Violence and Public Health

Firearm Prevalence and the Risk of Suicide
Matthew Miller, MD, MPH
David Hemenway, Ph.D.

The Costs and Benefits of Reducing Gun Violence
Philip J. Cook, Ph.D.
Jens Ludwig, Ph.D.

Interviews

Esta Soler and Lisa James, Family Violence Prevention Fund (FVPF)

Jacquelyn C. Campbell, Ph.D., RN, FAAN, Associate Dean at the Johns Hopkins University School of Nursing

Also Inside

Confronting the Global HIV Epidemic
Laura Tarter and Paul Farmer, MD

Malaria in Nigeria
Arese Carrington, MD, MPH

Legal Protections Against Genetic Discrimination
David C. Bowen, Ph.D., and Nancy Segal, JD
## Table of Contents

Features: Violence and Public Health

### Domestic Violence

Interview with Jacquelyn Campbell, *Associate Dean at the Johns Hopkins University School of Nursing*  
6

Interviews with Esta Soler and Lisa James, *Family Violence Prevention Fund*  
10

Shaping California’s Health Policy for Victims of Intimate Partner Violence  
*Connie Mitchell, MD*  
17
Gun Violence

The Costs and Benefits of Reducing Gun Violence
Philip J. Cook, Ph.D., and Jens Ludwig, Ph.D.
23

Firearm Prevalence and the Risk of Suicide: A Review
Matthew Miller, MD, MPH, Sc.D., and David Hemenway, Ph.D.
29

Linking Data to Save Lives: Recent Progress in Establishing a National Violent Death Reporting System
Deborah Azrael, Ph.D., Catherine Barber, MPA, and James Mercy, Ph.D.
38

In Focus

Confronting the Global HIV Epidemic: A Call for Equity
Laura Tarter and Paul Farmer, MD
43

Malaria: Its Human Impact, Challenges, and Control Strategies in Nigeria
Arese Carrington, MD, MPH
54

Eradicating Malaria: High Hopes or a Tangible Goal?
Ilana Brito
61

Health Highlights

The DNA Code Meets the United States Code: Legal Protections Against Genetic Discrimination
David C. Bowen, Ph.D., and Nancy Segal, JD
67

TV, Drugs, and Health Care: Evaluating and Combating the Influence of Direct-to-Consumer Advertising on the Prescription Drug Market
Gwyneth Card
77

Physicians’ Asthma Prescribing Habits: Challenges to Popular Therapeutic Narratives of Racial Disparities in Asthma Morbidity
Jennifer Clark
87
Editor’s Note

In the Fall 2001 issue of the *Harvard Health Policy Review*, we focus on one of the most significant public health issues facing American society: violence. In the wake of September’s tragic events, we need no reminder that the threat of violence is a grim reality in our society. Nonetheless, this issue’s feature endeavors to enhance our understanding of violence as a public health problem. In particular, we examine violence in two of its most common manifestations: gun violence and domestic or intimate partner violence (IPV).

Only in the past two decades have doctors, lawmakers, and government agencies come to view violence as a public health problem. Previously, it was understood solely as a criminal justice issue, and the health care community was largely left out of the discussion. However, the costs of violence to our society and to the health care system are undeniable. Moreover, in the face of these realities, physicians, nurses, and policymakers alike have come to realize how the health care system can play a critical role in the documentation, prevention, and treatment of cases of gun and domestic violence. The healthcare community is increasingly adopting this new perspective.

We hear the voice of this new outlook in the pair of interviews that begins our focus on domestic violence. Jacquelyn Campbell, a recognized expert on IPV, along with Esta Soler and Lisa James of the Family Violence Prevention Fund (FVPF), discuss trends in national domestic violence legislation and the role of the health care system in handling IPV cases. An article by Dr. Connie Mitchell on California’s groundbreaking IPV legislation accompanies our interviews on this subject.

*How much do we value our safety?* This is the provocative question that Phillip Cook, Director of the Sanford Institute of Public Policy at Duke University and Jens Ludwig, Assistant Professor of Public Policy at Georgetown University, ask in their article to open our section on gun violence. The authors take a unique approach by arguing that the costs of gun violence should not be understood by traditional measures, such as medical expenditures, but “as the flipside of the value of safety.” In the following article, Matthew Miller and David Hemenway, both of the Harvard School of Public Health, consider whether reducing firearm availability is actually correlated with reduced firearm and total suicide rates. Finally, Deborah Azrael, Catherine Barber, and James Mercy, from the Harvard Injury Control Research Center, con
sider the need for a national violence surveillance system that provides information about the circumstances of suicides and homicides.

The In Focus section of our Fall 2001 issue looks at public health problems in developing nations, which are, of course, of a different nature. Transmittable diseases take a devastating toll on these populations, particularly on the poor. Laura Tarter and Dr. Paul Farmer, Director of the Program in Infectious Disease and Social Change at Harvard Medical School, argue that treatment must accompany prevention efforts in addressing the global HIV epidemic. In the articles that follow, Dr. Arese Carrington and undergraduate, Ilana Brito, examine the intractable problem of malaria in developing countries. Carrington focuses on risk control strategies while Brito discusses the challenges faced by researchers striving to develop a vaccine.

Additional articles in this issue showcase a range of significant topics. David Bowen and Nancy Segal outline the current status of federal and state laws pertaining to genetic discrimination. In addition, recent Harvard graduate, Gwyneth Card, enters the debate surrounding direct-to-consumer advertising of pharmaceutical products. Finally, a study by undergraduate, Jenn Clark, looks at physicians’ prescribing habits for clues about racial disparities in asthma morbidity.

We are very pleased to hear that the Harvard Health Policy Review is making an impact on our readership. Bruce Vladeck’s and Harry Cain’s articles from our Spring 2001 issue helped frame the debate when they were cited in a recent Congressional hearing on the future of the Health Care Financing Association (HCFA – now the Center for Medicare and Medicaid Services). We strive to inform all of our readers about significant health policy issues. We also hope to share our journal with a growing national readership. Organizations or persons interested in receiving the Harvard Health Policy Review are encouraged to request subscriptions. Please contact us at our email address: epihc@hcs.harvard.edu.

David Sclar
Editor-in-Chief
Fall 2001
Interview with Jacquelyn Campbell

Conducted by Sarah Park

HHPR: Domestic violence or Intimate Partner Violence (IPV) has traditionally been viewed as a criminal justice issue. When did it become a health care concern?

JC: I track it back to 1985 when former Surgeon General Everett Koop called together a group of experts to talk about violence as a public health problem. Violence in general, up until that point, had not been defined as a health problem. Family violence – child abuse, wife abuse, and elder abuse were three of the topics considered at the conference. Later, Mark Rosenberg, Jim Mercy, and a lot of other people at the CDC were instrumental in looking at violence as intentional injury. Framing violence under an injury framework took it squarely into the health domain.

