Annals of Internal Medicine

Reviewer: Shalowitz, David

Title: Publishing Commentary by Authors with Conflicts of Interest: When, Why and How

First Author: Editors, Annals

Citation: Annals of Internal Medicine 2004; 141: 73-74

Summary: Editorial responding to criticisms of Annals for publishing a randomized trial authored by an investigator with industry ties. The editors make the claim that while avoiding publishing articles involving potential conflicts is easy, it is better to balance the potential loss in objectivity against the benefit that expert opinion provides to the medical community.

Reviewer: Shalowitz, David

Title: The Relationship Between Having a Living Will and Dying in Place

First Author: HB Degenholtz

Citation: Annals of Internal Medicine 2004; 141: 113-117

Summary: Shows that those who complete living wills are more likely to die outside a hospital. Suggests that studies of living wills to date are biased because they've been sampling only hospitalized patients. See also Joan Teno's brief article in this issue which calls for public policy decisions on end-of-life care. Algorithm, anyone?

Archives of Internal Medicine

Reviewer: Krohmal, Ben

Title: Good and Bad Dying from the Perspective of Terminally Ill Men

First Author: Elizabeth Vig, Robert Pearlman

Citation: Archives of Internal Medicine 2004; 164: 997-981

Summary: Survey of 26 terminally ill men finds that *surprise* people have different views of what constitutes a good or a bad death.

Reviewer: Krohmal, Ben

Title: Resuscitating Advance Directives

First Author: Bernard Lo, Robert Steinbrook

Citation: Archives of Internal Medicine 2004; 164: 1501-1506

Summary: One of a series of articles in this issue addressing problems with advance directives. This paper presents a broad overview of problems with advance directions, and makes a number of recommendations, including making advance directive more informal, and asking for preferences regarding how much discretion proxies should be given

Bioethics

Reviewer: Wendler
Title: The quest for legitimacy
First Author: C Weijer
Citation: Bioethics 2004; 18: 293-300
Summary: Frank's good friend Charles Weijer, a member of the CIOMS committee, argues that the process of revising the guidelines intentionally ignored the views of the committee (Reidar, are you listening?) and ignored relevant stakeholders in order to impose its views on them.

Reviewer: Wendler
Title: To strengthen consensus consult the stakeholders
First Author: CC Macpherson
Citation: Bioethics 2004; 18: 283-292
Summary:

Reviewer: Wendler
Title: essential properties and the right to life
First Author: D Stretton
Citation: Bioethics 2004; 18: 264-282
Summary: Argues, contrary to Lee, that a sufficiently great change in quantity can support a radical difference in how we treat different individuals.

Reviewer: Wendler
Title: The pro-life argument from substantial identity
First Author: P Lee
Citation: Bioethics 2004; 18: 249-263
Summary: The author argues that it is wrong to kill us because we are each a human, and this has been true of each of us from the time of conception. To argue that our personhood depends on some attribute(s) we develop post-conception is to think that a mere quantitative difference can be the basis for treating different entities in radically different ways. Second, it requires that one draw an arbitrary line concerning how much of the attribute in question is need to confer a right to life.

Reviewer: Wendler

Title: Adequate conscious life and age-related need

First Author: D Waring

Citation: Bioethics 2004; 18: 234-248

Summary: The author assesses Kamm's argument that the distribution of scarce organs should be based on individual need, defined as how much adequate conscious life individuals will have had at the time of their deaths. The author argues that this account does not, as Kamm supposes, avoid substantive debate over the quality of various lives, since it relies on a view of what constitutues an 'adequate' life beyond mere consciousness. In addition, the author argues that need so defined is not always inversely proportional to age; an older individual might have endured years of non-adequate conscious life, hence, have greater need than a younger individual who has had a flourishing life.

Reviewer: Wendler

Title: The problem of abortion

First Author: S Gibson

Citation: Bioethics 2004; 18: 221-233

Summary: The author argues that non-feminist accounts of the morality of abortion, which focus on the moral status of the fetus, as well as feminist accounts, which focus on the woman's relationship to the fetus, and others, are both irresolvable. She argues that progress can be made by emphasizing the rights of woman to make their own choices as moral agents

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Reviewer: Wendler

Title: Feminist Discourse on Sex Screening

First Author: F Moazam

Citation: Bioethics 2004; 18: 205-220

Summary: Most feminists oppose sexual selection against female embryos. However, some libertarian feminists endorse this practice on the grounds that it increases women's reproductive options. The author argues that, in societies where women do not control their reproductive lives, more options does not imply more choices for women.

British Medical Journal

Reviewer: Ben Wilfond

Title: Patients' evlauation of informed consent to postponed information

First Author: Boter, Han

Citation: British Medical Journal 2004; 329: 86-87

Summary: This paper describes the response of subjects after being informed after six months of particiation in a research study about outreach stroke care that the initial informed consent proceedure did not include information about all research objectives because of concern that this would influence the results of the study. There were 102 respondants in the current study. Only two descibed their response to the disclosure as negative.

This was a very brief paper so it is difficult to fully undestand both what was done and what was the response.

Reviewer: Ben Wilfond

Title: Genetic Information: a joint account

First Author: Parker, M

Citation: British Medical Journal 2004; 329: 165-167

Summary: This is a case analysis related to two sisters how see the same geneticist. One sister finds out her child has DMD and does not want to disclose this to her pregant sister because she is opposed to abortion. The other sister is pregant and wants to make sure that her fetus does not have serious condition because she would terminate.

The authors argue that such information should be considered not under a "personal account" model where the burden of proof was needed to justify disclosure to the second sister, but rather under a "joint account" model where the presumption would be to share unless one could demonstrate a serious harm by the disclosure.

Reviewer: grady

Title: Lessons from developing nations on improving health care

First Author: Berwick, D

Citation: British Medical Journal 2004; 328: 1124-1129

Summary: Describes what we can learn from the resourcefulness and teamwork of certain program sin developing countries. Uses 2 examples (Peru and Russia). And describes types of assets teams use for leverage (eg consolidating aims, using teams, building infrastructure, altering policy environment, and scaling up). Author also discusses barriers including politics, lack of infratructure, leadership, language,roles etc.

