, C. Infante, S. Santos, M. Asseiro, C. Ferreira

Ethics, Medicine and Public Health, June 2023

Open Access

Summary

Background

Informed consent is essential in current medical practice and should be a gold standard to be sought in all instances when doctors interact with patients. The aim of this study was to evaluate compliance to the guidelines of the Portuguese health entity regarding the correct filling process of informed consent.

Methodology

An audit was conducted at the operating rooms of a tertiary teaching hospital center in Portugal, in March 2021, in order to verify the presence of informed consent in the clinical file of surgical patients. A representative cohort of 202 clinical files was collected.

Results

An informed consent document was found in only 47% of the clinical files. Merely 21.8% of the informed consent documents included all the items recommended by the guidelines of the Portuguese health entity. Most of these informed consent documents (SIC) included only basic information, with only a small minority including reports about the surgical procedure, information regarding treatment, possible consequences of a missed treatment or complications and possible treatment alternatives. These results do not conform to the standard regulations of the Portuguese health guidelines regarding SIC.

Conclusion

Even though improvements in SIC were attained in recent years, our study suggests that the implementation of SIC is still suboptimal in surgical practice. It is important to raise awareness for the obtention of SIC by the healthcare team, given the ethical importance of such a document in the context of any invasive procedure.

Deception and informed consent in studies with incognito simulated standardized patients: empirical experiences and a case study from South Africa

Original Article

Benjamin Daniels, Jody Boffa, Ada Kwan, Sizulu Moyo

Research Ethics, 22 May 2023

Open Access

Abstract

Simulated standardized patients (SPs) are trained individuals who pose incognito as people seeking treatment in a health care setting. With the method's increasing use and popularity, we propose some standards to adapt the method to contextual considerations of feasibility, and we discuss current issues with the SP method and the experience of consent and ethical research in international SP studies. Since a foundational discussion of the research ethics of the method was published in 2012, a growing number of studies have implemented this method to collect data on the quality of care in a variety of settings around the world. We draw from that experience to provide empirical foundations for a popular approach to ethical approval of such studies in the United States and Canada, which has been to obtain a waiver of informed consent from the health care providers who are the subjects of the research. However, the majority of studies to date have evaluated quality of care outside the U.S., requiring additional ethical consideration when partnering with international institutions. We discuss these considerations in the context of a case study from a completed SP study in South Africa, where informed consent is constitutionally protected.

Consent and refusal of procedures during labour and birth: a survey among 11 418 women in the Netherlands

Original Research

Marit Sophia Gerardina van der Pijl, Margot Klein Essink, Tineke van der Linden, Rachel Verweij, Elselijn Kingma, Martine H Hollander, Ank de Jonge, Corine J Verhoeven

BMJ Quality & Safety, 22 May 2023

Abstract

Background

Informed consent for medical interventions is ethically and legally required; an important aspect of quality and safety in healthcare; and essential to person-centred care. During labour and birth, respecting consent requirements, including respecting refusal, can contribute to a higher sense of choice and control for labouring women. This study examines (1) to what extent and for which procedures during labour and birth women report that consent requirements were not met and/or inadequate information was provided, (2) how frequently women consider consent requirements not being met upsetting and (3) which personal characteristics are associated with the latter.

Methods

A national cross-sectional survey was conducted in the Netherlands among women who gave birth up to 5 years previously. Respondents were recruited through social media with the help of influencers and organisations. The survey focused on 10 common procedures during labour and birth, investigating for each procedure if respondents were offered the procedure, if they consented or refused, if the information provision was sufficient and if they underwent unconsented procedures, whether they found this upsetting.

Results

13 359 women started the survey and 11 418 met the inclusion and exclusion criteria. Consent not asked was most often reported by respondents who underwent postpartum oxytocin (47.5%) and episiotomy (41.7%). Refusal was most often over-ruled when performing augmentation of labour (2.2%) and episiotomy (1.9%). Information provision was reported inadequate more often when consent requirements were not met compared with when they were met. Multiparous women had decreased odds of reporting unmet consent requirements compared with primiparous (adjusted ORs 0.54–0.85). There was considerable variation across procedures in how frequently not meeting consent requirements was considered upsetting.

