Social Justice Is a Global Issue:
Ethical Pandemic Planning

To the Editor: The Centers for Disease Control and Prevention is pleased to see “Planning for an Influenza Pandemic: Social Justice and Disadvantaged Groups,” by Lori Uscher-Pines and colleagues (Jul-Aug 2007). As representatives of CDC’s Public Health Ethics Committee, we recognize the importance of a robust ethical framework for public health that attends to issues of social justice and addresses the needs of vulnerable populations who might be adversely affected by a pandemic. We also agree with Lawrence Gostin, who pointed out in a commentary in the same issue that social justice requires more than fair distribution of benefits and burdens—it requires action.

CDC has established both an external Ethics Subcommittee of the Advisory Committee to the Director, composed of leading ethicists from throughout the United States, and an internal CDC Public Health Ethics Committee. The Ethics Subcommittee is collaborating with CDC to develop ethics guidance. Ethical Guidelines in Pandemic Influenza, which was released in March 2007, recognizes the importance of addressing the needs of populations likely to be marginalized, of developing fair procedural justice mechanisms, and of diversity in ethical decision-making. It serves as a resource for CDC decision-makers as well as CDC’s state and local partners. It informs CDC’s operational plan for detecting and responding to a pandemic of avian influenza (http://www.cdc.gov/flu/pandemic/OPLAN/BaseOPLAN.pdf), which in turn cascades into the plans of the Department of Health and Human Services and the U.S. government as a whole.

Uscher-Pines and colleagues point out that social justice is a global issue. We agree. CDC’s vision is “Healthy people in a healthy world through prevention.” CDC and other U.S. government agencies have invested significant resources to help prepare developing nations for an influenza pandemic. The efforts undertaken include building capacity to investigate avian influenza and implementing control measures in countries most likely to be impacted by a pandemic. CDC partners with governments to help build workforces and systems to detect and respond to epidemics through Field Epidemiology Training Programs. The Global Diseases Detection Program extends CDC partnerships to include laboratories and population-based surveillance and response. CDC also supports the World Health Organization’s Collaborating Centers for Surveillance, Epidemiology and Control of Influenza by providing technical assistance and training. These efforts are conducted both for humanitarian reasons and because it is in the world’s interest to control potential pandemics wherever they emerge, as illustrated by the successful global response to severe acute respiratory syndrome.

As public health officials continue to prepare for a possible pandemic of avian influenza, it is important to emphasize the value of grounding these efforts in an ethical framework. Addressing the needs of disadvantaged and vulnerable groups is a vital part of that.

Drue Barrett
Mark White
Centers for Disease Control and Prevention

To the Editor: The article by Lori Uscher-Pines and colleagues addresses an important issue in the great enterprise of preparing societies for the next pandemic: considering the needs of minority and deprived groups and involving them in the preparation process. This article is one of a number of publications appearing in the past two years that undertake remote analyses of published national pandemic plans. These analyses are valuable as they can suggest lacunae, and this particular article is especially helpful because Uscher-Pines and colleagues have found that the English-language plans they have addressed do not directly mention this significant topic. Though the seminal guidance, WHO’s 2005 checklist for pandemic plans face a number of methodological challenges, and so it may be wrong to conclude that the minority groups issue is quite as neglected as Uscher-Pines et al. suggest. Working with the European Commission and WHO European Region, The European Centre for Disease Prevention and Control (ECDC) has recently completed an exhaustive rolling program of joint national self-assessments of pandemic preparedness in the thirty member states of the European
Union and European Economic Area (http://www.ecdc.europa.eu/Health_topics/Pandemic_Influenza/Assessment_tool.html). An analysis of written plans in 2005 might have come to the same conclusion as Uscher-Pines and colleagues. However, in working with these countries, ECDC found that quite a number of them have addressed the needs of minority groups to greater or lesser extents; they simply did not mention this in their written plans.

Drawing from the experience in Europe, what other difficulties do these remote analyses of pandemic plans face?

