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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 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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Editor's Note: CICI Webinar Series

On October 20th 2021 the GE2P2 Global Foundation's Center for Informed Consent Integrity continued a series of webinars focused on integrity in informed consent. Foundation President David Curry, who has led the Foundation's Center for Vaccine Ethics and Policy since 2008, opened the session with a discussion on the intersection of limited supply of WHO/SRA [Stringent Regulatory Authority] reviewed vaccines, licensing and use of "questionable" vaccines outside WHO/SRA review, growing vaccine hesitancy/refusal as a global challenges, growing use of mandates of various types but specifically involving young persons and a return to FTF education, and limited options for young people who find themselves with few options to exercise. After the initial presentation participants on the call shared local perspectives.

Following a successful first year, we are pausing the CICI webinar series to evaluate future directions. Please watch for updates.

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

No new content identified for the following established categories:
BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
HUMANITARIAN CONTEXT
POLICY GUIDANCE/PROGRAM ACTION

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

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COVID-19

Parental consent for vaccination of minors against COVID-19

Nina Shevzov-Zebrun, Arthur Caplan
Vaccine, October 2021; 39(44) pp 6451–6453
Introduction
As of May 2021, emergency use authorization (EUA) for Pfizer's COVID-19 (COVID) vaccine applies to minors at least 12 years of age—some 25 million adolescents across the United States [1], [2]. While this change marks a critical step towards herd immunity and return to normality in everyday life, it also raises a host of questions concerning parental consent for vaccination of minors in pandemic times, most notably: should parental consent be required for COVID vaccine administration?

Informed Consent for Neck of Femur Fracture Surgery During the Covid-19 Pandemic: An Evidence-Based Approach

R Cuthbert, D Ferguson, B Kayani, S Haque, A Ali, A Parkar, P Bates, K Vemulapalli
British Journal of Surgery, 12 October 2021; 108 (Supplement 6)
Abstract
Background
Surgical intervention for neck of femur fractures continues to be prioritised during the Covid-19 pandemic. However, there remains a lack of clarity for clinicians during the consent process. This study quantifies additional perioperative risks for Covid-19 positive patients undergoing neck of femur fracture surgery and establishes an evidence-based framework for facilitating informed consent during the Covid-19 pandemic.
Method
259 patients undergoing neck of femur fracture surgery in four hospitals at the epicentre of the United Kingdom's first wave of Covid-19 were recruited. 51 patients were positive for Covid-19. Predefined outcomes were recorded in a 30-day postoperative period.
Results

Odds of intensive care admission were 4.64 times higher (95% CI 1.59-13.50, p = 0.005) and odds of 30-day mortality were 3 times higher (95% CI 1.22-7.40, p = 0.02) in Covid-19 positive patients. 74.5% of Covid-19 positive patients suffered post-operative complications. 35.3% of Covid-19 positive patients developed lower respiratory tract infection with 13.7% progressing to acute respiratory distress syndrome. 9.8% of Covid-19 positive patients experienced symptomatic thromboembolic events with a 3.9% incidence of pulmonary emboli.

Conclusions

The implications of Covid-19 on the informed consent process for neck of femur fracture surgery are profound. Covid-19 positive patients should be consented for increased risk of postoperative complications (including lower respiratory tract infection, acute respiratory distress syndrome and thromboembolic events), longer inpatient stay, increased frequency of intensive care admission and higher risk of mortality.

The Implication of Telephone Consultations During COVID-19 Pandemic on Informed Consent

N Ayoub, F Gareb, M Akhtar

British Journal of Surgery, 12 October 2021; 108 (Supplement 6)

Abstract

Aim

Is to find whether telephone consultations have affected patient's comprehension of the proposed surgical management and possible risks until the day of surgery and accordingly ability for informed consent.

Method

This study included a sample of patients admitted to QEQM hospital for elective day case surgery during November 2020 and had only telephone consultation when referred for surgery. A feedback survey assessing quality of information given to patients before and on day of surgery was filled by the patients after the procedure.

Results

The sample included 40 patients undergoing different procedures [cholecystectomy (25), inguinal hernia repair (25), rectal examination under anaesthesia (5), ventral hernia repair (2), incisional hernia (2), inguinal lymph node biopsy (1)]. It was found that 27.5% of patients didn't have thorough explanation of possible risks and no explanation about postoperative care in 35%.20% were not provided a leaflet about procedure, 57.5% had concerns before surgery and 75% of patients wished for a leaflet with illustrative diagrams, explanation of risks with their management to be able to take the right decision and majority of these patients were from cholecystectomy subgroup.

Conclusions

The lack of face-face appointment affected greatly the informed consent process resulting in patient dissatisfaction which raised the need for new leaflets containing diagrammatic explanation of procedures and possible risks with their management to ensure fulfilment of autonomy principle.

The right to respect for family life, consent, minors and Gillick competence

Richard Griffith

British Journal of Nursing, 2 October 2021; 30(17)

Abstract

Richard Griffith, Senior Lecturer in Health Law at Swansea University, discusses the statement made by the UK vaccines minister that healthy 12–15-year-olds could override their parents' decision on coronavirus vaccination.

An audit on our procedural consent forms for complication of covid-19 during the pandemic

O. C. Chaudhary, A. N. Najdawi, K. N. Noureldin, M. D. Dworkin

Colorectal Disease, 2021; 23(supplement 1) pp 78-79

Abstract

Aims

COVID-19 has had a global impact over the last 12 months Currently there have been over 2 millions deaths from close to 100 millions infected patients. With the changes from face to face consultations to remote virtual/phone/video consultations the consent process for common procedures both elective and emergency have been affected RCSE have produced a document published 30 June 2020 setting out the main principles of the consent process and providing advice on what additional information should be included in conversations with patients while COVID-19 is still prevalent in society

Method

During 1st November to 28th November all patients in Southend University Hospital undergoing an operation were identified on a near daily basis. Wards reviewed Castlepoint -Orthopaedic Princess Anne -Elective Windsor -General Surgery/Urology Eastwood -Gynaecology Hockley -Acute surgical admissions

Discussion and Conclusion

Operation notes were reviewed and patients with COVID-19 complications mentioned were identified and recorded in an excel spreadsheet Only 72% of consent forms mentioned COVID-19 as a recognised complication 92% of consultants (n = 14) mentioned COVID-19 compared to 60% (n = 30) for registrars and 78% (n = 9) for SHOs There was no obvious difference between elective and emergency consenting process.

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BIOMEDICAL RESEARCH

Leveraging Blockchain Technology for Informed Consent Process and Patient Engagement in a Clinical Trial Pilot

Baldwin C. Mak, Bryan T. Addeman, Jia Chen, Kim A. Papp, Melinda J. Gooderham, Lyn C. Guenther, Yi Liu, Uli C. Broedl, Marianne E. Logger

Blockchain in Healthcare Today, 14 October 2021; 4

Abstract

Objective

Despite the implementation of quality assurance procedures, current clinical trial management processes are time-consuming, costly, and often susceptible to error. This can result in limited trust, transparency, and process inefficiencies, without true patient empowerment. The objective of this study was to determine whether blockchain technology could enforce trust, transparency, and patient empowerment in the clinical trial data management process, while reducing trial cost.