Reviewer: grady

Title: Genetics, race, ethnicity, and health

First Author: Pearce, N

Citation: British Medical Journal 2004; 328: 1070-1072

Summary: Authors argue that it is a common misconception that genotype determines phenotype. Genetics is just one pice of a larget picture, and few diseases are purely hereditary. Race as usually understood can explain littlle in terms of overall genetic variation. Most known health related genetic vzariants are random mutations in subpopulations or result from regional selection not race. Causes of high mortality and morbidity in indigenous people relates more to ethnicity than to race or genetics. Overemphasis on genetics diverts attention and resources from more important influences on health.

Hastings Center Report

Reviewer: Shalowitz, David

Title: Moral Standards for Research in Developing Countries

First Author: Participants in 2001 Conference on Ethical…

Citation: Hastings Center Report 2004; 34: 17-27

Summary: Discussion of benefits that should be received by communities of research participants in developing countries. Justifies a switch from the CIOMS "reasonable availability" requirement to a requirement of "fair benefits" to these communities. The authors write that avoiding exploitation in research interactions entails providing fair benefits that are sensitive to the level of risk entailed by the research. Reasonable availability of successful intervention is too static a requirement to consistently be the fairest and most appropriate benefit to a community. The authors suggest three principles to guide provision of fair benefits: (1) Fair benefits (2) Collaborative Partnership and (3) Transparency [of research]. See figure p. 23

Reviewer: Shalowitz, David

Title: Schiavo: A Hard Case Makes Questionable Law

First Author: R Dresser

Citation: Hastings Center Report 2004; 34: 8-9

Summary: Discusses the recent right-to-die case in Florida. Points out that legislation introduced to block the removal of feeding tube circumvented the normal procedures in place for modifying regulations on end-of-life decision-making. Highlights problems when appointed guardian makes end-of-life decisions that are fought by other family members. Perhaps use of an algorithm would avoid these difficulties?

Reviewer: Shalowitz, David

Title: Monitoring and Manipulating Brain Function

First Author: MJ Farah

Citation: Hastings Center Report 2004; 34: 35-45

Summary: Good overview/review article on current technologies for monitoring and imaging brain function. Provides a nice summary of ethical issues in neurologic enhancement at the end.

Reviewer: Krohmal, Ben

Title: Zerhouni's Answer Buoys Supporters

First Author: Constance Holden

Citation: Hastings Center Report 2004; 304r: 1088-1088

Summary: News piece describes a May 15th letter from the NIH director to congress in which the administration admits for the first time that access to more stem cell lines would speed stem cell research. Also mentions New Jersey and California initiatives to fund stem cell research at the state level.

Health Affairs

Reviewer: Sabik, Lindsay
Title: TRENDS: Place Of Death: US Trends Since 1980
First Author: Flory, James
Citation: Health Affairs 2004; 23: 194-200
Summary:

Reviewer: Sabik, Lindsay
Title: TRIPS And The Global Pharmaceutical Market
First Author: Barton, John H.
Citation: Health Affairs 2004; 23: 146-154
Summary: This paper reviews the debate over the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and subsequent agreements. Specifically, it looks at the tension between making drugs available in developing countries and protecting property rights that produce research incentives and at the complications that arise from various arrangements.

Reviewer: Sabik, Lindsay
Title: The General Agreement On Trade in Services: Implications For Health Policymakers
First Author: Belsky, Leah
Citation: Health Affairs 2004; 23: 137-145
Summary: The authors give an overview of the GATS and, in particular, on its effect on health services. They then address hows the GATS affects public services, how the GATS affects countries' ability to pursue national objectives, and whether the GATS restricts states' ability to define their health care systems democratically. Finally, they look at implications for the US health care system in particular.

Reviewer: Krohmal, B
Title: Painful Deception
First Author: Frank Miller, response by Tor Wager
Citation: Health Affairs 2004; 304: 1109-1111
Summary: Frank's letter to the editor responds to a previously published study on placebo analgesia in which subjects were misled. Frank notes that the study itself and its supplemental online material (SOM) failed to report IRB approval, subject debriefing, and subjects' responses to the deception, and questions the study author's claim to have obtained informed consent. Wager agrees that more information should have been provided, but argues that risk was minimal, deception necessary and outweighed by benefits, and that as a result informed consent was possible.

Reviewer: Sabik, Lindsay

Title: How Do Patents And Economic Policies Affect Access to Essential Medicines In Developing Countries?

First Author: Attaran, Amir

Citation: Health Affairs 2004; 23: 155-165

Summary: The author argues that the debate over drug provision in the developing world is off point, looking at the number of drugs on the WHO's "essential medicines" list that are patentable (and actually patented) and contending that the real problem is not patent law, but poverty and lack of infrastructure in poor countries.

Health Economics

Reviewer: Sabik, Lindsay

Title: Does NICE have a cost-effectivenes threshold and what other factors influence its decisions? A binary choice analysis

First Author: Devlin, Nancy

Citation: Health Economics 2004; 13: 437-452

Summary: This paper looks at decisions made by NICE regarding whether treatments or interventions should be funded by the NHS. The authors find that there does appear to be a QALY threshold of sorts in determing funding, but it gives the probability of an intervention being approved, rather than a clear yes or no decision above or below a single number cut-off. The authors also find that cost-effectiveness along with uncertainty and the burden of disease predict NICE decisions better than cost-effectiveness alone.

Reviewer: Sabik, Lindsay

Title: Why Cost-effectiveness should trump (clinical) effectiveness: the ethical economics of the South West quadrant

First Author: Dowie, Jack

Citation: Health Economics 2004; 13: 453-459

Summary: The author describes the possible outcomes in assessing the cost-effectiveness of a new intervention: the four outcomes depend on whether the new intervention is more or less clinically effective and more or less costly than the old. When the new outcome is less costly and more effective or more costly and less effective, the decision on whether to use it is clear. When the intervention is more effective and more costly or les effective and less costly the decision is less clear. Typically when the new intervention is more effective and more costly a threshold based on willingness to pay of some sort is used to establish whether the increase in clinical effectiveness is worth the increase in cost. The author argues that the same should be the case when the new intervention is less costly and less effective--a threshold should be established and the decision should be based on whether the decrease in effectivess is counter-balanced by the decrease in cost. Yet, in practice, if a new intervention is any less clinically effective than the intervention currently used, it will not be used regardless of cost. The author considers two arguments supporting this approach and counters both of them, holding that the same technique should apply as does when the new intervention is more effective and more costly.