Conclusions

Consent for performing a procedure is frequently absent in Dutch maternity care. In some instances, procedures were performed in spite of the woman's refusal. More awareness is needed on meeting necessary consent requirements in order to achieve person-centred and high-quality care during labour and birth.

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RIGHTS/LEGAL/LEGISLATIVE

Judging in a Brave New World?: Adjudicating Cases of Parental Refusal on Religious Grounds to Consent to Medical Treatment

Michelle Flynn

Journal of Law, Religion and State, 15 June 2023

Abstract

This article considers case law concerning parental refusal to consent to medical treatment of a child based on religious belief or conscience. The focus of enquiry is on three pivotal decisions of the Irish Superior Courts which will serve to chart the development of judicial reasoning in this contentious area of law. In the last few decades, Ireland has experienced significant changes in its population and attitudes toward religion as a result of increased immigration, multiculturalism, and secularism. This case law analysis reveals that there has been a shift from a test that examines the motivations or reasons for parental decision making to

one that focuses on the effect on the child. This shift in focus raises concern about the extent to which the religious or conscientious objection of a parent concerning a child's medical treatment will be considered in future cases. The present analysis provides an illuminating example of the way in which religion and the state can be in tension with each other.

The Legal History of Informed Consent

Máté Julesz

Journal on European History of Law, 2023; 14(1) p 161-171

Abstract

Human experiments during the national socialist and communist eras remind us that medical research involving human subjects should have legal limitations. Nowadays, in medical malpractice cases, instead of simple medical consent, the informed consent of the patient or a proxy is required to exculpate the health care provider sub judice. The origin of these types of medical consent is discussed with special regard to their development before and during the twentieth century. Simple medical consent appeared in England in the Slater v. Baker and Stapleton case of 1767. The legal history of medical consent dates back to at least the eighteenth century, although informed consent arose as late as in the Nuremberg Code and was literally called "informed consent" in the Salgo v. Leland Stanford Jr University Board of Trustees case of 1957 in the US. Despite the international rules of informed consent in effect in medical research involving human subjects and in health care provision, we still find countries with medico-legal cultures differing from Western norms. For example, the Confucian style of informed consent in China, involving the family's role in granting or declining informed consent, sometimes collides with the expectations of the Food and Drug Administration in the US or those of the European Medicines Agency in the EU. Moving different medico-legal cultures closer to each other should be an important objective of both international lawmakers and national legislators.

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FREE PRIOR INFORMED CONSENT (FPIC)

Canadian experience with Indigenous free, prior and informed consent in resource development

David Bursey, Claire Lingley, Christina Joynt

Australian Environment Review, 1 May 2023

Abstract

This article reviews the Canadian experience with government efforts to reconcile Indigenous and Crown governance rights in resource development decisions. The specific focus of this review is on how the concept of free, prior and informed consent ('FPIC') is working its way from the pages of the 'United Nations Declaration of Rights of Indigenous Peoples' ('UNDRIP') into Canadian law and policy. As explained later, the policy approaches have been incremental, building on Canada's existing Aboriginal rights framework. We also offer perspectives on how those involved in resource development are adapting their approach to relations with local Indigenous communities. To give the discussion context for the Australian reader, we begin with a brief summary of the Canadian legal framework for Indigenous rights, as well as the efforts to implement UNDRIP.

> *Editor's note: The 'United Nations Declaration of Rights of Indigenous Peoples' ('UNDRIP) is available here: https://social.desa.un.org/issues/indigenous-peoples/united-nations-declaration-on-the-rights-of-indigenous-peoples*

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MEDICAL/SURGICAL

Informed consent process for emergency surgery: A scoping review of stakeholders' perspectives, challenges, ethical concepts, and policies

Olivia Kituuka, Ian Guyton Munabi, Erisa Sabakaki Mwaka, Moses Galukande, Michelle Harris, Nelson Sewankambo

SAGE Open Medicine, 16 June 2023

Open Access

Abstract

Background

A scoping review of literature about the informed consent process for emergency surgery from the perspectives of the patients, next of kin, emergency staff, and available guiding policies.

