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**Center for Informed Consent Integrity**

# *Informed Consent: A Monthly Review*

***February 2022***

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This digest aggregates and distills key content addressing informed consent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations.

Each month we monitor *Google Scholar* for the search terms "consent" and "informed consent" in title and available text. After careful consideration, a selection of these results appear in the digest. We also monitor other research analysis and guidance beyond the journal literature globally. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

*Informed Consent: A Monthly Review* is a service of the Center for Informed Consent Integrity (CICI), a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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



No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
FREE PRIOR INFORMED CONSENT (FPIC)

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

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## COVID-19

### Medical research, data sharing, and properly informed consent

*Notebook*
Sheila M. Bird
**Royal Statistical Society, 25 January 2022**
*Abstract*
When Sheila M. Bird agreed to participate in a Covid surveillance study, she did not realise her negative test result and personal details would be passed to NHS Test and Trace. Here, she calls for closer scrutiny of privacy policies by research ethics committees, and clearer communication with study participants

### Informed consent during pandemics: Experimental medicine, experienced consent

M. Botes
**South African Journal of Bioethics and Law, 2021; 14(3) pp 93-96**
*Abstract*
No known cure exists for COVID-19, and medical practitioners are exhausted and at their wits' end trying to find treatments that prevent patients from ending up in hospital or intensive care, or even dying. A variety of treatments tried by medical practitioners include standard registered medicine, investigational or so-called experimental, unapproved or preapproved medicines, emergency or compassionate-use authorised medicine and pre-market approved medicine. However, the medicines that can be accessed via each of these categories are at different stages of efficacy testing and knowledge about adverse effects, dosages and risks. To obtain ethical and legal informed consent, medical practitioners must deal with a lot of medical uncertainty, and care must be taken to ensure that the patient understands the difference in risks they may be willing to take depending on the medicine's stage of development. Often additional information is required to obtain ethical consent as opposed to legal consent. A purely legal approach to informed consent, especially when dealing with the medical uncertainties of health emergencies and pandemics, may lead to patients' consent lacking in enough substance to be truly considered legal and ethical. Informed consent as respect for autonomy in this sense requires more than the patient's explicit agreement or compliance with a certain treatment proposal. This article explains the difference in consent content attached to each different stage of a medicine's development, especially considering the additional difficulties posed by obtaining truly informed consent during a pandemic with uncertain characteristics, treatment and solutions.

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## BIOMEDICAL RESEARCH

## Struggling With Extensive Informed Consent Procedures for Cancer Trails – Is There Even a Benefit for the Patients?

Tilch M, Moringlane A, Schranz M, Theobald M, Hess G

**Research Square, 3 January 2022**

*Abstract*

*Purpose*

Informed consent procedures in clinical trials often differ in length and complexity to those in clinical routine care. Little is known about the benefit of extensive procedures as intended in clinical trials compared to procedures in routine cancer treatment.

*Methods*

In two different clinical studies performed at a comprehensive cancer center, we compared patients' comprehension and satisfaction of current informed consent procedures in routine clinical care with the level of comprehension and satisfaction of patients treated within clinical trials. Patients with a new cancer diagnosis and recent informed consent received a questionnaire about satisfaction, comprehension, time management and physician-patient relationship of the informed consent process. Patients in cohort 1 consented to cancer treatment within a clinical trial and were additionally interviewed in a structured way; patients in cohort 2 consented to "standard" chemotherapy and received a follow-up questionnaire after 6 months.

*Results*

In cohort 1, 82 patients completed the questionnaire and had an additional structured interview. They were treated in 41 different trials, receiving up to 40 pages of educational material. In cohort 2, 89 patients completed the first and 52 completed the follow-up questionnaire after receiving a standard informed consent form of 6 pages. Subjective understanding and satisfaction with the information provided was equally very high. However, deficits in objective understanding were observed in both cohorts.

*Conclusion*

Extensive informed consent procedures for clinical cancer trials have not been associated with a higher level of satisfaction or measurable objective understanding, therefore the benefit seems to be limited.

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## SOCIAL SCIENCE RESEARCH

## "Informed Consent in the Refugees and Immigrants Mental Health Researches - A Qualitative Systematic Review and Recommendations"

Fatemah Samir Alghamdi

**Arab Journal for Scientific Publishing, January 2022**

*Open Access*

*Abstract*

The refugee and migration crisis is at its most critical consideration in history. Millions of people fled their countries to save their lives from armed conflicts or natural disasters that impacted their mental and physical health. This article aimed to map out the body of published articles in the refugees' and immigrants' researches to highlight the method of informed consent process that is crucial for the Institutional Review Boards. This research systematically reviewed published literature between 2010 and 2020 on acquiring informed consent among refugees and immigrants. This systematic review was conducted in the Association of Computing Machinery (ACM), PschInfo, EBSCO, and PubMed using Preferred Reporting Items of Systematic Review and Meta-Analyses (PRISMA) framework to identify the process of informed consent in researches that addressed mental health and related issues among refugees and immigrants. A total of 32 qualitative and quantitative research genres were reviewed to highlight the informed consent procedure in refugees and immigrants researches between 2010 to 2020. The current research found out three themes: a

third party involvement, participants' educational level, and ethical violation in the informed consent process. Also, this research suggested the multifaceted informed consent to maximize their search outcomes and elude ethical violations.

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## GENOMIC MEDICINE/GENE EDITING

### Consent for rapid genomic sequencing for critically ill children: legal and ethical issues

*Original Article*
Christopher Gyngell, Fiona Lynch, Zornitza Stark, Danya Vears
**Monash Bioethics Review, 31 December 2021; 39 pp 117–129**
*Abstract*
Although rapid genomic sequencing (RGS) is improving care for critically ill children with rare disease, it also raises important ethical questions that need to be explored as its use becomes more widespread. Two such questions relate to the degree of consent that should be required for RGS to proceed and whether it might ever be appropriate to override parents' decisions not to allow RGS to be performed in their critically ill child. To explore these questions, we first examine the legal frameworks on securing consent for genomic sequencing and how they apply to the specific context of RGS for critically ill children. We then use a tool from clinical ethics, the Zone of Parental Discretion, to explore two case studies and identify under which circumstances it might be appropriate for parental refusal of RGS to be overridden. We argue that RGS may be a context where, in addition to assessing the complexity of the test offered, it is ethically appropriate to consider an effect on patient outcomes when deciding the degree of consent required. We also suggest that there are some contexts where it may be ethically justified to perform RGS, even when it is actively against the wishes of the parents. More work is needed to examine exactly how 'time-sensitive' exceptions to current guidance on consent for genomic sequencing could be formulated and operationalised for RGS for critically ill-children.