Design

In this proof of concept pilot, we deployed a Hyperledger Fabric-based blockchain system in an active clinical trial setting to assess the impact of blockchain technology on mean monitoring visit time and cost, non-compliances, and user experience. Using a parallel study design, we compared differences between blockchain technology and standard methodology.

Results

A total of 12 trial participants, seven study coordinators and three clinical research associates across five sites participated in the pilot. Blockchain technology significantly reduces total mean monitoring visit time and cost versus standard trial management (475 to 7 min; P = 0.001; €722 to €10; P = 0.001 per participant/visit, respectively), while enhancing patient trust, transparency, and empowerment in 91, 82 and 63% of the patients, respectively. No difference in non-compliances as a marker of trial quality was detected.

Conclusion

Blockchain technology holds promise to improve patient-centricity and to reduce trial cost compared to conventional clinical trial management. The ability of this technology to improve trial quality warrants further investigation.

Expectations, experiences and preferences of patients and physicians in the informed consent process for clinical trials in oncology

Original Article

Laura Gangeri, Sara Alfieri, Margherita Greco, Marta Scrignaro, Elisabetta Bianchi, Paolo Casali, Davide Ferraris, Claudia Borreani

Supportive Care in Cancer, 7 October 2021

Abstract

Purpose

The aim of the present study was to explore (1) informed consent (IC) representations, level of understanding, needs, and factors that influence the willingness of cancer patients to participate in randomized controlled trials (RCTs) (phase I) and (2) representations, experiences, and critical issues of physicians involved in the same process (phase II).

Methods

Semi-structured interviews were conducted with 20 cancer patients who had been asked to enroll in a phase II/III RCT (phase I). Two focus groups were conducted with 13 physicians enrolled in the same process (phase II). The content produced was analyzed through a thematic analysis.

Results

The themes that emerged in the first phase I were grouped into six categories: IC representation, randomization, experimentation, meeting with the physician, factors that influence the willingness to participate, and trial participants' needs. The themes emerged in the phase II were grouped into four: IC representation, critical issues of the IC, relationship, and recruitment of trial participants. Each theme is articulated into sub-themes and deeply discussed.

Conclusion

This study highlights (1) the gap between what is ethically demanded in a RCT consultation and the reality of the situation and (2) the difference in perceptions between patients and physicians with reference to the meaning, objectives, and level of understanding of IC.

Deferred Consent in an Acute Stroke Trial from a Patient, Proxy, and Physician Perspective: A Cross-Sectional Survey

Original Work

Inez Koopman, Dagmar Verbaan, W. Peter Vandertop, Rieke van der Graaf, Erwin J. O. Kompanje, René Post, Bert A. Coert, Martine C. Ploem, Wouter M. Sluis, Féline E. V. Scheijmans, Gabriel J. E. Rinkel, Mervyn D. I. Vergouwen

Neurocritical Care, 5 October 2021

Open Access

Abstract

Background

In some acute care trials, immediate informed consent is not possible, but deferred consent is often considered problematic. We investigated the opinions of patients, proxies, and physicians about deferred consent in an acute stroke trial to gain insight into its acceptability and effects.

Methods

Paper-based surveys were sent to patients who were randomly assigned in the Ultra-early Tranexamic Acid After Subarachnoid Hemorrhage (ULTRA) trial between 2015 and 2018 in two tertiary referral centers and to physicians of centers who agreed or declined to participate. The primary outcome measure was the proportion of respondents who agreed with deferral of consent in the ULTRA trial. Secondary outcomes

included respondents' preferred consent procedure for the ULTRA trial, the effect of deferred consent on trust in physicians and scientific research, and the willingness to participate in future research.
Results
Eighty-nine of 135 (66%) patients or proxies and 20 of 30 (67%) physicians completed the survey. Of these, 82 of 89 (92%) patients or proxies and 14 of 20 (70%) physicians agreed with deferral of consent in the ULTRA trial. When asked for their preferred consent procedure for the ULTRA trial, 31 of 89 (35%) patients or proxies indicated deferred consent, 15 of 89 (17%) preferred immediate informed consent, and 32 of 89 (36%) had no preference. None of the patients' or proxies' trust in physicians or scientific research had decreased because of the deferred consent procedure. Willingness to participate in future studies remained the same or increased in 84 of 89 (94%) patients or proxies.
Conclusions
A large majority of the surveyed patients and proxies and a somewhat smaller majority of the surveyed physicians agreed with deferred consent in the ULTRA trial. Deferred consent may enable acute care trials in an acceptable manner without decreasing trust in medicine. Future research should investigate factors facilitating the responsible use of deferred consent, such as in-depth interviews, to study the minority of participants who agreed with deferred consent but still preferred immediate informed consent.

Institutional Improvements in Readability of Written Informed Consent Forms Sustained Post-Revised Common Rule

Alison Caballero, Katherine J Leath, Jennifer M Gan
Journal of Clinical and Translational Science, October 2021
Abstract
Obtaining informed consent is a fundamental and ethical practice within human subjects research. Informed consent forms (ICFs) include a large amount of information, much of which may be unfamiliar to research subjects, and the revised Common Rule resulted in several required additions to that language. As limited health literacy impacts many potential subjects, efforts should be made to optimize subjects' ability to read and understand ICFs. In this brief report, we describe an assessment of ICFs at an academic medical center to evaluate longitudinal changes in readability with the introduction and update of a plain language ICF template.

The Timing of Research Consent

Benjamin Sachs
Ethical Theory and Moral Practice, 28 September 2021
Open Access
Abstract
This essay is about the timing of research consent, a process that involves (potential) participants being given information about, among other things, upcoming research interventions and then being invited to waive their claims against those interventions being undertaken. The standard practice, as regards timing, is as follows: (potential) participants are invited to waive all their claims at a single moment in time, and that point in time immediately follows the information-provision. I argue that there we're not justified in keeping to this practice. What we ought to do is disaggregate the claim-waiving part of the process and move it later, such that the (potential) participant is invited to waive her claim against the undertaking of any given intervention only the immediate moment before that intervention is to be undertaken.

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SOCIAL SCIENCE RESEARCH

Multicenter Social Media Community Consultation for an Exception From Informed Consent Trial of the XStat device (PhoXstat Trial)

Original Article

Shannon W. Stephens, Paige Farley, Sean P. Collins, Monica D. Wong, Ashley B. Panas, Bradley M. Dennis, Neal Richmond, Kenji Inaba, Karen N.Brown, John B. Holcomb, Jan O. Jansen

Journal of Trauma and Acute Care Surgery, 5 October 2021

Abstract

Introduction

Community Consultation (CC) is a key step for Exception from Informed Consent (EFIC) research. Using social media to conduct CC is becoming more widely accepted, but has largely been conducted by single sites. We describe our experience of a social media-based CC for a multicenter clinical trial, coordinated by the lead clinical site.

Methods

Multicenter CC administered by the lead site and conducted in preparation for a three-site prehospital randomized clinical trial. We utilized Facebook and Instagram advertisements targeted to the population of interest. When "clicked" the advertisements directed individuals to study-specific websites, providing additional information and the opportunity to opt out. The lead institution and one other hospital relied on a single website, whereas the third center set up their own website. Site views were evaluated using Google analytics.