**Complexity of plans.** As planning has become multilayered (national, regional, and local) and multisectoral (involving government, health care communities, educational systems, and the private sector), it has become harder, if not impossible, for the remote viewer to review a country’s plans in their entirety.

**Language.** The main purpose of national plans is to convey information to the country in the national language. Sometimes an English language version is developed, but this is usually a summary. Reviewers who only look at English-language versions (as in this article) will rarely receive a complete view.

**Plans vs. preparedness.** Written plans may simply be pieces of paper, and their completeness and elegance does not necessarily reflect true preparedness, or how well they have involved those who will have to make them work when the pandemic inevitably comes.

**Anatomy vs. physiology.** Undertaking exercises, like the massive European Union exercise “Common Ground,” is essential to determine what may actually work. In a sense, plans can represent anatomy but not physiology. ECDC’s work has shown that a complex relationship exists between countries’ written plans and how well they will actually function in a pandemic, both within the countries themselves and among each other globally.

**Need for validation.** For the reasons mentioned above, remote analyses may be wrong or misleading. Those undertaking them should check with the countries to see whether what they have concluded from reading the plans is actually the case.

Having said all this, Uscher-Pines and colleagues have made a very valid point. I hope that WHO and the United Nations System Influenza Coordinator will attend to it.

**Angus Nicoll**  
European Centre for Disease Prevention and Control

To the Editor: The issues of interest to bioethicists have expanded in recent decades to include not just those topics generated in clinical care and research, but also those raised by studies and interventions involving populations. As a result the field has begun to change in several ways. The issues on the table now include those of concern to the 90 percent of the world’s people whose health needs are addressed by just 10 percent of global spending on health. Equally important, sustained attention is finally being paid the third principle in the familiar autonomy/beneficence/justice triumvirate.

Anyone seeking proof of this shift need look no further than “Planning for an Influenza Pandemic,” in which the concept of justice is instantiated within countries’ efforts to prepare for a pandemic. Yet the article also demonstrates the difficulties in deciding what obligations to which groups must be met under which circumstances. For example, should responding to the burdens imposed on those made worse off by antipandemic activities (poor families whose poultry are destroyed when avian influenza is detected in their village) get priority over protecting those persons who are already the most disadvantaged (those who, prior to a pandemic, are already most at risk of death or serious disability because of lack of health care)? That the pandemic plans of most countries have not encompassed a move from the first to the second may be re-
grettable but less noteworthy than the willingness of countries to address ethical dilemmas explicitly. Issues of justice are not raised uniquely by the prospect of an influenza pandemic; rather, they are inherent in every aspect of the manner in which public health activities—and health services more broadly—are planned, financed, and carried out.

Health officials, of course, always recognized that they have to trade off achieving one objective for another, with resulting winners and losers. What has changed in recent years is the manner in which the issues are brought to the surface and the willingness to seek ethics guidance. At the World Health Organization, we saw this in the initiative to scale up treatment for HIV/AIDS (WHO, Guidance on Ethics and Equitable Access to HIV Treatment and Care, 2004), and now it is even more apparent in pandemic planning, as described by Lori Uscher-Pines and her coauthors. The question for bioethicists is: having articulated this need, are we actually prepared to respond? Thanks to the Bellagio Group, led by Professors Faden and Karron, for illustrating the value in an ethical checklist for pandemics.

The World Health Organization has been laying out a project on ethical issues in pandemic influenza preparedness since 2006. The main focus has been on questions of equitable access to treatment and prophylaxis (including for disadvantaged populations), obligations of and to health care workers in a pandemic, public health measures, and international cooperation. A strong emphasis of the project has been on fair process and on the inclusion of all stakeholders in the planning process. A WHO guidance document entitled “Ethical Considerations in Developing a Public Health Response to Pandemic Influenza” is in press, along with four background papers on the abovementioned topics. Capacity-building activities on pandemic preparedness and response, including the ethical aspects of planning, have been ongoing in WHO’s regions and among its member states.

We hope these and other efforts will bring increased attention to the need of involving vulnerable groups in decision-making and designing special measures for them in the event of a pandemic.