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## HEALTH DATA

### Health data: when children reach the age of consent

*World View*
Jillian Hastings Ward
**Nature Medicine, 6 January 2022**
*Open Access*
*Excerpt*
Parents give consent for their children's health data to be used in research, but what happens when the children reach adulthood, and how can researchers keep families involved in the meantime? COVID-19 vaccinations for teenagers have been in the news, which raises questions about parental influence over the decision of children to get vaccinated — or not. In some countries, including the UK, children under the age of 16 can give consent for medical treatment once they are deemed able to fully appreciate what is involved (sometimes known as 'Gillick competence'). This is of growing importance for children whose parents have signed them up for genetic research and other studies that use their health data. When and how do children get a say in what happens to their health data?..

## CrowdMed-II: a blockchain-based framework for efficient consent management in health data sharing

Chaochen Hu, Chao Li, Guigang Zhang, Zhiwei Lei, Mira Shah, Yong Zhang, Chunxiao Xing, Jinpeng Jiang, Renyi Bao

**World Wide Web, 1 January 2022**

*Open Access*

*Abstract*

The healthcare industry faces serious problems with health data. Firstly, health data is fragmented and its quality needs to be improved. Data fragmentation means that it is difficult to integrate the patient data stored by multiple health service providers. The quality of these heterogeneous data also needs to be improved for better utilization. Secondly, data sharing among patients, healthcare service providers and medical researchers is inadequate. Thirdly, while sharing health data, patients' right to privacy must be protected, and patients should have authority over who can access their data. In traditional health data sharing system, because of centralized management, data can easily be stolen, manipulated. These systems also ignore patient's authority and privacy. Researchers have proposed some blockchain-based health data sharing solutions where blockchain is used for consensus management. Blockchain enables multiple parties who do not fully trust each other to exchange their data. However, the practice of smart contracts supporting these solutions has not been studied in detail. We propose CrowdMed-II, a health data management framework based on blockchain, which could address the above-mentioned problems of health data. We study the design of major smart contracts in our framework and propose two smart contract structures. We also introduce a novel search contract for searching patients in the framework. We evaluate their efficiency based on the execution costs on Ethereum. Our design improves on those previously proposed, lowering the computational costs of the framework. This allows the framework to operate at scale and is more feasible for widespread adoption.

## Informed Consent in Digital Data Management [BOOK CHAPTER]

Elisabeth Hildt, Kelly Laas

**Codes of Ethics and Ethical Guidelines, 1 January 2022; pp 55-81 [Springer]**

*Abstract*

This article discusses the role of informed consent, a well-known concept and standard established in the field of medicine, in ethics codes relating to digital data management. It analyzes the significance allotted to informed consent and informed consent-related principles in ethics codes, policies, and guidelines by presenting the results of a study focused on 31 ethics codes, policies, and guidelines held as part of the Ethics Codes Collection. The analysis reveals that up to now, there is a limited number of codes of ethics, policies, and guidelines on digital data management. Informed consent often is a central component in these codes and guidelines. While there undoubtedly are significant similarities between informed consent in medicine and digital data management, in ethics codes and guidelines, informed consent-related standards in some fields such as marketing are weaker and less strict. The article concludes that informed consent is an essential standard in digital data management that can help effectively shape future practices in the field. However, a more detailed reflection on the specific content and role of informed consent and informed consent-related standards in the various areas of digital data management is needed to avoid the weakening and dilution of standards in contexts where there are no clear legal regulations.

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## TECHNOLOGY/OTHER MEDIATION

## An enhanced participant information leaflet and multimedia intervention to improve the quality of informed consent to a randomised clinical trial enrolling people living with HIV and obesity: a protocol for a Study Within A Trial (SWAT)

*Study Protocol*

Lydia O'Sullivan, Stefano Savinelli, Stephen O'Hare, Sinéad Holden, Ciara McHugh, Patrick Mallon, Peter Doran

**Trials, 17 January 2022; 23(50)**

*Open Access*

*Abstract*

*Background*

It is the investigator's responsibility to communicate the relevant information about a clinical trial to participants before they provide informed consent to take part. Systematic reviews indicate that participants often have a poor understanding of the concepts which are key to ensuring valid informed consent, such as randomisation and risks/discomforts. Paper-based participant information leaflets and informed consent forms (PIL/ICFs) are becoming longer and are often too complex for many participants. Multimedia interventions and enhanced PIL/ICFs have been trialled in an attempt to improve participants' understanding of various aspects of research studies. However, there is insufficient empirical evidence to determine how effective such interventions are. This protocol describes a study to evaluate whether an enhanced PIL/ICF and website help research participants to understand important information about a human immunodeficiency virus (HIV) randomised clinical trial.

*Methods*

This Study Within A Trial (SWAT) is a prospective, multi-centre, randomised, controlled, parallel-group study embedded in a host clinical trial. The host trial (the SWIFT trial; EudraCT: 2019-002314-39) is a prospective, multi-centre, randomised, open-label, controlled trial investigating if semaglutide along with dietary advice assists individuals with HIV and obesity to lose weight, compared to dietary advice alone. For the SWAT, participants will be randomised in a 1:1 ratio to either the control (standard PIL/ICF) or the intervention (an enhanced PIL/ICF and a website which includes animations). The enhanced PIL/ICF and website were developed in line with the guidance from organisations which promote plain English and accessible public-facing materials in conjunction with HIV Ireland, a HIV advocacy organisation, and our previous work on consent documents. The primary outcome of the SWAT is the quality of informed consent, assessed by a validated comprehension test—the modified Deaconess Informed Consent Comprehension Test (DICCT). The DICCT will be administered within 48 h of consent to the host trial. The secondary is recall, measured by the modified DICCT questionnaire scores 2 weeks post-consent to the host trial.

