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governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

July 2019

This digest is intended to aggregate and distill key content around informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

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

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

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

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GENOMIC MEDICINES/GENE THERAPY

Consent and Autonomy in the Genomics Era

Rachel Horton, Anneke Lucassen
Current Genetic Medicine Reports, 2 May 2019; 7(2) pp 85–91
Open Access
Abstract
Purpose of Review
Genomic tests offer increased opportunity for diagnosis, but their outputs are often uncertain and complex; results may need to be revised and/or may not be relevant until some future time. We discuss the challenges that this presents for consent and autonomy.
Recent Findings
Popular discourse around genomic testing tends to be strongly deterministic and optimistic, yet many findings from genomic tests are uncertain or unclear. Clinical conversations need to anticipate and potentially challenge unrealistic expectations of what a genomic test can deliver in order to enhance autonomy and ensure that consent to genomic testing is valid.
Summary
We conclude that 'fully informed' consent is often not possible in the context of genomic testing, but that an open-ended approach is appropriate. We consider that such broad consent can only work if located within systems or organisations that are trustworthy and that have measures in place to ensure that such open-ended agreements are not abused. We suggest that a relational concept of autonomy has benefits in encouraging focus on the networks and relationships that allow decision making to flourish.

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HUMANITARIAN CONTEXT

Mention of ethical review and informed consent in the reports of research undertaken during the armed conflict in Darfur : a systematic review

Research Article
Ghaiath Hussein, Khalifa Elmusharaf
BMC Medical Ethics, 13 June 2019; 20(40)
Open Access
Abstract
Background
Armed conflict in Darfur, west Sudan since 2003 has led to the influx of about 100 international humanitarian UN and non-governmental organizations to help the affected population. Many of their humanitarian interventions included the collection of human personal data and/or biosamples, and these activities are often associated with ethical issues. A systematic review was conducted to assess the proportion of publicly available online reports of the research activities undertaken on humans in Darfur between 2004 and 2012 that mention obtaining ethical approval and/or informed consent.
Methods
This systematic review is based on a systematic literature search of Complex Emergency Database, ReliefWeb, PubMed), followed by a hand search for the hardcopies of the eligible reports archived in the Centre for Research on the Epidemiology of Disasters (CRED) in Brussels.
Results

The online search showed that out of the 68 eligible studies, 13.2% (9) reported gaining ethical approval and 42.6% (29) that an informed consent was obtained from the participants. The CRED search included 138 eligible reports. None of these reports mentioned gaining ethical approval and 17 (12.3%) mentioned obtaining informed consent from their participants.

Conclusions

The proportion of studies reporting ethical review and informed consent was smaller than might be expected, so we suggest five possible explanations for these findings. This review provides empirical evidence that can help in planning ethical conduct of research in humanitarian settings.

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YOUNG PERSONS

Gavi, NEC, and Simprints to deploy world's first scalable child fingerprint identification solution to boost immunisation in developing countries [PRESS RELEASE]

gavi.org, 6 June 2019

Excerpt

Gavi, the Vaccine Alliance, NEC Corporation, and Simprints Technology Ltd. have signed a memorandum of understanding on the use of biometrics to improve immunisation coverage in developing countries.

Despite enormous progress over the past two decades, there are still approximately 20 million children who do not receive a basic course of vaccines worldwide, leaving them exposed to some of the world's deadliest diseases.

One key cause is the fact that only half of all children under 5 in sub-Saharan Africa are currently registered at birth, leaving many without an official identity. This makes it difficult for health practitioners to ensure these infants get the vaccines they need at the right time.

Guided by Gavi's experience and expertise in immunisation, this new project will combine Simprints' biometric fingerprint technology and NEC's reinforced authentication engine to help create digital identities for children 1-5 years of age and boost immunisation coverage in developing countries.

This new partnership will deploy the world's first scalable fingerprint identification solution to give children aged 1-5 a digital ID linked to an accurate, complete medical record. All biometric records will be stored securely by Simprints, a UK-based non-profit social enterprise, after caregivers give informed consent to having their children's biometric data taken…

> *Editor's note: The Foundation has expressed concern to GAVI about the management and potential misuse of this digital ID system beyond its intent to support infant immunization.*

Mature minors and self-determination in medical consent law: a comparison between the Italian legal system and the English legal system

Giulia Binatoa

Interdisciplinary Journal of Family Studies, 5 May 2019

Open Access

Abstract

Italian Law no. 219 of 2017 reforms medical consent law and introduces advanced healthcare directives. No changes are made to general private law rules on children capacity, including medical consent within parental responsibility. In accordance with the recent innovations brought by the Italian reform of filiation, children have a right to be heard and express their own view on the treatment over their person, proportionately to their age and understanding. The paper criticizes the Italian medical consent law dispositions on children who have sufficient understanding. Making a systematic comparison between the Italian situation and the so-called mature minor doctrine in English law, the paper specifically examines the

assumption that the child's right to be heard outside a judicial proceeding may be instrumental to assure self-determination of children within their fundamental rights of life, dignity and health.