HHPR: When were the first IPV studies published in health-related journals?

JC: They were published before Koop’s conference. In 1979, two pioneers of the violence field, Evan Stark and Anne Flitcraft, wrote one of the hallmark violence articles in the International Journal of Health Services. It was about domestic violence and its interface with a big healthcare system. In 1977, Barbara Parker and Dale Schumaker published the first nursing research on domestic violence in the American Journal of Public Health. This was the first article about domestic violence published in a mainstream public health journal.

Doctors, Victims, and the Police

HHPR: According to the Family Violence Prevention Fund (FVPF), a well-respected national domestic violence organization with a strong and unique emphasis on healthcare, “Healthcare providers are often in the best position to help victims of domestic violence and their children – but only if they are trained to screen patients for domestic violence, to recognize the signs of abuse, and to intervene effectively.” What makes the position of healthcare providers unique?

JC: The reason that may be is because many battered women do not seek help from the criminal justice system or a shelter until things are really bad. And that’s probably as it should be. We in the health care system see women before it gets bad. We may see them for minor injuries or when mental health problems related to abuse first start.
But even more importantly, we see women on a regular basis at primary care visits and prenatal care visits.

**HHPR:** Do you feel that there is greater trust between a victim and a healthcare provider than between a victim and the criminal justice system?

**JC:** Not necessarily. It depends on what the person’s experience has been with the criminal justice system. What is more telling is the fact that people perceive — and rightfully so — that the criminal justice system and the health care system have two different functions. The criminal justice system doesn’t come into play until the woman is defining the violence as a crime.

We have lots of evidence that when the violence first begins, the victim does not perceive it as a crime. When these episodes first begin, the victim is very invested in trying to fix the problem behind the episodes rather than seeking a criminal justice remedy. The same with shelters; women don’t usually think about shelters. One of the key things healthcare providers can do is be the bridge that allows the woman to see that shelter services and advocacy services might be very useful for her.

**HHPR:** What are your views on mandatory reporting of domestic violence by healthcare professionals to the police?

**JC:** Mandatory reporting has been a difficult issue to sort through. On the face of it, it seemed like a really good idea that allowed the criminal justice system to be involved quickly and, hopefully, to prevent further injury and serious problems.

Women often are very pleased to have someone else take the responsibility of calling the police. If the police get involved, the woman can say it was the doctor who did it. However, there is a significant minority of battered women who are concerned that they would be in more danger if the police were called. Some women say that if they knew there was mandatory reporting they just wouldn’t tell their healthcare provider about the abuse.

We are researching what is happening with mandatory reporting and whether or not it is keeping women out of jeopardy. Once we have some really good studies, maybe we can figure out a viable mandatory reporting system.

## National Domestic Violence Legislation

The Violence Against Women Act of 2000 (VAWA 2000) passed with overwhelming support in both the House and Senate and was signed into law by former President Clinton last fall. It provides $3.3 billion over five years to address domestic violence, with law enforcement and shelter services receiving $925 and $875 million respectively.

**HHPR:** Several new VAWA 2000 programs have been slated to receive funds, including a study of state laws addressing insurance discrimination against victims of domestic violence. Aside from this, there seems to be little mention of healthcare issues. Can you explain the absence of a role for healthcare providers in this legislation?

**JC:** I think it is somewhat unfortunate. But at the same time you would never want to take funding away from the shelter services or the very necessary criminal justice services to widen the health services. And I
think there has been and will be some health-related programs, such as funding for shelter programs that are housed in the healthcare system.

There is not a clear-cut method of funding expanded domestic violence services within the healthcare system. We think that there is a cost-benefit advantage, but that has yet to be definitively demonstrated. There have been initiatives funded through the Department of Health and Human Services (HHS), but because they are not legislated through the VAWA, they are subject to variations. What happens depends on who's in charge of what office.

HHPR: So the lack of legislation affects the availability of programs and services. How would you describe the relationship between legislators and healthcare professionals in enacting legislation that deals with domestic violence?

JC: Because so much of healthcare in the US is private, there's always a tension between what can be legislated as we have seen in our various attempts at "healthcare reform." It's difficult. We see potential in Medicaid programs to more fully serve domestic violence issues, but they're so chronically under-funded for basic healthcare, and we have so many people who are totally uninsured. All of these things conspire to make it difficult to address domestic violence. It's very difficult to make the case that programs for domestic violence should come before other badly needed programs. Part of the challenge is to get legislators to look at the entire healthcare system.

Medical Privacy Protection

On April 14, 2001, the HHS's new medical privacy regulations, the first comprehensive federal medical privacy laws in U.S. history, went into effect.

HHPR: What is the significance of the new privacy regulations for victims of domestic violence (the Federal Standards for Privacy of Individually Identifiable Health Information)?

JC: They are extremely important and really needed, but they bear some monitoring in terms of just how they are implemented. We have to make sure that victims of domestic violence do not get singled out for exclusion, as they have been in the past.

I don't believe that insurance companies specifically targeted domestic violence victims for discrimination. Instead, because women experiencing IPV tend to have more health problems, IPV apparently became one of the variables sometimes factored into insurance calculations used for underwriting guidelines. There are many conditions that go into the algorithms that insurers use to decide who should be insured. And those algorithms are what our insurance system is based on. It is not an easy issue to address in all its complexity. The policy actions brought forth through the leadership of Nancy Durborow and the Pennsylvania Coalition Against Domestic Violence (PCADV) and others attempt to regulate insurance practices so that insurers cannot take domestic violence into account.

The Organizations Behind Role Model States

HHPR: Pennsylvania and California are commonly viewed as forerunners when it comes to state health care legislation concerning domestic violence. Is there something unique about these states?
JC: Yes. The PCADV is one of the oldest and most active coalitions. It has always been active in the policy arena and in providing shelter services. And it has had the steadiest action to fund advocacy services in health care settings. They have managed to pass state legislation that provides funding for advocacy services in the health care settings across the state. They have been on the forefront of the health-domestic violence connection for years and years.

HHPR: And California?

JC: What has been important there is the efforts of the FVPF plus the legislation that was passed in the 90s. It mandated training for health care professionals in domestic violence and also mandated reporting of domestic violence by health care professionals. So California, like Pennsylvania, had early state legislation activities. What’s possible in health care legislation is often at the state level.

Advancement without Legislation

HHPR: Can you give us an example of an important advance that has occurred within the past 20 years?

JC: Routine screening. In the early 1980s, there was no thought of screening for domestic violence. It was first in prenatal care that that notion came forward due to the work of the American College of Obstetricians and Gynecologists. Now I think there is probably some form of routine screening in most prenatal care settings, at least the public ones. Routine screening is much more common in emergency department settings now.

HHPR: Has this advance come about through statewide legislation or through health care professionals’ realization of the importance of screening?

