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Informed Consent: A Weekly Review

5 January 2019

This weekly digest is intended to aggregate and distill key content around informed consent from a broad spectrum of practice domains and organization types including key agencies/IGOs, NGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations. We also monitor a spectrum of peer-reviewed journals and general media channels. We recognize that this spectrum/scope yields an indicative and not an exhaustive product.

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

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Journal Articles

Bulletin of the World Health Organization
Volume 97, Number 1, January 2019, 1-72
https://www.who.int/bulletin/volumes/97/1/en/
RESEARCH

National age-of-consent laws and adolescent HIV testing in sub-Saharan Africa: a propensity-score matched study

– Britt McKinnon & Ashley Vandermorris
http://dx.doi.org/10.2471/BLT.18.212993

Abstract

Objective
To estimate the association between legal age of consent and coverage of human immunodeficiency virus (HIV) testing among adolescents in countries with high HIV-burden.
Methods
We analysed data from adolescents aged 15–18 years, who participated in Demographic and Health Surveys or AIDS Indicator Surveys between 2011 and 2016, in 15 sub-Saharan African countries. To improve balance in the distribution of measured individual- and country-level characteristics, we used propensity score matching between adolescents in countries with more versus less restrictive age-of-consent laws (≤ 15 years versus ≥ 16 years). We estimated the percentage of individuals who self-reported that they have done an HIV test in the past 12 months and compared the differences in such testing rates among adolescents exposed to lower versus higher age-of-consent laws. We also investigated effect modifications by sex and age.
Findings

Legal age of consent below 16 years was associated with an 11.0 percentage points higher coverage of HIV testing (95% confidence interval, CI: 7.2 to 14.8), corresponding to a rate ratio of 1.74 (95% CI: 1.35 to 2.13). HIV testing rate had a stronger association with lower age of consent among females than males. The testing rates differences were 14.0 percentage points (95% CI: 8.6 to 19.4) for females and 6.9 percentage points (95% CI: 1.6 to 12.2) for males (P-value for homogeneity = 0.07).

Conclusion

This study provides evidence to support the recent World Health Organization's recommendations that countries should examine current laws and address age-related barriers to uptake of sexual and reproductive health services.

Clinical Nursing Research

Vol 28, Issue 1, 2019

https://journals.sagepub.com/toc/cnr/current

Articles

Participants' understanding of informed consent for biobanking: a systematic review

ER Eisenhauer, AR Tait, SY Rieh…

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Abstract

Nurses are increasingly asked to obtain consent from participants for biobanking studies. Biobanking has added unique complexities to informed consent. The purpose of this systematic review was to evaluate participants' level of understanding of the information presented during the informed consent process unique to the donation of biological specimens for research. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were utilized to conduct the review. PubMed, EMBASE, CINAHL, PsycINFO, Scopus, Web of Science, and ProQuest bibliographic databases were searched. Results indicated that elements of informed consent unique to biobanking were poorly understood. Most studies had authors or funding associated with a biobank. Only one study disclosed and assessed participants' understanding of moral risks. Increased disclosures, values-clarification, and presenting information via multiple modalities may facilitate understanding. There is a need to improve the quality of informed consent for biobanking studies by utilizing standardized instruments, definitions, and encouraging research about informed choice outside the biobanking industry.

Ethics & International Affairs

Winter 2018 (Issue 32.4) December 2018

https://www.ethicsandinternationalaffairs.org/2018/winter-2018-issue-32-4/

ESSAY

The Universal Declaration of Human Rights at Seventy: Progress and Challenges [Full text]

S. İlgu Ozler

Abstract

Now is a good time to take stock of the global progress made toward achieving the ideals enshrined in the Universal Declaration of Human Rights (UDHR), which was passed by the UN General Assembly seventy years ago. Though the UDHR has played a vital role in advancing human rights globally, threats to human rights are ever present. Two issues in particular stand out as barriers to further progress. The first is state sovereignty, which presents a fundamental challenge to any effort to establish universal norms. Without strong global institutional mechanisms to ensure implementation, UDHR's impact remains limited. The second major concern is the "siloing" of human rights efforts, whereby civil and political rights have been given primacy over social and economic rights. Emphasis on some principles to the exclusion of others undermines the comprehensive advancement of human rights. The current state of affairs is a product of the collective failure to address human rights holistically and to implement real monitoring and accountability measures for states, which are directly charged with upholding them within their borders.

Journal of Adolescent Health
January 2019 Volume 64, Issue 1, p1-140
https://www.jahonline.org/issue/S1054-139X(17)X0016-5
Editorials

Adverse Childhood Experiences and Resilience: Implications for Marginalized and Vulnerable Young People
Scott B. Harpin
p3–4 Published in issue: January 2019
Excerpt

This month's Journal of Adolescent Health features a fascinating and innovative study by epidemiologists Clements-Nolle and Waddington [1], examining the roles that resilience and youth assets play in mitigating emotional distress for youth in two U.S. juvenile corrections systems. This piece brings together an amalgam of youth development concepts in a manner that elegantly explains their positive power in the lives of marginalized youth. While significant findings of the protective buffering of resilience among teens are not new to adolescent research—as pointed out by the authors—the strength of these findings among a large sample of our most vulnerable adolescents is very important for those of us working with similar populations of young people. The unifying factor is how youth are getting through their days having lived through any number of Adverse Childhood Experiences (ACEs)…

Original Articles

Adverse Childhood Experiences and Psychological Distress in Juvenile Offenders: The Protective Influence of Resilience and Youth Assets
Kristen Clements-Nolle, Rachel Waddington
p49–55
Published in issue: January 2019

Our findings suggest that programs and policies that promote internal resilience and protective factors across multiple levels of influence may protect juvenile offenders exposed to childhood trauma from psychological distress.