Efforts to address these gaps are already underway in some countries. The guidance document “Getting through Together: Ethical Values for a Pandemic,” published by New Zealand’s National Ethics Advisory Committee in 2007, demands the involvement of and special considerations for traditionally disadvantaged groups. The document identifies the Maori as a vulnerable group and calls explicitly for their inclusion in decision-making regarding pandemic preparedness to ensure that their protection receives particular attention.

The WHO was carrying out a project on ethical issues in pandemic influenza preparedness to ensure that their ambitions in Developing a Public Health Response to Pandemic Influenza have been noted. We are especially gratified that the Bellagio Principles, on which this project has been based, were to bring attention to the need to address the rights and interests of disadvantaged groups in pandemic planning and response.

Drs. Reis and Nicoll discuss limitations in the methods we employed, most of which are already noted in our paper. However, Dr. Nicoll’s point about English language translations frequently representing only summaries of national plans does not apply to our analysis, as we were restricted ourselves only to full translations of national plans.

As Drs. Barrett, White, and Reis note, it is encouraging that international organizations and national authorities such as the WHO, ECDC, and the U.S. CDC are increasingly providing ethics guidance that addresses the special needs of disadvantaged groups. The WHO is particularly to be commended for developing sophisticated and useful ethics guidance documents that focus on questions of fairness and inclusion. At the national level, the importance of ethics guidance also should not be underestimated. We are especially gratified that New Zealand’s “Getting Through Together: Ethical Values for a Pandemic,” which draws attention to the needs of the Maori, cites the Bellagio Principles. However, in its Checklist for Pandemic Influenza Preparedness and Response Plans, the Bellagio Group specifically emphasized that the rights and interests of disadvantaged groups should be addressed directly in national plans.

National plans are approved by the highest relevant level of government. Thus, including disadvantaged groups in them reflects a commitment in national policy that ethics guidance documents do not. While we agree with Dr. Nicoll that the “completeness and elegance [of national plans] does not necessarily reflect true preparedness,” they represent a critical first step and provide validation and po-

To the Editor: In their article, Uscher-Pines and colleagues address a very important issue in pandemic influenza planning. We fully agree with the Bellagio Group that both traditionally disadvantaged groups as well as those likely to be disproportionately affected by a pandemic require special attention in pandemic planning and response measures.

A shortcoming of their analysis is that they included only national pandemic preparedness plans available in English, which ignores some French-speaking and other developing countries. Nonetheless, their findings suggest that, at least explicitly in the plans, important gaps in planning exist with regard to disadvantaged populations.

The authors alone are responsible for the views expressed in this letter, and they do not necessarily represent the decisions, policy, or views of the World Health Organization.
ceptual support for those who work to ensure protection of disadvantaged groups in practice. Even as we make progress in other crucial aspects of preparedness, we cannot truly be “prepared to respond,” as Professor Capron maintains, without including the needs and interests of disadvantaged groups in national pandemic-preparedness plans.

The HIPAA Headache

To the Editor: There once was a happy time when HIPAA referred to insurance reforms that increased access and tried to reduce costs. Owing to its gargantuan privacy rule, HIPAA is now known mainly as the source of constant headaches and endless strife over whether patients’ medical records are adequately protected. The privacy rule was meant to pave the way for electronic claims processing, but the naïve goal of achieving “administrative simplification” has encountered the medical world’s monumental complexity.

Medical professionals have always been subject to firm legal and ethical rules about confidentiality and patients’ rights, enforced by serious sanctions such as tort suits. These rules worked reasonably well prior to HIPAA’s much sterner enforcement, but to make HIPAA even more oppressive, Richard Sobel (“The HIPAA Paradox: The Privacy Rule That’s Not,” Jul-Aug 2007) proposes giving patients the right to consent to various uses of their medical information.

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signal timing, etc., at various speeds and conditions with sufficient margin for error that most accidents were avoided, gridlock would surely prevail. Yet this is more or less what Richard Sobel argues HIPAA should do for medical records, even though intangible privacy interests are surely less important than reducing carnage on the highways.

