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Symposium Articles

SYMPOSIUM

Ethical and
Legal Issues in
Pediatrics

Guest edited by
Robert M. Sade

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*Letter from
the Editor*

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INTRODUCTION

Ethical and Legal Issues in Pediatrics

Robert M. Sade

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Screening of Newborns for Disorders with High Benefit-Risk Ratios Should Be Mandatory

Nicole Kelly, Dalia Chehayeb Makarem, and Melissa P. Wasserstein

Newborn screening has evolved to include an increasingly complex spectrum of diseases, raising concerns that screening should be optional and require parental consent. Early detection of disorders like PKU and MCAD is essential to prevent serious disability and death in affected children. These are examples of high benefit-risk ratio disorders because of the irrefutable health benefits of early detection, coupled with the low risks of treatment. The dire consequences of not diagnosing an infant with a treatable disorder because of parental refusal to screen are wholly unacceptable. Thus, we believe that newborn screening for disorders with high benefit-risk ratios should continue to be mandatory.

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Informed Consent Should Be a Required Element for Newborn Screening, Even for Disorders with High Benefit-Risk Ratios

Norman Fost

Over-enthusiastic newborn screening has often caused substantial harm and has been imposed on the public without adequate information on benefits and risks and without parental consent. This problem will become worse when genomic screening is implemented. For the past 40 years, there has been broad agreement about the criteria for ethically responsible screening, but the criteria have been systematically ignored by policy makers and practitioners. Claims of high benefit and low risk are common, but they require precise definition and documentation, which has often not occurred, undermining claims that involuntary testing is justified. Even when the benefits and risks are well established, it does not automatically follow that involuntary testing is justified, a position supported by the widespread tolerance for parental refusal of immunizations and newborn screening.

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Newborn Male Circumcision with Parental Consent, as Stated in the AAP Circumcision Policy Statement, Is Both Legal and Ethical

Michael T. Brady

Newborn male circumcision is a minor surgical procedure that has generated significant controversy. Accumulating evidence supports significant health benefits, most notably reductions in urinary tract infections, acquisition of HIV and a number of other sexually transmitted infections, penile cancer, phimosis, paraphimosis, balanitis and lichen sclerosis. While circumcision, like any surgical procedure, has risks for complications, they occur in less than 1 in 500 infants circumcised and most are minor and require minimal intervention. The CDC and the American Academy of Pediatrics (AAP) believe that health benefits of circumcision outweigh the risks. For this reason, the AAP believes that parents should be allowed to make the decision concerning circumcision of their male infants after receiving non-biased information on health risks and health benefits.

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Circumcision Is Unethical and Unlawful

J. Steven Svoboda, Peter W. Adler, and Robert S. Van Howe

The foreskin is a complex structure that protects and moisturizes the head of the penis, and, being the most densely innervated and sensitive portion of the penis, is essential to providing the complete sexual response. Circumcision—the removal of this structure—is non-therapeutic, painful, irreversible surgery that also risks serious physical injury, psychological sequelae, and death. Men rarely volunteer for it, and increasingly circumcised men are expressing their resentment about it.

Circumcision is usually performed for religious, cultural and personal reasons. Early claims about its medical benefits have been proven false. The American Academy of Pediatrics and the Centers for Disease Prevention and Control have made many scientifically untenable claims promoting circumcision that run counter to the consensus of Western medical organizations.

Circumcision violates the cardinal principles of medical ethics, to respect autonomy (self-determination), to do good, to do no harm, and to be just. Without a clear medical indication, circumcision must be deferred until the child can provide his own fully informed consent.

In 2012, a German court held that circumcision constitutes criminal assault. Under existing United States law and international human rights declarations as well, circumcision already violates boys' absolute rights to equal protection, bodily integrity, autonomy, and freedom to choose their own religion. A physician has a legal duty to protect children from unnecessary interventions. Physicians who obtain parental permission through spurious claims or omissions, or rely on the American Academy of Pediatrics' position, also risk liability for misleading parents about circumcision.

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Cardiac Surgical Repair Should Be Offered to Infants with Trisomy 18, Interrupted Aortic Arch and Ventricular Septal Defect

Minoo N. Kavarana

The management of children born with trisomy 18 is controversial, and both providers and parents often have differing opinions. Many parents choose to terminate the pregnancy while others go forward, making decisions based on their beliefs, understanding, and physician recommendations. Physicians are similarly divided regarding treatment of these children, as some feel that aggressive treatments are futile while others defer to the parents' wishes.

Interrupted aortic arch with ventricular septal defect in children with trisomy 18 presents an ethical dilemma that highlights the kinds of controversies in medical decision making facing physicians on a daily basis. Repair of interrupted aortic arch with ventricular septal defect poses a high risk to newborns with or without trisomy 18. Therefore, the option for surgery should be treated as with any routine informed consent process. Parents should be counseled about the risks, benefits, alternatives, and the likelihood of success both short and long term and be should offered a choice between surgery and palliative care.

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Infants with Trisomy 18 and Complex Congenital Heart Defects Should Not Undergo Open Heart Surgery

Eric M. Graham

Aggressive medical and surgical interventions have not been clearly demonstrated to improve survival in neonates with trisomy 18; there are no data that demonstrates improved quality of life for these children after these interventions; and these interventions are clearly associated with significant morbidity, resource allocation, and cost.