Objectives

To provide an overview of the informed consent process for emergency surgery; the challenges that arise from the perspectives of the patients, emergency staff, and next of kin; policies that guide informed consent for emergency surgery; and to identify any knowledge gaps that could guide further inquiry in this area.

Methods

We searched Google Scholar, PubMed/MEDLINE databases as well as Sheridan Libraries and Welch Medical Library from 1990 to 2021. We included journal articles published in English and excluded non-peer-reviewed journal articles, unpublished manuscripts, and conference abstracts. The themes explored were emergency surgery consent, ethical and theoretical concepts, stakeholders' perceptions, challenges, and policies on emergency surgery. Articles were reviewed by three independent reviewers for relevance.

Results

Of the 65 articles retrieved, 18 articles were included. Of the 18 articles reviewed, 5 addressed emergency informed consent, 9 stakeholders' perspectives, 7 the challenges of emergency informed consent, 3 ethical and theoretical concepts of emergency informed consent, and 3 articles addressed policies of emergency surgery informed consent.

Conclusion

There is poor satisfaction in the informed consent process in emergency surgery. Impaired capacity to consent and limited time are a challenge. Policies recommend that informed consent should not delay life-saving emergency care and patient's best interests must be upheld.

Creation of a risk of harms informed consent form for dry needling: A nominal group technique

Edmund C. Ickert, David Griswold, Ken Learman, Chad Cook

Musculoskeletal Science and Practice, August 2023

Abstract

Background

When consenting patients to dry needling treatment, it is necessary to inform patients of potential risks of harms.

Objectives

The aim of this study was to identify elements and framework for an Informed Consent (IC) risk of harm statement to improve patient decision-making.

Design

A virtual Nominal Group Technique (vNGT) methodology was used to achieve consensus among participants to identify what needs to be on a consent form, how it should be framed, and what it should state so patients understand the true risks.

Methods

Eligible participants were identified as one of four groups: legal expert, policy expert, dry needling expert, or patient. The vNGT session consisted of 5 rounds of idea generation and final consensus voting which lasted for 2 h.

Results

Five individuals consented to participate. Of the 27 original ideas, 22 reached consensus including ones specifically related to a risk of harms statement: identifying risks and discomforts, identify different sensations, and using a classification to order risks by severity. Consensus was achieved with percent agreement of ≥ 80%. The constructed risk of harm statement had a reading level of grade 7 and provided a list of stratified risks associated with dry needling.

Conclusion

The generated risk of harm statement can be incorporated on IC forms that require disclosure of risks in both the clinical and research setting. Additionally, further elements were identified by panel participants about defining the framework for an IC form outside of the risk of harm statement.

Survey of Informed Consent Procedures in Urology: Disclosing Resident Participation to Patients

Eric A. Singer, Alexandra L. Tabakin, Arnav Srivastava, Labeeqa Khizir, Juliana E. Kim

Journal of Clinical Ethics, Summer 2023; 34(2) pp 190-195

Abstract

The American Urological Association (AUA) and American College of Surgeons (ACS) codes of professionalism require surgeons to disclose the specific roles and responsibilities of trainees to patients during the informed consent process. The objective of this study is to analyze how these requirements are met by urology training programs. An anonymous electronic survey was distributed to the program directors (PDs) of the 143 Accreditation Council for Graduate Medical Education urology residency programs in the United States in 2021. Information was collected regarding program demographics, aspects of the program's consent process, and the disclosure to patients of the role and participation of residents in their surgery. There were 49 responses to the survey (34.3% response rate). Nearly 70 percent of PDs reported that attending physicians lead the consent process. The topics covered during consent discussion include possible complications (25%), expected recovery time (23%), length of the surgery (22%), the people involved (18%), and their specific roles (7%). Many PDs do not explicitly discuss trainee involvement (48.8%) or when a resident is to perform the majority of the case (87.8%). The majority of PDs (78.8%) communicate medical student involvement, but 73.2 percent reported having a patient decline participation of a trainee after describing their role. Despite the AUA and ACS codes of professionalism, many urologists do not disclose resident involvement in surgery to patients. Further discussions are needed to explore how to better balance resident education and patient autonomy.