*Discussion*

The results of this SWAT will add to the methodological evidence base on the use of multimedia to improve the quality of informed consent to randomised clinical trials.

## Cognitive Testing of an Electronic Consent Platform: Researcher Perspectives

Daniel Robins, Rachel Brody, Irena Parvanova, Joseph Finkelsein

**Nurses and Midwives in the Digital Age, December 2021**

*Open Access*

*Abstract*

This study focuses on feedback from domain experts to assess usability and acceptance of the E-Consent electronic consent platform. Quantitative and qualitative data were captured throughout the usability inspection, which was structured around a cognitive walkthrough with heuristics evaluation. Additional surveys measured biobanking knowledge and attitudes and familiarity with informed consent. A semi-structured qualitative interview captured open-ended feedback. 23 researchers of various ages and job titles were included for analysis. The System Usability Scale (SUS) provided a standardized reference for usability and satisfaction, and the mean result of 86.7 corresponds with an 'above average' usability rating in the >90th percentile. Overall, participants believe that electronic consenting using this platform will be faster

than previous workflows while enhancing patient understanding, and human rapport is still a key component of the consent process. Expert review has provided valuable insight and actionable information that will be used to further enhance this maturing platform.

## Developing an e-consent system

B. K. Burke, N. Grover, L. Zhang, N. Amdeeb, E. Liu, A. Sapozhnikova

**Clinical Trials, 2021; 18(supplement 5) pp 87-88**

*Abstract*

With the COVID-19 pandemic, the ability to coordinate and manage research studies remotely has become increasingly important. Most systems offer a variation of a mobile interface for study participants to complete self-administered questionnaires outside of the clinical setting. However, there was a need for functionality to allow a potential participant to virtually and electronically complete a screening questionnaire and provide consent. The web development team and research staff at the George Washington University Biostatistics Center collaborated to create a web-based public form and electronic informed consent system. This system allows potential participants to be screened and join studies without the need to be physically present to sign regulatory documents. The e-consent system is based on the Biostatistics Center's existing electronic patient report outcome system. Users are able to access the system on a variety of devices, as the display is tailored to the size of the screen. To assure data quality and security, the system incorporates reCAPTCHA verification, email verification, tailored in-system messaging, personal links and codes, link expiration, electronic signature, and encryption. Existing features from the electronically patient report outcome system-such as skip patterns, range checks, lookup tables, and partial saving-were utilized to minimize data quality issues. In describing the design, implementation, successes, and challenges of this system, the Biostatistics Center team hopes to inform other coordinating centers and research studies interested in utilizing virtual enrollment systems for remote research.

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# CAPACITY TO CONSENT

## Empowering patients with dementia to make legally effective decisions: a randomized controlled trial on enhancing capacity to consent to treatment

*Research Article*

Aoife Poth, Susanne Penger, Maren Knebel, Tanja Müller, Johannes Pantel, Frank Oswald, Julia Haberstroh

**Aging & Mental Health, 6 January 2022**

*Abstract*

*Objectives*

As our society ages, the incidence of age-related diseases increases and with it the number of medical treatments that require informed consent. Capacity to consent is often categorically questioned in persons with dementia (PwD) without appropriate assessment, depriving them of their right to autonomous decision-making. Supportive structures for PwD that comply with legal requirements are lacking. The EmMa project tried to overcome this shortcoming by developing and testing possible supportive measures to enhance the informed consent process for PwD.

*Method*

These enhanced consent procedures (ECPs) were tested in a randomized controlled trial with 40 PwD. It was hypothesized that strengths-based ECPs could improve capacity to consent to a drug treatment in PwD as measured with a semi-structured interview.

*Results*

Against the expectations, no effect of the ECPs on capacity to consent could be found, but the ECPs improved understanding of information in PwD.
*Conclusion*
To empower PwD in clinical settings, however, all aspects of capacity to consent should be targeted with specific aids that are implemented carefully and selectively. More research on possible aids for ECPs is urgently needed in order to enable ethically and legally robust informed consent. In particular, effective ways to improve both reasoning and appreciation are yet to be found.

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## YOUNG PERSONS

### The proxy dilemma: Informed consent in paediatric clinical research - a case study of Thailand

Sheila Varadan, Salin Sirinam, Kriengsak Limkittikul, Phaik Yeong Cheah
**Developing World Bioethics, 24 January 2022**
*Abstract*
Informed consent is an essential requirement for the ethical conduct of research. It is also a necessary requirement for the lawful conduct of research. Informed consent provides a legal basis to enroll human subjects in clinical research. In paediatric research, where children do not generally enjoy a presumption of competence, a legal representative must authorise a child's enrolment. Determining who should act on behalf of the child is a matter of law, rather than ethical principle. But, if national laws are lacking or do not reflect socio-cultural realities, legal uncertainty can arise, which can have implications for children's enrolment in clinical research. Using Thailand as its case study, this paper contemplates how international legal frameworks, such as the UN Convention on the Rights of the Child, could be leveraged to navigate legal uncertainty in the informed consent process, enabling more children to access and participate in paediatric clinical research.

