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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

December 2019

This digest aggregates and distills 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
SOCIAL SCIENCE RESEARCH
RIGHTS/LEGAL/LEGISLATIVE
FREE PRIOR INFORMED CONSENT

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REAL WORLD POLICY/PROGRAM ACTION

United Republic of Tanzania lowers age of consent for HIV testing

UNAIDS
29 November 2019
Press Release
The United Republic of Tanzania has approved a change to the law that lowers the age of consent for HIV testing from 18 years to 15 years. The amendment to legislation also makes self-testing for HIV legal, also from the age of 15 years.

"These amendments will significantly accelerate our intention to meet the 90–90–90 goals, which aim at ending the AIDS epidemic by 2030," said Ummy Mwalimu, Minister of Health, Community Development, Gender, Elderly and Children. The ministry was instrumental in tabling the amendments to the legislation.

The 90–90–90 targets are ambitious treatment targets to help end the AIDS epidemic. They aim to ensure that, by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people who know their HIV status will be on antiretroviral therapy and 90% of all people on antiretroviral therapy will be virally suppressed.

The changes to the law will contribute to improved access to HIV testing for adults aged 15 years and over.

At the end of 2018, the progress on the 90–90–90 targets in the United Republic of Tanzania was 78–92–87. In 2018, there were 72 000 new HIV infections in the country. While this is a 13% reduction from 2010, it is below the 28% reduction across eastern and southern Africa.

"I congratulate the Government of the United Republic of Tanzania on its leadership and high-level political commitment to the AIDS response. UNAIDS will continue to work hand-in-hand with all our partners to ensure that access to HIV testing and treatment continues to expand," said Leo Zekeng, UNAIDS Country Director in the United Republic of Tanzania.

Guidelines for ethical research on sexual exploitation involving children

ECPAT - ECPAT is the only child right's organisation that is solely focusing on ending the sexual exploitation of children (ecpat.org)
29 November 2019
Press Release
…The Guidelines for Ethical Research on Sexual Exploitation involving Children offer a framework for ethical research design in this area. They guide the reader through four steps in research design and implementation and set up a series of 'ethical tasks' that should be undertaken in your research project…
Excerpt
Introduction
Doing research involving children in the context of sexual exploitation raises a range of ethical questions and dilemmas. Some of these are similar for any research with human participants or vulnerable groups; but others are very specific to children affected by sexual exploitation (see 'Ethics of Research on Sexual Exploitation Involving Children' for a review of the literature). This document provides guidance for negotiating these ethical questions for a range of people engaged in field research (from lead researchers to data collectors)…
Informed Consent
…Even though not always legally required, with research involving children, it is also ethically appropriate to also obtain 'assent 'from child participants. Obtaining 'assent' means to formally get permission from the child that they want to participate (not to just assume they do because a parent/caregiver gave consent). Children have the right to participate, but they also have the right to choose whether to express or not

express those views6 This “means that the child must not be manipulated or subjected to undue influence or pressure…”

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GENOMIC MEDICINE/GENE EDITING

A framework for tiered informed consent for health genomic research in Africa

Victoria Nembaware, Katherine Johnston, Alpha A. Diallo, Maritha J. Kotze, Alice Matimba, Keymanthri Moodley, Godfrey B. Tangwa, Rispah Torrorey-Sawe, Nicki Tiffin
Nature Genetics, 28 October 2019; 51 pp 1566–1571
Abstract
A generic framework for providing participant information and implementing a tiered consent process for health genomic research in Africa can help to harness global health benefits from sharing and meta-analysis of African genomic data while simultaneously respecting and upholding the autonomy and individual choices of African research participants.