Reviewer: Sabik, Lindsay

Title: When does quality-adjusting life-years matter in cost-effectiveness analysis?

First Author: Chapman, Richard H

Citation: Health Economics 2004; 13: 429-436

Summary: The authors investigated the impact of quality-of-life adjustments on cost-effectiveness analyses by comparing ratios from published studies that reported both incremental cost/life-year (LY) and cost/quality adjusted life year (QALY). They found that in over two-thirds of the cases the difference between cost/LY and cost/QALY was relatively small and adjusting for quality of life had little effect on the final cost-effectiveness ratio. In a small number of cases, quality-adjustment had a significant impact on the cost-effectiveness result. In about a fifth of the cases quality-adjustment led to a ratio moving across some set cost-efectiveness threshold. In looking at the types of cases in which adjusting for quality of life had a significant impact on the final cost-effectiveness ratio, the authors found that quality-adjustment is most important when considering chronic conditions with palliative interventions associated with long-term negative side effects. The authors suggest that this result can be used in considering whether quality of life adjustment is necessary in cost-effectiveness studies depending on the condition and treatment in question, particularly when time and resources available to conduct the CEA are limited.

JAMA

Reviewer: Hampson, Lindsay

Title: Clinical Trials in Sub-Saharan Africa and Established Standards of Care

First Author: Kent, David

Citation: JAMA 2004; 292: 237-242

Summary: Guidelines specified in the 2000 version of the Declaration of Helsinki require that research participants in the controal arm of a study must receive the "best proven" therapeutic method. OBJECTIVE: Researchers sought to determine whether recently published trials conducted in sub-Saharan Africa met standards of care consistent with best current clinical standards for HIV treatment, TB treatment, and malaria prevention. METHODS: Researchers included all randomized controlled trials published during or after January 1998 that had been conducted in sub-Saharan Africa in 3 clinical domains: HIV tx, TB tx, and malaria prevention. Best current standards of care were determined by published guidelines for well-resourced settings, which was then compared to the actual care offered in the trial.
RESULTS: Only 16% of trials provided care that met guidelines:
-HIV: 3%
-TB: 100%
-Malaria: 72% (intervention group), 10% (control group)
81% of trials were reviewed by a host African institution and 64% were reviewed by an institution in a developed country.
CONCLUSIONS: Researchers and IRBs are taking local level of care into account when determining the clinical standards for trials in sub-Saharan Africa.

Reviewer: Hampson, Lindsay

Title: Effect of a Decision Aid on Knowledge and Treatment Decision Making for Breast Cancer Surgery/Effect of a Computer-Based Decision Aid on Knowledge, Perceptions, and Intentions About Genetic Testing for Breast Cancer Susceptibility

First Author: Whelan, Timothy

Citation: JAMA 2004; 292: 435-452

Summary: Two articles that examine the use of a decision aid on knowledge and decision making related to breast cancer.
-First study tested the use of a decision board to inform patients about different treatment options. Patients in the decision board group had higher knowledge scores about their tx options (66.9 vs 58.7), less decisional conflict (1.4 vs 1.62), and were more satisfied with their decision making (4.5 vs 4.32).
-Second study tested the use of a computer program vs. genetic testing to educate patients about breast cancer. The computer program was more effective for increasing knowledge of breast cancer and genetic testing, but genetic counseling was more effective at reducing anxiety and facilitating more accurate risk perceptions.

Reviewer: Litton, Paul

Title: Book Review of "U.S. Health Care and the Future Supply of Physicians"

First Author: Book written by E. Ginzberg and P. Minogiannis

Citation: JAMA 2004; 291: 2491-2491

Summary:

Reviewer: Litton, Paul

Title: The Challenge to Improve Global Health

First Author: Lee, K., Walt, G., Haines, A.

Citation: JAMA 2004; 291: 2636-2638

Summary: The authors discuss the International Finance Facility (IFF), which is an entity proposed by the British Chancellor of the Exchequer, intending to increase aid from rich to poor countries to improve health. The authors support this proposal even if it is insufficient to meet all its lofty aims, which include the "Millenium Development Goals" agreed upon by members of the UN, IMF, World Bank, and OECD.

Reviewer: Litton, Paul

Title: Book Review of "Global Inequalities at Work: Work's Impact on the Health of Individuals, Families, and Societies"

First Author: Book edited by J. Heymann

Citation: JAMA 2004; 291: 2647-2648

Summary:

Reviewer: Litton, Paul

Title: Participation in Cancer Clinical Trials: Race-, Sex-, and Age-Based Disparities

First Author: Murthy, V., Krumholz, H., Gross, C.

Citation: JAMA 2004; 291: 2720-2726

Summary: Report of a study to "characterize the representation of racial and ehtnic minorities, the elderly, and women in cancer trials sponsored by the [NCI]." Researchers aimed to "estimate the relative risk ratio of enrollment for … minorities to that of white patients" during the relevant time periods.
Conclusion: "Racial and ethnic minorities, women, and the elderly were less likely to enroll in cooperative group cancer trials than were whites, men, and younger patients, respectively."

Reviewer: Litton, Paul

Title: Hindu Bioethics for the Twenty-first Century

First Author: Book written byS. Cromwell Crawford

Citation: JAMA 2004; 291: 2759-2760

Summary:

Reviewer: Hull, Sara

Title: Expanding Insurance Coverage Through Tax Credits, Consumer Choice, and Market Enhancements: The AMA Proposal for Health Insurance Reform

First Author: DJ Palmisano

Citation: JAMA 2004; 291: 2237-2242

Summary: This article outline's the AMA's proposal for health insurance reform, which is based on a system of tax credits for the purchase of insurance for all non-elderly individuals. This would replace the current tax exclusion of employer-based health insurance with tax credits that are inversely related to income and that are contingent on seeking coverage for the entire family. This would promote choice of individually owned health insurance (and all the good things that presumably go along with choice). Employers could still offer employment-based coverage, but employees would not be limited to these options. This, the authors argue, would lead to plans that are more responsive to consumer needs and would keep premiums from rising.