Results

The CC took 8 weeks to complete for each site. The advertisements were displayed 9.8 million times, reaching 332,081 individuals, of whom 1,576 viewed one of the study-specific websites. There were no opt-outs. The total cost was $3,000. The costs per person reached were $1.88, $2.00 and $1.85 for each of the three sites. A number of site-specific issues (multiple languages, hosting of study-specific websites) were easily resolved.

Conclusion

This study suggests it is possible for one institution to conduct multiple, simultaneous, social media-based CC campaigns, on behalf of participating trial sites. Our results suggest this social media CC model reaches many more potential subjects and is economical and more efficient than traditional methods.

The ethics of quality improvement studies: do the needs of the many outweigh the needs of the few?

Editorial

Peter A. Goldstein

British Journal of Anaesthesia, 4 October 2021

Summary

Clinical research involving human subjects and quality improvement (QI) projects share a common goal of seeking to improve human health, whether by directly changing the standard of care (research) or by improving the process(es) by which that care is delivered (QI). Whether a QI project requires informed consent (written or oral) is a function of the risk–benefit analysis of the study; such a determination should not be at the sole discretion of the investigators, but should come from an appropriately constituted review board with expertise in the ethics of biomedical research.

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GENOMIC MEDICINE/GENE EDITING

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

Laurence Woollard, Richard Gorman, Dakota J. Rosenfelt

Therapeutic Advances in Rare Disease, 31 August 2021; 2 pp 1-16

Open Access

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

Data protection-compliant broad consent for secondary use of health care data and human biosamples for (bio)medical research: towards a new German national standard

Sven Zenker, Daniel Strech, Kristina Ihrig, Jahns, Roland, Gabriele Müller, Christoph Schickhardt, Georg Schmidt, Ronald Speer, Eva Winkler, Sebastian Graf von Kielmansegg, Johannes Drepper

OSF Preprints, 7 October 2021

Open Access

Abstract

Background

The secondary use of deidentified but not anonymized patient data is a promising approach for enabling precision medicine and learning health care systems. In most national jurisdictions (e.g., in Europe and North America), this type of secondary use requires patient consent. While various ethical, legal, and technical analyses have stressed the opportunities and challenges for different types of consent over the past decade, no country has yet established a national consent standard accepted by the relevant authorities.

Methods

A working group of the national Medical Informatics Initiative in Germany conducted a requirements analysis and developed a GDPR-compliant broad consent standard involving all relevant stakeholder groups and authorities.
Results
This paper presents the broad consent text together with a guidance document on mandatory safeguards for broad consent implementation. The mandatory safeguards comprise i) independent review of individual research projects, ii) organizational measures to protect patients from involuntary disclosure of protected information, and iii) comprehensive information for patients and public transparency. This paper further describes the key issues discussed with the relevant authorities, especially the position on additional or alternative consent approaches such as dynamic consent.
Discussion
Both the resulting broad consent text and the national consensus process are relevant for similar activities internationally. A key challenge of aligning consent documents with the various stakeholders was explaining and justifying the decision to use broad consent and the decision against using alternative models such as dynamic consent. Public transparency for all secondary use projects and their results emerged as a key factor in this justification. While currently largely limited to academic medicine in Germany, the first steps for extending this broad consent approach to wider areas of application, including smaller institutions and medical practices, are currently under consideration.

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CAPACITY TO CONSENT

Reliability of self-report versus the capacity to consent to treatment instrument to make medical decisions in brain metastasis and other metastatic cancers

Original Research
Mackenzie E. Fowler, Dario A. Marotta, Richard E. Kennedy, Adam Gerstenecker, Meredith Gammon, Kristen Triebel
Brain and Behaviour, 2 October 2021
Open Access
Abstract
Objective
To evaluate the ability of persons with metastatic cancer to self-assess their medical decision-making capacity (MDC). To investigate this, we compared an objective measure of MDC with self-ratings and evaluated predictors of agreement.
Methods
Data were obtained from a cross-sectional study of metastatic cancer patients at a large academic medical center. Across all standards of MDC, sensitivity, specificity, and reliability using Gwet's AC1 statistic were calculated using the objective measure as the gold standard. Logistic regression was used to evaluate predictors of agreement between the measures across all MDC standards.
Results
In those with brain metastases, high sensitivity (greater than 0.7), but low specificity was observed for all standards. Poor reliability was observed across all standards. Higher age resulted in higher odds of disagreement for Standard 3 (appreciation) (OR: 1.07, 95% CI: 1.00, 1.15) and Standard 4 (reasoning) (OR: 1.05, 95% CI: 1.00, 1.10). For Standard 3, chemotherapy use and brain metastases compared to other metastases resulted in higher odds of disagreement (Chemotherapy: OR: 5.62, 95% CI: 1.37, 23.09, Brain Metastases: OR: 5.93, 95% CI: 1.28, 27.55). For Standard 5 (understanding), no predictors were associated with disagreement.
Conclusions

For less cognitively complex standards (e.g., appreciation), self-report may be more valid and reliable than more cognitively complex standards (e.g., reasoning or understanding). However, overall, MDC self-report in the current sample is suboptimal. Thus, the need for detailed assessment of MDC, especially when patients are older or used chemotherapy, is indicated. Other studies should be conducted to assess MDC agreement longitudinally.

Awareness and Perception of Healthcare Providers about Proxy Consent in Critical Care Research

Research Article

Rania Mahafzah, Karem H. Alzoubi, Omar F. Khabour, Rana Abu-Farha

Critical Care Research and Practice, 30 September 2021

Open Access

Abstract

Objective

Proxy consent respects patients' autonomy when they are incapable of providing consent for research participation. Healthcare providers need to understand the ethical regulations and practices relevant to the proxy consent process. Thus, this study aimed to assess the knowledge and attitudes of healthcare providers about research proxy consent in the ICU setting.

Methods

A cross-sectional survey-based design was used in the study. Study participants were resident and specialist physicians, registered nurses, and registered pharmacists from ICU units in Jordan. Participants were asked to fill out a questionnaire developed to assess their knowledge and attitudes towards informed proxy consent for research studies conducted at the ICU.

Results

In this study, 145 healthcare providers completed the study questionnaire. The healthcare providers agreed that the purpose of the proxy consent is to inform the participants about the potential benefits (66.9%) and risks (66.9%) related to the research to study and respect patient's autonomy (44%), to discuss alternative options (62.1%), and to protect the researchers from any litigation (84.1%). Regarding the assessment of proxy consent, 65.5% of respondents believed that relatives are considered as an authorized legal representative for an informed consent decision on behalf of their ICU patients (65.5%) as they are knowledgeable about patients' values and preferences and have the desire to provide the necessary help. Respondents also agreed that the informed consent process should explain research protocols and procedures (76.6%), therapeutic alternatives (84.1%), potential benefits (41.4%), and potential risks (44.1%) and that participation in the research is voluntary (66.9%). No significant differences in the responses were found among different groups of healthcare providers.

Conclusion

The majority of healthcare providers had inadequate awareness about the ethical aspects regarding the informed proxy consent process. Providing training regarding the informed consent process can improve the quality of the proxy consent process in clinical research studies in the ICU setting.