Editor’s note: The article also appears under CULTURAL/COUNTRY CONTEXT

Dynamic Consent: An Evaluation and Reporting Framework

Research Article
Megan Prictor, Megan A. Lewis, Ainsley J. Newson, Matilda Haas, Sachiko Baba, Hannah Kim, Minori Kokado, Jusaku Minari, Fruzsina Molnár-Gábor, Beverley Yamamoto, Jane Kaye, Harriet J. A. Teare
Journal of Empirical Research of Human Research Ethics, 15 November 2019
Abstract
Dynamic consent (DC) is an approach to consent that enables people, through an interactive digital interface, to make granular decisions about their ongoing participation. This approach has been explored within biomedical research, in fields such as biobanking and genomics, where ongoing contact is required with participants. It is posited that DC can enhance decisional autonomy and improve researcher–participant communication. Currently, there is a lack of evidence about the measurable effects of DC-based tools. This article outlines a framework for DC evaluation and reporting. The article draws upon the evidence for enhanced modes of informed consent for research as the basis for a logic model. It outlines how future evaluations of DC should be designed to maximize their quality, replicability, and relevance based on this framework. Finally, the article considers best-practice for reporting studies that assess DC, to enable future research and implementation to build upon the emerging evidence base.

Editor’s note: The article also appears under BIOBANKING

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HUMANITARIAN CONTEXT

Abstract 391: Variation in Time to Notification After Enrollment in Trials Conducted Under Exception From Informed Consent for Emergency Research [POSTER PRESENTATION]

Graham Nichol, Rui Zhuang, Tom P Aufderheide, Eileen Bulger, Clifton W Callaway, Jim Christenson, Mohamud R Daya, Ahamed H Idris, Peter Kudenchuk, Laurie J Morrison, Martin A Schreiber, George Sopko, Jeremy Sugarman, Christian Vaillancourt, Henry E Wang, Myron Weisfeldt, Susanne May
Circulation, 11 November 2019; 140(supplement 2)
Open Access
Abstract

Context
Research in an emergency setting is challenging because the window of opportunity to treat may be short, and preclude time to obtain informed consent from the patient or their representative. Such research can be conducted under exception from informed consent (EFIC) if specific criteria are met. In the United States, this includes notification of an enrolled subject or their representative as soon as feasible after enrollment so that they have autonomy to opt out from ongoing study participation. To date, there is limited empiric information about time to notification (TTN).
Objective
To describe variation in TTN among sites participating in randomized trials conducted under exception from informed consent for emergency research.
Methods
Notification strategies were determined at each site prior to initiation of subject enrollment, and approved by a local institutional review board or equivalent. TTN was summarized overall, as well as stratified by site and clinical outcome among patients enrolled in multiple trials conducted by the Resuscitation Outcomes Consortium (ROC).
Results
Included were 34,868 patients enrolled in four trials. Of these, 33,805 had with out-of-hospital cardiac arrest; and 1,063 had life-threatening traumatic injury. TTN varied (Table).
Conclusions
There is large variation in TTN in trials conducted under EFIC for emergency research. Early notification is difficult; delayed notification may reduce the autonomy of patients or their representative.

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BIOMEDICAL RESEARCH

Study of Awareness and Practice of Informed Consent Process Among Clinical Trial Participants and Their Motives Behind Participation

Research Article
Rajesh Ranjan, Nidhi B. Agarwal, Prem Kapur, Amit Marwah, Rizwana Parveen
Asia Pacific Journal of Public Health, 3 November 2019
Abstract
Process to obtain informed consent is an essential component in research involving human subjects. However, much is not known about the level of awareness participants have about optimal consenting process and the motives that drive their participation in the trials. A cross-sectional study was conducted among volunteers who had been participating in clinical trials in contract research organizations of Delhi. Validated questionnaires were used to assess their knowledge, attitude, and practice of informed consent process. Most of the volunteers, 226 (56.5%), had participated in 1 to 3 clinical trials. Majority (54%) were unaware about any informed consent document. None of them were aware of their right of profession competence, privacy and integrity, transparency, nonexploitation, and nonusage of their biological samples. Effective implementation of principles of informed consenting is largely lacking among contract research organizations in Delhi, India. This could potentially cause risk to the participants.

Informed Consent in Clinical Trials for Persons with Dementia

Joan G Carpenter
Innovation in Aging, 8 November 2019; 3(Supplement 1)
Abstract
Informed consent is one of the most important processes during the implementation of a clinical trial; special attention must be given to meeting the needs of persons with dementia in nursing homes who have impaired

decision making capacity. We overcame several challenges during enrollment and consent of potential participants in a pilot clinical trial including: (1) the consent document was designed for legally authorized representatives however some potential participants were capable of making their own decisions; (2) the written document was lengthy yet all seven pages were required by the IRB; (3) the required legal wording was difficult to understand and deterred potential participants; and (4) the primary mode of communication was via phone. We tailored assent and informed consent procedures to persons with dementia and their legally authorized representative/surrogate decision maker to avoid risking an incomplete trial and to improve generalizability of trial results to all persons with dementia.