### Preoperative Opioid Informed Consent and Prescribing Practices in Children Undergoing Orthopaedic Trauma Surgery

Brendan A. Williams, Lacey C. Magee, Christopher A. Makarewich, Ishaan Swarup, Lia W. McNeely, Apurva S. Shah
**Journal of the American Academy of Orthopaedic Surgeons, 24 January 2022; 6(1)**
*Open Access*
*Abstract*
*Introduction*
This study sought to examine prescribing practices for pediatric patients undergoing orthopaedic trauma surgery and assess the effect of state-mandated preoperative informed consent for opioids.
*Methods*
A retrospective single-institution cohort study was done between 2016 and 2018 for surgically managed isolated orthopaedic trauma with cohorting based on the presence of preoperative opioid consent. Analyses examined cohort demographic and procedural factors associated with the number of opioid doses prescribed.
*Results*
A total of 1,793 patients met the study criteria. The proportion of patients prescribed opioids ($P = 0.0378$) and the number of doses ($P < 0.001$) were lower in consented patients. Differences were greater among those receiving solution (versus tablets). No cohort differences were observed in refill needs. Nonopioid medications prescribing increased. Multivariate analysis identified multiple factors, including preoperative opioid consent ($P = 0.013$) associated with fewer prescribed opioid doses.
*Discussion*

After the implementation of preoperative opioid consenting, patients were prescribed fewer opioid doses after pediatric orthopaedic trauma surgery. The increased utilization of nonopioid therapies was also evident. These changes occurred despite a shorter length of hospital stay and without changes in the studied proxies of postoperative pain control. An increased awareness of opioid risks through formal consent discussion may help to facilitate reduced reliance on opioids for children in the postoperative period.

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## RIGHTS/LEGAL/LEGISLATIVE

### Amending Federal Regulations to Counteract Language Barriers in the Informed Consent Process

**Voices in Bioethics, 8 January 2022; 8**

Suzanne Mistretta

*Abstract*

As English is the predominant language of research protocols in the United States, non-English speaking subjects face language barriers during clinical trial enrollment. Federal regulation 45 C.F.R. 46 requires that a research subject receive information about a clinical trial “in language understandable to the subject or the legally authorized representative." A researcher may enroll a subject using short-form consent when a long-form translation in the subject’s native language is not available. However, the abbreviated short form does not adequately inform the subject of the study’s purpose and potential risks. United States Department of Health and Human Services (HHS) leaders should amend federal guidance to provide specific details on obtaining proper informed consent when there is a language barrier. The code of federal regulations should also establish a standard for quality translation services and interpreters. This paper will review current federal regulations and draft policy, analyze literature describing hospital experiences, and discuss non-compliance areas. This author recommends an amendment to federal policy, which is important because it helps ensure the rights of study participants under the principle of justice.

*Editor’s note: “Voices in Bioethics operates in partnership with Columbia University Libraries.”*

### The Unbearable Lightness of Informed Consent in Post Mortem Fertilization

Elena Grasso

**European Review of Private Law, 2021; 29(6) pp 945 – 968**

*Abstract*

The current increase in global infertility rate and the consequent access to medically assisted procreation have contributed to the fragmentation of the reproductive process. This is also due to the development of cryopreservation techniques for gametes and embryos, whose use is therefore progressively delayed over time, sometimes even after the death of one of the partners. However, few European countries permit post mortem fertilization. Following a reconstruction of the legislation of those EU Member States allowing the practice, this contribution focuses on the jurisprudential reaction in countries, such as France, Germany and Italy, where post mortem fertilization is prohibited by the legislature. In doing so, the role of informed consent is highlighted, especially where it was not expressed by the deceased, due to an unexpected and sudden fatal event, and the surviving partner wants a child from the deceased. Based on a comparison with the findings of US scholars, this article elaborates further on the advantages of the default option in gamete retrieval for procreative purposes, which is increasingly requested also by parents looking for genetic continuity. Perceived differently outside the Western legal tradition, the lack of offspring opens the doors to recognize the interest of pursuing by post mortem fertilization a family genetic heritage.

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## CULTURAL/COUNTRY CONTEXT

### The acceptability of delayed consent for prehospital emergency care research in the Western Cape province of South Africa

Willem Stassen, Sanjeev Rambharose, Lee Wallis, Keymanthri Moodley

**PLOS One, 21 January 2022**

*Open Access*

*Abstract*

*Background*

Informed consent is an essential prerequisite for enrolling patients into a study. Obtaining informed consent in an emergency is complex and often impossible. Delayed consent has been suggested for emergency care research. This study aims to determine the acceptability of prehospital emergency care research with delayed consent in the Western Cape community of South Africa.

*Methods*

This study was an online survey of a stratified, representative sample of community members in the Western Cape province of South Africa. We calculated a powered sample size to be 385, and a stratified sampling method was employed. The survey was based on similar studies and piloted. Data were analysed descriptively.

*Results*

A total of 807 surveys were returned. Most respondents felt that enrolment into prehospital research would be acceptable if it offered direct benefit to them (n = 455; 68%) or if their condition was life-threatening and the research would identify improved treatment for future patients with a similar condition (n = 474; 70%). Similar results were appreciable when asked about the participation of their family member (n = 445; 66%) or their child (n = 422; 62%) regarding direct prospects of benefit. Overwhelmingly, respondents indicated that they would prefer to be informed of their own (n = 590; 85%), their family member's (n = 593; 84%) or their child's (n = 587; 86%) participation in a study immediately or as soon as possible. Only 35% (n = 283) agreed to retention data of deceased patients without the next of kin's consent.

*Conclusion*

We report majority agreement of respondents for emergency care research with delayed consent if the interventions offered direct benefit to the research participant, if the participant's condition was life-threatening and the work held the prospect of benefit for future patients, and if the protocol for delayed consent was approved by a human research ethics committee. These results should be explored using qualitative methods.

### The use of consent forms in a "call from class" model of dental care for Australian Indigenous children

*Brief Report*

N Stormon

**Health Promotion Journal of Australia, 19 January 2022**

*Open Access*

*Abstract*

*Issues addressed*

Dental caries is one of the most prevalent non-communicable diseases in children. Indigenous children reported a disproportionately higher prevalence of dental disease compared to their age-matched counterparts. To improve access to dental care a community-controlled service provides culturally appropriate dental services on the site of an Indigenous primary and secondary school. The dental clinic utilises a "call from class" model of care. Consent forms seeking permission to undertake a dental examination without a parent/guardian present during school hours are sent home. When the forms are returned, the student is located in class and a dental examination is undertaken.

*Methods*

A retrospective audit of dental records from 2019 and 2020 were undertaken. The number of consent forms sent and returned were recorded.