Reviewer: Shalowitz, David

Title: Genetic Research and Health Disparities

First Author: P Sankar

Citation: JAMA 2004; 291: 2985-2989

Summary: Argues that genetic research has been overemphasized as a method of alleviating health disparities in the United States. Suggests that relying too heavily on genetic (as opposed to environmental?) explanations of disparities could reinforce racial/ethnic stereotypes and worsen gaps in health between groups.

Journal of General Internal Medicine

Reviewer: Hull, Sara

Title: Medical Debt and Aggressive Debt Restitution Practices: Predatory Billing Among the Urban Poor

First Author: TP O'Toole et al.

Citation: Journal of General Internal Medicine 2004; 19: 772-778

Summary: This article describes results of a survey of 274 adults receiving care through 10 safety net provider sites in Baltimore to determine the extent to which these patients carry medical debt, what practices are used to collect these debts, and what effect it has on health-seeking behavior. This sample was 77% African-American, 55% male, 47% homeless, and 34% with less than a 12th grade education. 46% reported having a medical debt, and 39% had been referred to a collection agency. 67% of those with debt or who had been referred to a ccollection reported that this affected their seeking subsequent care (no longer going to that site, delaying seeking care, or only going to Ers for care when needed). In the multiple logistic regression model, having less than a 12th grade education and being homeless were associated with a change in health seeking behavior, while having a chronic illness or using a community health clinic for usual care were protective. The authors conclude that aggressive debt retrieval appears to have a negative effect on subsequent health seeking behavior among those least capable of navagating the health system.

Journal of Health Politics, Policy and Law

Reviewer: Frank Lovett

Title: How Does Private Finance Affect Public Health Care Systems? Marshaling the Evidence from OECD Nations

First Author: Tuohy, C H

Citation: Journal of Health Politics, Policy and Law 2004; 29: 359-396

Summary: This article surveys the aggregate impact of private health spending on public heath care, in a survey of the major OECD nations. (For example, does a greater role for private financing drain resources or public support for public health care?) Nicely surveys the main outlines of different health finance systems, discusses the complexities of how public and private financing can interact.

To determine whether public and private spending complement or substitute one another, the authors construct a lag effect model, with country and year dummies to control for country-specific factors and global market shocks respectively. They find that public spending in a given country in a given year is significantly and negatively correlated with private spending in that country in previous years. In other words, a rise in private spending is correlated with a decline in public spending a few years down the road. This and other findings lead the authors to conclude that “increasing the private share of total health care expenditures does not offer a solution to the challenges facing publicly financed systems.”

Some objections to their methods are: first, that the magnitude of the effects they report seem quite small, that they never indicate their R-squared values, and that the diversity of health finance systems may render cross-national statistical comparisons dubious.

Reviewer: Sobolski, Greg

Title: Enrolling Children in Public Insurance: SCHIP, Medicaid, and State Implementation

First Author: Kronebusch, K.

Citation: Journal of Health Politics, Policy and Law 2004; 29: 451-489

Summary: OVERVIEW:
The Balanced Budget Act of 1997 gave states grants to create State Children's Health Insurance Program (SCHIP). This study examines its impact on low-income (family income 200% below poverty line) uninsured children, and suggests policy reforms that might benefit uninsured children. Specifically, the authors consider the implementation of administrative models, eligibility standards, enrollment simplifcation, crowd-out, and cost sharing requirements.

METHODS:
All data about health insurance and participation in govt. programs were obtained from the March 2001 Current Population Survey. The authors restricted the sample to children below 400% of poverty level.
This data set formed the basis for their policy/program models.

RESULTS:
Of the three administrative models (SCHIP as Medicaid expansion; separate SCHIP; combination programs), SCHIP as medicaid expansion enrolls more children (2.7-3.3% more enrollment).

Also leading to higher enrollment are the implementation of presumptive eligibility (6.4% increase) and self-declaration of income (3.5%), and the reomval of asset tests (6.1%).

Further, the authors determine that strict welfare reform reduces enrollment (1.3-2.6% decrease). Finally, the authors project that if all states adopted facilitating policy options, enrollment of poor children could rise from 42% to 58%.

Reviewer: Frank Lovett

Title: Voting With Their Feet: Patient Exit and Intergroup Differences in Propensity for Switching Usual Source of Care

First Author: Tai-Seale, M

Citation: Journal of Health Politics, Policy and Law 2004; 29: 491-514

Summary: Patient exit is supposed to drive competition among health-care providers and improve efficiency. But the effectiveness of patient exit in driving competition depends on its being a signal of dissatisfaction with service. The author examines the extent to which this is true, using household survey data collected between 1996 and 1997 by the Community Tracking Study. Basically he finds that the health care market is insufficiently elastic to properly drive competition. This is because, on the one hand, people are reluctant to exit, even when they are unsatisfied with their care; and because, on the other hand, many exits are involuntary.

Journal of Law, Medicine and Ethics

Reviewer: Litton, Paul

Title: Making Risk-Benefit Assessments of Medical Research Protocols

First Author: Rajczi, A

Citation: Journal of Law, Medicine and Ethics 2004; Summer: 338-347

Summary: Generally, IRBs are instructed to approve a research protocol only if its benefits outweigh its risks. Rajczi aims to undermine this requirement for government-run IRBs. First, he argues that, due to limitations on our knowledge and foresight, we usually cannot possibly estimate and compare the risks and benefits of a proposed protocol. Second, he suggests an alternative, which he believes is more consistent with the principles of a liberal democracy: a protocol has an acceptable combination of risks and benefits if competent and informed decision-makers would choose to accept them. At least two advantages of this principle, on the author's account, are the following: (1) it allows IRBs to consider very personal reasons subjects may have, such as a need for the money offered to enroll, and (2) its application allows us to avoid making harm-benefit calculations when such calculations are impossibly difficult.

Reviewer: Litton, Paul

Title: Does Ethics Theory Have a Future in Bioethics?

First Author: Beauchamp, T.

Citation: Journal of Law, Medicine and Ethics 2004; Summer: 209-217

Summary: Beauchamp argues that the relationship between bioethics and philosophy is troubled because moral theorists have refused to show how their ethical theories apply to real practical problems in medicine, and while many philosophers work primarily in bioethics, these philosophers have neither appealed to nor grounded their practical arguments in abstract moral theory. He argues that the future relationship of philosophy and bioethics depends on whether philosophers will "develop theories and methods more closely attuned to practice." Specifically, he argues that discussions in meta-ethics once provided insight for bioethics, but no longer do; that philosophers have not shown practical relevance of their theories of moral justification (such as Daniels' support of reflective equilibrium and Brody/Miller's practice-based model); and that conceptual analyses of moral concepts, such as autonomy, have not provided any practical guidance.