Editor's note: The article also appears under COGNITIVE CHALLENGES

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TECHNOLOGY/OTHER MEDIATION

20 Development of an application for digital capture of informed consent in research [POSTER]

Azariah Kusi-Yeboah, Dan Ward, Ross Murray, Daiana Bassi, Sue Conner, Yun Fu, Dean Mohamedally, Gemma Molyneux, Graham Roberts, Neil Sebire

Archives of Disease in Childhood, 22 November 2019; 104(supplement 4)

Abstract

Introduction

Clinical trials and research studies are vital for treatment innovations. In order to give informed consent, participants are provided with information sheets that describe the study in detail. The current system is paper based and documents must be retained and archived. The aim of this project was to create a system to digitalise the process.

Method

As part of a joint collaboration between GOSH and UCL computer science (CS) through the industry exchange network programme, we developed a mobile application for digital capture and management of consent. The application was based on a standard 3-tier (presentation, logic and data), software architecture pattern. The presentation tier consists of mobile and web applications. The mobile app was developed in Ionic4, while the web app makes use of Bootstrap to create fully responsive web pages. The logic tier, which contains the application's functional business logic, was written in Node.js and consists of the RESTful APIs the mobile and web app use to access data. The data tier comprises of a MySQL database.

Results

A web application was developed to create study documentation that can be viewed and completed on a mobile app. The system allows for the management of study documents to ensure version control. User profiles for staff can be created to control access to studies, therefore only staff with permission can access documentation and consent participants to a research study. The application allows information sheets to be sent to by email to participants, and for signatures to be taken digitally. All completed paperwork can be stored on a cloud database.

Conclusion

A proof of principle system for capturing consent electronically has been developed. This system could be further enhanced to provide a screen reader function and could incorporate animations or films to enhance the description of research studies to children.

Editor's note: GOSH refers to the Great Ormond Street Hospital and UCL to the University College London.

Privacy Nudges: An Alternative Regulatory Mechanism to Informed Consent for Online Data Protection Behaviour

Sheng Yin Soh

European Data Protection Law Review, 1 October 2019; 65

Abstract
The informed consent paradigm of data protection law in the EU has failed to foster privacy-protective behaviour online, due to findings from behavioural science such as bounded rationality and asymmetric information. Hence, this article proposes a soft partnership approach through the use of "privacy nudges" as an alternative regulatory tool to informed consent to nudge users towards more optimal privacy protection decisions. This article also discussed the potential benefits of privacy nudges, some of the main critiques of nudging and future direction for improvement.

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BIOBANKING

Dynamic Consent: An Evaluation and Reporting Framework

Research Article
Megan Prictor, Megan A. Lewis, Ainsley J. Newson, Matilda Haas, Sachiko Baba, Hannah Kim, Minori Kokado, Jusaku Minari, Fruzsina Molnár-Gábor, Beverley Yamamoto, Jane Kaye, Harriet J. A. Teare
Journal of Empirical Research of Human Research Ethics, 15 November 2019
Abstract
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Editor's note: The article also appears under GENOMIC MEDICINE/GENE EDITING

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COGNITIVE CHALLENGES

Informed Consent in Clinical Trials for Persons with Dementia

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Editor's note: The article also appears under BIOMEDICAL RESEARCH

What is needed to obtain informed consent and monitor capacity for a successful study involving People with Mild Dementia? Our experience in a multi-centre study

Jennifer NW Lim, Rosa Almeida, Vjera Holthoff-Detto, Geke DS Ludden, Tina Smith, Kristina Niedderer
International Mind Conference, 19-20 September 2019; Dresden Germany
Open Access
Abstract
Strategies on informed consent process and capacity monitoring for mild dementia research are at developing state. We reflected on our experience and found that the successful collection of informed consent and full participation of PwD required the involvement of familiar healthcare professionals/care workers/staff at the recruitment and data collection stages and this needs to occur in an active support environment. Time is another important factor affecting the success of the study.