JC: It’s not really been through legislation. California is the only state that has a state law that addresses this at least peripherally. The health care professional organizations, individual health care professionals, and also the efforts of the health care association, the JCAHO (the Joint Committee on Accreditation of Healthcare Organizations) have brought about these advances.

The JCAHO has not mandated routine screening, but they have mandated that there be policies and procedures for all forms of family violence in every health care setting. They have mandated that there be training and that there be attention to the issue of admission and discharge. The JCAHO has strengthened its standards every year since 1990. That represents an enormous step forward.

The American College of Nurse Midwives is an example of a professional organization that has really taken on this issue. It has mandated that there be training for nurse midwives on domestic violence both in their basic training and on their board exams. Exams are a very important place for health care professionals to advance the issue. It has been a very broad-based effort to try to address both basic education and continuing education. Institutional change and funding for institutional change, on the other hand, have been difficult.

HHPR: Thank you very much.
Interview with Esta Soler and Lisa James

Conducted by Sarah Park

HHPR: What distinguishes the Family Violence Prevention Fund (FVPF) from other national domestic violence organizations?

ES: The FVPF, as a national organization working both nationally and internationally, has decided to focus a lot on health care. There are many other organizations that work on domestic violence - such as the National Coalition Against Domestic Violence and the National Network to End Domestic Violence, which is a state coalition - but health care isn’t a key component for them. There are also state coalitions who have health care as a main focus, but the national organizations currently do not. We are the nation’s resource center on health care and domestic violence. We have a federal grant to do that.

HHPR: How do you see the Family Violence Prevention Fund’s role in healthcare policy?

ES: We have been working on the issue of domestic violence and healthcare policy since the early eighties. We started by working with emergency rooms. We saw very early on that it’s important to look at the main entry points where people go who may be victims of domestic violence, including those who are suffering from a whole host of sequelae because of domestic violence. On the side of public policy and domestic violence, there have been two main strategies. One has been the community-based shelters - crisis housing programs. The other has been the law enforcement, criminal justice system. And while we have worked in those areas, what we saw around health care was that very few people actually wind up going to shelters and a significant number of people call the police. However, many more people go and get health care.

The opportunities we saw in the healthcare system were huge because everybody winds up in the healthcare system for one reason or another. It may not even be because you’re going to seek help around an incidence of violence. We saw that if we could create an overarching and comprehensive healthcare policy, then we would have the opportunity to work with hundreds of state coalitions to change the way health care is delivered.

Esta Soler is the founder and Executive Director of the San Francisco-based Family Violence Prevention Fund (FVPF). She has been appointed to serve on the Presidential Commission on Crime Control and Prevention and the National Advisory Council on Violence Against Women.

Lisa James is the programming director of the FVPF’s National Health Care Standards Campaign.
of thousands of people because that’s where they’re at. We believe that screening should be part of the routine exam that you have when you go in for your annual physical or your gynecological exam. The medical exam, which includes a whole host of questions about a variety of social and health-related behaviors, should also ask about domestic violence.

I think one of the main principles of service provision - and organizing - is that you’ve got to meet people where they’re at. You can’t wait for them to call you. It just doesn’t work.

The Players

**HHPR:** How would you describe the relationship between academia, public policy makers, and non-profit organizations in working together to accomplish major goals such as passing legislation?

**LJ:** I think that partnership is critical, particularly the role of academia in the area of research and evaluation - not only of the health impact of domestic violence - but of what the interventions’ outcomes are. We need to see significant funding and collaboration put towards evaluating screening and intervention for domestic violence in healthcare setting. In order to promote that practice nationwide, we’ve got to have both the data that supports its effectiveness and the policies that encourage healthcare providers and health systems that do so in a way that respects the safety and the confidentiality of victims.

We’ve got to have the advocacy groups at the table to represent victims of violence and to make sure those laws and policies - or any research that’s being conducted - don’t, in fact, cause more harm than good. So that’s a great question - the relationship between researchers, legislators, and advocates is a critical partnership that we’re trying to continue to foster as we develop a national health initiative on domestic violence.

And the Pieces

**HHPR:** What are the key areas that the FVPF sees as critical to promoting an improved healthcare response to domestic violence?

**LJ:** This isn’t exactly an exhaustive list: reporting – states should not mandate that women and doctors report violence to the police, insurance – victims should not be discriminated against (they have been in the past), training - healthcare providers need to learn how to recognize and help a victim, screening – meaning asking women during checkups whether they are victims of abuse, and protocols – health systems must have clear steps for doctors to follow.

The Trouble with Mandatory Reporting

**HHPR:** Does mandatory reporting help victims of domestic violence?

**LJ:** No. Further endangering the victim is the problem with mandating the reporting of domestic violence to the law enforcement without the victim’s consent. There’s a very real fear of retaliation. If we were confident that the batterer would be put
away and safely out of arm’s reach, that might be a different story. But in many cases, the best scenario for the patient is not to have her perpetrator either arrested or re-released.

However, when states have had mandatory reporting laws, we found that the awareness of domestic violence as a household issue increased because the healthcare providers are particularly concerned with liability and their ethical and legal obligation. So it’s been good in that way in many states.

**HHPR:** Who should be making the decision to report domestic violence – the victim, the doctor, or the law?

**LJ:** It’s critical that we leave the decision-making power in the hands of the victim. She knows what’s best for her. We have also found, anecdotally, on a large scale, that many victims of violence are hesitant to come to the healthcare setting because they know about the reporting requirement, so they’re hesitant to disclose. And more frightening is that they’re hesitant even to seek health care.

**HHPR:** To ensure that the victim is in control of her medical records and safety, who should be responsible for protecting the confidentiality of what goes on during the checkup – the healthcare system or the criminal justice system?

**ES:** What you don’t want is to turn all of the intervention and screening that’s going on in the healthcare system - albeit not as much as we want - into a law enforcement program. We want it to be a healthcare program. We’re not saying that we should create separate and unequal laws with respect to domestic violence. We do agree that you must report a serious felonious assault, but not every incidence of domestic violence is like that.

Mandatory reporting undermines the responsibility of the physician, and there’s no evidence that the criminal justice system is the best place for all situations, so why do that? It just creates an additional burden — and the efficacy of that is still very much in doubt.

The National Academy of Science’s report from a couple years ago told states that you should not do mandatory reporting until you do the research to see whether it’s the right way to go. So there’s been a real slowing down of that public policy.

We believe very strongly that the whole approach to the issue of domestic violence is not just about health intervention and screening. It is about setting a public health framework on this issue. The strategies that you use are different than if you just set a criminal justice framework. For us, the public health and the healthcare system are two of the places where we really would like to see a significant shift away from having this almost sole reliance on the institution of the justice system to deliver this service. We haven’t seen that shift, but that’s what we’re working on.

