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Symposium Articles

SYMPOSIUM

**Under Attack:
Reconceptual-
izing Informed
Consent**

Valerie Gutmann
Koch and
Nanette R. Elster

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*Letter from
the Editor*

Cover image ©Getty Images

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INTRODUCTION

**Under Attack: Reconceptualizing
Informed Consent**

*Valerie Gutmann Koch and
Nanette R. Elster*

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Informed Consent: Charade or Choice?

George J. Annas

Informed consent has historically been described as critical in theory, but incapable of realization in practice, a superficial charade rather than an autonomous choice. This observation should help inspire us to reform our practice to make sure that informed choice actually upholds patient dignity, promotes rational decision-making, and protects self-determination

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**Certified Patient Decision Aids:
Solving Persistent Problems with
Informed Consent Law**

Thaddeus Mason Pope

The legal doctrine of informed consent has overwhelmingly failed to assure that the medical treatment patients get is the treatment patients want. This Article describes and defends an ongoing shift toward shared decision making processes incorporating the use of certified patient decision aids.

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**Informed Consent as Societal
Stewardship**

Nadia N. Sawicki

When individual patients' medical decisions contribute to population-level trends, physicians may struggle with how to promote justice while maintaining respect for patient autonomy. This article argues that this tension might be resolved by using the informed consent conversation as an opportunity to position patients as societal stewards.

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**Flying Too Close to the Sun:
Lessons Learned from the Judicial
Expansion of the Objective Patient
Standard for Informed Consent
in Wisconsin**

Arthur R. Derse

The Wisconsin Supreme Court, after adopting the doctrine of the objective (reasonable) patient standard, expanded it in bold and innovative ways over nearly four decades, until the Wisconsin legislative and executive branches drastically reversed this course. The saga has implications for other jurisdictions considering adoption or expansion of the objective patient standard doctrine

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**A New Age of Patient Transparency:
An Organizational Framework for
Informed Consent**

Kenneth Campbell and Kayhan Parsi

With the many changes occurring in today's healthcare organizations, patients are increasingly equipped with a vast quantity of health care data and being more included in the healthcare decision-making process. The new approach we propose incorporates a new patient-organization framework that examines relevant historical, legal and ethical elements within the doctrine of informed consent in addition to examining the role of new healthcare organizations' obligations to include data to support addressing issues such as population health, health outcomes and health disparities within the informed consent. There is a growing consensus among healthcare professionals that using an evidence-based organizational informed consent framework to improve the informed consent process can lead to better comprehension, health outcomes, transparency and improved patient trust and retention overall.

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Living Organ Donation and Informed Consent in the United States:

Strategies to Improve the Process

Macey L. Henderson and Jed Adam Gross

About 6,000 individuals participate in the U.S. transplant system as a living organ donor each year. Organ donation (most commonly a kidney or part of liver) by living individuals is a unique procedure, where healthy patients undergo a major surgical operation without any direct functional benefit to themselves. In this article, the authors explore how the ideal of informed consent guides education and evaluation for living organ donation. The authors posit that informed consent for living organ donation is a process. Though the steps in this process are partially standardized through national health policy, they can be improved through institutional structures at the local, transplant center-level. Effective structures and practices aimed at supporting and promoting comprehensive informed consent provide more opportunities for candidates to ask questions about the risks and benefits of living donation and to opt out voluntarily. Additionally, these practices could enable new ways of measuring knowledge and improving the consent process.

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Informed Consent in Dentistry

Kevin I. Reid

A review of literature regarding informed consent in dentistry reveals a paucity of information and minimal scholarship devoted to this subject. But this begs the question about informed consent somehow being different for dentistry than for medicine or other healthcare delivery. My account draws distinctions where appropriate but is rooted in the premise that informed consent is an ethical construct applicable to vulnerable people as patients independent of what type of treatment or body part being considered. This paper highlights the crucial importance of the process of informed consent and refusal in dentistry, underscoring its important place in oral healthcare. This paper will not address the unique circumstances involving consent in those without capacity or focus on informed consent in the research setting; our focus will be on those patients with full decision-making capacity in the clinical setting. I will emphasize the importance of disclosure of treatment options and highlight the benefits of shared-decision-making in the informed consent process.

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Informed Consent Is the Essence of Capacity Assessment

Jeffrey P. Spike

Informed consent is the single most important concept for understanding decision-making capacity. There is a steady pull in the clinical world to transform capacity into a technical concept that can be tested objectively, usually by calling for a psychiatric consult. This is a classic example of medicalization. In this article I argue that is a mistake, not just unnecessary but wrong, and explain how to normalize capacity assessment.

Returning the locus of capacity assessment to the attending, the primary care doctor, and even to ethics consultation in today's environment will require a substantial effort to undo

a strong but illusory impression of capacity assessment. Hospital attorneys as well as clinical ethicists with a sophisticated understanding of health law can be in the vanguard of this reorientation.

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Beyond Canterbury: Can Medicine and Law Agree about Informed Consent? And Does It Matter?

Marc D. Ginsberg

Informed consent is central to the law of the physician-patient relationship, respecting patient autonomy. This paper addresses a conflict between law and medicine in defining informed consent. Additionally, it addresses the possibility that patients prefer not to be "informed" and would defer decision-making to their physicians.

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Shouldn't Dead Be Dead? The Search for a Uniform Definition of Death

Ariane Lewis, Katherine Cahn-Fuller, and Arthur Caplan

In 1968, the definition of death in the United States was expanded to include not just death by cardiopulmonary criteria, but also death by neurologic criteria. We explore the way the definition has been modified by the medical and legal communities over the past 50 years and address the medical, legal and ethical controversies associated with the definition at present, with a particular highlight on the Supreme Court of Nevada Case of Aden Hailu.

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Research Capacity Strengthening in Low- and Middle-Income Countries: Ethical Explorations

Adnan A. Hyder, Abbas Rattani, and Bridget Pratt

With developed country governments and high resource institutions engaging in research in low- and middle-income countries (LMIC), we argue that these entities have a moral obligation to help build and strengthen research infrastructure and capacity so local scientists and institutions can adequately conduct studies to understand and resolve the health burdens in low and middle income countries. We explore the moral justifications and motivations behind engaging in research capacity strengthening in the health sector in LMIC at multiple levels. In highlighting these issues, this paper aims to initiate a global discourse around why capacity development in LMIC has a moral basis at the individual, institutional and system levels.

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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*.

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Negotiating Commercial Interests in Biospecimens

Jessica L. Roberts

Proposed changes to the Common Rule would require publicly funded researchers to disclose whether a subject's biospecimens could be used for commercial profit and whether the subject will share in those proceeds. Disclosing commercial interests will inform research participants that their tissue may have commercial value, a possibility that those individuals might not have previously considered. The proposed changes may then provide people with an opportunity to negotiate commercial rights in their biospecimens despite the well-accepted legal precedent that individuals maintain no interests in their excised tissue.

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Is There a Particular Ethical Practice and Policy Space in North America for Uncontrolled Kidney Donation after Circulatory Death?

Jeffrey Kirby

Despite successful transplantation outcomes in Europe, uncontrolled organ donation after circulatory determination of death (uDCDD) has essentially been a non-starter in North America. In this paper, I identify and explore a set of interesting, ethics-related considerations that are of relevance to this organ donation-transplantation practice. The analysis provides a theoretical platform for my development of a proposal for the creation of a particular ethical practice and policy space for kidney uDCDD in the U.S. and Canada that recognizes and aims to effectively address the various, identified challenges and constraints.

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