Written Surgical Informed Consent Elements in Pediatric Differences of Sex Development: Pediatric Urologist and Endocrinologist Perspectives

Zoe K. Lapham, Melissa Gardner, Sydney Sheinker, Kristina I. Suorsa-Johnson, Barry A. Kogan, Peter A. Lee David E. Sandberg

Frontiers in Urology, 2 June 2023

Abstract

Introduction

Elective aspects of surgical management of pediatric differences of sex development (DSD) are associated with controversy. We examined pediatric urologist and endocrinologist perspectives regarding recommended and existing informed consent elements for written consent documents prior to pediatric genital surgery.

Methods

Focus groups with pediatric urologist and endocrinologist members of the Societies for Pediatric Urology (SPU, n=8) or Pediatric Endocrine Society (PES, n=8) were held to identify elements of informed consent for

DSD-related urogenital surgery. Elements were subsequently included in web-based surveys in 2003 and 2020 (SPU: n=121 and 143; PES: n=287 and 111, respectively). Participants rated their level of agreement with including each element in informed consent documents. In 2020, participants reported whether documents they use in clinical practice incorporate these elements.

Results

Groups identified four elements of informed consent: on-going debate over pediatric genital surgery; potential needs for multiple procedures; possible gender change and surgical reversal; and non-surgical alternatives. Across both years and both specialties, a majority (79% to 98%) endorsed the four elements, with significant between-group differences. Significantly more PES than SPU participants reported not knowing whether specific elements were included in current written informed consent; of those who knew, the majority (66% to 91%) reported inclusion.

Discussion

Specialists agree with including these four elements in written informed consent documents. Endocrinologists are not always familiar with the exact elements included. The degree to which non-surgeon members of the care team should be involved in the written informed consent process is an open question.

Surgical classification using natural language processing of informed consent forms in spine surgery

Michael D Shost, Seth M Meade, Michael P Steinmetz, Thomas E Mroz, Ghaith Habboub

Neurosurgical Focus, June 2023; 54(6)

Abstract

Objective

In clinical spine surgery research, manually reviewing surgical forms to categorize patients by their surgical characteristics is a crucial yet time-consuming task. Natural language processing (NLP) is a machine learning tool used to adaptively parse and categorize important features from text. These systems function by training on a large, labeled data set in which feature importance is learned prior to encountering a previously unseen data set. The authors aimed to design an NLP classifier for surgical information that can review consent forms and automatically classify patients by the surgical procedure performed.

Methods

Thirteen thousand two hundred sixty-eight patients who underwent 15,227 surgeries from January 1, 2012, to December 31, 2022, at a single institution were initially considered for inclusion. From these surgeries, 12,239 consent forms were classified based on the Current Procedural Terminology (CPT) code, categorizing them into 7 of the most frequently performed spine surgeries at this institution. This labeled data set was split 80%/20% into train and test subsets, respectively. The NLP classifier was then trained and the results demonstrated its performance on the test data set using CPT codes to determine accuracy.

Results

This NLP surgical classifier had an overall weighted accuracy rate of 91% for sorting consents into correct surgical categories. Anterior cervical discectomy and fusion had the highest positive predictive value (PPV; 96.8%), whereas lumbar microdiscectomy had the lowest PPV in the testing data (85.0%). Sensitivity was highest for lumbar laminectomy and fusion (96.7%) and lowest for the least common operation, cervical posterior foraminotomy (58.3%). Negative predictive value and specificity were > 95% for all surgical categories.