**Insurance Discrimination**

**HHPR:** How have insurance companies treated victims of domestic violence in the past?

**LJ:** A while back, we found that a number of insurance companies were discriminating against the victims of violence and denying them insurance, basically putting them
and their experience as a victim of domestic violence on par with people like hanggliders or people who do highly dangerous activities.

**HHPR**: And how have states responded?

**LJ**: Before the Pennsylvania Coalition Against Domestic Violence (PCADV) took this issue on, a lot of the major insurance companies were denying coverage to victims of violence. It was only through the hard work of the Pennsylvania Coalition in helping states pass laws that prohibited insurance discrimination that we’ve come quite far in this area.

Twenty-two states have enacted legislation that protects victims of domestic violence. The leadership there is thanks to Nancy Durborow from the PCADV. Overall, we still need to continue to work to strengthen those discrimination laws, because as we encourage providers to screen, intervene, and document, we definitely don’t want it to then come back to the victim and harm her in some other way.

**Screening for What?**

**HHPR**: What are doctors looking for when they screen women?

**LJ**: Doctors have to look for more than just injuries. When we first started doing this work, we trained healthcare providers on how to identify signs and symptoms for victims of violence. As we learned more from research on the whole host of health problems that are associated with domestic violence, we recognized that you can’t screen based on indicators alone. Otherwise you’re going to miss a huge portion of the victims who are coming into the healthcare setting. Routine screening is a critical component of an intervention. Victims have said in research that simply bringing up the issue is one of the most important interventions.

**National Legislation: A Criminal Justice Lens**

**HHPR**: Domestic violence was first recognized as a healthcare policy issue in the 1980s. Yet, most legislation, including the Violence Against Women Act, which was re-authorized in 2000, has not included a role for healthcare providers. How do you explain this absence?
The Violence Against Women Act from September of 1994 was part of President Clinton’s work on crime control legislation. VAWA was one of many components to a large omnibus crime bill that the President signed into law on, I believe, September 13, 1994. And health never got in there in part because VAWA was always written as a crime bill.

It was supposed to provide resources to prosecutors and to police officers and a little bit to the judiciary and to victim advocates who work in the criminal justice system. We have never, at this point in time, had a bill with the health piece of the strategy that has reached the same kind of prominence as the criminal piece.

HHPR: What do you see as the history or significance of VAWA?

ES: When it passed in 1994, it was the first major piece of legislation subsequent to the Family Violence Prevention and Services Act, which was adopted in the early eighties. It was a bill that funded shelters in the United States. This was the first time that there was a recognition that we have a social problem on our hands that required an expenditure and a political will to do something about it. Before that, I think the Family Violence Prevention and Services Act was a relatively small bill and a relatively small appropriation.

VAWA, by being part of a crime bill at a time in this country when crime was a big issue, raised the level of the concern. When you have social problems, you need public visibility, because without it, you have no public policy because people don’t think it’s a social problem. So I think that was the biggest positive.

HHPR: Do you think that the next re-authorization might introduce healthcare programs?

ES: I don’t know if it will be in VAWA. What we’re working on, and what we hope to build support for, is a whole public health strategy, and a prevention strategy, to deal with the issue of domestic violence. That’s our challenge. Whether it ends up in VAWA or in a separate piece of legislation (it’s governed by separate congressional committees because prevention and public health are very different from crime control in this country), we’re going to push for it.

We feel it’s critical because right now, the response that we have out there is narrow, and we should be figuring out how to intervene earlier with families that are riddled with domestic violence. And we also have to ask ourselves, “How do we prevent it?” We can’t just wait for a horrific act to happen and then provide resources. It’s just not the right thing to do.

Medical Privacy Protection: Preventing Further Abuse

HHPR: You had mentioned that 22 states had passed legislation related to medical privacy for victims of domestic violence. Is the Federal Standards for Privacy of Individually Identifiable Health Information legislation, the Department of Health and Human Services’ new medical privacy regulations, a national bolster to the state-wide legislations, or do they differ greatly?

LJ: It’s a little different. The 22 states’ legislation looks strictly at insurance companies specifically discriminating against vic-
tims of violence and denying them coverage. That is one component of our concern about medical records’ privacy. On one hand, it is important for a healthcare provider to ask about violence, identify victims, and then document it, so we can study and understand domestic violence as a healthcare issue. But if that information gets sent out to a variety of different places, including the insurance company, and the insurance company denies the victim coverage, that’s obviously not going to help her.

HHPR: Aside from the threat of insurance discrimination, why do IPV victims need extra protections?

LJ: Sharing information from medical records can have other unfortunate negative ramifications. Again, the issue of retaliation comes up. In many cases, medical records are not that private, and inappropriate disclosure of health information can really harm the victim. We have seen some cases where medical records and results of visits have been sent home. After the perpetrators discovered that the victim has gotten care for her injuries, they retaliated with further violence.

Employers, law enforcement agencies, and even members of the victim’s community can discover domestic violence in the records. They may either discriminate against the victim or alert the perpetrator. The community members are of particular concern in smaller, more rural areas. There’s a huge web of information that gets disseminated once anything is in the medical record. For domestic violence victims, it’s not just a matter of privacy, it’s a matter of safety, and in some cases it’s life-threatening information.

We were working on including specific pieces that would protect victims of domestic violence when the Secretary of Health and Human Services, Tommy Thompson, put out the federal standards for privacy of medical and health information. There are a number of key areas where you need to pull out victims of domestic violence and add extra protections for them.

We were quite pleased that a number of protections that we requested for victims of domestic violence were actually included in the new medical privacy rules.

HHPR: And what were some of these protections, specifically?

LJ: Some key protections have to do with keeping the victim in control of her medical records. A victim of violence must be informed in advance so she has an opportunity to agree or to object or to restrict certain uses of her or his healthcare information. Providers have to obtain patient consent prior to disclosing or using the health information for treatment or payment for their healthcare operations.

There are also many regulations about how to restrict disclosure and how to accommodate reasonable requests by the patients of how they want to communicate with the healthcare system. Perhaps they would send bills to a different place than their home if they want. They can set up a P.O. box if they want, and health plans must accommodate those reasonable requests in order to communicate with the patient. Those are some examples.

Another important measure to protect victims of violence concerns who has access to both their records and access to visitation when a victim of domestic violence is in care. In many cases, it’s direct family members or spouses, but obviously in the
case of domestic violence, the spouse might be the person who actually put them in the hospital. So if the patient chooses, they should be able to have the right to limit both the health information and the access to the patient within the healthcare setting for obvious reasons. These are a few of the about fifteen or twenty major protections included in the legislation.

**HHPR:** How long would it take to evaluate the effectiveness of the new federal standards for privacy?

**LJ:** The key to these regulations and making them effective will be the actual implementation of them. It's yet to be seen how comprehensive that will be. It will take some work at the state level to ensure that health plans are implementing the new regulations, not only specific to domestic violence, but across the board.