Editor's note: This article also appears under RIGHTS/LEGAL/LEGISLATIVE

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COGNITIVE CHALLENGES

Lack of informed consent for surgical procedures by elderly patients with inability to consent: a retrospective chart review from an academic medical center in Norway

Research

Jorgen Dahlberg, Vegard Dahl, Reidun Forde, Reidar Pedersen

Patient Safety in Surgery, 22 June 2019; 13(24)

Open Access

Abstract

Background

Respect for patient autonomy and the requirement of informed consent is an essential basic patient right. It is constituted through international conventions and implemented in health law in Norway and most other countries. Healthcare without informed consent is only allowed under specific exceptions, which requires a record in the patient charts. In this study, we investigated how surgeons recorded decisions in situations where the elderly patient's ability to provide a valid informed consent was questionable or clearly missing.

Method

We investigated all medical records of patients admitted to surgical departments in a Norwegian large academic emergency hospital over a period of 38 days (approximately 5000 patients). We selected records of patients above the age of 70 (570 patients) and searched through these 570 medical records for any noted clear indications of inability to consent such as "do not understand", "confused" etc. (102 patients). We read through all the medical records on these 102 patients noting any recordings on lack of informed consent, any recordings on reasoning and process hereto. We also took note whether there were clear indications on the use of coercion.

Results

None of the 102 included patients´ charts contained legally valid recorded assessments (for example related to the patients´ competence to consent) when patients without the ability to consent were admitted and provided healthcare.

Some charts contained records that the patient resisted treatment, thus indicating treatment with coercion. In these situations, we did not find any documentation related to legal requirements that regulate the use of coercion.

Discussion and conclusion

We found a substantial lack of compliance with the legal requirements that apply when obtaining valid informed consent. There are many possible reasons for this: Lack of knowledge of the legal requirements, disagreement about the rules, or that it is simply not possible to comply with the extensive formal and material legal requirements in clinical practice. The results do not point out whether the appropriate measures are amending the law, educating and requiring more compliance from surgeons, or both.

Questions about informed consent related to the use of haptic suits as assistive technologies for people with intellectual and developmental disabilities

Fiachra O'Brolcháin, Aviva Cohen

International Journal of Applied Ethics, 31 May 2019; 30

Open Access

Abstract

Technological innovation is witnessing the convergence of haptic technologies with real-time 3D virtual environments and / or augmented reality technologies. Among the diverse applications of these innovations is their use as assistive technologies for people with intellectual and developmental disabilities, or people with cognitive deficits, such as dementia.

This article focuses on the issue of informed consent in relation to research and the use of these technologies (hereafter referred to simply as haptic suits). Informed consent is a standard requirement in the ethics of research, as well as in care settings, so it will be necessary for tests with haptic suits in general and, when used as assistive technology. Given the emphasis on the participation of people with intellectual or developmental disabilities in the research and design of assistive technologies for their use, the issue of informed consent is compelling.

> *Editor's note: This is a Spanish language publication. In reviewing available definitions for haptic technologies we found the following: "the science of applying touch sensation and control to interact with computer developed applications".*

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TECHNOLOGY/OTHER MEDIATION

Research ethics for mobile sensing device use by vulnerable populations

Samantha Breslin, Martine Shareck, Daniel Fuller
Social Science & Medicine, July 2019; 232 pp 50-57
Abstract
Devices equipped with sensors to track mobility, such as through Global Position Systems (GPS) and accelerometery, are increasingly being used for research. Following Canadian, US, and International guidelines there is a need to give special consideration when conducting research with vulnerable populations. This paper examines specific ethical concerns for conducting research with mobile sensing devices for use by vulnerable populations, considering aspects of both research design and research process. Drawing on insights from feminist design and aligned fields, such as participatory design and action research, we contend that any research design and process for working with vulnerable populations must be developed in collaboration with the particular groups and communities who are part of the research. As part of this process of collaborative research, we discuss risks in terms of the lack of control over data associated with choosing commercial devices, as well as practicality and obtrusiveness of devices for the wearer. We also discuss the significance of informed consent and refusal and issues relating to security and safety during research. As part of the collaborative research design and process, we argue that participants should be given as much control over their data as possible. Based on this discussion, we provide recommendations for researchers to consider, which are broadly relevant for research using mobile sensing devices but particularly significant in relation to vulnerable populations.