Journal of Medical Ethics
January 2019 - Volume 45 - 1
http://jme.bmj.com/content/current
Original articles

Uninformed refusals: objections to enrolment in clinical trials conducted under an Exception Room Informed Consent for emergency research (13 December, 2018) Free
Victoria Vorholt, Neal W Dickert
Abstract

Clinical trials in emergency situations present unique challenges, because they involve enrolling individuals who lack capacity to consent in the context of acute illness or injury. The US Department of Health and Human Services and Food and Drug Administration regulations allowing an Exception from Informed Consent (EFIC) in these circumstances contain requirements for community consultation, public disclosure and restrictions on study risks and benefits. In this paper, we analyse an issue raised in the regulations that has received little attention or analysis but is ethically complex. This challenge is when to solicit and honour objections to EFIC trial enrolment, including from non-legally appointed representatives. We address novel questions involving whose objections should be honoured, what level of understanding is necessary for objections to be considered valid and how hard investigators should work to offer an opportunity to object. We present a set of criteria that provide conceptual and practical guidance. We argue that objections should be honoured if they undermine one of the key assumptions that allows for the permissibility of EFIC trials: that individuals would likely not object to enrolment based on their values or preferences. We then clarify the practical implications of this approach through examination of three cases of refusal in an EFIC study.

Qualitative Health Research
Volume 29 Issue 2, January 2019
http://qhr.sagepub.com/content/current
Review article Open access

Barriers and enablers to adolescent self-consent for vaccination: A mixed-methods evidence synthesis

Harriet Fisher, Sarah Harding, Matthew Hickman, John Macleod, Suzanne Audrey
Pages 417-429

Abstract

Introduction
The recent global expansion of routine adolescent vaccination programmes has the potential to protect young people against infectious diseases and improve their health. Although the legal framework in many countries permits young people to consent for vaccinations if competent, lack of written parental consent can still prevent uptake. We aimed to review systematically the associated barriers and enablers to implementation of adolescent self-consent procedures.
Methods
A comprehensive search strategy of ten databases from inception to June 2018 was undertaken to identify relevant qualitative and quantitative studies. Titles, abstracts and full texts were assessed for eligibility, and the methodological quality of eligible primary studies evaluated. Thematic synthesis methods were used to interpret and combine qualitative data, and to identify overarching themes as well as similarities and differences within themes. Quantitative data were summarised and, because the data were sufficiently similar in focus, were integrated within the qualitative framework.
Results
Twenty-five publications related to 23 studies were included. Three themes were identified which related to the policy framework, protection, and self-determination. Despite supportive national policy frameworks, implementation of adolescent self-consent procedures can be prevented by local policies, professionals' misunderstandings of the legal framework and the context in which the vaccination programme is delivered. Motivation to protect young people's health increased acceptability of adolescent self-consent, but implementation might be prevented to protect the reputation of professionals or relationships with parents. Further, maintaining the role of parents as decision-makers for their child's healthcare was frequently prioritised over enabling young people's autonomy to consent.
Conclusions
Barriers to the implementation of adolescent self-consent procedures have implications for young people's health and uptake of vaccination programmes. There is a need to clarify the policy framework and challenge the primacy of parental consent.

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Book Chapters

Principles of Regenerative Medicine (Third Edition)
Edited by: Anthony Atala, Robert Lanza, ... Robert Nerem
Elsevier, 2019
Chapter 76 - Ethical considerations
RM Green - , Pages 1331-1343
Abstract
Because human stem cells have potential for human development and because they are potent biologic agents, research or clinical translation using them raises many ethical questions. Here I explore eight leading questions: (1) Is it necessary to use human embryos? (2) Is it morally permissible to destroy a human embryo? (3) May one benefit from others' destruction of embryos? (4) May we create an embryo to destroy it? (5) May we clone human embryos? (6) May we use human stem cells to create chimeras? (7) May we genetically modify human embryos? (8) Are there special considerations governing the use of stem cells in clinical research and clinical applications?

International Human Rights of Children
Editors: Ursula Kilkelly, Ton Liefaard
Springer, Singapore, 2019
Chapter - Children's Right to Health
J Tobin pp 277-298
Abstract
The aim of this chapter is to, first, examine the meaning of the right to health for children and, second, explore the practical ways in which this right might be relevant to addressing children's health needs. It is argued that despite the considerable ambiguity associated with the right to health, there is now a well-developed body of academic commentary and jurisprudence from the human rights treaty monitoring bodies which provides a persuasive understanding of the key feature of a child's right to health. This right will be shown to be of relevance to advocacy efforts, the development of policies and programs, service delivery, and research to address children's health needs.

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