**Close to Home**

**HHPR:** From personal experience, I know that the volunteer training program for the Cambridge-based Transition House, the oldest domestic violence shelter on the East Coast, puts very little emphasis on the healthcare side of domestic violence. I suspect, given what you’ve said about the uniqueness of the FVPF’s views, that most volunteers across the country are not aware of the possibility of intervening on the healthcare front.

However, there are many undergraduate volunteers who might be interested in the healthcare aspect. How might they get involved? Do you think there is a role for college-age volunteers in your national Health Cares About Domestic Violence Day (October 10, 2001) initiative?

**LJ:** Absolutely. One of the reasons for having Health Cares About Domestic Violence Day is to raise awareness of domestic violence as a health issue. Even people who are involved in the field, despite the incredible work going on around the country, aren’t aware about it.

People don’t see domestic violence as a healthcare issue. But it's a huge healthcare issue. It is currently at epidemic proportions, and its impact is much more than just injuries. It's frightening, actually, how detrimental the violence can be to a victim’s health and how incredibly helpful the health system is as a point of identifying victims that we’re not reaching through shelters. So, yes, that is one of the goals of this day.

We not only need to target clinicians and encourage them to screen. We also need volunteers and domestic violence advocates to encourage providers to screen for domestic violence. We must raise awareness about domestic violence as a health issue among the general public.

With regard to the Health Cares About Domestic Violence Day initiative, we have a number of student organizations, including the American Medical Student Association and the American Women’s Medical Student Association, that are participating, particularly student health care organizations and domestic violence coalitions.
Shaping California’s Health Policy for Victims of Intimate Partner Violence

Connie Mitchell, MD

Intimate partner violence (IPV), once thought of as a criminal and social justice issue, has been shaped over the last fifteen years as a public health issue. California is a leader in enacting new statutes and health policies that support women’s health in general and intimate partner violence in particular. These policies have improved identification, documentation and surveillance, law enforcement affiliations, professional education, forensic examination, community prevention efforts and funding of services for victims of violence.

A Brief History of National IPV Health Policy

In 1985, former United States Surgeon General C. Everett Koop brought national attention to domestic violence as a public health problem. National policies of major medical organizations such as the American Medical Association, the American Public Health Association, the College of Obstetricians and Gynecologists and the American Academy of Pediatrics have all strongly supported health care identification and intervention in family violence. The Joint Commission on Accreditation of Healthcare Organizations provided guidelines and standards for the improved recognition and initial intervention in domestic violence. The National Center for Injury Prevention and Control at the Centers for Disease Control (CDC) established the Family and Intimate Violence Prevention Team in 1993. In 1995, the Association of American Medical Colleges strengthened the curriculum on family violence. And in 1999, the CDC published guidelines for research that defined and promoted the phrase intimate partner violence that is now dominant in the medical literature but still used interchangeably with domestic violence elsewhere.

Victim advocacy organizations worked throughout the 70’s and 80’s to strengthen the criminal justice response to perpetrators while providing support and safe havens for women and children victims of domestic violence. In the last ten years, these same organizations have promoted screening, safety planning, and patient education by health practitioners. Battered women’s service providers have aligned with hospitals...
to provide on-site advocacy services and to increase the identification and documentation of IPV patient care.

**The Health Impact of IPV**

Intimate partner violence is attracting the attention of the healthcare system as evidence mounts about the acute and long-term health impact of IPV on adults and children and the subsequent costs to the delivery system. Clinical studies indicate that 37-54% of women patients in the outpatient setting report a history of physical, sexual or emotional abuse in their lifetime.6,7 The long term and acute consequences of domestic violence include injuries, increased complications in pregnancy, reproductive health problems, stress related illnesses, somatization, depression, Post Traumatic Stress Disorder, suicide, and substance abuse.8-10 Increases in negative health behaviors such as smoking, alcohol and drug abuse, sexual risk-taking, and overeating have also been reported. The health impact of domestic violence on children includes direct physical abuse, “caught in the crossfire” injuries, neglect, and emotional trauma as witnesses to violence and abuse.11-13 Recent studies on the long-term health effects of adverse childhood events have associated childhood exposure to domestic violence with high-risk health behaviors as adults.14-18

Cost studies suggest this is an issue deserving of systemic and institutional attention. The cost of IPV to the healthcare system has been estimated at $857.3 million annually.19 When direct costs to the health care system are combined with indirect costs to society, total health care costs of IPV can escalate into the billions of dollars.20 Other studies have not only found that IPV patients generate significant healthcare costs, but also that the costs of their care may exceed the costs of care for a comparable non-IPV patient.21,22

**IPV Health Policy in California**

In 1996, the California Elected Women’s Association for Education and Research published “Violence Against Women in California”, an outline of public policy options regarding violence against women. In 1997, the Office of Women’s Health drafted a policy report titled “Preventing Domestic Violence: A Blueprint for the 21st Century.” This report identified six key goals for the state: 1) strengthen and expand domestic violence programs and resources, 2) protect children and youth from domestic violence, 3) ensure abuser accountability, 4) promote economic independence for domestic violence victims, 5) prevent domestic violence, and 6) improve state government operations relating to domestic violence.

**Identification:** In 1995, California enacted a screening law (Health and Professions Code §§1233.5, 1259.5) that required, as a condition of licensure, screening protocols and practices for California’s licensed clinics and hospitals. Compliance has been variable; some hospitals elect to have a chart prompted screen for every patient interaction, others have opted for chart prompted screens for select groups of “at-risk” patients, and others have fostered healthcare screening by providing more professional education or more streamlined access to IPV services. These policy changes have been enacted with evidence that patients and experts alike, believe verbal screening in a sensitive manner to be acceptable and helpful,23,24 but without evidence that such in-
tervention leads to improved outcomes. A recent study in California showed that higher rates of screening were associated with recent IPV education, use of IPV patient education materials, and practices that screen for other health and safety risks. Although institutions have been mandated to provide protocols, there is currently no screening mandate of individual licensed practitioners.

**Professional Education:** While the Business and Professions Code §2191 directs the Division of Medical Licensing to consider requiring continuing education on domestic violence for renewed licensure, it does not require proof of such training for new licensure. California medical and nursing schools are required to include domestic violence education in their curriculums, and social workers must have 6 hours of domestic violence education for clinical licensure. A special fund was created to receive revenues from court-ordered batterer fines upon conviction of a misdemeanor or felony domestic violence assault. The fund supports additional professional training and education about domestic violence.

Training health care providers to better address the medical and forensic needs of victims of abuse was needed. Legislation in 1995 (Penal Code §13823.93) created a standardized training program called the California Medical Training Center (CMTC) funded through the Office of Criminal Justice Planning with a budget of $1.4 million per year. The Training Center’s primary goal is to develop and deliver standardized training in the identification, forensic examination and care of victims of child abuse, domestic violence, elder abuse and sexual assault.