Independent Articles

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Raising Genomic Citizens: Adolescents and the Return of Secondary Genomic Findings

Maya Sabatello and Paul S. Appelbaum

Whole genome and exome sequencing (WGS/WES) techniques raise hope for a new scale of diagnosis, prevention, and prediction of genetic conditions, and improved care for children. For these hopes to materialize, extensive genomic research with children will be needed. However, the use of WGS/WES in pediatric research settings raises considerable challenges for families, researchers, and policy development. In particular, the possibility that these techniques will generate genetic findings unrelated to the primary goal of sequencing has stirred intense debate about whether, which, how, and when these secondary or incidental findings (SFs) should be returned to parents and minors. The debate is even more pronounced when the subjects are adolescents, for whom decisions about return of SFs may have particular implications. In this paper, we consider the rise of "genomic citizenship" and the main challenges that arise for these stakeholders: adolescents' involvement in decisions relating to return of genomic SFs, the types of SFs that should be offered, privacy protections, and communication between researchers and adolescents about SFs. We argue that adolescents' involvement in genomic SF-related decisions acknowledges their status as valuable stakeholders without detracting from broader familial interests, and promotes more informed genomic citizens.

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Ethical and Legal Challenges Associated with Public Molecular Autopsies

Quianta L. Moore, Mary A. Majumder, Lindsey K. Rutherford, and Amy L. McGuire

There is a national movement supporting the retention and use of bio-specimens from deceased individuals for the purpose of genetic testing. This manuscript discusses the significance of postmortem genetic testing in the context of death determination by medical examiners (i.e., public molecular autopsies). We highlight distinctive concerns that are raised in the areas of consent, confidentiality, and return of results when genetic testing is performed as part of a public molecular autopsy. We believe our manuscript will contribute to the development of a robust ethical and legal framework for genetic testing in this context.

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Individual Responsibility for Promoting Global Health: The Case for a New Kind of Socially Conscious Consumption

Nicole Hassoun

The problems of global health are truly terrible. Millions suffer and die from diseases like tuberculosis, HIV/AIDS, and malaria. One way of addressing these problems is via a Global Health Impact labeling campaign (<http://global-health-impact.org/>). If even a small percentage of consumers promote global health by purchasing Global Health Impact products, the incentive to use this label will be substantial. One might wonder, however, whether consumers are morally obligated to purchase any these goods or whether doing so is even morally permissible. This paper suggests that if the proposal is implemented, purchasing Global Health Impact labelled goods is at least morally permissible, if not morally required. Its argument should, moreover, be of much more general interest to those considering different kinds of ethical consumption.

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Kings to Cowards: One-Punch Assaults

Jason Schreiber, Angela Williams, and David Ranson

Methodology: Literature Review and medico-legal commentary. Results: Fatal one-punch assaults have been reported extensively in the media. This article provides a commentary on recent policy developments and legislative amendments in Australia regarding so called 'one-punch' assaults. Comparisons are made with the situation in other jurisdictions including the UK, US, and Europe. The clinical forensic medical aspect of fist strikes to the head and face is examined in the context of the recent media attention and public interest these cases have attracted. The increased recognition of the risk of harm and death inherent in these types of assaultive behavior is reflected in the policy and legislative changes that have taken place in some jurisdictions. Conclusion: One punch strikes may result in a range of injuries that can include permanent neurological impairment and death. Recent media and community concern regarding these cases and the need for stronger deterrence has resulted in a change in public policy and consequent legislative amendments.

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Biobank Regulation in South Korea

Won Bok Lee

Like many other countries, South Korea has recognized the importance of biobanks as a tool for medical research and has engaged in two very important tasks to foster biobanking infrastructure: funding biobanks and setting up rules to protect the integrity of biobanks that share potentially sensitive personal information.

Columns

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CURRENTS IN CONTEMPORARY BIOETHICS

The End of the HIPAA Privacy Rule?

Mark A. Rothstein

The HIPAA Privacy Rule is notoriously weak because of its incomplete coverage, numerous exclusions and exemptions, and limited rights for individuals. The three areas in which it provides the most protection are fundraising, marketing, and research. Provisions of the 21st Century Cures Act, pending in Congress, and the Notice of Proposed Rulemaking to amend the federal research regulations (Common Rule), awaiting final regulatory action, would weaken the privacy protections for research. If these measures are adopted, the HIPAA Privacy Rule would have so little value that it might not be worth the aggravation and burden.

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PUBLIC HEALTH LAW

Taxing Sugar-Sweetened Beverages to Lower Childhood Obesity

Sarah A. Wetter and James G. Hodge, Jr.

Consumption of sugar-sweetened beverages (SSBs) contributes to multiple health problems including obesity, diabetes, and tooth decay, especially among children. Excise taxation has been proven efficacious in changing purchasing behaviors related to tobacco use with resulting improvements in public health outcomes. Similar taxes applied to SSBs are starting to take hold internationally and domestically. SSB taxes have been proposed in over 30 U.S. jurisdictions since 2009, but only Berkeley (CA) has passed and implemented one to date. Given empirical evidence of their effectiveness, governments should consider implementation of SSB excise taxes based on uniform definitions of SSBs and other factors.

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Calendar

Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of *JLME*.

Next Issue:

Interrogating Informed Consent in Times of Controversy: Technology, Society, and Contemporary Problems

A Symposium Guest Edited by Michele Goodwin and Harriet Washington