A randomized, controlled trial of video supplementation on the cataract surgery informed consent process

Journal Article
Zhang MH, Haq ZU, Braithwaite EM, Simon NC, Riaz KM
Graefe's Archive for Clinical and Experimental Ophthalmology, 30 May 2019; pp 1-10
Abstract
Purpose
To assess the effects of the American Academy of Ophthalmology's 2015 patient education video on patient information retention and anxiety preoperatively, on the day of surgery and postoperatively.
Methods

This is a prospective, surgeon-blinded randomized controlled trial at the University of Chicago Medical Center. Ninety-one patients with a diagnosis of first-eye cataract were randomized into either a video or control group. Subjects in both groups received face-to-face discussion with the surgeon and an informational brochure at the preoperative evaluation. Participants in the video group then viewed a four-minute educational video at the preoperative evaluation and on the day of surgery. Both groups completed an information retention quiz and a state anxiety assessment at the preoperative visit, on the day of surgery, and on the postoperative week one visit. Subject understanding of cataract surgery was measured using a twelve-question multiple choice quiz. State anxiety was measured by State Trait Anxiety Inventory-Y1 survey score.

Results

Participants in the video group did not score significantly higher on the information retention quiz compared with the control group at the preoperative evaluation (8.7 ± 2.4 vs 7.7 ± 2.5, P = 0.07), but did so on the day of surgery (11.2 ± 0.8 vs 8.4 ± 1.7, P < 0.001) and postoperative week 1 visit (10.8 ± 1.5 vs 9.0 ± 2.0, P < 0.001). Subjects in the video group were significantly less anxious on the day of surgery (26.4 ± 5.1 vs 41.1 ± 10.3, P < 0.001).

Conclusions

Video supplementation to the traditional informed consent process demonstrated an improvement in patient understanding of cataract surgery at multiple timepoints and decreased anxiety on the day of surgery.

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BIOMEDICAL RESEARCH

A limited number of medicines pragmatic trials had potential for waived informed consent following the 2016 CIOMS ethical guidelines

Original Article

RafaelDal−Ré, CristinaAvendaño−Solà, Anthoniusde Boer, Stephan K.James, Frits R.Rosendaal, RichardStephens, JohnPA Ioannidis

Journal of Clinical Epidemiology, 15 June 2019

Abstract

Objective

European regulations do not allow modification or waiver of informed consent for medicines randomized controlled trials (RCTs) where the three 2016 Council for International Organizations of Medical Sciences (CIOMS) provisions are met (consent would be impractical or unfeasible, yet the trial would have high social value and pose no or minimal risk to participants). We aimed to identify whether any such trials of medicines were being conducted in Europe.

Study design and Setting

Survey of all phase 4 'ongoing' RCTs on the EU clinical trial register between 1/July/2016 and 30/June/2018, to identify those with potentially high levels of pragmatism. Trials that were excluded: those conducted on rare diseases; masked (single-, double-blind) trials; single-center trials; those where one could expect to lead patients to prefer one intervention over the other; and miscellaneous reasons. The degree of pragmatism of the RCTs was self-assessed by trials' investigators by means of the PRECIS-2 tool. Investigators of those trials considered to be highly pragmatic, assessed the fulfillment of the three CIOMS provisions. Seven patients assessed the social value of the RCTs. Finally, 33 members of 11 research ethics committees (RECs) assessed the social value of the trials and whether they posed no more than minimal risk to participants. Investigators, patients and REC members assessed the fulfilment of the CIOMS provisions as 'Yes', 'Not sure' or 'No'.

Results

Of the 636 phase 4 trials, 420 were RCTs, and 21 of these (5%) were candidates to be pragmatic. Investigators of 15 of these 21 RCTs self−assessed their trial's degree of pragmatism: 14 were highly pragmatic. Of these

14, eight fulfilled the three CIOMS provisions. Assessments by patients and RECs were inconsistent for several trials.

Conclusions

We found few low−risk participant−level pragmatic RCTs that could be suitable for modified or waived participants' informed consent. European regulators should consider amending the current regulation and encouraging the conduct of such trials.