Reviewer: Litton, Paul

Title: Clinical Ethics and the Road Less Taken: Mapping the Future by Tracking the Past

First Author: Rubin, S., and Zoloth, L.

Citation: Journal of Law, Medicine and Ethics 2004; Summer: 218-225

Summary: Based on their work in clinical ethics consultation, the authors make a number of recommendations to the field. For example, they advocate the use of committees, instead of individual "experts" or smaller sub-committees, for clinical ethics consultations, because, in part, committees provide a broad range of moral perspectives. They also call for certain academic work concerning the nature of the field. For example, they argue that clinical ethics should be interdisciplinary, but the identity of the "clinical ethicist' should be clarified; and that the goal of clinical ethics should be to heighten awareness of moral dilemmas and to provide guidance, not to negotiate them away.

Kennedy Institute of Ethics Journal

Reviewer: Martin, A

Title: Convening a 407 Panel for Research Not Otherwise Approvable: "Precursors to Diabetes in Japanese American Youth" as Case Study

First Author: Ross, Lanie Friedman

Citation: Kennedy Institute of Ethics Journal 2004; 14: 115-210

Summary: Overview:
Examines the protocol in the title (from U of Wash), for which a 407 panel was convened in 2001. A 407 panel reviews research that either seeks to enroll healthy children with no prospect of direct benefit and poses more than minimal risk or seeks to enroll children with a disorder or condition but offers no prospect of direct benefit and poses "more than a minor increase" over minimal risk.

Specifics:
Discusses, through comparison with previously approved and rejected diabetes studies involving children, how to interpret "minimal risk" and "more than a minor increase over minimal risk." Concludes that the study methodology poses the former but not the latter. (Study involves insertion of one IV, infusion of glucose, and Tanner staging to determine sexual maturity.)

Finds that the study nevertheless requires 407 review because it seeks to enroll healthy children with no prospect of direct benefit, and poses more than minimal risk. (Participants include non-obese Japanese-American children and their caucasian cousins.)

Suggests the study eligibility requirements should be changed to limit participation to children who are genuinely "at risk" for type 2 diabetes. This change would eliminate the need for 407 review and increase the study's scientific value.

Concludes with a general critique of the 407 process for pokiness and lack of transparency.

Reviewer: Martin, A

Title: Risk Standards for Pediatric Research: Rethinking the *Grimes* Ruling

First Author: Wendler, D

Citation: Kennedy Institute of Ethics Journal 2004; 14: 115-210

Summary: Overview:
This brilliant author first argues that the Maryland Court of Appeal's decision regarding the KKI lead abatement studies hands down a standard of acceptable risk in pediatric research that is inconsistent with federal risk standards.

He then draws a parallel between a dilemma of pediatric research and a dilemma of multinational research--in both arenas we seem forced to choose between avoiding the exploitation of populations in less fortunate circumstances than average at the cost of neglecting research that may improve those circumstances and doing this research while possibly exploiting the less fortunate.

He then proposes that a modified risk standard designed to dissolve the dilemma in multinational research should be imported to pediatric research. This new standard establishes as the default that children should not be exposed to risks greater than those present in the daily lives of average children unless it meets requirements of 1) Relevance, 2) Scientific necessity, 3) Sufficient benefit, 4) and Nonmaleficence.

Reviewer: Frank Lovett

Title: Oversight of Research Involving the Dead

First Author: Wicclair, M R

Citation: Kennedy Institute of Ethics Journal 2004; 14: 143-164

Summary: This paper reviews the question of institutional review for research on cadavers. At the University of Pittsburgh, a special Committee for Oversight of Research Involving the Dead (CORID) was created to address these issues and review research protocols.

Authors note that IRB oversight is not required under HHS policies, since cadavers do not counts as “human subjects” according to regulatory definitions. Nevertheless, they advocate institutional oversight on six grounds. First, to protect the interests of the dead, including ensuring respect for their premortem preferences, confidentiality, and a respectful treatment of their bodies. Second, to protect the interests of the deceased’s families. Third, to provide ethical guidance for researchers who want such help. Fourth, to promote uniform ethical standards. Fifth, to rationally elaborate general ethical principles into specific criteria for cadaver research. And sixth, to protect researchers and institutions from unfounded criticism. They also suggest general standards for the institutional review process, along the lines one would expect.

They prefer establishing special CORIDs, rather than expanding the jurisdiction of existing IRBs, partly because HHS policies might make the latter reluctant to take up the job. Though it provides a decent overview of the issues, this article attempts no theoretical innovations so far as I can tell.

Reviewer: Frank Lovett

Title: Social Contract Theory and Just Decicision Making: Lessions from Genetic Testing for the BRCA Mutations

First Author: Williams-Jones, B

Citation: Kennedy Institute of Ethics Journal 2004; 14: 115-142

Summary: How should decisions concerning whether or not to extend public health insurance to cover privately-developed and patented technologies and services be made? The authors of this paper employ social contract theory a la Rawls and Daniels to develop an account of a just decision-making process. The problem arises because the private ownership of medical technologies and services creates market incentives that run counter to the goals of efficiency and equity in public health insurance. These difficulties are highlighted in a case-study of a genetic testing technology for breast and ovarian cancer (the BRAC test), over which a private Canadian company partially secured patent rights.

On the Rawls-Daniels theory, rational decisions-makers in an original position would adopt a principle of equality of opportunity, the satisfaction of which would require that everyone's basic health care needs are met. This entails an entitlement to those health services needed to maintain normal health, but not to all possible health services. The issue would then hinge on whether a given service (like BRAC testing) is needed in the required sense. Following a proposal by Daniels and Sabin, the authors propose that these determinations should be made by experts, subject to four requirements: namely, that any decision should be (1) made according to rationales that are public and transparent, (2) based on appeals to evidence that all reasonable parties could accept, (3) subject to appeal and revision; and (4) that these guidelines are publicly regulated and enforced. Returning to the case-study, the authors note various ways in which the process in Canada failed according to these standards. They also propose modifying the Daniels and Sabin criteria to include some dimension of public involvement.