There is no other long-term strategic training effort in the nation. The CMTC depends upon physician leadership, requires statewide consensus building and promotes interdisciplinary intervention. The CMTC has provided leadership in creating clinical guidelines and forensic standards for abuse victims. It is believed that forensic examination, documentation, and presentation of testimony by trained health providers can minimize further traumatization of patient-victims and improve evidence collection thus protecting the rights of both victims and perpetrators. Current efforts include creating and updating state examination forms so they are electronically compatible and creating a standardized evidence collection process in order to coordinate medical examiner procedures with crime lab capabilities.

**Patients as crime victims:** Healthcare and criminal justice services overlap when a patient is also a victim of a crime. In 1994, California’s suspicious injury reporting law (PC §11160) was amended to provide immunity to healthcare providers who reported a patient with suspicious injuries and domestic violence was specifically listed as a reportable crime. Adding domestic violence to reportable crimes brought heightened awareness and concerns were raised about its potential benefits and risks. Healthcare providers, often in conjunction with advocacy and law enforcement, have met in several counties to address how best to comply with the law. They have developed protocols, on a county-by-county basis, that attempt to comply in a manner that is ethical, protective of patients as much as possible yet without minimizing the danger and criminal nature of the event. While survey studies indicate concern among healthcare providers and patients about healthcare reports to law enforcement, outcome studies of risks and benefits are needed in order to craft protocols or amend...
legislation appropriately.

In domestic violence prosecutions, the medical record and photo documentation of injuries have been significantly associated with increased prosecution and sentencing rates. Medical forensic examiners have been used to examine, collect evidence, document and provide courtroom testimony for child abuse and sexual assault victims. Hospital-based centers and examination teams provide forensic services for child abuse and sexual assault victims, and some of these have been expanding services to include victims of domestic violence and elder abuse. The crossover nature of violence, particularly family violence, is apparent to those working in the field and thus such centralization of services seems a natural progression. California has legislated standardized exam forms, protocols, and practices in child abuse and sexual assault that may soon be extended to domestic violence and elder abuse.

Programmatic interventions: A variety of other programs and initiatives have also contributed to an improved healthcare response to victims of domestic violence.
• The 1994 Battered Women’s Protection Act (BWPA) appropriated over $11 million annually to support battered women’s shelters making access to these services easier for healthcare professionals.
• The women’s Health Initiative, signed by then Governor Pete Wilson included $524,000 annually for training and epidemiology of domestic violence.
• The California Insurance Code §10144.2 and the Health and Safety Code §§1374.7 and 10144.3 was revised to prohibit discrimination against domestic violence victims by life, disability or health insurers.
• The Office of Victims of Crime (Government Code §13959-13969.5) defines general policy and procedures for the victims of crime restitution fund. Healthcare providers who provide medical or mental health services for victims can be reimbursed through this fund.
• Hospital discharge data is collected and tracked by the Office of Statewide Health Planning and Development. Both ICD-9 codes and E-codes for domestic violence are collected on all admitted patients and, beginning in 2002, will include data from hospital emergency departments as well.

Prevention: There is little consensus about what prevention might look like beyond a few generalities. For example, there seems little doubt that effective drug and alcohol treatment would go a long way towards reducing many serious and fatal intentional and non-intentional injuries. The Proposition 10 Tobacco Tax money is earmarked for early childhood intervention of children ages 0-5 and domestic violence has been designated as a priority issue. Given the negative impact of domestic violence on children, early parent education and maternal and child welfare screening practices could constitute a major prevention effort in the state. Other prevention measures include:
• A restraining order database linked to gun sales applications.
• Domestic Violence Death Review Teams (Penal Code §11163.5) to conduct an interdisciplinary mortality review and identifying avenues of prevention and improved intervention.
• Domestic Violence Coordinating Councils legislated to promote interdisciplinary programs and interventions on a county by county basis.
Future Direction

The California Medical Training Center and the Family Violence Prevention Fund co-sponsored a conference of researchers and public policy makers in 2000 called “DVY2K” that made specific recommendations regarding IPV health policy and research needs in California. California is also one of twelve states to receive grant money from the Family Violence Prevention Fund with additional support from the California Department of Health Services, to create leadership teams that promote IPV health policy change and public health education. The Leadership Team has identified six existing health intervention programs where minor policy changes could bring about major efforts to increase the early identification of IPV in adults and children.

No single health policy change will dramatically decrease the incidence of IPV or improve the health system’s ability to respond to victims. A public health approach, just as has been applied to tobacco smoking or motor vehicle accidents, can be expected to have an effect in reducing domestic violence. A strategic analysis of barriers and opportunities, coupled with the commitment of health leadership to make incremental and persistent change, can result in an overall IPV health policy shift that benefits patients and the community.

References

Each year, approximately 30,000 people in the United States die as a result of gunfire and about 80,000 people are wounded. While nearly everyone agrees that these figures are too high, what exactly should be done about the problem? One informal slogan held by some advocates is that any intervention targeted against gun violence is worthwhile “so long as one life is saved.”

But as a guide for improving the lives of Americans, this slogan is not helpful. Would those who adhere to it endorse a program that prevented a single firearm injury, but had an operating cost equal to the entire federal government’s annual budget? This program would meet the informal test of saving a life, but would deprive tens of millions of disadvantaged and elderly families of governmental assistance with housing, food, health care, and education upon which they desperately depend. Anyone who would be unwilling to support this program implicitly accepts the idea that benefits and costs are relevant for judging gun policies, and that some gun-oriented interventions are not worthwhile even if they would save lives. Thus, estimates for the costs of gun violence and the benefits of reducing it are crucial for identifying worthwhile interventions.

For some, calculating the costs of gun violence may conjure up a dry accounting exercise of totaling up medical expenditures and earnings lost due to injury. But in our view, an exercise of this sort misses the point (Max and Rice, 1993). The public concern with gun violence has little to do with the resulting burden on our healthcare system or the reduction in the size of the labor force due to death and disability.

Rather, especially for children and their families, the effects of gun violence have everything to do with concerns about safety. Avoiding and preventing gun violence is a costly enterprise in both the public and private spheres, but most people would be willing to pay more to reduce that threat. Thus, the cost of gun violence is the flipside of the value of safety, and that is the per-
spective that we develop further in the remainder of this essay.

Valuing Safety

The idea of conducting benefit-cost analysis in the area of crime and injury avoidance strikes many people as being disturbing since life should be priceless. Economists would agree up to a point, noting that human lives are “priceless” in the sense that they are not regularly bought and sold in the marketplace. It is usually true that no feasible sum of money can fully compensate the family and friends of the victims of fatal gunshot injuries. Nevertheless, courts do regularly place a price on life in setting damages for personal injury suits; legislatures and regulatory agencies are routinely required to decide how much an increment in safety is worth.