Conclusions

Utilizing NLP for text classification drastically improves the efficiency of classifying surgical procedures for research purposes. The ability to quickly classify surgical data can be significantly beneficial to institutions without a large database or substantial data review capabilities, as well as for trainees to track surgical experience, or practicing surgeons to evaluate and analyze their surgical volume. Additionally, the capability to quickly and accurately recognize the type of surgery will facilitate the extraction of new insights from the correlations between surgical interventions and patient outcomes. As the database of surgical information

grows from this institution and others in spine surgery, the accuracy, usability, and applications of this model will continue to increase.

Exploring informed consent in midwifery care

Anna Madeley

British Journal of Midwifery, 31 May 2023; 31(6)

Abstract

One of the single most important tenets of healthcare ethics is that of informed consent. Situated in ethical, legal and human rights frameworks, informed consent at its core represents the ability to retain autonomy over one's bodily integrity and to decide freely who can and cannot touch them. While consent at its simplest means being able to say yes or no, facilitating informed consent requires a more nuanced understanding of a dynamic process that, for midwives and other healthcare professionals, might seem challenging. The aim of this article is to provide a brief introduction to historical context and key legal cases that set the foundations for that which constitutes informed consent. This article focuses on what 'informed' means in relation to consent and, importantly, aims to dispel myths around receiving informed consent in contemporary midwifery practice.

Blockchain innovation for consent self-management in health information exchanges

Chad Anderson, Arthur Carvalho, Mala Kaul, Jeffrey W. Merhout

Decision Support Systems, 30 May 2023

Abstract

With the increasing digitalization of health data, patients need to make informed decisions about the online sharing of their protected health information. This necessitates a robust technical infrastructure that enables patients to self-manage consent and the trusted exchange of this information across sharing entities. Unfortunately, current health information exchange systems in the U.S. are limited in both these regards. While there is recent work on digital patient consent management, there is limited work that provides effective solutions for patient self-management of consent. Further, interoperability issues in the way health information exchanges are currently architected and differences in regulations across localities exacerbate the challenges of consent management. In this research, we survey potential patients' willingness to self-manage healthcare-related consent. Having established the desire for consent self-management, we propose a solution that enables the seamless sharing of patient consent across different healthcare providers and health information exchanges. Specifically, we use a rigorous design science approach to create a blockchain-based, self-managed patient consent system and we evaluate the design through an instantiated prototype. The results of our study should be useful to researchers in healthcare information management as well as to practitioners designing consent management systems. Our research contributes to design science research with an innovative, rigorously evaluated, design principles-based artifact that addresses a critical problem of sharing protected health information.

The evolution of informed consent in gastroenterology

Research Article

Fallon O'Neill, Parker O'Neill, Sierra Schaffer, Andrew Poullis

Medico-Legal Journal, 30 May 2023

Abstract

With medical litigation on the rise, physicians require a nuanced understanding of the legalities of consenting patients to reduce their liability while practising evidence-based medicine. This study aims to a) clarify the legal duties of gastroenterologists in the UK and USA when gaining informed consent and b) provide recommendations at the international and physician level to improve the consent process and reduce liability.

A bibliometric analysis of the Web of Science database with the MeSH terms “gastroenterology” and “informed consent” yielded 383 articles, of which 228 were excluded due to not meeting the inclusion criteria. Of the top 50 articles, 48% were from American institutions and 16% were from the UK. Thematic analysis showed 72% of the articles discussed informed consent in relation to diagnostic procedures, 14% regarding treatment, and 14% regarding research participation.

Both the USA and the UK have progressed from previously paternalistic Natanson case (1960) and Bolam test (1957), respectively, where physicians were held to the standard of a “reasonable and prudent medical doctor”. The American Canterbury case (1972) and the British Montgomery case (2015) radically shifted the standard of disclosure during the consent process by requiring physicians to explain all information pertinent to a “reasonable patient”.