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YOUNG PERSONS

Informed consent as a situated research process in an ethnography of incarcerated youth in Denmark [BOOK CHAPTER]

Tea Terbenfeldt Bengtsson
Complexities of Researching with Young People, December 2019; chapter 10
Excerpt
In this chapter I reflect on the complexities of obtaining informed consent when doing ethnography with incarcerated youth. Through concrete examples, it is demonstrated that it is often impossible to obtaining informed consent through standardized research practice. Thus, informed consent cannot be standardized if we are to conduct ethically grounded ethnographies with vulnerable youth but must be developed as a situated research practice throughout the research process…

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CULTURAL/COUNTRY CONTEXT

A framework for tiered informed consent for health genomic research in Africa

Victoria Nembaware, Katherine Johnston, Alpha A. Diallo, Maritha J. Kotze, Alice Matimba, Keymanthri Moodley, Godfrey B. Tangwa, Rispah Torrorey-Sawe, Nicki Tiffin
Nature Genetics, 28 October 2019; 51 pp 1566–1571
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A generic framework for providing participant information and implementing a tiered consent process for health genomic research in Africa can help to harness global health benefits from sharing and meta-analysis of African genomic data while simultaneously respecting and upholding the autonomy and individual choices of African research participants.

Editor's note: The article also appears under GENOMIC MEDICINE/GENE EDITING

Patients' decision-making in the informed consent process in a hierarchical and communal culture

Original Article
Astrid Pratidina Susilo, Brahmaputra Marjadi, Jan van Dalen, Albert Scherpbier
The Asia Pacific Scholar, 3 September 2019; 4(3) pp 57-66

Open Access
Abstract
Objective
To investigate patients' decision-making in the informed consent process in a hierarchical and communal culture.
Methods
This qualitative study took place in an Indonesian hospital and was conducted in line with the Grounded Theory approach. Fifteen patients and twelve family members were interviewed to understand the patients' decision-making process and factors that contributed to this process. Interview transcripts were analysed using the constant comparison method.
Results
Patients used information to develop an explanation of their illness and treatment. They consented to a medical procedure if information from their physicians matched their own explanation. An increasing severity of the disease urged patients to decide, even when a satisfying explanation had not been developed. A hierarchical relationship between physicians and patients hampered patients' discussing concerns or sharing emotions with their physicians. To maintain a harmonious relation with their physicians, patients accepted that some questions remained unanswered even after a decision had been made.
Conclusion
The strong hierarchical and communal context added to the complexity in the physician-patient relationship and consequently influenced patients' decision-making. In addition to strengthening physicians' communication skills, involving other health professionals as patient advocates or mediators is recommended to ensure patients make voluntary and informed decisions.

Informed Consent as Fulfillment of Rights and Obligations in Therapeutic Transactions Indonesian Medical Services

Teguh Anindito
Advances in Social Science, Education and Humanities Research, 2019; 358
Abstract
The informed consent principle functions to protect the autonomy and integrity of individuals who have the right to make their own choices freely for treatment to be carried out by doctors/medical personnel. According to MKDKI 80% of the 135 cases reported were caused by poor communication between doctors and patients. This study aims to analyze informed consent in therapeutic transactions as a fulfillment of rights and obligations for doctors and patients. The research was conducted in a normative juridical method, emphasizing the norms in legislation, theories, and doctrines related to health law, especially the study of informed consent. The data obtained is analyzed by the logic of deduction, taking into account the legal concept in the system of legislation. The results of the study find that urgency of informed consent is to protect and increase patient autonomy, protect patients and prevent manipulative and coercive actions and increase the attitude of self-awareness of the medical team. Therefore, medical personnel must be rational as both medics and moralists. Medical personnel needs to pay attention to the implementation of informed consent and standard professional practice in accordance with applicable regulations.

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MEDICAL/SURGICAL

Acting In Good Faith: Operating Without Truly Informed Consent

Jeffrey G. Gaca
The Annals of Thoracic Surgery, December 2019; 108(6) pp 1613-1614
Abstract

Patients who undergo cardiac surgical procedures represent the full spectrum of society, from those who obsessively research, investigate, and query the treating physicians prior to an operation to those who want to hear nothing at all about an upcoming procedure. This latter group of patients often will say, “Doc, I trust you, just do what you think is right.” The key question in this scenario1 is should the surgeon proceed with mitral valve repair without truly informed consent? Informed consent comprises several important fundamental elements, including (1) competence, (2) disclosure, and (3) voluntariness.