Though the desire of the authors to employ concrete cases is admirable, the result is unimpressive: their theoretical contribution is weak, and the chosen case study so complex that the discussion sinks under a morass of details.

Lancet

Reviewer: Sabik, Lindsay

Title: Registering clinical trials: an essential role for WHO

First Author: Pang, Tikki

Citation: Lancet 2004; 363: 1413-1414

Summary: This brief commentary describes current barriers to disseminating results of clinical trials, particularly those conducted in developing countries and those that are not in English and not indexed in any English-language database. The authors support proposed efforts by the WHO to establish a global controlled trials register, and describe how they believe it could best be implemented.

Reviewer: Sabik, Lindsay
Title: Education and practice: Global health equity
First Author: Farmer, Paul
Citation: Lancet 2004; 363: 1832-1832
Summary: The authors describe current health inequities world wide and announce the launch of a global health equity residency at Boston's Brigham and Women's Hopsital, which will allow internal medicine residents to train in public health and specifically address inequalities of access and outcome.

Reviewer: Sabik, Lindsay
Title: Antiretrovirals give new hope and new life to South Africans
First Author: Kapp, Claire
Citation: Lancet 2004; 363: 1710-1710
Summary: Brief article describing the roll-out of antiretroviral treatment in HIV/AIDS clinics throughout South Africa and the positive effect on the morale of staff and patients.

Reviewer: Sabik, Lindsay
Title: Preimplantation genetic diagnosis
First Author: Sermon, Karen
Citation: Lancet 2004; 363: 1633-1641
Summary: This article presents a thorough review of the literature on preimplantation genetic diagnosis (PGD). The authors describe the history of the procedure, indications for PGD, different techniques used, evidence about results and outcomes, and new technologies being used. They also review different ethical arguments for and against the use of PGD in various circumstances. These include non-disclosure PGD, in which the parents do not want to know their carrier status, but want disease-free offspring, and PGD to select for an HLA matched sibling to donate stem cells to a sick child, among others.

Reviewer: Sabik, Lindsay
Title: Central American trade pact may limit access to generics
First Author: Replogle, Jill
Citation: Lancet 2004; 363: 1612-1613
Summary: This feature article decribes the proposed terms of the Central American Free-Trade Agreement (CAFTA), comparing it to the WTO's Trade-Related Aspects of Intellectual Proprty Rights (TRIPS). The proposed CAFTA is particularly limiting because its terms regarding the exclusivity of undisclosed data. Opponents of the agreement are particularly concerned about potential effects on public health due the the restrictions on generic drugs that would result.

Reviewer: Sabik, Lindsay

Title: India pressed to relax rules on clinical trials

First Author: Sharma, Dinesh

Citation: Lancet 2004; 363: 1528-1529

Summary: This feature article describes the debate in India over whether to ease regulations regarding clinical research. India is described as an ideal setting for clinical research in certain respects, with vast populations both with common communicable diseases that typically affect poor countries and with diseases common in wealthy countries such as type 2 diabetes. Evidence shows that patient recruiting is much faster in India than in the US or Europe, and suggests that the cost of conducting trials in India is less than half of similar trials conducted in the USA. Regulations set up to protect citizens from exploitation by foreign companies forbid phase I trials of drugs developed outside India, and restrict phase II and III trials until similar studies have been done in other countries. The pharmaceutical industry is pushing for the government to relax these restirctions, but critics have voiced fears about exploitation.

Reviewer: Sabik, Lindsay

Title: Assessment of NICE guidance on two surgical procedures

First Author: Ryan, James

Citation: Lancet 2004; 363: 1525-1526

Summary: The authors review trends in wisdom tooth extraction and total hip replacement since the release of NICE guidance in 2000 stating that pathology-free impacted third molars should not be operatied on and that cemented hip prostheses be used due to the absence of cost-effectiveness evidence for non-cemented prostheses. In neither case did they find evidence of significant decreases in the procedures recommended against. They suggest more active dissemination of guidance, including training, monitoring and review.

Reviewer: Sabik, Lindsay

Title: More inquity in the UK National Health Service

First Author: Dartnall, W

Citation: Lancet 2004; 363: 1478-1478

Summary: This letter to the editor expresses outrage over the NHS decision to follow the NICE recommendation to fund one cycle of IVF (and likely three in the future) for women in the UK. The author argues that since individuals with serious medical conditions are being made to pay for treatment to keep themselves alive, using taxpayer money to correct childlessness is grossly unfair.

Reviewer: Sabik, Lindsay

Title: Gender-based violence, relationship power, and risk of HIV infection in women attending entenatal clinics in South Africa

First Author: Dunkle, KL

Citation: Lancet 2004; 363: 1415-1421

Summary: While there is increasing talk of a relationship between gender-based violence or inequality and women's HIV risk, most studies on the topic have taken place in the US and have targeted high-risk populations. This article describes a cross-sectional survey of 1366 women presenting for antenatal care in four South Africa clinics. The researchers surveyed the women regarding topics including past experience of intimate partner violence, child sexual assault, forced first intercourse, current involvement with a controlling partner, hihg-risk behavior, etc. They controlled for the women's high-risk behavior and found that intimate partner violence (OR 1.48, 95% CI 1.15-1.89) and high levels of male control in a women's current relationship (1.52, 1.13-2.04) were both associated with HIV seropositivity. This type of information raises interesting policy questions about the best approaches to reducing the spread of HIV and AIDS.

Reviewer: Martin, A

Title: Creation of a drug fund for post-clinical trial access to antiretrovirals

First Author: Ananworanich, J

Citation: Lancet 2004; 364: 101-102

Summary: Reports on the HIV Netherlands Australia Thailand Research Collboration's (HIV-NAT) efforts to make post-clinical trial antiretrovirals more accessible.

Reviewer: Sabik, Lindsay

Title: More aid is needed to halve world poverty, says report

First Author: Bosch, Xavier

Citation: Lancet 2004; 363: 1448-1448

Summary: News article summarizing the message of the Global Monitoring report. The report claims that most developing countries will not meet the Millennium Development Goals (including halving the proportion of the population in extreme poverty by 2015) unless more aid is effectively delivered to these countries.