It is our recommendation that a two-pronged approach be taken; a) creation of international guidelines for consenting patients for invasive procedures in gastroenterology, and b) development of internationally standardised endoscopy consent forms containing all the details pertinent to a “reasonable patient”.

Examining the variation in consent in general surgery

Research Article

A Sebastian, L Wyld, JL Morgan

The Annals of The Royal College of Surgeons of England, 23 May 2023

Abstract

Introduction

Consent is a fundamental aspect of surgery and expectations around the consent process have changed following the Montgomery vs Lanarkshire Health Board (2015) court ruling. This study aimed to identify trends in litigation pertaining to consent, explore variation in how consent is practised among general surgeons and identify potential causes of this variation.

Methods

This mixed-methods study examined temporal variation in litigation rates relating to consent (between 2011 and 2020), using data obtained from National Health Service (NHS) Resolutions. Semi-structured clinician interviews were then conducted to gain qualitative data regarding how general surgeons take consent, their ideologies and their outlook on the recent legal changes. The quantitative component included a questionnaire survey aiming to explore these issues with a larger population to improve the generalisability of the findings.

Results

NHS Resolutions litigation data showed a significant increase in litigation pertaining to consent following the 2015 health board ruling. The interviews demonstrated considerable variation in how surgeons approach consent. This was corroborated by the survey, which illustrated considerable variation in how consent is documented when different surgeons are presented with the same case vignette.

Conclusion

A clear increase in litigation relating to consent was seen in the post-Montgomery era, which may be due to legal precedent being established and increased awareness of these issues. Findings from this study demonstrate variability in the information patients receive. In some cases, consent practices did not adequately meet current regulations and therefore are susceptible to potential litigation. This study identifies areas for improvement in the practice of consent.

To find out how knowledgeable patients at tertiary care institutions are about giving informed consent and receiving counseling

Original Research

Mohammad Sufyan

Journal Of Cardiovascular Disease Research, 26 March 2023; 4(14)

Abstract

Aim
The purpose of this study is to find out how knowledgeable patients at tertiary care institutions are about giving informed consent and receiving counseling.
Material and Methods
Two groups made up the whole of the research: the first group consisted of fifty surgical trainees from general surgery, orthopaedics, obstetrics, and ENT, while the second group included fifty patients who had had a variety of surgical procedures. Both groups were exposed to the identical conditions over the same time period of the research. For the purpose of determining whether or not the counselling session addressed all of the essential components of providing informed consent for the surgical treatment, we have developed a systematic questionnaire.
Results
The final analysis took into account each of the 50 residents as well as the 50 patients. The risks and repercussions of the procedure were described in detail by 45 (or 90%) of the resident physicians as one of the most important aspects of the informed consent process. Natural history, the progression of the illness, and the prognosis were discussed by 19 resident physicians (38 percent), but alternative therapies and the name of the procedure were cited by 17 (34 percent) and 15 (30 percent), respectively. The patients themselves gave their permission in 37 (74%) of the instances, while their spouses gave their consent in 13 (26%) of the cases. Verbal permission was selected by 35 surgeons (70%) while written consent was selected by 15 surgeons (30%) as the technique of choice for getting agreement for minor operations and local anesthesia.
Conclusion
By adding patient counseling and intensifying patient selection, it is possible to increase both the overall happiness of patients and the results overall. A template for informed consent that includes all of the necessary information and leaves flexibility for customization needs to be established so that the process of obtaining informed consent may be completed more quickly.

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GENERAL/OTHER

Chapter 4 Capacity-Increasing Technologies and the Problems of Informed Consent

Book Chapter
Military Ethics and the Changing Nature of Warfare, 2023 [Brill]
Jean-François Caron
Abstract
Obtaining informed consent from members of the armed forces prior to their use of capacity-increasing technologies or medicines is plagued by numerous hurdles. This chapter argues that there are reasons to rethink the relevance of this criterion in favor of rethinking how these technologies and medicines ought to be tested in their developmental phase.

# # # #

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