Improving Consent Documentation in the Medical Intensive Care Unit

Original Article

Armin Krvavac, Pujan H. Patel, Ghassan Kamel, Zeyu Hu, Nirav Patel

Curesus, 17 November 2019; 11(11)

Open Access

Abstract

The contemporary patient-centered medical practice relies upon the acquisition of informed consent, which serves as written proof that the patient has recognized and agreed to the risks and benefits of their treatment. Well-documented informed consent forms are not only reflective of important ethical practices in medicine but can also serve as legal documents to protect healthcare providers from undue liabilities. We conducted a quality improvement project with the intention to improve the accuracy and completeness of consent form documentation in the medical intensive care unit.

The evaluation of consent forms before our intervention revealed that only 6.8% were correctly completed, with an average of 10.2 out of 14 (73%) essential items correct. Our intervention involved a multifaceted approach that included targeted education in combination with process improvement. The post-intervention results at one month revealed improvement in consent form accuracy from 6.8% to 60% ($p = 0.0001$), with an increase in the average number of essential items documented correctly from 10.2 to 13.5 ($p = 0.0001$). Data were collected three months post-intervention to evaluate for sustained improvement. Results revealed a significant decrease in consent form accuracy to 39% when compared to the one-month post-intervention data but still maintained a statistically significant improvement when compared to initial baseline data; 6.8% to 39% ($p = <0.01$).

Following the intervention, overall consent form accuracy improved significantly at our institution. Furthermore, these positive adjustments persisted when assessed at three months post-intervention despite the decrease as compared to one-month post-intervention. This trend suggests that our multifaceted intervention was able to increase the quality and accuracy of consent form documentation successfully.

Informed consent in obstetrics: a survey of pregnant women to set a new standard in informed consent for emergency obstetric interventions [POSTER]

Tracey Sturgeon, Huma Ayaz, Kirsty McCrorie, Kate Stewart

BMJ Leader, 3 November 2019; 3(A9)

Open Access

Abstract

Respect for autonomy supports the rights of women to make their own decisions about care as laid out by the Supreme Court ruling on Montgomery (2015). Consent for emergency procedures in obstetrics presents a significant challenge. Consent obtained when a woman is exhausted, influenced by endogenous or exogenous chemicals or in fear of her unborn child’s safety cannot be considered to be informed. An opportunistic survey of pregnant women in Highland region was conducted over 6 weeks in community and secondary care antenatal clinics. Primary objective-determine women’s current understanding of emergency obstetric interventions in labour to guide our work in achieving informed consent. Secondary objective-compare regional and Scottish national delivery data to allow realistic counseling of women regarding possibility of such interventions. Results were analysed and comments qualitatively explored. Labour and delivery expectations of survey participants were compared to regional and Scottish national delivery data

(2018). We found that many women were uncertain regarding possibility of intervention. Both prim and parous women requested more information; some specifically asked for up-to-date statistics. Regional and Scottish national delivery intervention rates were comparable. Current intervention rates (by regional and Scottish national data) are significantly higher than expected. Our data is in keeping with Scottish data so this is likely an issue in other regions too. Our survey showed pregnant women may not have realistic expectations of delivery outcomes. Pregnant women need information based on regional and national data to foster realistic expectations of labour or delivery; empowering decision-making and ensuring peri-partum emergency consent is still informed consent. A multi-disciplinary approach to a novel means of obtaining informed consent will allow NHS Highland to lead the way in implementing change to improve the care of our pregnant women.