Clinical Image Consent Requirements: Variability among Top Ten Medical Journals

Juan N. Lessing, Nicholas M. Mark, Matthew K. Wynia, Ethan Cumbler

Journal of Academic Ethics, 21 June 2019; pp 1–5

Abstract

The consent process for publication of clinical images in medical journals varies widely. The extent of this variation is not known. It is also not known whether journals follow their own stated best practices or the guidance of the International Committee of Medical Journal Editors (ICMJE). We assessed consent requirements in a sample of 10 top impact factor general medicine journals that publish clinical images, examining variability in consent requirements for clinical image publication and congruence of requirements with the recommendations of the ICMJE. Clinical image consent requirements varied widely from journal to journal. None of the studied journals, even amongst n = 4 ICMJE members or n = 8 journals who self-report adherence to ICMJE guidelines, comply with all of the recommendations of the ICMJE. Half of studied journals require a journal-specific consent form. Among top medical journals there is significant heterogeneity in consent requirements for clinical images. Variability of consent requirements is neither practical nor rational; inconsistent requirements create uncertainty for authors, present impediments to dissemination of scholarship, and undermine a shared professional understanding of how best to protect patient privacy. We propose adopting a standardized consent form and process for publication of identifiable images in medical journals, with uniform elements and explicit definitions.

Informed consent for early-phase clinical trials: therapeutic misestimation, unrealistic optimism and appreciation

Original Research

Jodi Halpern, David Paolo, Andrew Huang

BMJ, 12 June 2019

Abstract

Unrealistic therapeutic beliefs are very common—the majority of patient-subjects (up to 94%) enrol in phase 1 trials seeking and expecting significant medical benefit, even though the likelihood of such benefit has historically proven very low. The high prevalence of therapeutic misestimation and unrealistic optimism in particular has stimulated debate about whether unrealistic therapeutic beliefs in early-phase clinical trials preclude adequate informed consent. We seek here to help resolve this controversy by showing that a crucial determination of when such therapeutic beliefs are ethically problematic turns on whether they are causally linked and instrumental to the motivation to participate in the trial. Thus, in practice, it is ethically incumbent on researchers to determine which understanding and beliefs lead to the participant's primary motivation for enrolling, not to simply assess understanding, beliefs and motivations independently. We further contend that assessing patient-subjects' appreciation as a component of informed consent—it is already an established component of decision-making capacity assessments—can help elucidate the link between understanding-beliefs and motivation; appreciation refers to an individual's understanding of the personal significance of both the medical facts and the experience of trial participation. Therefore, we recommend that: (1) in addition to the usual question, 'Why do you want to participate in this trial?', all potential participants should be asked the question: 'What are you giving up by participating in this trial?' and (2) researchers should consider the settings in which it may be possible and practical to obtain 'two-point consent'.

Informed Consent Issues for Cell Donors

Methods in Molecular Biology Book Series

Insoo Hyun

Chimera Research, 8 June 2019; pp 67-74

Abstract

Stem cell-based chimera research depends on the free and voluntary provision of human biomaterials necessary for the derivation of pluripotent stem cell lines. Informed consent requirements for the procurement of human embryos, gametes, and somatic cells must take into account unique features of biomedical research involving the use of immortal cell lines that carry their donors' genetic information. The extent and basis for donors' rights, including the right to withdraw from research, are explored here in detail.

Parents' and clinicians' views on conducting paediatric diagnostic test accuracy studies without prior informed consent: qualitative insight from the Petechiae in Children study (PiC)

Original Article

Thomas Waterfield, Mark D Lyttle, Michael Shields, Derek Fairley, Damian Roland, James McKenna, Kerry Woolfall

BMJ, 7 June 2019

Abstract

Objective

The Petechiae in Children (PiC) study assesses the utility of presenting features and rapid diagnostic tests in the diagnosis of serious bacterial infection in feverish children with non-blanching rashes. An embedded qualitative study explored parents' and clinicians' views on the acceptability of the PiC study, including the use of research without prior consent (RWPC) in studies of diagnostic test accuracy.

Design

Semistructured qualitative interviews. Analysis was thematic and broadly interpretive, informed by the constant comparative approach.

Participants

Fifteen parents were interviewed 55 (median) days since their child's hospital attendance (range 13–95). Five clinicians involved in recruitment, and consent were interviewed.