Reviewer: Martin, A

Title: Justice, ethnicity, and stem-cell banks

First Author: Bok, Hilary

Citation: Lancet 2004; 364: 118-121

Summary: Background:
It is not possible to design a stem-cell bank so that all can benefit because: a. In the immediate future, stem-cell therapies will involve the transplantation of donor stem cells, and the only reliable defence against immune rejection includes a close matching of HLA types between the donor and the recipient, and b. For a number of reasons, including financial cost, it is not feasible to maintain enough lines to ensure that every potential recipient will receive a good match.

To make matters really hairy, the frequency with which particular haplotypes occur varies a great deal across ancestral/ethnic groups. So, in countries where the majority population is, say, white, a bank that consists of the stem-cell lines with the 50 most common haplotypes will be able to benefit primarily white people.

Bok et al defend what they call the "ancestral/ethnic representation strategy" for determining what lines to include in a bank. This strategy is to design the bank so that an equal proportion of memebers of each ancestral/ethnic group in the country can find a match. They consider and reject an argument for this strategy that appeals to an obligation to ameliorate the effects of past and current injustices, because other strategies are better suited to satisfying this obligation. Instead, they put forward an argument from the expressive aspect of the strategy.

Main argument:
1. A strategy that aims simply to maximize benefits to the greatest number of people will, in practice in places like the US and Europe, prevent most members of non-white ancestral/ethnic groups from finding matches in the bank.
2. Since, in the US and Europe, the members of such groups have been subject to discrimination, it would be reasonable for them to wonder whether their interests had been taken seriously by those who designed the bank.
3. We should not act in ways that give some members of our societies reason to doubt that they are regarded as full and equal citizens who interests are taken seriously, especially when those doubts have often been well-founded.
4. The ethnic-representation strategy makes stem-cell therapies available to the greatest number of people that is consistent with an expression of respect for the fundamental equality of members of minority ancestral/ethnic groups.

Therefore, we should adopt this strategy.

Reviewer: Martin, A
Title: No "access for al" to US Government HIV/AIDS research
First Author: Auerbach, JD
Citation: Lancet 2004; 364: 109-110
Summary: Criticizes the U.S. government's decision to limit the number of federal scientists attending the XV International AIDS conference in July 04, on the grounds that it deprived international scientists of the opportunity to learn from and collaborate with U.S. scientists.

Reviewer: Martin, A
Title: HIV and sexual health in the UK: politics and public health
First Author: Power, Lisa
Citation: Lancet 2004; 364: 108-109
Summary: Argues against some poposals UK government is considering, to implement HIV testing for people applying to enter the UK. Such a policy would be inhumane and cost ineffective and, further, would do little to stem the rising tide of HIV incidence in the UK.

Reviewer: Martin, A
Title: Rotavirus vaccines
First Author: Narula, D
Citation: Lancet 2004; 364: 245-246
Summary: Argues/suggests that if a vaccine is not affordable to a population at its current price, trials of the vaccine in that population are in violation of the Helsinki Declaration, which suggests that trials be done in populations who are directly to use the drug.

New England Journal of Medicine

Reviewer: zeke
Title: Health Care for Homeless Persons
First Author: Levy, BD, O;
Citation: New England Journal of Medicine 2004; 350: 2329-2332
Summary: Reviews challenges to provide health care to the homeless: 1) inadequate housing and clothese increases medical conditions; 2) many have psychiatric problems, 3) 8-9 concurrent illnesses; 4) poverty making medications etc hard to afford.

Call for hospitals to address homelessness in discharge planning.

Reviewer: Frank Lovett
Title: Doctors and Torture
First Author: Lifton, R J
Citation: New England Journal of Medicine 2004; 315: 415-416
Summary: Discusses possible complicity of medical professionals in recent prison abuse (Abu Ghraib, etc.) scandals. E.g.: doctors may have failed to report abuse, and may have provided medical information that could be used in torturing prisoners. Calls for a better understanding of how medical personnel respond to the pressures of military conditions.

Reviewer: Frank Lovett
Title: In The Name of Public Health -- Nazi Racial Hygiene
First Author: Bachrach, S
Citation: New England Journal of Medicine 2004; 351: 417-420
Summary: Retrospective on German “racial hygiene” programs. History “reminds us of the importance of maintaining democratic checks” on the “application of biomedical research. ”

Reviewer: Frank Lovett
Title: Public Registration of Clinical Trials
First Author: Steinbrook, R
Citation: New England Journal of Medicine 2004; 351: 315-317
Summary: Should there be public registration of all clinical trials (even in the private sector), regardless of outcome (even when the results are negative)? Steinbrook notes some arguments in favor of public registration, but also that private research is often done by companies with a proprietary interest in their data. Most of the article discusses how public registration might work. Concludes that public registration is “an idea whose time has come.”

Reviewer: Frank Lovett
Title: Zygote and "Clonote" -- The Ethical Use of Embryonic Stem Cells
First Author: McHugh, P R
Citation: New England Journal of Medicine 2004; 351: 209-211
Summary: (Editors asked two member of President’s commission whether there should be federally-funded stem cell research, or whether it should be allowed at all). McHugh argues that somatic-cell nuclear transfer (SCNT) could produce stem-cells for research purposes that would not face moral objections of using embryonic stem-cells. This argument hinges on seeing a moral difference between SCNT and in vitro fertilization, which McHugh notes not everyone on the President’s commission did. He supports President’s compromise on stem-cell research.

Reviewer: Frank Lovett

Title: Health Care Reform and the Crisis of HIV and AIDS in South Africa

First Author: Benatar, S R

Citation: New England Journal of Medicine 2004; 351: 81-92

Summary: Review article concerning the challenges faced by the emerging democracy in South Africa with respect to health care inequalities in general, and the HIV/AIDS crisis especially. The author surveys the successes (improved primary care access and responsiveness to the social determinants of health) and failures (erosion of public tertiary care) of various measures to redress the serious inequalities in health care. Notes that the government's HIV/AIDS policies have been particularly misguided, but may finally be on the right track.