*Results*

In 2019, 87% (n= 220) of the school population were sent consent forms. Of the forms issued, 70% (n=154) were returned. Almost all students required further treatment (90%, n=137) and were sent a treatment consent form. Of the total student population, 67% (n=171) were not seen or had outstanding treatment from unreturned forms. Proportions of incomplete treatment and unseen students were similar in 2020 (64%, n=173). In this model barriers are lessened by providing a free dental service on the school site.

*Conclusions*

Consent is an ethical and legal necessity to undertake dental examination and treatment. Using physical forms were effective for gaining consent for most children. However, less than half of the school population's dental treatment were completed. Future studies should be conducted to explore the acceptability of using consent forms by parents/guardians and different models to gain consent for children from complex social circumstances.

## [Quantitative Analysis of Informed Consent on Caesarean Section at Patria IKKT Hospital, West Jakarta]

Nurmayantih, Nanda Aula Rumana, Daniel Happy Putra, Puteri Fannya

**SEHATMAS (Jurnal Ilmiah Kesehatan Masyarakat), January 2022; 1(1) pp 34-40**

*Abstract*

Informed Consent is the consent given by the patient or his family on the basis of an explanation of the medical/surgical action to be performed on the patient and this informed consent must be complete. In performing sectio caesarea, the informed consent sheet is not filled in, so any action taken can be categorized as malpractice. Researchers found that there were still many incomplete informed consent forms, especially informed consent for sectio caesarea surgery. The purpose of the study was to determine the quantitative analysis of informed consent for sectio caesarea at the Patria IKKT Hospital for the period March - April 2021 based on 4 components, namely knowing the completeness of patient identification, author authentication, and completeness of important reports, good records. This type of research is quantitative with descriptive design and data collection techniques are observation, checklist. This research was conducted using systematic random sampling method. The results of the study of 90 informed consent sheets for sectio caesarea, the average completeness of the patient identification filling component was 100%, the important component of filling out the report was an average of 86%, the author's authentication component had an average of 97.9%, the component of filling out good notes had an average of 97.9%. the average completeness is 93.7%. The results of the recapitulation of quantitative analysis have an average completeness of 94.4%.

*Editor's note: "SEHATMAS is a Scientific Journal published by the Indonesian Science Literacy Foundation"*

## Patients' Experience on Practice and Applicability of Informed Consent in Traditional Medical Practice in KwaZulu-Natal Province, South Africa

*Research Article*

Francis Akpa-Inyang , Elizabeth Ojewole, Sylvester C. Chima

**Evidence-Based Complementary and Alternative Medicine, 2022**

*Open Access*

*Abstract*

*Background*

Informed consent (IC) is constitutionally protected in South Africa based on individual rights to bodily integrity and well-being. In terms of the law, patients cannot be involved in medical treatment or research without IC. This study explored patients' experience on practice and applicability of IC in African traditional

medicine (ATM) in Msunduzi and eThekwini municipalities, KwaZulu-Natal province, South Africa, to evaluate whether important elements of IC such as full information disclosure, capacity, understanding, and volition are considered or being applied during ATM.

*Methods*

This cross-sectional quantitative study was conducted using semistructured questionnaires administered to patients attending traditional health practitioners' (THPs') treatment centres. Stata V15.1 was used to analyse variables including descriptive and inferential data analysis.

*Results*

One hundred and twenty-nine (129) participants completed this study, of which 62% were females. Most participants were in the age range of 26–35 (38.8%). All respondents were IsiZulu home-language speakers, single (62.8%), employed (48%), and with some tertiary education (48.8%). Most patients were informed about their diagnosis (58.9%), treatment benefits (79.8%), and recommended treatment (79.8%). Fewer were informed about risks of treatment (36.4%), right of refusal (3.1%), and risks of refusing recommended treatment (0.8%). All participants reported satisfaction with information disclosed by the THPs and did not feel coerced to accept treatment. Consent was obtained verbally in all cases. The majority of participants (76.7%) sought surrogate assistance when consulting THPS, and 81.4% preferred being informed about all treatment risks. Most respondents also preferred involvement in healthcare decision-making during ATM.

*Conclusion*

This study reveals that most patients consulting THPs in the KwaZulu-Natal province for treatment are aware of their right to information disclosure and the need to reach agreement before involvement in ATM treatment procedures. The study also showed that some key elements of IC are currently being applied during ATM practice in South Africa.

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## MEDICAL/SURGICAL

### A New Layer of Informed Consent: Discussions and Documentation Regarding Sensitive Examinations in Surgery

*Surgical Perspectives*

Lauren R. Wilson, Courtney Tanner, Sandra L. Wong

**Annals of Surgery, March 2022; 3(1)**

*Mini-Abstract*

A growing number of states have statutes regulating the performance of sensitive examinations on anesthetized patients. The scope of the examinations covered includes breast, pelvic, prostate, and rectal examinations, increasing the impact of these laws on surgeons. There is a broadening focus on obtaining consent for any provider and learner performing these examinations.

### American Society for Gastrointestinal Endoscopy guideline on informed consent for GI endoscopic procedures

*Guideline*

ASGE Standards of Practice Committee, Andrew C. Storm, Douglas S. Fishman, James L. Buxbaum, Nayantara Coelho-Prabhu, Mohammad A. Al-Haddad, Stuart K. Amateau, Audrey H. Calderwood, Christopher J. DiMaio, Sherif E. Elhanafi, Nauzer Forbes, Larissa L. Fujii-Lau, Terry L. Jue, Divyanshoo R. Kohli, Richard S. Kwon, Joanna K. Law, Swati Pawa, Nirav C. Thosani, Sachin Wani, Bashar J. Qumseya

**Gastrointestinal Endoscopy, February 2022; 95(2) pp 207-215**

*Abstract*

Informed consent is the cornerstone of the ethical practice of procedures and treatments in medicine. The purpose of this document from the American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee is to provide an update on best practice of the informed consent process and other issues around informed consent and shared decision-making for endoscopic procedures. The principles of informed consent are based on longstanding legal doctrine. Several new concepts and clinical trials addressing the best practice of informed consent will help guide practitioners of the burgeoning field of GI endoscopic procedures. After a literature review and an iterative discussion and voting process by the ASGE Standards of Practice Committee, this document was produced to update our guidance on informed consent for the practicing endoscopist. Because this document was designed by considering the laws and broad practice of endoscopy in the United States, legal requirements may differ by state and region, and it is the responsibility of the endoscopist, practice managers, and other healthcare organizations to be aware of local laws. Our recommendations are designed to improve the informed consent experience for both physicians and patients as they work together to diagnose and treat GI diseases with endoscopy.