Results

Parents and clinicians supported RWPC for the PiC study and future emergency paediatric diagnostic test accuracy studies as long as there is no harm to the child and emergency care is not delayed. Parents and clinicians made recommendations around the timing and conduct of a consent discussion, which were in line with RWPC guidance. Parents enrolled in the PiC study preferred a design that included consent discussions with the research team over the alternative of 'opt-out' consent only.

Conclusions

This embedded qualitative study demonstrates that RWPC is appropriate for use in paediatric emergency studies of diagnostic test accuracy and that the approach used in PiC was appropriate. Future diagnostic studies involving additional invasive procedures or an opt-out only approach to consent would benefit from exploring parent and clinician views on acceptability at the pretrial stage.

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SOCIAL SCIENCE RESEARCH

The Effect of Framing and Placement on Linkage Consent

Joseph W Sakshaug, Alexandra Schmucker, Frauke Kreuter, Mick P Couper, Eleanor Singer

Public Opinion Quarterly, 20 June 2019

Open Access

Abstract

Numerous surveys link interview data to administrative records, conditional on respondent consent, in order to explore new and innovative research questions. Optimizing the linkage consent rate is a critical step toward realizing the scientific advantages of record linkage and minimizing the risk of linkage consent bias. Linkage consent rates have been shown to be particularly sensitive to certain design features, such as where the consent question is placed in the questionnaire and how the question is framed. However, the interaction of these design features and their relative contributions to the linkage consent rate have never been jointly studied, raising the practical question of which design feature (or combination of features) should be prioritized from a consent rate perspective. We address this knowledge gap by reporting the results of a placement and framing experiment embedded within separate telephone and Web surveys. We find a significant interaction between placement and framing of the linkage consent question on the consent rate. The effect of placement was larger than the effect of framing in both surveys, and the effect of framing was only evident in the Web survey when the consent question was placed at the end of the questionnaire. Both design features had negligible impact on linkage consent bias for a series of administrative variables available for consenters and non-consenters. We conclude this research note with guidance on the optimal administration of the linkage consent question.

Linking Survey and Twitter Data: Informed Consent, Disclosure, Security and Archiving

Luke Sloan, Curtis Jessop, Tarek Al Baghal, Matthew Williams

University of Essex Research Repository, 11 June 2019

Open Access

Abstract

Linked survey and Twitter data present an unprecedented opportunity for social scientific analysis, but the ethical implications for such work are complex – requiring a deeper understanding of the nature and composition of Twitter data to fully appreciate the risks of disclosure and harm to participants. In this paper we draw on our experience of three recent linked data studies, briefly discussing the background research on data linkage and the complications around ensuring informed consent. Particular attention is paid to the vast array of data available from Twitter and in what manner it might be disclosive. In light of this, the issues of maintaining security, minimising risk, archiving and re-use are applied to linked Twitter and survey data. In the conclusion we reflect on how our ability to collect and work with Twitter data has outpaced our technical understandings of how the data is constituted and observe that understanding one's data is an essential prerequisite for ensuring best ethical practice.

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CULTURAL/COUNTRY CONTEXT

Free, Prior, and Informed Consent in the Philippines: A Fourth World Critique

Interdisciplinary Studies in Human Rights book series (CHREN, volume 3)

Armi Beatriz E. Bayot

Human Rights in the Extractive Industries, 14 June 2019; pp 281-309

Abstract

When it comes to the planning and execution of resource use activities, indigenous peoples' voices do not carry the same weight as those of states—not even when the activity at issue will have a profound and irreversible impact on indigenous peoples' survival. As illustrated by how the norm of free, prior, and informed consent (FPIC) is implemented in the Philippines, this is due to competing state-centric international and domestic legal norms that privilege state prerogatives over natural resources vis-à-vis indigenous peoples' rights over their territories. The doctrine of state sovereignty is so fundamental in international law that states' acknowledgment of indigenous peoples' rights, in general, and FPIC, in particular, continue to be qualified by this doctrine. FPIC, therefore, remains to be a regime of unfulfilled promise due to the inherent power imbalance in the international law framework in which it exists, which is based on a Western conception of state sovereignty that denies the (pre-)existence and validity of indigenous polities and their historical sovereignty. The way forward is to assert indigenous peoples' participation in international law-making, based on their right to self-determination and historical sovereignty, to empower them to influence the content of other norms of international law that affect them—not just those international law norms that ostensibly exist specifically for the protection of indigenous peoples (such as FPIC).