Reviewer: Frank Lovett

Title: Embryo Ethics -- The Moral Logic of Stem-Cell Research

First Author: Sandel, M J

Citation: New England Journal of Medicine 2004; 351: 207-209

Summary: (Editors asked two member of President's commission whether there should be federally-funded stem cell research, or whether it should be allowed at all). Sandel considers two objections to stem-cell research: (1) it is wrong in itself, (2) it begins a slippery slope towards research that is wrong. Argues that neither objection is persuasive, but that researchers should consider both objections seriously. Just as not every acorn is an oak tree, so not every embryo is the moral equivalent of a person. Carries out a persuasive reductio objection to the claim that embryos count as people.

Reviewer: Frank Lovett

Title: The Price Tag on Progress -- Chemotherapy for Colorectal Cancer

First Author: Schrag, D

Citation: New England Journal of Medicine 2004; 351: 317-319

Summary: Discusses "sticker shock" of some new cancer treatments. Goes on to argue that the failure to examine public cost-effectiveness of such treatments will inevitably threaten the integrity of the public health system.

Reviewer: Zeke

Title: The Cost of Admission--Tiered Copayments for Hospital Use

First Author: Steinbrook, R

Citation: New England Journal of Medicine 2004; 350: 2539-2542

Summary: The article examines the phenomena of charging patients different amounts depending whether they use different hospitals. Hospitals in the prefereed teir get no or lower co-pays, others have higher co-pays around $400. Co-pay levels oare determined by cost-effectiveness--especially costs and quality. Key unanswered questions are: 1) effect on outcomes; 2) do they reduce costs; 3) not clear patients like this.

Science

Reviewer: Krohmal, Ben

Title: House Committee Slams NIH's Plan on Consulting

First Author: Jocelyn Kaiser

Citation: Science 2004; 304: 1091-1091

Summary: News piece on Zerhouni's exchange with members of Congress regarding industry payment to NIH employees. Zerhouni agrees with an NIH panel's recommendation to continue to allow carefully regulated outside funding of NIH employees in order to attract and retain top level scientists. Many Congress members remain unconvinced, some accuse scientists of conflict of interest, and a bill is in the works to address the issue. This piece is one of a number Science has done on this issue.

Reviewer: Krohmal, Ben

Title: South Korean Cloning Team Denies Improprieties

First Author: Dennis Normile

Citation: Science 2004; 304: 945-945

Summary: News piece on South Korean team that produced an embryonic stem cell line from cloned human cells. A Nature article accuses the research team of using eggs from one of its own members, raising concerns about possible coercion. The team denies this and blames a miscommunication. The team is also accused of ignoring social consensus by performing the research before January 2005, when a law allowing strictly regulated therapeutic cloning takes effect.

Reviewer: Ben Krohmal

Title: NIH Weighs Demand to Force Sharing of AIDS Drug Patents

First Author: David Malakoff

Citation: Science 2004; 304: 1427-1429

Summary: News piece on AIDS activists' demand that NIH use the "march in" clause of the 1980 Beyh-Dole act to roll back prices of the AIDS drug Norvir which was developed with NIH funding. The law requires that government funded inventions be available to the public on "reasonable terms," or the funding agency has the right to "march in" and force patent holders to license patents to other companies. There are questions regarding whether "reasonable terms" includes price, and whether "marching in" would discourage future private licensing of publicly funded inventions.

Reviewer: Krohmal, Ben

Title: Buried Data Can be Hazardous to a Company's Health

First Author: Eliot Marshal

Citation: Science 2004; 305: 1576-1577

Summary: News piece on New York State Attorney General's threat to prosecute companies that fail to make negative trial results public, bolstering effort to create a public registry of all clinical trial results. The move is a response to GSK's handling of data on the safety of Paxil in children.

Reviewer: Hampson, Lindsay

Title: Genomic Research and Human Subject Privacy

First Author: Lin, Zhen

Citation: Science 2004; 305: 183-183

Summary: This brief article discusses the difficulty of protecting human subject privacy while still making genetic information (especially DNA sequences) available to the academic community. Because SNPs contain information that can be used to identify individuals (as few as 75 statistically independent SNPs would be able to identify one individual), subjects are at risk of being identified and other genotypic, phenotypic, and other information linked to that individual in public records would also become available. While HIPAA generally forbids sharing identifiable data without patient consent, it does not specifically address the use or disclosure policies for human genetic data. Researchers must learn how to balance the need for data to conduct future genomic research and the need to protect subjects' privacy.

Reviewer: Hampson, Lindsay

Title: Crime, Culpability, and the Adolescent Brain

First Author: Beckman, Mary

Citation: Science 2004; 3-5: 596-599

Summary: This article discusses the debate about whether to teenagers under 18 should be able to get the death sentence. In 2002 the U.S. Supreme Court rules against the death penalty for mentally retarded persons (Atkins v. Virginia), finding that mentally retarded people shouldn't be executed because their capacity for "reasoning, judgment, and control of their impulses" is reduced. In a case going before the U.S. Supreme Court this fall (Christopher Simmons), the defense will argue that executing 16- and 17-year olds is cruel and unusual punishment, arguing that the Atkins standard should be applied to everyone under 18. In July, 8 medical and mental health organizations (including the AMA), filed a brief asserting that developmental biology and behavioral literature supports the argument that adolescent brains have not reached their full adult potential. These data show:
-The brain is still growing and maturing during adolescence, not reaching its full growth until anywhere from 20-25 (different structures)
-Adults use distributive and collaborative interactions among distant brain regions whereas adolescents rely on local brain regions (different use)
-Teenagers are more prone to erratic behavior than adults (different response)
Defense lawyers hope to equate juvenile culpability to that of mentally retarded persons.

Reviewer: Hampson, Lindsay

Title: Privacy Rule Creates Bottleneck for U.S. Biomedical Researchers

First Author: Kaiser, Jocelyn

Citation: Science 2004; 305: 168-169

Summary: An article blaming HIPAA (Health Insurance Portability and Accountability Act) for hindering research--HIPAA requires researchers to get an individual's written permission for each use of patient data in a study. A survey conducted last year by AAMC found that it had a "profoundly negative impact" on many kinds of research. The article claims that the largest impact is on population-based case control studies, outcomes studies (many smaller, rural hospitals are dropping out of these studies because of the associated costs), research involving databases, and pedigree/genetic information studies. AAMC argues that the research already approved by an IRB under the Common Rule should be exempt.