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TECHNOLOGY/OTHER MEDIATION

Comparing a Multimedia Digital Informed Consent Tool With Traditional Paper-Based Methods: Randomized Controlled Trial

Fuad Abujarad, Peter Peduzzi, Sophia Mun, Kristina Carlson, Chelsea Edwards, James Dziura, Cynthia Brandt, Sandra Alfano, Geoffrey Chupp

JMIR Formative Research, 19 October 2021; 5(10)

Abstract

Background
The traditional informed consent (IC) process rarely emphasizes research participants' comprehension of medical information, leaving them vulnerable to unknown risks and consequences associated with procedures or studies.
Objective
This paper explores how we evaluated the feasibility of a digital health tool called Virtual Multimedia Interactive Informed Consent (VIC) for advancing the IC process and compared the results with traditional paper-based methods of IC.
Methods
Using digital health and web-based coaching, we developed the VIC tool that uses multimedia and other digital features to improve the current IC process. The tool was developed on the basis of the user-centered design process and Mayer's cognitive theory of multimedia learning. This study is a randomized controlled trial that compares the feasibility of VIC with standard paper consent to understand the impact of interactive digital consent. Participants were recruited from the Winchester Chest Clinic at Yale New Haven Hospital in New Haven, Connecticut, and healthy individuals were recruited from the community using fliers. In this coordinator-assisted trial, participants were randomized to complete the IC process using VIC on the iPad or with traditional paper consent. The study was conducted at the Winchester Chest Clinic, and the outcomes were self-assessed through coordinator-administered questionnaires.
Results
A total of 50 participants were recruited in the study (VIC, n=25; paper, n=25). The participants in both groups had high comprehension. VIC participants reported higher satisfaction, higher perceived ease of use, higher ability to complete the consent independently, and shorter perceived time to complete the consent process.
Conclusions
The use of dynamic, interactive audiovisual elements in VIC may improve participants' satisfaction and facilitate the IC process. We believe that using VIC in an ongoing, real-world study rather than a hypothetical study improved the reliability of our findings, which demonstrates VIC's potential to improve research participants' comprehension and the overall process of IC.

The application and promotion of electronic informed consent

Y. Dong, L. Qin, W. Wu, C. Tang, W. Long, Z. Yang, L. Ling, L. Lu
Chinese Journal of Evidence-Based Medicine, 2021; 21(7) pp 851-857
Abstract
Under the background of the global COVID-19 pandemic, electronic informed consent (eConsent) utilizes technology to provide a new method and idea for clinical trials. It has the advantages of convenience and efficiency, which greatly improves the efficiency of clinical trials. At present, this concept has not been put forward in China while it has been clarified clearly abroad, and some countries have launched a variety of trials and formulated various regulations to further standardize the eConsent. Based on the current situation of eConsent in China, this study analyzed the design and implementation of eConsent, summarized relevant domestic and foreign laws and regulations, and proposed opportunities and challenges for electronic informed consent as well as the relevant preparations for the implementation of this technology in China.

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YOUNG PERSONS

Beyond Agree or Disagree: A Consent Story and Storytelling for Indonesian Children

Fitri Arlinkasari, Debra Flanders Cushing, Evonne Miller

Ethics and Integrity in Research with Children and Young People, 4 November 2021

Abstract

Researchers face many ethical challenges when conducting research with children. Ethical issues can be even more significant when researchers work with children from low-income urban settings in the Global South. This chapter presents reflections on research conducted with children aged 6–12 years old who live in Jakarta, Indonesia. Underpinned by the new sociology of childhood, the study was designed to gather these children's perspectives on child-friendly public spaces in their neighbourhoods. A range of qualitative methods were used including child-led tours, drawings, observations and interviews. As part of the study, the authors developed and reflected on the use of story and storytelling to deliver the research information and obtain the children's consent to participate. The authors' experience demonstrates that story and storytelling supported children's competence and engaged them in a meaningful informed consent process. This approach is especially relevant for children with low literacy skills and whose parents or caregivers may not be available to help children decide on their participation in research. The chapter concludes with recommendations for effectively approaching this ethical challenge in future social research with children from similar backgrounds.

Assent or Consent? Engaging Children in Ethnographic Study [BOOK CHAPTER]

Ruth Barley

Ethics and Integrity in Research with Children and Young People, 4 November 2021 [Emerald Publishing Limited]

Abstract

Can children give their informed consent to participate in a research study, or can they only provide assent? This chapter explores this tricky question by drawing on three stages of a longitudinal ethnography within a multi-ethnic school in the north of England. Illustrative examples are used to show how the ability to give consent is not based on age alone, but rather on children's experiences and confidence, the type of research conducted, and the researcher's own expertise in communicating with children. The chapter provides examples of children's active and ongoing negotiation of consent and through their choice to withdraw consent, 'correct' the researcher's interpretations, actively produce their own written field notes and reflect on data collected as part of fieldwork. To facilitate consent, children were given time and space to familiarise themselves with the researcher and the study. Actively involving children in all stages of the study highlighted the importance of familiarisation and participation to the processes of informed consent to ensure children's ongoing and meaningful involvement in the research.

Stakeholder-informed conceptual framework for financial burden among adolescents and young adults with cancer

Original Article

Suzanne C. Danhauer, Mollie Canzona, Reginald D. Tucker-Seeley, Bryce B. Reeve, Chandylen L. Nightingale, Dianna S. Howard, Nicole Puccinelli-Ortega, Denisha Little-Greene, John M. Salsman,

Psycho-Oncology, 26 October 2021

Abstract

Background

Cancer and its treatments can result in substantial financial burden that may be especially distressing for adolescents and young adults (AYAs) since they are at a developmental stage focused on completing one's education and establishing independence. The purpose of this study was to develop a conceptual model of financial burden among AYA cancer patients to inform development of a financial burden measure.

Methods

In-depth concept elicitation interviews were conducted with a purposive-selected stakeholder sample (36 AYAs and 36 AYA oncology healthcare providers). The constant comparative method was used to identify themes that illustrate AYAs' experience of financial burden by stakeholder groups.
Results
Eleven financial burden themes emerged: (1) impact of socioeconomic status and age; (2) significant cancer costs; (3) indirect cost "ripple effects"; (4) limited awareness of costs (adolescents); (5) emotional impact; (6) feeling overwhelmed navigating the health care system; (7) treatment decision modifications; (8) reducing spending; (9) coping strategies; (10) financial support; and (11) long-lasting impact. The conceptual model highlights the importance of material, psychosocial, and behavioral domains of financial burden with an emphasis on phase along the cancer continuum and developmental stage in the experience of financial burden for AYAs.
Conclusions
Issues presented in the voice of AYA patients and providers highlight the profound impact of financial burden in this survivor group. The next step in this work will be to develop and test a patient-reported measure of financial burden among AYA cancer survivors.