When Congress established a national speed limit of 55 miles per hour in 1974, the highway fatality rate dropped dramatically (Clotfelter and Hahn, 1978). But much of the public, including the commercial trucking interests, eventually demanded a return to higher speed limits despite the likely increase in fatalities, and Congress complied. Individual consumers are also forced to make decisions in the face of what might be thought of as a “quality-quantity” tradeoff for our lives. Should we spend extra to obtain a car with anti-lock brakes, or save the money for our child’s college fund? Should we pay an extra $10,000 to buy a house that is farther away from the local nuclear plant?

To be clear, policy makers and private citizens are making judgments about the value of *ex ante* reductions in the risk of injury, before the identity of those who will be injured is known. While most people would give up much of their net worth to save themselves or a loved one from certain death, their willingness to pay for small reductions in the risk of death is more limited. The “value of a statistical life” is the summation of what people will pay for small reductions in the probability of death, with values defined similarly for statistical injuries and other health hazards. If each person in a community of 100,000 is willing to pay $50 to reduce the number of deaths in that community by one per year, then the value of a statistical life to those residents equals $5 million.

The amount people will pay to reduce the risk of a gunshot injury will presumably depend on how it affects them, their families, and their communities. Sometimes the monetary value of greater safety comes directly from a spreadsheet. For example, the sharp decline in the rate of violent crime during the 1990s have brought widespread gains in property values to many homeowners in urban neighborhoods. But most of what is at stake are intangible commodities not traded in the marketplace, i.e. freedom from the threat of gun violence and relief from the need to take steps to reduce that threat.

The “willingness-to-pay (WTP)” approach leads to quite a different picture of the dollar cost of gun violence from the standard public health approach. This “cost of illness (COI)” approach defines the costs of gun violence as the medical expenses incurred by victims plus lost productivity. This method ignores most of what is captured in WTP: the subjective value of safety, concern about others’ welfare, and the costs of prevention and avoidance.

In our book, *Gun Violence: The Real Costs*, (Cook and Ludwig, 2000), we show that medical expenses and lost productivity ac-
tually make up very little of the societal burden of gun violence. For example, the costs of medical treatment to victims for all gunshot injuries in 1997 was on the order of $1.9 billion. But this figure overstates the net effects of gun violence on total medical expenditures in the U.S., since gunshot victims would have required medical services at some point over their lifetime if they had not been shot. If one subtracts the estimated lifetime medical costs that victims would have incurred had they not been shot from the costs that they actually incurred as a result of their wounds, the net costs of gun violence to the medical system are on the order of $400 million to $1.2 billion. While this is not a trivial sum, these net medical expenditures represent only a small share of the overall costs of gun violence. The lesson is that the cost-of-illness approach understates the benefits to society from reducing gunshot injuries.

Quantifying the Costs of Gun Violence: Willingness-to-Pay Estimates

One of the standard methods for estimating the value of reductions in the risk of injury is to examine people’s marketplace behaviors. A number of studies have attempted to estimate the value that people place on the risk of workplace accidents by comparing the wage differences associated with jobs that have high versus low risks of injury (see for example Viscusi, 1992, 1993). This approach is impractical for estimating the costs of gun violence, in part because there are no good data available on the risks of gunshot injury for different occupations. And even if such data existed, isolating the effects of injury risks on wages from the effects of other job characteristics is quite difficult. In our view, the most promising approach for estimating what people would pay to reduce the volume of gun violence in society is to ask them directly. This “contingent valuation (CV)” approach attempts to infer people’s preferences towards non-market goods, such as improvements to health and safety by creating hypothetical market scenarios within the context of a social science survey. The CV method has a long tradition within the area of environmental economics, where analysts are regularly confronted with the difficult problem of valuing improvements to the environment. While contingent valuation remains somewhat controversial within the broader economics profession (see for example Hanemann, 1994 versus Diamond and Hausman, 1994), for the purposes of studying the costs of gun violence, the CV method is an improvement over its alternatives.

Our own contingent valuation estimates represent the first attempt to use this method to estimate the costs of crime. We rely on data from a nationally representative telephone survey of 1,200 American adults conducted in 1998 by the National Opinion Research Center (NORC) at the University of Chicago, one of the nation’s leading survey organizations. After a series of questions asking about their attitudes toward government and various current or proposed gun regulations, respondents were asked:

Suppose that you were asked to vote for or against a new program in your state to reduce gun thefts and illegal gun dealers. This program would make it more difficult for criminals and delinquents to obtain guns. It would reduce gun injuries by about 30 percent but taxes would have
The survey software randomly determines the size of the tax increase that the respondent is asked about, so that answers for each of the three dollar amounts are available for approximately one-third of the sample. Respondents are then asked a follow-up question where the dollar amount asked about in the initial referendum question is either doubled or halved, depending on whether the respondent’s initial answer was positive or negative, respectively.

The survey results suggest that a broad cross-section of the public is affected by gun violence, as evidenced by the substantial proportion of households who are willing to pay more in taxes each year to reduce gunshot injuries. Seventy-six percent of all respondents report that they would pay $50 more per year in taxes to reduce crime-related gunshot injuries by 30 percent, while 64 percent say they would pay $200 more in taxes. A formal statistical analysis suggests that the average American household would pay $239 more per year in taxes to fund such a program.

Given the total number of households in the U.S. – equal to 102.5 million in 1998 (U.S. Bureau of the Census, 1999) – we estimate that all households together are willing to pay $24.5 billion to reduce assault-related gunshot injuries by 30 percent. We can approximate the public’s WTP to eliminate all crime-related gunshot injuries by multiplying the WTP for a 30 percent reduction by 3.33. The actual cost of a 100 percent reduction may exceed this approximation if some preventive behaviors are only eliminated in response to a complete elimination of gun violence (for example if airport metal detectors stay in place so long as there are any gun crimes). On the other hand, our approximation may be too low if the public derives diminishing marginal returns from additional reductions in gun violence. In any case, this approximation suggests that the value to society of eliminating crime-related gunshot injuries is approximately $82 billion.