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RIGHTS/LEGAL/LEGISLATIVE

Playing by the rules: Impact of the new General Data Protection Regulation on retrospective studies: A researcher's experience

M H van der Ree, R A Scholte, P G Postema, J R de Groot
European Heart Journal, 21 June 2019; 40(24) pp 1900–1902
Open Access
Excerpt
...Despite the retrospective nature of the study, informed consent is required for the reuse of care data in the context of scientific research. For participants of the PREDICT-AF study, consent for the reuse of care data was available as part of the informed consent form of this prospective study. For the control cohort, however, no such consent was available. This was our first barrier: only a physician who is directly involved in the patient's medical care, and not an investigator, is allowed to approach potential study participants and ask for informed consent. This physician is also allowed to ask for the patient's permission for another person to approach him or her and ask for consent. As the control patients of our retrospective study were no longer under the treatment of the two hospitals that performed the PREDICT-AF study, this implied approaching approximately 50 referring cardiologists of the control patients and ask for their cooperation. These cardiologists would then have to personally ask their patients permission to be approached by the investigator, who could then ask for informed consent. This procedure put some serious constraints on the timelines of our envisioned data collection…

The side effects of deemed consent: changing defaults in organ donation

Current Controversy
David M Shaw
Journal of Medical Ethics, 22 June 2019
Abstract
In this Current Controversy article, I describe and analyse the imminent move to a system of deemed consent for deceased organ donation in England and similar planned changes in Scotland, in light of evidence from Wales, where the system changed in 2015. Although the media has tended to focus on the potential benefits and ethical issues relating to the main change from an opt-in default to an opt-out one, other defaults will also change, while some will remain the same. Interaction of these other defaults with the principal one raise

several ethical issues that may complicate efforts to use deemed consent to increase donation rates. Most significantly, changing the main default will have the effect of changing the default for patients' families, who play a vital role in the consent process.

Mature minors and self-determination in medical consent law: a comparison between the Italian legal system and the English legal system

Giulia Binatoa

Interdisciplinary Journal of Family Studies, 5 May 2019

Open Access

Abstract

Italian Law no. 219 of 2017 reforms medical consent law and introduces advanced healthcare directives. No changes are made to general private law rules on children capacity, including medical consent within parental responsibility. In accordance with the recent innovations brought by the Italian reform of filiation, children have a right to be heard and express their own view on the treatment over their person, proportionately to their age and understanding. The paper criticizes the Italian medical consent law dispositions on children who have sufficient understanding. Making a systematic comparison between the Italian situation and the so-called mature minor doctrine in English law, the paper specifically examines the assumption that the child's right to be heard outside a judicial proceeding may be instrumental to assure self-determination of children within their fundamental rights of life, dignity and health.

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

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BIOBANKING

Reconsidering Dynamic Consent in Biobanking: Ethical and Political Consequences of Transforming Research Participants Into ICT Users

Alexandra Soulier

IEEE Technology and Society Magazine, 10 June 2019; 38(2) pp 62-70

Abstract

Biobanks are not new. However, the scope of their application is growing, especially in genomics. Biobanks are also currently being reorganized to enable more genomic samples to be made available for different types of studies. Some future uses of the biobanks cannot be anticipated.

'I haven't met them, I don't have any trust in them. It just feels like a big unknown': a qualitative study exploring the determinants of consent to use Human Fertilisation and Embryology Authority registry data in research

Qualitative research

Claire Carson, Lisa Hinton, Jenny Kurinczuk, Maria Quigley

BMJ, 30 May 2019; 9(5)

Open Access

Abstract

Objectives

To explore why and how fertility patients decide to allow (or deny) the use of personal data held in the Human Fertilisation and Embryology Authority registry for linkage and research.

Design

A qualitative study was conducted using in-depth face-to-face interviews and an online survey to garner information on experience and opinions from fertility clinic patients and staff. Verbatim transcripts were analysed using the 'one sheet of paper' method to identify themes.

Setting

Women and men were recruited between September 2015 and December 2017, via fertility clinics across England and online advertising, then interviewed at a location convenient to them.

Participants

20 patients and 9 staff were interviewed, 40 patients completed the online survey.

Results

Consent for disclosure (CD) forms are completed at a stressful time, when patients often feel overwhelmed; these forms were considered a low priority. Perceptions of benefit (to individuals, to wider society) and harm (misuse of data, impact of disclosure on child) influenced consent. Important themes included: understanding of the forms; trust in those asking, in researchers, in the Human Fertilisation and Embryology Authority (HFEA); and wider attitudes to data use. Issues influencing response, and thus the representativeness of the HFEA data set, were highlighted.