Informed Consent, Confidentiality, and Practitioner Disclosure in Therapeutic Work with Youth: A Systematic Review of Practitioners' Perspectives

Systematic Review
Rachelle E. Thannhauser, Zoe A. Morris, Nicholas Gamble
Adolescent Research Review, 11 October 2021
Abstract
Mental health practitioners provide therapeutic interventions to youth on a daily basis, yet sparse research exists to inform ethical decision-making. It is commonly understood that therapeutic work with youth is ethically complex especially when considering informed consent and confidentiality, both of which have practical limitations. This review synthesized literature which reported practitioners' perspectives (e.g., psychologists, social workers) on ethical decision-making about informed consent and confidentiality in therapeutic work with youth. Specifically, this review aimed to amalgamate relevant professional perspectives on work with youth who may be considered "Mature Minors" or "Gillick Competent," indications of capacity to consent to intervention. Included studies (n = 25) largely originated in North America (40%), suggesting an underrepresentation of culturally diverse practitioners and help-seeking youth in available literature. Most studies concentrated on confidentiality (72%) and few considered decision-making related to informed consent. Adolescent risk-behavior and related potential for harm were prevalent factors in practitioners' decision-making. This review demonstrates that practitioners endorse disparate decision-making factors and are limited in consensus to breach confidentiality. As such, practitioners demonstrate variance in approach to working with this developmentally vulnerable population.

Aligning Family–Clinician Expectations During Pediatric Surgical Informed Consent; Development and Implementation of an Innovative Communication Skills Workshop

Adena Cohen-Bearak, Elaine C. Meyer, Lauren Mednick, Pamela Varrin, Lisa Burgess, Pia Kuhlmann, Sigall Bell, Craig Lillehei
Journal of Continuing Education in the Health Professions, 1 October 2021
Abstract
Introduction
Aligning expectations during the informed consent process before a child's surgery is an important element of good communication that benefits both surgical staff and families. We developed and evaluated a 2-hour pilot interprofessional workshop to improve the communication and relational skills of pediatric surgeons and nurse practitioners.
Methods

Focus groups with families identified key challenges in the process of informed consent. An interprofessional team, including parents whose children had experienced complex surgeries, developed the workshop collaboratively. A realistic simulation with professional actors portraying parents allowed surgical staff to practice communication skills and receive feedback about the parent perspective. Participants completed a postworkshop evaluation to determine whether the workshop met its objectives and whether they would change practice.

Results

Five key themes identified for the workshop included customize communication; align expectations; share clinical uncertainty; recognize/attend to emotions; and identify team members. Thirty-five clinicians participated in a workshop, and 89% completed evaluations. Three-quarters reported the learning to be valuable, and 64% were likely to change practice. Eighty-seven percent would recommend the workshop to other colleagues, and 58 to 74% felt more prepared to achieve each of eight specific skills.

Discussion

An innovative workshop for pediatric surgical practitioners to align family–clinician expectations can help improve clinician communication skills and comfort with informed consent. Keys to workshop development included involving parents to identify themes and participate as workshop co-faculty; enlisting leadership and recruiting surgical champions; and using pre-existing meetings to ease scheduling challenges of busy practitioners. Booster sessions may facilitate the desired cultural changes.

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RIGHTS/LEGAL/LEGISLATIVE

"I Agree to Disagree": Comparative Ethical and Legal Analysis of Big Data and Genomics for Privacy, Consent, and Ownership

Review Article

Seema Belani, Georgina C. Tiarks, Neil Mookerjee, Vijay Rajput

Cureus, 13 October 2021

Abstract

Statement of Purpose

Digital healthcare, as it relates to big data and genomics, presents a real threat to privacy and ownership rights for individuals and society.

Research Question/Hypothesis

Our experience with genomics provides a lens to facilitate the way we navigate toward a future health data space. Contemporary and innovative legal and ethical models can be applied to concepts of privacy, ownership, and consent in relation to big data.

Significance

Technological innovation has transformed healthcare at a faster rate than legal reform, security measures, and consent policies can adapt. The Health Information Portability and Accountability Act (HIPAA) has been recognized as a work in progress, with respect to big data as it relates to healthcare and individual wellbeing. The shortcomings of HIPAA, and its application to big data, can be paralleled with its prior limitations surrounding genomics in the last two decades. The Genetic Information and Nondiscrimination Act (2008) and Genomic Data Sharing Policy (2015) were established to overcome HIPAA's inadequacies concerning genetic discrimination and security. These policies can serve as a basic model for our approach to legislative reform as it relates to privacy risks with big data generated in healthcare and from healthy individuals in society who are not patients. In addition to notions of privacy, concepts of ownership and consent have become increasingly vague and opaque. The technological advancements have facilitated access and transmission of information, such that big data can be sold for financial gain for commercial enterprise. This applies to genomics, with companies like 23andMe, in addition to big data, as it relates to big tech giants like

Apple or Google who oversee wearable and search term data. Clarity of ownership within a digital healthcare arena needs to be defined through ethical and legal frameworks at a global level.

Approach

A narrative review of the literature published between 2010 and 2021 was performed using PubMed and Google Scholar. Articles discussing privacy, security, ownership, big data, and genomics were included as relevant literature.

Importance

As a society, we are at a crossroads; we must determine the extent of privacy that we are willing to give for science and society. We cannot continue with the current status quo in hope that individual will be used for the greater good of society. We need to strive for a cohesive approach to combat privacy violations by encouraging legislative reform, ethical accountability, and individual responsibility.

Learning from informed consent litigation to improve practices: A systematic review

Karine Giudici-Wach, Pierre Gillois, Thomas Remen, Frédérique Claudot

Patient Education and Counseling, 8 October 2021

Abstract

Objective

To describe the reasons that lead judges to qualify malpractice as a lack of information, then rule in favour or not of the health professional (HP).

Methods

We conducted a systematic review of case law relating to the breach of disclosure obligations over a ten-year period from 2010 to 2020. We used 3 legal databases: Légifrance, Dalloz and Lexis 360, all identified as the most exhaustive.

Results

Of the 514 law cases included: judges found malpractice owing to lack of information in 377 (73.3%) cases. Among the latter, malpractices were lack of risk information (N = 257, 68.2%), lack of proof of information (N = 243, 64.5%) and/or lack of information on therapeutic alternatives (N = 49, 13.0%). These malpractices resulted in a conviction of the HP in 268 (71.1%) of the cases.

Conclusion

Case law is an important source of information for improving the quality of HP, lawyers, and judges' practices.

The Informed Consent Doctrine in Legal Malpractice Law

Vincent R. Johnson

St. Mary's Journal on Legal Malpractice & Ethics, 6 October 2021; 11(2)

Open Access

Abstract

The doctrine of informed consent is now deeply embedded into the law of legal ethics. In legal malpractice litigation, the doctrine holds that a lawyer has a duty to disclose to a client material information about the risks and alternatives associated with a course of action. A lawyer who fails to make such required disclosures and fails to obtain informed consent is negligent, regardless of whether the lawyer otherwise exercises care in representing a client. If such negligent nondisclosures cause damages, the lawyer can be held accountable for the client's losses. Shifting the focus of a legal malpractice action from garden-variety negligence (such as ignorance of the law, late filing of a complaint, or failure to safeguard client funds or data) to a lack of informed consent can potentially transform a losing case into a winner. Among other things, the doctrine has the potential to simplify and clarify the plaintiff's argument, which may be especially useful if the case is tried to a jury. The informed consent doctrine also makes sense as a matter of public policy, because clients have a right to control important matters related to their representation. This Article explores the informed consent doctrine in legal malpractice law. It discusses the rise of the informed consent doctrine in medical

malpractice law and traces the transplantation of the language and principles of informed consent, first, into the law of lawyer discipline, and then into the law of lawyer civil liability. The Article explores what the relevant legal malpractice case law says about the obligation to obtain informed consent. Finally, the Article addresses certain pivotal issues in the operation of the informed consent doctrine in claims by clients against lawyers, including the nature of lawyer disclosure obligations, the limits imposed by the scope of the representation, the role of expert testimony, and the standard for proving factual causation.