Interventions to Improve Informed Consent: Perhaps Surgeons Should Speak Less and Listen More

Invited Commentary

Peter Angelos

JAMA Surgery, 30 October 2019

Exceprt

High-quality informed consent is central to the ethical practice of surgery. In this issue of JAMA Surgery, Schwarze and colleagues report on a novel attempt to increase patient engagement and well-being by sending older surgical patients a question prompt list (QPL) before their visit with a surgeon. For older patients undergoing high-risk operations, the authors have appropriately pointed out that the surgical procedure is often the start of a lengthy hospitalization and subsequent substantial changes in their ability to live independently or return to preoperative health status. They sought to improve the informed consent process for this group of vulnerable patients by working with surgeons to develop an informational brochure with a list of 11 questions to prompt patients and family members to ask their surgeons about treatment options, expectations for recovery, and management of potential serious complications…

Infringement of the right to surgical informed consent: negligent disclosure and its impact on patient trust in surgeons at public general hospitals – the voice of the patient

Research Article

Gillie Gabay, Yaarit Bokek-Cohen

BMC Medical Ethics, 28 October 2019; 20(77)

Open Access

Abstract

Background

There is little dispute that the ideal moral standard for surgical informed consent calls for surgeons to carry out a disclosure dialogue with patients before they sign the informed consent form. This narrative study is the first to link patient experiences regarding the disclosure dialogue with patient-surgeon trust, central to effective recuperation and higher adherence.

Methods

Informants were 12 Israelis (6 men and 6 women), aged 29–81, who underwent life-saving surgeries. A snowball sampling was used to locate participants in their initial recovery process upon discharge.

Results

Our empirical evidence indicates an infringement of patients' right to receive an adequate disclosure dialogue that respects their autonomy. More than half of the participants signed the informed consent form with no disclosure dialogue, and thus felt anxious, deceived and lost their trust in surgeons. Surgeons nullified the meaning of informed consent rather than promoted participants' moral agency and dignity.

Discussion

Similarity among jarring experiences of participants led us to contend that the conduct of nullifying surgical informed consent does not stem solely from constraints of time and resources, but may reflect an underlying

paradox preserving this conduct and leading to objectification of patients and persisting in paternalism. We propose a multi-phase data-driven model for informed consent that attends to patients needs and facilitates patient trust in surgeons.

Conclusions

Patient experiences attest to the infringement of a patient's right to respect for autonomy. In order to meet the prima facie right of respect for autonomy, moral agency and dignity, physicians ought to respect patient's needs. It is now time to renew efforts to avoid negligent disclosure and implement a patient-centered model of informed consent.

Informed consent for whole blood donation

Brian Grainger, Peter Flanagan

Vox Sanguinis, 21 October 2019

Open Access

Abstract

Background and objectives

It is recognized that blood transfusion services have an ethical duty to obtain informed consent from their voluntary, non-remunerated donors. This right was most recently affirmed by the 2017 revision of the International Society of Blood Transfusion (ISBT) Code of Ethics. However, the constituent elements necessary to adequately inform such consent have not been definitively established.

Materials and methods

This review evaluates the historical background to informed consent in medicine and as it has been applied to blood donation. The question of what information should be disclosed is then considered with regard to existing statutory requirements in both the United States and EU as well guidance from relevant international organizations. The emerging ethical issues around repurposing of donated blood for sale as recovered plasma and use in research are included in this analysis.

Results

A reasonable basis is found in the literature to advocate that valid informed consent of blood donors should encompass: the donation process itself and potential adverse effects, the need for pre-donation transfusion-transmissible infection (TTI) screening, potential non-transfusion uses of derived products, requirements to obtain and store personal information, the consequences that non-disclosure of such information may have for both the donor and the recipient and reassurance as to the confidentiality of this information.

Conclusion

Informed consent is a key component of the duty of care between a blood service and its donor. We identify essential elements that should be present for such consent to be considered valid.

Editor's note: Vox Sanguinis is an International Society of Blood Transfusion publication.

Cardiologists' and patients' views about the informed consent process and their understanding of the anticipated treatment benefits of coronary angioplasty

Survey Study

Felicity Astin, John Stephenson, Joy Probyn, Janet Holt, Keith Marshall, Dwayne Conway