Conclusions

Understanding what is being asked, and trust in those organisations keeping and using personal data, affects individual decisions to consent to disclosure. Patients were influenced by the wider context of infertility, as well as general concerns about data sharing and security. Low consent rates, which vary by clinic and likely also by patients' characteristics, have adverse implications for research conducted using HFEA data collected after 2008. Public understanding of data use and security is relatively poor; increased public trust in, and awareness of, research based on routine data could improve consent to data use and reduce the risk of bias.

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GENERAL/OTHER

Concise Consent Forms Appreciated—Still Not Comprehended: Applying Revised Common Rule Guidelines in Online Studies

Research Article

Evan K. Perrault, Seth P. McCullock

Journal of Empirical Research on Human Research Ethics, 6 June 2019

Abstract

As informed consent documents have historically gotten lengthier, recent revisions to federal Common Rule guidelines now require consent forms that are "concise" and presented in ways that "facilitate comprehension." The current research sought to apply these guidelines by developing a consent process for an online study that was only 71 words and also allowed participants a choice to either continue directly to the study or learn more about the study to which they were consenting. All participants (100%, N = 429) decided to continue directly to the study, choosing to forgo additional information about the study and the institutional review board (IRB) approval process. Participants indicated they liked this streamlined consent process, even though on average they only comprehended about half of the information this streamlined process contained. A plurality of participants indicated they would like to see this style of streamlined consent continued in future online studies. However, if we want to continue referring to informed consent as informed, future research should be welcomed and supported by IRBs to seek ways to apply the newest Common Rule guidelines while increasing comprehension; otherwise, informed consent will likely always remain an oxymoron.

Hormone replacement therapy: informed consent without assessment?

Response

Toni C Saad, Bruce Philip Blackshaw, Daniel Rodger

Journal of Medical Ethics, 22 June 2019

Abstract

Florence Ashley has argued that requiring patients with gender dysphoria to undergo an assessment and referral from a mental health professional before undergoing hormone replacement therapy (HRT) is unethical and may represent an unconscious hostility towards transgender people. We respond, first, by showing that Ashley has conflated the self-reporting of symptoms with self-diagnosis, and that this is not consistent with the standard model of informed consent to medical treatment. Second, we note that the model of informed consent involved in cosmetic surgery resembles the model Ashley defends, and that psychological assessment and referral is recognised as an important aspect of such a model. Third, we suggest that the increased prevalence of psychiatric morbidity in the transgender population arguably supports the requirement of assessment and referral from a mental health professional prior to undergoing HRT.

Editor's note: This article is a response to the viewpoint article which can be found at this link

Complexity of Clinical Decision Making: Consent, Capacity, and Ethics

Review Article

Annette Askren, Paula Leslie

Seminars in Speech and Language, June 2019; 40(03) pp 162-169

Abstract

Speech–language pathologists (SLPs), and really their patients, are often faced with challenging clinical decisions to be made. Patients may decline interventions recommended by the SLP and are often inappropriately labeled "noncompliant." The inappropriateness of this label extends beyond the negative charge; the patient's right to refuse is, in fact, protected by law. Anecdotal exchanges, social media platforms, and American Speech-Language-Hearing Association forums have recently revealed that many SLPs are struggling with the patient's right to decline. Many are not comfortable with the informed consent process and what entails patients' capacity to make their own medical decisions. Here, we discuss the basics of clinical decision-making ethics with intent to minimize the clinician's discomfort with the right to refuse those thickened liquids and eliminate the practice of defensive medicine.

Moving Beyond Informed Consent to Dynamic or Shared Consent: The Clinical and Legal Framework of a More Patient-Centred Approach [MA DISSERTATION]

Thandi S Mabeba

University of Pretoria; Faculty of Law, 28 October 2018

Open Access

Abstract

Obtaining the consent of a patient is at the centre of medical practice and as such medical practitioners need to ensure proper patient's approval in the administration of medical services or prescription of medical products. Informing a patient about the medical implications involved in the procedure they are about to undergo is not sufficient as patient needs to be fully engaged. The transcendence beyond informed consent to shared or dynamic consent is the core focus of discussion in this work. It is argued in this work, that there has to be policy that deals with specifically with consent across a broader spectrum of the provision healthcare goods and services.