Is medicine really all that more vulnerable? No. There has been no crisis of poor treatment, ruined lives, or wholly neglected care owing to inadequately-protected medical privacy—only highly speculative possibilities, leading (or misleading) survey questions, and a small set of incompletely-reported incidents. Similar fear-mongering about misuse of genetic information has led to the current situation in genetic medicine: peoples’ false assumptions about social risks are deterring useful genetic testing, even though the actual risks are mostly negligible. (See Henry Greely’s article in the

Consent sounds simple and innocuous, but consent’s other shoe is the right to refuse—meaning the right to insist on doing things exactly the way each patient wants.

This experience should be enough for us not to heed a Chicken-Little cry that the sky of privacy might fall down. But even conceding that some legitimate fear exists, do we really want to erect the massive scaffolding of rigid legalistic and bureaucratic formalisms needed to keep this threat from materializing? We must remember that, prior to HIPAA, no law or ethic prevented giving patients consent rights to uses of their medical information. Students of privacy would do well to think harder about why that was the case.

Mark A. Hall
Wake Forest University
To the Editor: Richard Sobel offers a thorough analysis of one limitation of the HIPAA privacy rule—namely, that it constitutes a disclosure regulation rather than a regulation guaranteeing privacy in the fullest sense of the word. The privacy rule requires that providers give patients notices of their privacy practices but does not forbid disclosures without patient consent.

I would like to point out, however, that the lack of a general consent requirement is only one of many shortcomings of the HIPAA privacy rule. Equally important is the rule’s very narrow scope of coverage. The only entities covered under the rule are health plans, health care clearinghouses, and health care providers who transmit health information electronically for particular purposes. Other businesses can use and disclose health information for their own purposes without violating HIPAA. Employers, for example, hope to hire and retain healthy employees, rather than ones who have absenteeism and productivity problems and submit expensive medical insurance claims. Lenders want customers to be healthy enough to work and pay back their loans. Drug companies want to know which patients are receiving what drugs so they can better tailor advertising materials. A simple but essential safeguard for the security and confidentiality of health information is to expand the HIPAA privacy rule so that it covers all who knowingly process health information for business purposes.

Second, the privacy rule fails to provide a private cause of action for those who have been harmed by privacy breaches. The Department of Health and Human Services is to enforce the rule, but since its enactment in 2003, no civil fines have been imposed on offenders, and only four criminal prosecutions have been initiated. Perhaps as a consequence, compliance has been lax. In a 2006 survey, only 56 percent of providers reported complying with HIPAA’s security regulations, and 39 percent acknowledged suffering health information security breaches. A private cause of action that allows an individual to sue on her own behalf is needed to establish effective deterrence and meaningful remedies.

Third, a component of the privacy rule called the HIPAA security rule, which governs the security of electronic medical records, lacks specificity and fails to provide sufficient guidance for implementation. For example, the rule requires covered entities to encrypt health information where appropriate to protect its confidentiality, but it fails to specify how encryption should be achieved. It also does not require use of the best-known encryption techniques. The security rule would be greatly enhanced by applying a best practices standard that requires organizations to identify and employ commonly used best practices with respect to all of the rule’s standards.

The threats to health information privacy and security are real and growing. In order to meaningfully address these threats, the HIPAA privacy rule must be amended in a variety of ways so that it provides effective protection and remedies for the American public.

Sharon Hoffman
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Richard Sobel replies:

These letters explain further the paradox of HIPAA as a disclosure rule. As Hoffman notes and I’ve discussed elsewhere, HIPAA must cover entities like employers, lenders, and drug companies (and Internet sites), improve security, and create a private cause of action, since DHHS enforcement is limited. Additionally, “national purposes” like law enforcement or civil litigation that permit outside access to medical information must improve consent and due process, since medical records can get patients into trouble with the law.

Hall addresses how HIPAA has morphed from rules providing coverage for the security and confidentiality of health care providers who transmit health information electronically for particular purposes, “privacy protective behaviors” will likely increase: patients will attempt to protect their privacy if policy, legislation, and computers fail to do so. The American Hospital Association estimated that requiring consent would constitute only about 5 percent of HIPAA costs, so the expense of privacy protective behaviors and defensive medical tests may well exceed the expense of getting consent.