European Journal of Cardiovascular Nursing, 9 September 2019

Abstract

Background: Percutaneous Coronary Intervention (PCI) is a common revascularisation technique. Serious complications are uncommon, but death is one of them. Seeking informed consent in advance of PCI is mandatory. Research shows that PCI patients have inaccurate perceptions of risks, benefits, and alternative treatments. Aim: To assess cardiologists' and patients' views about the informed consent process and anticipated treatment benefits. Methods: Two cross-sectional, anonymous surveys were distributed in England. An electronic version to a sample of cardiologists, and a paper based version to patients recruited from 10 centres. Results: A sample of 118 cardiologists and 326 patients completed the surveys. Cardiologists

and patients shared similar views on the purpose of informed consent; however, over 40% of patients and over a third of cardiologists agreed with statements that patients do not understand, or remember, the information given to them. Patients placed less value than cardiologists upon the consent process and over 60% agreed that patients depended on their doctor to make the decision for them. Patients' and cardiologists views on the benefits of PCI were significantly different; notably, 60% of patients mistakenly believed PCI was curative. Conclusions: The PCI informed consent process requires improvement to ensure that patients are more involved and accurately understand treatment benefits to make an informed decision. Redesign of the patient pathway is recommended to allow protected time for health professionals to engage in discussions using evidence based approaches such as 'teach back' and decision support which improve patient comprehension.

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GENERAL/OTHER

Meaningful Consent From a Willfully Noninformed Patient

Michael E. Bowdish, Peter F. Crookes
The Annals of Thoracic Surgery, December 2019; 108(6) pp 1613-1614
Abstract
The cornerstone of contemporary medical practice is the belief that the patient has a right to self-determination.1 A doctor who performs a procedure in the absence, or in defiance, of the patient's expressed wishes is guilty of battery. This is rare nowadays. It is more common for it to be alleged that the potential downside of treatment was not explained clearly enough, and that if it had been, the patient would not have consented to the procedure. Or that, because no alternatives were offered, there was de facto coercion to undergo a particular procedure.

Waived Consent in Perinatal/Neonatal Research—When Is It Appropriate?

Review Article
Wade D. Rich, Anup C. Katheria
Fronteirs in Pediatrics, 26 November 2019
Open Access
Abstract
Informed consent is a process ensuring that subjects enrolled in research are appropriately informed of the risks and benefits. While this process is well-defined when it is possible and practical to obtain consent prior to the research intervention, it can be less clear in cases of deferred or waived consent. Defining minimal risk, such as when research is attempting to determine which of two currently practiced interventions is safest and/or most effective, is critical to moving forward in establishing appropriate care in newborns. For perinatal/neonatal research the challenge lies between the ethical justification for approaching women in labor or under medication vs. the scientific integrity of excluding a number of subjects that may potentially benefit the most from an intervention. Researchers must work with their IRBs as well as families who have participated in trials to determine the most appropriate method for obtaining informed consent from expectant parents. Clinical researchers and IRBs ultimately need to find a middle ground for the appropriate use of deferred or waived consent.

Vulnerability and the Consenting Subject: Reimagining Informed Consent in Embryo Donation

Rebecca Hewer
Feminist Legal Studies, 14 November 2019; 27(3) pp 287-310
Open Access

Abstract
Informed consent is medico-legal orthodoxy and the principal means by which research encounters with the body are regulated in the UK. However, biomedical advancements increasingly frustrate the degree to which informed consent can be practiced, whilst introducing ambiguity into its legal significance. What is more, feminist theory fundamentally disrupts the ideologically liberal foundations of informed consent, exposing it as a potentially inadequate mode of bioethical regulation. This paper explores these critiques by reference to a case study—embryo donation to health research, following fertility treatment, as regulated by the HFEA 1990—and contends that informed consent cannot adequately respond to the material realities of this research encounter. Thereafter, by drawing on feminist theories of vulnerability, this paper proffers an alternative bioethical approach, which calls for structural reform in recognition of the fundamentally bilateral constitution of self and society and a renewed appreciation for the affective/dispositional tenor of lived experience.

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Informed Consent: A Monthly Review Addendum

GLOSSARY

Blockchain

Using cryptography to keep exchanges secure, blockchain provides a decentralized database, or "digital ledger", of transactions that everyone on the network can see. This network is essentially a chain of computers that must all approve an exchange before it can be verified and recorded.
Initial citation from Informed Consent Monthly Review

Deferred Consent

Informed consent obtained after a specific intervention which it references, termed deferred consent or retrospective consent.
Editor's note: Sometimes referred to as waived consent
Initial citation from Informed Consent Monthly Review