Risk Management for a Legally Valid Informed Consent

Guerra F, La Rosa P, Guerra F, Raimondi L, Marinozzi S, Miatto I, Vergati D, Ndokaj A, Gasperini N, Corridore D, Nardi GM, Mazur M, La Torre G, Ottolenghi L

La Clinica Terapeutica, 1 September 2021; 172(5) pp 484-488

Abstract

Gelli-Bianco law (Law no. 24/2017) [Italy] intervenes both in order to divide healthcare liability between the healthcare professional and the facility in which he/she exercises and to incentivize the latter to adopt an organizational model suitable for managing the risk associated with the provision of any healthcare service, including the information for consent. In fact, the healthcare facility must guarantee clear, complete and adequate information on the specific case, which, therefore, cannot consist of standard forms to be signed by the patient, under penalty of a flawed consent to treatment and consequent healthcare liability in the event of an adverse event. The regulation mandates that safety must be guaranteed through proper prevention tools and health care risk management, in conjunction with the most effective use of structural, technological and organizational resources available. It further spells out the obligation of health care professionals to contribute to risk prevention while administering health care procedures. For this reason, the consent information constitutes a source of risk for the responsibility of the healthcare provider and the Facility and it must necessarily be managed. Risk Management is the management tool that can allow the healthcare facility to improve the quality and safety of the services provided, optimizing the risk of adverse events through proper monitoring of the same. This paper will be published, following a special agreement, on the two journals "Igiene e Sanità Pubblica" and "La Clinica Terapeutica", in Italian and in English, in order to increase the diffusion to a wider audience.

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FREE PRIOR INFORMED CONSENT (FPIC)

Regulation of Natural Resources Located in Indigenous Communities Territory under the Principles of Consultation and Free, Prior-Informed Consent: Perspectives in Selected Countries

John S. Ombella

African Journal of International and Comparative Law, November 2021; 29(4)

Abstract

Natural resources have long been said to be under the sovereign ownership of the states in whose borders they are found. Sovereignty grants such a state not only the ownership but also the power to regulate their access and use. States' inability to convert the resources into tangible socio-economic development has witnessed massive contractual agreements with multinational companies to harness the same. Multinational companies and state contractual arrangements seem to have ignored other potential stakeholders like communities dependent on natural resources for their survival. Consequently, communities such as those of indigenous peoples who depend on available natural resources like rivers, lakes, forests and other ecological resources are victimised in the state-multinational contractual arrangements and implementation. Internationally, principles such as consultation and free and prior-informed consent seem to regulate access

and use of resources located in indigenous communities. This article shows how such principles guarantee the indigenous communities their existence in cases of large-scale development in their territory.

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CULTURAL/COUNTRY CONTEXT

A Multiethnic Asian Perspective of Presumed Consent for Organ Donation: A Population-Based Perception Study

Mark D. Muthiah, Melissa Sin Hui Chua, Konstadina Griva, Ivan Low, Wen Hui Lim, Cheng Han Ng, Jeff Y. F. Hwang, Jason C. H. Yap, Shridhar G. Iyer, Glenn K. Bonney, Vathsala Anantharaman, Daniel Q. Huang, Eunice Xiang-Xuan Tan, Guan-Huei Lee, Alfred W. C. Kow, Bee Choo Tai

Frontiers in Public Health, October 2021

Open Access

Abstract

Background

Organ shortage is still a world-wide problem, resulting in long waiting lists for kidney, liver, and heart transplant candidates across many transplant centers globally. This has resulted in the move toward presumed consent to increase deceased organ donation rates. However, there remains a paucity of literature on public attitude and barriers regarding the opt-out system, with existing studies limited to Western nations. Therefore, this study aimed to understand public sentiment and different barriers toward organ donation from the perspective of Singapore, a highly diverse and multiethnic Asian society.

Methods

A cross-sectional community semi-structured interview was conducted in a public housing estate in Singapore. Pilot test was undertaken before participants were interviewed face-to-face by trained personnel. All statistical evaluations were conducted using Stata. The $\chi 2$-test compared subgroups based on patient characteristics while multivariable logistic regression identified predictors of willingness to donate/ assent. Effect estimates were quantified using odds ratio (OR).

Findings

Out of 799 individuals, 85% were agreeable to organ donation after death and 81% were willing to assent to donations of family members' organs, which declined by 16% ($p < 0.001$) after a clinical scenario was presented. Demographic factors including ethnicity, education, marital, and employment status affected willingness to donate and assent. Knowledge correlated significantly with willingness to donate and assent. In particular, knowledge regarding brain death irreversibility had the strongest correlation (AOR 2.15; 95% CI 1.60–2.89). Muthiah et al. Presumed Consent for Organ Donation

Conclusions

Organ donation rates remain low albeit presumed consent legislation, due to patient-level barriers, including but not limited to knowledge gaps, cultural values, religious backgrounds, and emotional impact at relatives' death. To effectively boost donor rates, it is crucial for policy makers to invest in public education and improve transplant provisions and family protocols.

Chinese speaking patients' understanding of information and consent related to their surgical experience

Janine Bothe, Meng Chen

Journal of Stomal Therapy Australia, September 2021; 41(3) pp 16-21

Abstract

The aim of this qualitative study was to explore the use of interpreters among Chinese speaking inpatients having a surgical procedure at an Australian metropolitan hospital. The summary of the findings are: Patients often understood it to be their obligation to seek language assistance from their family members or friends.

For this reason patients did not request an interpreter either during their visit to the surgeon (when written consent is routinely completed) or during hospitalisation. It is common practice for 'bilingual' surgeons to obtain informed consent even if the patient perceives that the surgeon cannot speak the language fluently. Staff under-utilised interpreters even if they were available and their benefits understood. These findings provide valuable information in which to plan for improvement in the stomal service and the wider organisation. Education and information can be shaped to improve the use of healthcare interpreters to the non-English speaking population at key milestones in their hospital journey.

Perception of immigrants: free consent and access to health services

Cléa Adas Saliba Garbin, María Elizabeth Peña Téllez, Tânia Adas Saliba, Artênio José Isper Garbin

Revista Bioétic, July-September 2021; 29(3)

Abstract

This study aims to identify the perception of Cuban immigrants about the free and informed consent form and access to dental and medical care. This is a cross-sectional descriptive survey conducted with a sample of immigrants from a medium-sized municipality in the state of São Paulo. Data were collected by means of a questionnaire addressing the form and the access to dental and medical care both in Brazil and in their country of origin, as well as sociodemographic aspects. The results indicate that immigrants have access to medical and dental care, but little knowledge about the consent form during treatment. Considering that a well-designed consent term and patient knowledge promotes the successful performance of procedures, physicians and dentists need to adopt measures for a safe professional practice.