## Digital Online Anaesthesia Patient Informed Consent before Elective Diagnostic Procedures or Surgery: Recent Practice in Children—An Exploratory ESAIC Survey (2021)

Claudia Neumann, Grigorij Schleifer, Nadine Strassberger-Nerschbach, Johannes Kamp, Gregor Massoth, Alexandra Görtzen-Patin, Dishalen Cudian, Markus Velten, Mark Coburn, Ehrenfried Schindler, Maria Wittmann

**Journal of Clinical Medicine, 19 January 2022**

*Open Access*

*Abstract*

*Background*

One undisputed benefit of digital support is the possibility of contact reduction, which has become particularly important in the context of the COVID-19 pandemic. However, to the best of our knowledge, there is currently no study assessing the Europe-wide use of digital online pre-operative patient information or evaluation in the health sector. The aim of this study was to give an overview of the current status in Europe.

*Methods*

A web-based questionnaire covering the informed consent process was sent to members of the European Society of Anaesthesia and Intensive Care Medicine (ESAIC) in 47 European countries (42,433 recipients/930 responses). Six questions related specifically to the practice in paediatrics.

*Results*

A total of 70.2% of the respondents indicated that it was not possible to obtain informed consent via the Internet in a routine setting, and 67.3% expressed that they did not know whether it is in line with the legal regulations. In paediatric anaesthesia, the informed consent of only one parent was reported to be sufficient by 77.6% of the respondents for simple interventions and by 63.8% for complex interventions. Just over 50% of the respondents judged that proof of identity of the parents was necessary, but only 29.9% stated that they ask for it in clinical routine. In the current situation, 77.9% would favour informed consent in person, whereas 60.2% could imagine using online or telephone interviews as an alternative to a face-to-face meeting if regulations were changed. Only 18.7% participants reported a change in the regulations due to the current pandemic situation.

*Conclusion*

Whether informed consent is obtained either online or on the telephone in the paediatric population varies widely across Europe and is not currently implemented as standard practice. For high-risk patients, such as the specific cohort of children with congenital heart defects, wider use of telemedicine might provide a benefit in the future in terms of reduced contact and reduced exposure to health risks through additional hospital stays.

## Symptomatic Features and Factors Associated With Do-Not-Resuscitate Consent in Advanced Cancer Patients Admitted to Palliative Care Ward

*Research Article*

Rongrong Fan, Siyu Yang, Xiaofan Bu, Yongyi Chen, Ying Wang, Boyong Shen, Cuiling Qiu, Xuying Li

**American Journal of Hospice and Palliative Medicine, 18 January 2022**

*Abstract*

This study aimed to conduct a retrospective cross-sectional study to investigate the prevalence of symptoms and symptom clusters on sociodemographic and disease characteristics, as well as factors associated with Do-Not-Resuscitate (DNR) consent. Advanced cancer patients were enrolled between 2018 and 2020 with available data. Demographic and clinical data were obtained for analysis from Hospital Information System (HIS) in China. Symptom clusters were extracted by hierarchical cluster analysis. Chi-square test and multiple logistic regression were conducted to investigate the prevalence characteristics of symptoms and influencing factors of DNR consent, respectively. 798 advanced cancer patients were enrolled. The most prevalent symptoms were pain (93%), anorexia (36.5%), and sleep disorders (34.2%). High heart rate was associated with poor performance status and more symptoms. Three clusters were extracted: fatigue-related, respiratory-circulatory system, and digestive system symptom clusters. The incidence of symptoms was statistically significant in age, gender, education level, residence, BMI, performance status, distress score, ADL, and primary pain level. The DNR signature rate was 15.5%. Female, distant metastasis, in-ward rescue, and appearance of dyspnea were independent influencing factors of DNR signature…

## Toward Personalized Informed Consent in Cancer Care

*Editorial*

Anne Lanceley

**Medical Anthropology, 18 January 2022**

*Excerpt*

…As the articles in this volume show, people with cancer may experience profound emotional distress, bewilderment, and loss and are often challenged to engage in life while living with symptomatic disease and closeness to death. This circumstance may dramatically alter support needs and personal relationships, threaten psychological well-being, and present challenges for patients and families to say and navigate a complex health care system. The papers present different facets of the profound uncertainty and unpredictability that characterizes twenty-first-century cancer care for patients and clinicians. To me the articles reflect patients' and health care professionals' struggle with the risk calculus involved in consenting to treatments where outcomes are unproven, a struggle that has recently been embellished by the uncertainty of COVID-19…

## Medical Student Attitudes on Explicit Informed Consent for Pelvic Exams Under Anesthesia

*Original Reports*

Benjamin E Zuchelkowski, Soukaina Eljamri, Jill E McDonnell, Bhavya Varma, Natalie G Stern, Scott D Rothenberger, Kavita Shah Arora, Judy C Chang

**Journal of Surgical Education, 17 January 2022**

*Abstract*

*Objective*

To obtain an overview of medical student attitudes on the need for explicit consent for pelvic exams under anesthesia performed for educational purposes

*Design*

From February to October 2020, 201 medical students at a single medical school in the United States participated in a cross-sectional survey after completion of the obstetrics and gynecology clerkship. Outcome

measures included endorsement of need for explicit informed consent for educational pelvic exams under anesthesia, and knowledge of informed consent processes for such exams.
*Setting*
University of Pittsburgh School of Medicine
*Participants*
Third- and fourth-year medical students
*Results*
Overall, 75% of medical students endorsed a need for explicit informed consent for educational pelvic exams under anesthesia, which extended to prostate, rectal, and breast exams under anesthesia. Additionally, 45% and 77% of these participants indicated that consent for educational pelvic exams under anesthesia should take the form of a separate signature line on the surgical consent form and/or a verbal form, respectively. Only 40% of students correctly identified institutional policy for obtaining informed consent for educational pelvic exams under anesthesia. Rotation with the oncologic surgical service ($p = 0.02$) and correct identification of institutional informed consent policies ($p = 0.002$) were associated with decreased perceptions of the importance of explicit informed consent for educational pelvic exams under anesthesia.
*Conclusions*
Medical students at the institution studied largely support explicit informed consent for educational pelvic and other sensitive exams under anesthesia, but a knowledge gap on institutional informed consent policy exists. Medical students support increased transparency and bodily autonomy. Due to the agreement of patients and medical students and the ethical rationale for this position, it may be appropriate for physicians and institutions to consider new processes of obtaining explicit informed consent for pelvic exams under anesthesia by medical students.