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MEDICAL/SURGICAL

Consent in gastrointestinal endoscopy: valid, informed and nurse-led

Christine Metcalf

Gastrointestinal Nursing, 19 June 2019; 17(5)

Abstract

Gastrointestinal endoscopy is generally safe, but these diagnostic and therapeutic interventions come with potential risks and thus require written, valid and informed consent, except in emergencies. Informed consent requires patients to receive and discuss information on the benefits, risks and nature of the procedure, as well as any alternatives. To consent, a patient must have the mental capacity to understand the information and use it to make and communicate a decision. Consent is a multi-stage procedure, beginning when endoscopy is first proposed and continuing into the intervention, as patients can withdraw consent during the procedure, whether sedated or not. For high-volume, low-risk procedures, the consent process can be safely delegated to qualified endoscopy nurses, with sufficient and relevant training, knowledge and support from the trust. Nurses competencies and other elements of the consent process should be regularly audited.

The Reading Level of Surgical Consent Forms in Hand Surgery

Original Research

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Open Access

Abstract

Purpose

The average United States adult reads at an eighth-grade reading level. In an effort to ensure that patients understand written medical information, the National Institutes of Health and American Medical Association suggest that patient-directed material be written at a sixth- to eighth-grade reading level. We hypothesized that the mean reading level of surgical consent forms for hand surgery is not at or below an eighth-grade reading level (the suggested maximum from the National Institutes of Health).

Methods

We conducted a retrospective review of consecutive consent forms used for hand surgery patients from 7 hand surgeons at our institution from June, 2017 to October, 2017. Consent forms were reviewed to collect the hand-written portion describing the procedure. We also assessed our institution's consent form template. This text was assessed for readability and reading level with the following tools: Flesch-Kincaid Grade Level and Flesch Reading Ease. We categorized the procedures written on each consent form by procedure type and then created simplified language for the same procedure below an eighth-grade reading level.

Results

Mean Flesch-Kincaid grade level of all consent forms was 10.5 (SD, 5.8) and mean Flesch readability was 33.6 (SD, 38.8), or difficult to read. A total of 78% and 58% of forms were written above the sixth- and eighth-grade reading levels, respectively. Readability was remarkedly poor; 94% and 88% of consent forms were written above sixth- and eighth-grade readability, respectively. The grade level of the consent form template was 17.1.

Conclusions

Most consent forms were written above a sixth- to eighth-grade reading level and may not have been well-understood by patients. It is possible for physicians to write on surgical consent forms at a reading level that patients are more likely to understand by opting for less specialty-specific words and writing in shorter sentences. Improving the readability of patient-directed materials is an approach to improving patient-centered care.

Informed Consent in Plastic Surgery, Evaluation of its Effectiveness for Mutual Satisfaction of Patient and Doctor: Comparison of Methods

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Abstract

Background

The acquisition of signed informed consent is not always enough to ensure adequate medical protection. Particularly in plastic surgery improving the doctor-patient relationship by understanding the patient's emotions and expectations becomes a determining factor when choosing the best therapeutic strategy for the subject in question, which may also include non-surgical eligibility.

Methods

90 patients, with various plastic surgery disabilities, were recruited and randomly divided into three groups: the 1st group underwent the "traditional" clinical interview, the 2nd to the clinical approach called Shared Decision Making (SDM), the third group received both the SDM and a questionnaire evaluating patient expectations (Expectation Questionnaire-Pgm). At the end of each interview, a specialist physician in Plastic, Reconstructive and Aesthetic Surgery was asked to fill in a questionnaire regarding his/her satisfaction with the method used. Likewise, the patient filled in a questionnaire on his/her satisfaction with the interview.

Results

For the doctors, the third method was superior in investigating patient expectations, emotions and personal preferences. For the patients, the third method score significantly higher than the first one for overall satisfaction, ability to evaluate personal preferences and needs; and higher than the first and second in assessing expectations.

Conclusions

For doctors, the SDM coupled with the Expectation Questionnaire-Pgm proved to be the most useful tool to understand patient expectations and emotions and thus improve the medical-patient relationship through shared decision-taking. The third method therefore makes for better patient coverage and improved informed consent, reducing the likelihood of litigation and better assessing non-fitness for operation.

Consent Obtained by Residents: Informed by the Uninformed?

Tait AR

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Abstract

Informed consent is central to the bioethical principle of respect for persons, a process that involves a discussion between the physician and patient with disclosure of information sufficient to allow the patient to make an informed decision about her or his care. However, despite the importance of informed consent in clinical practice, the process is often ritualized, perfunctory, and performed by individuals with little or no training in the consent process. This article discusses the lack of medical students' and residents' training in informed consent and questions the practice of allowing untrained residents and surrogates to obtain consent from patients.

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