Consent for Use of Genetic Data among US Hispanics/Latinos: Results from the Hispanic Community Health Study/ Study of Latinos

Sara Gonzalez, Garrett Strizich, Carmen R. Isasi, Simin Hua, Betsy Comas, Tamar Sofer, Bharat Thyagarajan, Krista M. Perreira, Gregory A. Talavera, Martha L. Daviglus, Sarah C. Nelson, Aida L. Giachello, Neil Schneiderman, Robert C. Kaplan

Ethnicity & Disease, 2021; 31(4)

Abstract

Inclusion of historically underrepresented populations in biomedical research is critical for large precision medicine research initiatives. Among 13,721 Hispanic Community Health Study/Study of Latinos (HCHS/SOL) enrollees, we used multivariable adjusted prevalence ratios to describe characteristics associated with participants' willingness to consent to different levels of biospecimen and genetic data analysis and sharing. At baseline (2008-2011), HCHS/SOL participants almost universally consented to the use of biospecimens and genetic data by study investigators and their collaborators (97.6%; 95%CI: 97.1, 98.0). Fewer consented to biospecimen and genetic data sharing with investigators not affiliated with the HCHS/SOL research team (81%, 95%CI: 80, 82) or any data sharing with commercial/for-profit entities (75%, 95%CI: 74, 76). Those refusing to share their data beyond the study investigators group were more often females, Spanish language-speakers and non-US born individuals. As expected, participants who were retained and reconsented at the six year follow up visit tended to embrace broader data sharing, although this varied by group. Over time, Puerto Ricans and Dominicans were more likely to convert to broader data sharing than individuals of a Mexican background. Our analysis suggests that acculturation and immigration status of specific Hispanic/Latino communities may influence decisions about participation in genomic research projects and biobanks.

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MEDICAL/SURGICAL

The 3-T Model of Informed Consent for Nonstandard Risk Donors: A Proposal for Transplant Clinical Practice

Alessandra Agnese Grossi, Federico Nicoli, Tullia Maria De Feo, Massimo Cardillo, Gabriella Biffa, Renzo Pegoraro, Carlo Petrini, Rosanna Torelli, Francesca Puoti, Giuseppe Rossini, Giuseppe Piccolo, Sergio Vesconi, Enrico Minetti, Barbara Pozzo, Giuseppe Vanacore, David Paredes, Antonio Grossi, Paolo Mario Picozzi

Transplantation Direct, November 2021; 7(11)

Abstract

Background

The risk of disease transmission from nonstandard risk donors (NSRDs) is low, and outcomes are similar or better relative to transplants performed with standard criteria donors. However, NSRDs have posed new ethical challenges to the informed consent (IC) process. Based on the shared decision-making model, coinciding with the 3 main timings of the IC process ([1] pretransplant assessments and waiting list registration, [2] time on the waiting list, and [3] time of the organ offer), we put forward a model (3-T Model) to summarize the knowledge on IC for NSRDs and to deliver conceptual and practical support to transplant providers on this emergent issue.

Methods

We searched PubMed and analyzed data from our area to provide evidence and ethical arguments to promote standardization of the timing of patient information, degree of patient participation, and disclosure of donor risk factors throughout the 3 stages of the time continuum leading to the potential acceptance of NSRDs.

Results

Each of the 3 timings carries special ethical significance and entails well-defined duties for transplant providers relative to patient involvement and information of the benefits and risks associated with NSRDs. Based on our framework, experience, and interpretation of the literature, we put forward a list of recommendations to combine standardization (ie, timing, content, and degree of patient participation) and individualization of IC.

Conclusions

The 3-T Model may enable the prevention of physicians' arbitrariness and the promotion of patient-centered care. Future studies will assess the effectiveness of the 3-T Model in transplant clinical practice.

Urology Consent Forms at a District General Hospital – a Quality Improvement Project

D Bernstein, A West, E Preston, P Premakumaran, N Suleyman, S Undre

British Journal of Surgery, 12 October 2021; 108 (Supplement 6)

Abstract

Aim

Consent is a core component of interaction between patients and healthcare professionals. Prior to surgery, forms are completed to record patient consent. As well as containing risks and benefits of the procedure, the consent form, as per guidelines1,2, must be legible and suitable to a patient's capacity. To evaluate compliance with local and national guidelines, a quality improvement project was undertaken at a district general hospital.

Method

Over a three-week period 30 urology consent forms were selected to assess adherence to local and national guidelines. The appropriateness of consent form, patient signature, legibility, acronym use and whether the patient was offered a carbon copy were assessed. After initial data collection, all urology staff consenting patients were notified of the findings and how best to improve guideline adherence. A further three-week data collection was undertaken, though the sample set was small due to Coronavirus and Christmas.

Results

The results confirmed that patients had appropriate consent forms filled out and were signed appropriately. After intervention, there was clear improvement in legibility, with no low legibility consent forms, and 100% vs 83% high or moderate legibility between data sets. Intervention also resulted in significant reduction of acronym use; 33% vs 60%. More patients were also offered to retain a carbon copy; 89% vs 40%.
Conclusions
Through this intervention of highlighting local and national guidance as compared to current practice, compliance drastically improved. As the pandemic subsides, we hope regular emails to surgical teams will improve consent form completion to better patient care.

Infrainguinal Bypass Informed Consent: An Audit Driven Standardisation Of Perioperative Risk Profiling

K Muhammad, H Al-Khaffaf
British Journal of Surgery, 12 October 2021; 108 (Supplement 6)
Abstract
Introduction
It is a fundamental good clinical practice in our medicolegal rights era to obtain standard, adequate, and transparent informed consent before any planned intervention. Currently, there are neither national approved vascular intervention-specific consents nor explicit guidelines for it. We aim to achieve a standardisation of perioperative risk profiling of infrainguinal bypass surgical consents and produce a model one.
Method
A retrospective analysis of 45 infrainguinal bypass consents (audit/reaudit) between (2013-2019) retrieved to evaluate quality and completeness against GMC 2008 guidance: "Consent: patients and doctors making decisions together". Data included basic consent requirements according to guidelines and specific risks of infrainguinal bypass. It was registered with the Trust Clinical Audit Department.
Results
(100%) of audit and reaudit consents documented the intended benefits of surgery. Inclusion into the National Vascular Registry (NVR) was achieved (0%) in audit vs (80%) in reaudit forms. Of the 19 documented postoperative complications, reaudit significant improvement observed in % of documenting 16 items with 9 complications recorded above 50%. The maximum number of audit documented risks was 15 (79%), the median 8 (42%), and the least was 3 (16%) compared to maximum 16 (84%), the median 10 (53%) and the least was 4 (21%) when reaudited, respectively.
Conclusions
Deficiencies in performing and adequately completing surgical consents still occur. Introducing a national pre-printed vascular intervention-specific consent is vital for accomplishing and maintaining a good clinical practice. It should include all complications with relative % risk to minimise errors, provide good quality consent, and promote clinical practice at a national level.