## Variation in the interpretation and application of the Medicaid sterilization consent form among Medicaid officials

*Original Research Article*
Colin B. Russell, Neena Qasba, Megan L. Evans, Angela Frankel, Kavita Shah Arora
**Contraception, 14 January 2022**
*Abstract*
*Objective(s)*
The Medicaid consent policy has been identified as a major barrier to desired permanent contraception, particularly for low-income communities and communities of color. As each state may modify their state Medicaid sterilization consent form, variation in the form has been reported. This study aims to characterize state-level variation in Medicaid Title XIX consent form interpretation and application.
*Study Design*
We aimed to collect primary data from Medicaid officials in all 50 United States from January to May 2020 via a 25-question electronic survey regarding state-level consent form implementation. Questions targeted consent form details and definitions, insurance and billing, clinician correspondence, and administrative processes. We used Qualtrics XM® to collect survey responses. We performed descriptive statistics on the survey responses. There were no exclusion criteria.
*Results*
We had 41 responses from 36/50 states (72% participation rate). Heterogeneity existed in the key definitions of “Premature Delivery” and “Emergency Abdominal Surgery.” One in five respondents reported the consent form was only available in English. Variation among Current Procedural Terminology codes covered in each state's sterilization policy were noted. Nearly a quarter of respondents did not know how Medicaid informed healthcare providers of consent form denials. Most participants (90%) were unaware of differences between state sterilization policies.
*Conclusion*

This study demonstrates variation in terms of consent form definitions, procedures covered, correspondence with clinicians, and administrative review processes among state Medicaid offices regarding the sterilization consent form. Greater transparency is necessary in order to reduce administrative barriers to desired permanent contraception.

## Consent Issues in the Management of Acute Ischemic Stroke

*AAN Position Statement*

Justin A. Sattin, Winston Chiong, Richard J. Bonnie, Matthew P. Kirschen, James A. Russell

**Neurology, 11 January 2022; 98(2)**

*Abstract*

This position statement briefly reviews the principle of informed consent, the elements of decisional capacity, and how acute stroke may affect this capacity. It further reviews the role of surrogate decision-making, including advance directives, next of kin, physician orders for life-sustaining treatment, and guardianship. In some cases of acute stroke in which the patient lacks decisional capacity and no advance directives or surrogates are available, consent to treatment may be presumed. The document describes the rationale for this position and various considerations regarding its application to IV thrombolysis, neuroendovascular intervention, decompressive craniectomy, and pediatric stroke. The document also reviews consent issues in acute stroke research.

## Procedural-based Specialties Benefit from a Formal Informed Consent and Disclosures Educational Program

*Original Reports*

Valeda Yong, Huaqing Zhao, Kimberly Gilmore, Jane Cripe, Charles Conklin, Elizabeth Dauer

**Journal of Surgical Education, 6 January 2022**

*Abstract*

*Objective*

At our tertiary academic center, residents undergo formalized training in obtaining informed consent and disclosing a complication. The informed consent portion has previously been shown to benefit a group of surgical and emergency medicine residents. We aimed to determine if the benefits from training persist across a larger number of procedural-based specialties and to ascertain the benefit of training in disclosing complications.

*Design*

This retrospective cohort study examined first-year residents from seven procedural-based specialties who participated in a formal informed consent and disclosures training program, consisting of a didactic lecture and two-part simulation. Two years after the start of the program, the disclosure scenario was added. Participants were given pre- and post-surveys assessing comfort and confidence in the informed consent and disclosure scenarios. Survey results were compared using the signed-rank test and Kruskal-Wallis test as appropriate.

*Setting*

This study occurred at Temple University Hospital, a tertiary academic institution in Philadelphia, PA.

*Participants*

First-year residents from 2014 to 2020 in seven procedural-based specialties, including general surgery, orthopedic surgery, otolaryngology, obstetrics and gynecology, emergency medicine, radiology, and anesthesia, participated in this study. One hundred and ninety-three residents completed the program and surveys.

*Results*

Residents reported improved confidence in filling out an informed consent form ($p = 0.036$) and more comfortable in obtaining informed consent ($p = 0.041$), as well as more confidence ($p = 0.018$) and comfort

(p = 0.001) in disclosing a complication. Surgical residents demonstrated greater confidence in obtaining informed consent (p = 0.009) and disclosing a complication (p = 0.0002) after training than non-surgical residents.

*Conclusions*

Across multiple procedural-based specialties, formal training in informed consent and disclosure of complications increases resident ability to perform these tasks. A formal training program is valuable for residents who are expected to perform these tasks across various specialties.

## Is Informed Consent Ever Truly Informed? [BOOK CHAPTER]

T. Johelen Carleton, Pringl Miller

**Difficult Decisions in Surgical Ethics, 1 January 2022; pp 77-89 [Springer]**

*Abstract*

The clinical ethical imperative to provide patients or their surrogate decision makers with relevant and tailored information is a serious endeavor that has challenged many generations of surgeons. The surgical informed consent process (SIC) is a critical aspect of surgical practice that is especially complex because patients are diverse individuals who do not automatically fit into algorithms. The sensitivity and specificity with which the SIC process must be embraced should be seen through the lens of each autonomous person. During SIC it is vital to understand what matters most to the patient. Only then can a surgeon facilitate a meaningful discussion that will honor a patient's rights, dignity, preferences, goals and values. This chapter will address the evolution of the medicolegal and ethical aspects of the surgical informed consent process and how to optimally satisfy the communication needs. Additionally, this chapter will explore the adaptations to the surgical informed consent process during the COVID-19 pandemic.