The fundamental ethical and medical issue is that consent is essential to the therapeutic process. The perception that privacy is threatened may mean patients are less willing to seek treatment. Patients need and benefit from the right to control use of their medical records. That creates fairer discussions between providers and patients about privacy—one of HIPAA’s purposes.

Patients have the right as citizens to consent under state codes and constitutional law. I don’t advocate “giving” this right, but rather returning it to law. While amending HIPAA to reinstate consent can address the problem, the current electronic records bills (like “Wired for Health”) would resolve it by adding consent to proposed new legislation. Medical colleagues and organizations should contact their congressional representatives to urge improving confidentiality and consent protections that already exist.
Futility Revisited

Much has been written in recent months regarding the Texas Advance Directives Act (TADA), including within the Hastings Center Report (Geoffrey Miller, “Ten Days in Texas,” Jul-Aug 2007). An essential point, however, remains to be made. When those of us involved in end-of-life care and decision-making consider the implications of a law such as the TADA, the fundamental question is not whether the TADA is perfect, but rather whether it is preferable to the status quo. I suggest that it may well be.

A common reason for ethics consultation is a family’s demand for a specific treatment that the physicians and nurses strongly believe is inappropriate. Medical professionals should not be required to do things they believe are wrong, but they also should generally not be in a position to unilaterally deny a family’s request, particularly for life-sustaining medical therapy, without careful review and due process. Several Connecticut hospitals have what we believe to be a fair process in place, referred to as a “Conscientious Practice Policy.” This policy, based on an American Medical Association recommendation, outlines a process of careful review that could in some cases find it permissible for physicians not to provide a therapy they feel is inappropriate. Nevertheless, physicians and nurses still sometimes find themselves doing things they think are needlessly cruel or otherwise inappropriate, despite the agreement of all who have reviewed the situation that what they are doing could (and sometimes clearly should) be stopped. They often continue, sadly but understandably, out of fear of litigation.

The status quo at many U.S. hospitals is that medical personnel sometimes feel forced to practice what they believe to be bad medicine, rather than risk the legal repercussions of refusing a family’s request. This seems unfair to those providers, but more importantly unfair to the patients, who in some cases are made to undergo painful interventions needlessly, or perhaps sometimes only to serve the emotional needs of the family. A thoughtful and thorough process established by any hospital or community might offer the patients, families, and physicians valuable guidance and safeguards, but can never offer protection from legal action. As such, it cannot truly offer effective protection for patients against needless and often painful interventions, nor can it provide protection for those who refuse to carry out such interventions. The TADA provides that very necessary protection.

The TADA is not perfect; better safeguards are needed. However, given the dismal state of end-of-life care throughout the country, the TADA is a step in the right direction.

Mark R. Mercurio
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Geoffrey Miller replies:

As far as the subject in hand is concerned, Dr. Mercurio and I agree on almost everything. We agree that a fundamental question concerning the Texas Advanced Directives Act (TADA) is whether it is preferable to a less strictly specified state law. We agree that there are clinical situations in which further treatment is medically inappropriate, that foregoing that treatment should occur in an atmosphere of agreement and trust, and that physicians have no absolute duty to provide treatments they believe will have no beneficial effect. Furthermore, for both of us, this is no academic interplay based on illusory drama, but is and has been very much a part of our professional lives. We both know the difficulties and pitfalls when foregoing life-sustaining treatment and appreciate the vital importance of the expression of professional virtues such as encouraging trust, knowledge, compassion, tact, and a maintenance of dignity. My argument is that the very specificity of the TADA may threaten these virtues and therefore be counterproductive. We should safeguard against the comfort of “a process” that might disguise what are otherwise value-laden judgments and recognize that the nature, constitution, and oversight of an ethics committee is insufficient to qualify it for a quasi-legal role. Dr. Mercurio is correct. Better safeguards are needed in the TADA. The unusual authority granted ethics committees and the coercive nature of the ten-day rule should be removed.