A Question of Consent—Coercion and Consent to Lobotomy, 1946–1958 [BOOK CHAPTER]

Jesper Vaczy Kragh
Lobotomy Nation, 10 October 2021; pp 291-335 [Springer]
Abstract
This chapter investigates a topic that has not been addressed in the literature on psychosurgery, i.e. the question of consent to lobotomy. The performance of lobotomy required the psychiatrist to obtain the consent of the patient, or his or her next of kin, to the treatment. The chapter analyses the role played by the consent requirement when neurosurgery was being considered. The consent issue gives an insight into the patient-doctor relationship and how psychiatrists interpreted patients' rights in the 1940s and 1950s. In addition, consent practices show that there were tensions between psychiatrists and neurosurgeons who

had different views about this. The consent question was significant to the discontinuation of psychosurgery, since the initial criticism of the treatment was raised due to complaints concerning lacking consent.

Rehearsal's effect on long-term recall and comprehension of orthodontic informed consent

Original Article

American Journal of Orthodontics and Dentofacial Orthopedics, 5 October 2021

Alexander R. Desman, Henry W. Fields, Andy Ni, Fonda G. Robinson, Brennan Skulski, Allen R. Firestone, David J. Heinlein

Abstract

Introduction

The purpose of this study was to determine if written rehearsal of informed consent improved 6-month recall and comprehension compared with the current best practices.

Methods

A consultation was provided and subjects read the modified informed consent document. They were randomized to group A (received the core and up to 4 custom elements of treatment, wrote what each image displayed) or group B (presentation of the 18 elements with core elements chunked at the end followed by up to 4 custom elements). Interviews recording knowledge recall/comprehension occurred immediately and after months later.

Results

Overall, no significant differences in baseline or 6-month follow-up scores were found between groups. Initially, group A outperformed group B in some core domains. There were no significant differences between groups in the change of scores from initial to follow-up. Follow-up scores were significantly lower than baseline scores ($P < 0.05$). Higher initial scores were associated with larger drops at follow-up. A decrease in knowledge >20% was common.

Conclusions

Overall the methods are comparable at baseline and 6-months. Initial content retention was roughly 60+%, with 6%-9% deterioration. For areas of treatment methods, risk, discomfort, and resorption at 6-months, the current processes failed the patient and left the practitioner vulnerable to risk management issues. Results support the rehearsal method with immediate feedback for misunderstandings as the preferred method for informed consent.

Consent for septoplasty: Are we meeting patients' expectations?

Research Article

Haseem Raja, Rishi Talwar

Medico-Legal Journal, 4 October 2021

Abstract

The requirements for informed consent were modified in 2015 following the UK Supreme Court judgment of Montgomery v Lanarkshire Health Board. This marked a decisive shift from the traditional paternalistic 'doctor knows best' model towards a more patient-centred approach. This study examines the current standard of consent for septoplasty and whether it complies with the law. We also report whether the 'reasonable patient' and surgeon agree about which risks should be discussed during the consent process. Ten complications were identified as common or serious via a literature search. Using questionnaires, 21 Ears, Nose and Throat surgeons were asked which of these they routinely discussed, and 103 patients were asked how seriously they regarded those complications. Results were compared using the Test of Proportions. Most surgeons routinely discuss all risks except negative change in sense of smell and numbness of upper incisors. The 'reasonable patient' regarded these two complications as serious or very serious. However, less than 70% of surgeons mentioned them. A significant proportion of Ears, Nose and Throat surgeons do not routinely mention all the risks that the 'reasonable patient' would want to know about

before undergoing a septoplasty. This may result in more clinical negligence claims, as managing a patient's reasonable expectations is an important factor.

Informed Consent, Advance Directives, and Shared Care Planning [BOOK CHAPTER]

Giuseppe Renato Gristina

Palliative Care in Cardiac Intensive Care Units, 30 September 2021; pp 83-97 [Springer]

Abstract

Knowing patient wishes regarding treatment acceptance or refusal is an essential aspect of care strategy, based on the principle of autonomy. In clinical practice, ignoring patient wishes or not taking them into proper consideration can lead to ethical and legal issues. In most cases patients hospitalized in general or specialized intensive care units (e.g., ICUs or cardiac intensive care units—CICUs), are unable to make autonomous decisions regarding their treatment due to disease severity. As a consequence, advance directives (ADs) could be a particularly effective tool to adequately guide doctor conduct with respect to patient values and wishes. In the USA and in many European countries, ADs have now been integrated in their legal systems but, despite their popularity, ADs have not yet achieved the expected result. In contrast, shared care planning (SCP) has been more successful. SCP is the process by which the quality of future patient care is discussed and planned according to the patient's values and preferences. Planning involves the patient, the healthcare professionals, and the family members. On one hand SCP can improve planning of future care for patients with advanced cardiovascular disease and document their preferences; on the other hand, it is unclear what role SCP has in improving the quality of patient life, reducing depression often associated with the disease, and increasing the caregiver satisfaction.

The Principle of Consensualism in Informed Consent Between Doctor and Patient

Lintang Yudhantaka, Mas Anienda Tien Fitriyah, Rosalia Dika Agustanti

Hang Tuah Law Journal, 20 September 2021; 5(1) [Indonesia]

Abstract

The term informed consent or consent for particular medical treatment was familiar in medical world. It brought security for both doctors who did their profession and patients who got information about the illness they were suffering from along with any medical treatment they would have. In fact, there were still many problems issued due to less-well implementation of informed consent. Therefore, this study aimed to analyze the characteristics of informed consent as the legal basis between doctor and patient and verify the establishment of agreement (i.e., consensus) in informed consent. It was a juridical-normative research with conceptual and statute approaches. The result of this study found that informed consent had distinctive characteristics compared with any other common agreements, in particular to its subject, object, and cause. Towards the establishment of consensus, it referred to the doctor's offering to do any medical treatment and patient's acceptance to have that treatment.

Patients' understanding of "informed consent" in plastic surgery

José Neder, Netto Roberto, Augusto de Carvalho Campos, Reginaldo Raimundo Fujita

Revista da Associação Médica Brasileira, August 2021; 67(8) [Brazil]

Summary

Objective

To assess the patient's understanding of the informed consent form before and after plastic surgery.

Methods

This was a prospective analytical descriptive study that utilized a questionnaire on informed consent before and after plastic surgery procedures.

Results

Comprehension of informed consent was higher before surgery than after surgery (p=0.016; question 15). The higher the scholarity, the higher the comprehension (s=0.151; p=0.045) before surgery (question 4). For the other questions, it was not possible to find a difference in the pattern of understanding and in the association with the educational attainment level after surgery (s=0.180; p=0.046; question 1).
Conclutions
The patients' level of comprehension of the details, outcomes, possible complications, and postoperative evolutions of surgical procedures, as stated by the informed consent form, is high.

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GENERAL/OTHER

Ethical Benefits and Drawbacks of Digitally Informed Consent [BOOK CHAPTER]

Wendy Charles, Ruth Magtanong
Applied Ethics in a Digital World, 2022 [IGI Global]
Abstract
As organizations steadily adopt remote and virtual capabilities, informed consent processes are increasingly managed by digital technologies. These digital methods are generating novel opportunities to collect individuals' permissions for use of private information but are blurring traditional boundaries of consent communication and documentation. Therefore, the rapid growth of digital technologies used for informed consent as well as the sheer volume of data resulting from electronic data capture are generating complex questions about individual engagement and data practices. This chapter presents emerging risks, benefits, and ethical principles about digital informed consent methods and technologies. For the areas where digital informed consent creates ethical uncertainties, ethical guidelines and user-design recommendations are provided.

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