## Investigating Key Factors Related to the Decision of a Do-Not-Resuscitate Consent

*Article*

Hui-Mei Lin, Chih-Kuang Liu, Yen-Chun Huang, Chieh-Wen Ho, Mingchih Chen

**International Journal of Environmental Research and Public Health, 31 December 2021; 19(428)**

*Open Access*

*Abstract*

*Background*

The decision to sign a do-not-resuscitate (DNR) consent is critical for patients concerned about their end-of-life medical care. Taiwan's National Health Insurance Administration (NHIA) introduced a family palliative care consultation fee to encourage family palliative care consultations; since its implementation, identifying which families require such consultations has become more important. In this study, the Taiwanese version of the Palliative Care Screening Tool (TW–PCST) was used to determine each patient's degree of need for a family palliative care consultation.

*Objective*

This study analyzed factors associated with signing DNR consents. The results may inform family palliative care consultations for families in need, thereby achieving a higher DNR consent rate and promoting the effective use of medical resources, including time, labor, and funding.

*Method*

In this retrospective study, logistic regression analysis was conducted to determine which factors affected the DNR decisions of 2144 deceased patients (aged ≥ 20 years), whose records were collected from the Taipei City Hospital health information system from 1 January to 31 December 2018.

*Results*

Among the 1730 patients with a DNR consent, 1298 (75.03%) received family palliative care consultations. The correlation between DNR consent and family palliative care consultations was statistically significant (p < 0.001). Through logistic regression analysis, we determined that participation in family palliative care

consultation, TW–PCST score, type of ward, and length of stay were significant variables associated with DNR consent.

*Conclusions*

This study determined that TW–PCST scores can be used as a measurement standard for the early identification of patients requiring family palliative care consultations. Family palliative care consultations provide opportunities for patients' family members to participate in discussions about end-of-life care and DNR consent and provide patients and their families with accurate medical information regarding the end-of-life care decision-making process. The present results can serve as a reference to increase the proportion of patients willing to sign DNR consents and reduce the provision of ineffective life-prolonging medical treatment.

## Complex surgery and optimal consent: A variety of opinions exist among healthcare professionals

Cillian Clancy, Niamh McCawley, John P. Burke, Deborah McNamara

**The Surgeon, 29 December 2021**

*Abstract*

*Background*

Establishing healthcare professional's views on optimal consent in complex surgery could guide tailored consent policy, improving the process in challenging scenarios. To date, no studies have established if professionals of differing specialities agree on major aspects of consent in areas such as emergency surgery and cancer surgery.

*Methods*

An anonymous web based survey was distributed to a variety of disciplines in a tertiary referral centre. Questions regarding optimal methods and timing of consent in emergency and cancer surgery were posed. Comparative analyses of quantitative data were performed using chi-squared test.

*Results*

57 responses were received from doctors and nurses of varying disciplines. Differences were found between doctors of separate specialities and nurses in opinion of optimal timing of consent ($p = 0.02$), consent validity over time ($p < 0.001$) and the utility of introducing more specific consent policy ($p = 0.01$). Almost all respondents agreed that healthcare professionals have differing ideas of what consent is.

*Conclusions*

This study demonstrates differences in opinion regarding optimal consent for cancer and emergency surgery. Consideration should be given to developing consensus among healthcare professionals regarding what consent for complex surgery constitutes.

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## GENERAL/OTHER

## Automating Cookie Consent and GDPR Violation Detection [CONFERENCE PAPER]

Dino Bollinger, Karelcc Kubicek, Carlos Cotrini, Davidcc Basin

**USENIX Security Symposium 2022, Boston, MA, USA; 10–12 August 2022**

*Abstract*

The European Union's General Data Protection Regulation (GDPR) requires websites to inform users about personal data collection and request consent for cookies. Yet the majority of websites do not give users any choices, and others attempt to deceive them into accepting all cookies. We document the severity of this situation through an analysis of potential GDPR violations in cookie banners in almost 30k websites. We identify six novel violation types, such as incorrect category assignments and misleading expiration times, and we find at least one potential violation in a surprising 94.7% of the analyzed websites. We address this

issue by giving users the power to protect their privacy. We develop a browser extension, called CookieBlock, that uses machine learning to enforce GDPR cookie consent at the client. It automatically categorizes cookies by usage purpose using only the information provided in the cookie itself. At a mean validation accuracy of 84.4%, our model attains a prediction quality competitive with expert knowledge in the field. Additionally, our approach differs from prior work by not relying on the cooperation of websites themselves. We empirically evaluate CookieBlock on a set of 100 randomly sampled websites, on which it filters roughly 90% of the privacy-invasive cookies without significantly impairing website functionality.

## Privacy and Informational Self-determination through Informed Consent: the Way Forward [CONFERENCE PAPER]

Mohamad Gharib

**International Workshop on SECurity and Privacy Requirements Engineering (SECPRE), 4 January 2022**

*Open Access*

*Abstract*

"I have read and agree to the Privacy Policy". This can be described as one of the biggest lies in the current times, and that is all what a service provider needs to acquire what can be called "informed consent", which allows it to do as it pleases with your Personal Information (PI). Although many developed countries have enacted privacy laws and regulations to govern the collection and use of PI as a response to the increased misuse of PI, these laws and regulations rely heavily on the concept of informational self-determination through the "notice" and "consent/choice" model, which as we will see is deeply flawed. Accordingly, the full potential of these privacy laws and regulations cannot be achieved without tackling these flaws and empowering individuals to take an active role in the protection of their PI. In this paper, we argue that to advance informational self-determination, a new direction should be considered. In particular, we propose a model for informed consent and we introduce a proposed architecture that aims at tackling existing limitations in current approaches.

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