Dynamic Consent

Term used to describe personalised online consent and communication platforms. Such platforms are primarily designed to achieve two objectives: 1) facilitate the consent process and 2) facilitate two-way, ongoing communication between researchers and research participants.
Initial citation from Informed Consent Monthly Review

eConsent

Electronic informed consent (eConsent) provides the same information, but in an electronic format that may include multimedia components such as images, audio, video, diagrams, reports, call out boxes and a digital signature which may aid the consenting process.
Initial citation from Informed Consent Monthly Review

Exception from Informed Consent (EFIC)

A pathway that allows investigators to enroll patients without consent from the patient, their family, or their legally authorized representatives.
Initial citation from Informed Consent Monthly Review

Free, Prior and Informed Consent (FPIC)

The standard FPIC, as well as Indigenous Peoples' rights to lands, territories and natural resources are embedded within the universal right to self-determination. The normative framework for FPIC consists of a series of international legal instruments including the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), the International Labour Organization Convention 169 (ILO 169), and the Convention on Biological Diversity (CBD), among many others, as well as national laws… FPIC is a specific right that pertains

to Indigenous Peoples and is recognized in the UNDRIP. It allows them to give or withhold consent to a project that may affect them or their territories. Once they have given their consent, they can withdraw it at any stage. Furthermore, FPIC enables them to negotiate the conditions under which the project will be designed, implemented, monitored and evaluated.
Editor's Note: We see this term of art as potentially contributing more widely because of its clarification of what IC might mean.
Initial citation from Informed Consent Monthly Review

Presumed Consent

The idea that someone is believed to have given permission for something unless they say they do not, used, for example, in some countries for organ donation.
Initial citation from Informed Consent Monthly Review

TOOLS FOR ASSESSMENT

Atlas.ti

ATLAS.ti is a powerful workbench for the qualitative analysis of large bodies of textual, graphical, audio and video data.
Initial citation from Informed Consent Monthly Review

Constant Comparison Method

Constant comparison is the data-analytic process whereby each interpretation and finding is compared with existing findings as it emerges from the data analysis.
Initial citation from Informed Consent Monthly Review

DICE

Web-based electronic informed consent application.
Initial citation from Informed Consent Monthly Review

Flesch-Kincaid Readability Scale

Readability test that tell what level of education someone needs to easily read a piece of text.
Initial citation from Informed Consent Monthly Review

Gillick Competence

The [term used] … to identify children aged under 16 who have the legal competence to consent to immunization, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions. Gillick competence is a functional ability to make a decision.
Initial citation from Informed Consent Monthly Review

Grounded Theory approach	Grounded theory sets out to discover or construct theory from data, systematically obtained and analysed using comparative analysis. *Initial citation from Informed Consent Monthly Review*
Likert Scale	A five (or seven) point rating scale [used] to measure attitudes directly, it allow[s] the individual to express how much they agree or disagree. *Initial citation from Informed Consent Monthly Review*
Meaning Equivalence Reusable Learning Objectives (MERLO)	Multi-dimensional database that allows the sorting and mapping of important concepts through exemplary target statements of conceptual situations, and relevant statements of shared meaning. *Initial citation from Informed Consent Monthly Review*
Oxford Video Informed Consent Tool (OxVIC)	Personalised video consent tool to enhance patient satisfaction in the preoperative consenting process. *Initial citation from Informed Consent Monthly Review*
REDCap	REDCap is a secure web application for building and managing online surveys and databases. *Initial citation from Informed Consent Monthly Review*
The System Usability Scale (SUS)	Provides a quick and reliable tool for measuring usability. It consists of a 10-item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree. *Initial citation from Informed Consent Monthly Review*

GUIDANCE DOCUMENTS

Declaration of Helsinki (DOH)	The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. *Initial citation from Informed Consent Monthly Review*
International Ethical Guidelines for Health-Related Research Involving Humans/ CIOMS Guidelines	The aim of the guidelines is to provide internationally vetted ethical principles and detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research in low-resource settings. *Initial citation from Informed Consent Monthly Review*

PRISMA Guidelines	PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions. *Initial citation from Informed Consent Monthly Review*
Revised Common Rule Guidelines	On January 19, 2017, the US Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subjects research (called the Common Rule)... The Revised Common Rule broadens the types of research that qualify for exemption. Several exempt categories have been revised, and there are new categories of exemptions. These changes to exemption will apply to research that is federally funded or supported. *Initial citation from Informed Consent Monthly Review*