Since these estimates come from survey responses about a hypothetical program, it is understandable to wonder whether they are meaningful in any way. Fortunately, several external benchmarks suggest that these survey responses are reasonable. First, the results of the NORC survey can be used to generate estimates of the value per statistical life saved, which turn out to be quite consistent with other estimates derived from analyzing actual marketplace data in other contexts (Viscusi, 1992, 1993). Secondly, the general pattern of responses to the gun survey are in accord with our expectations. For example, households with more income are more likely to vote in support of the intervention. Households with more children are also more likely to vote to reduce gun violence, presumably because such households experience a greater benefit from the intervention (in the form of risk reductions to household members) than those families with fewer members. Lastly, Anderson (1999) finds that the average household currently spends around $1,800 per year in taxes and consumption expenditures to fund the criminal justice system and private protective measures. Thus, it is implausible that the average household would spend an additional $239 per year to reduce the threat of gunshot injury by 30 percent, particularly since the fear of crime in America appears to be driven largely by the threat of violent crime (Zimring
Generating an estimate for the total costs of gun violence, beyond the costs of a partial reduction in crime-related gunshot injuries, requires some additional assumptions. Since our survey only captures crime-related gun violence, in order to estimate the costs of gun suicides and unintentional injuries, we turn to previous economic studies of the costs of workplace injuries and fatalities. Our review suggests that the costs of gun suicides and accidents is on the order of $10 to $20 billion per year, bringing the total costs of all gunshot injuries in the U.S. to about $100 billion. To put this number into perspective, $100 billion could be used to cover nearly two-thirds of those in America who are currently without health insurance, or to pay college tuition at a good public university for 27 million people – roughly the entire population of New York and New Jersey combined. And this reflects the costs of gun violence for just one year.

Where to Next?

Past investments in reducing gunshot injuries have had modest effects. However, the net benefit to society of these modest effects offers possible direction when evaluating gun legislation.

Data from the Kansas City Gun Experiment suggest that police patrols targeted against illegal gun carrying may be effective in reducing gun violence (Sherman, Shaw and Rogan, 1995). Unfortunately the exact magnitude of the program’s effects remain somewhat unclear. The treatment and comparison neighborhoods in the “experiment” may differ in other dimensions aside from receipt of the targeted police patrols. But under the most optimistic scenario, an investment of under $200,000 in additional police resources may have produced a reduction in gun violence with benefits of up to $22 to $100 million to society.

Our review also suggests that sentence enhancements for crimes committed with firearms appear to produce benefits in excess of costs, and that new gun regulations need to have only modest effects in order to generate net benefits to society. For example, one of the more promising regulations is to require that all new handguns be manufactured and sold with “personalized” technology, which makes the weapon inoperable by unauthorized users. This technology has the potential to save lives by making guns inoperable to children, despondent teens, or the criminals who are responsible for around 500,000 gun thefts each year (Cook and Ludwig, 1996).

The idea of mandating personalized gun technologies has been criticized in part because they will add to the price of new handguns. But if the personalized gun technology adds $100 to the purchase price of a new gun, this regulatory requirement will generate benefits that outweigh costs so long as the technology is able to prevent only one shooting per 10,000 units sold. Our best guess is that the effects of personalized gun technology should easily clear this bar, given that currently it appears that every 10,000 handguns sold are involved in about 3,000 robberies and assaults and 100 homicides (Roth and Koper, 1997).

Our bottom line is that we accept as a general principle the notion that some gun-oriented interventions may not be worthwhile even if they save lives. But in practice the costs of gun violence to society appear to be large enough to justify additional investments in reducing gunshot injuries.
Features: Violence and Public Health

References


Firearm Prevalence and the Risk of Suicide: A Review

Matthew Miller, MD, MPH, Sc.D.
David Hemenway, Ph.D.

In the United States, more people kill themselves with guns than by all other methods combined (Table 1). In 1998, the last year for which complete data are available, there were approximately 30,000 suicide deaths among Americans, of which 57% were caused by guns. The number of suicides (30,558) exceeded the number of homicides (17,894), and the number of gun suicides (17,420) exceeded the number of gun homicides (12,078). One really cannot discuss suicide in the United States without examining the role of firearms.

The age-adjusted suicide rate in the U.S. (11 per 100,000) slightly exceeds the death rate from leukemia (10 per 100,000) and pancreatic cancer (9 per 100,000), but is far less than the mortality rate from heart disease (270 per 100,000) or from cancer overall (204 per 100,000).

Although the risk of suicide increases with age, relative to most life threatening diseases, suicide disproportionately affects younger people. For 10-24 year olds, suicides account for 13% of all deaths, third only to motor vehicle crashes (43%) and homicides (17%) - exceeding the number of deaths due to all cancers (6%) and heart disease (4%) combined. Suicide also disproportionately affects men, despite suicide attempts being 4 times as common among women. This is largely explained by the fact that when men attempt suicide, they are far more likely to use a gun. Guns account for more completed suicides than any other means, not only among men but among women and children as well. This should not be surprising since, compared to other methods commonly used in suicides, firearms are among the most lethal. For example, a study in Canada found that 92% of gun attempts resulted in death compared to 78% of attempts using carbon monoxide or hanging, 67% of drowning attempts, and 23% of intentional drug overdoses.
This article reviews the empirical literature on the relationship between gun ownership levels and suicide rates. Throughout the literature an implicit question motivates research: are suicides largely determined by the strength of intent alone or does ready availability of lethal means increase the likelihood that susceptible individuals will take their own lives?  

Expert opinion and related evidence support the idea that both intent and instrumentality matter, and that individuals who commit suicide often do so when confronting a severe but temporary crisis. For example, in one study of 18 men who survived a self-inflicted intentional gunshot wound to the face, subsequent suicide attempts were uncommon. In another study of self-inflicted gunshot wounds that would have proven fatal without emergency treatment, none of the 30 attempters had written a suicide note, and more than half reported suicidal thoughts for less than 24 hours. After two years, none of the 30 people attempted suicide again.

### International Studies

#### Developed Nations

A problem with international studies is the difficulty in fully accounting for the disparate cultural factors that may influence the incidence and method of suicide. Additional problems with these studies are that data on suicides may not be completely comparable across nations, and data on gun availability are not routinely collected. On the other hand, a virtue of international comparisons is that gun availability and suicide levels are often so variable that it is possible to spot significant differences even when the sample size is small.

The few international studies that address the gun-suicide question suggest that firearm availability affects the method of suicide and may have an influence on the total level of suicides, especially among youth. The evidence, however, is far from convincing that gun ownership levels are related to overall suicide rates for all age groups. The U.S., for example, has the highest levels of gun ownership, but its overall suicide rate is only 16th out of 26 high-income countries. One study found a statistically significant relationship between gun ownership levels and suicide rate across 14 developed nations (e.g. where survey data on gun ownership levels were available), but the association lost its statistical significance when additional countries were included.

For youth, however, there does appear to be an international association between suicide and firearm availability.
gun ownership levels and suicide. Among children aged 5-14, the U.S. suicide rate was, on average, twice as high as the suicide rate among other high-income countries. This two-fold increased risk of suicide among U.S. children was accounted for by a U.S. firearm suicide rate that was ten times higher than the firearm suicide rates in other high-income nations. There was no difference in the rate of non-firearm suicide (Table 2). In another study of 15-24 years olds among the 17 high-income countries for which data were available, the correlation between household gun ownership levels and suicide rates was .46 (p=.06).

In another study that benefited from careful collection of demographic data but involves only two countries, Sloan et al compared the suicide rates for the years 1985-1987 in Seattle, Washington to those in Vancouver, British Columbia. These large port cities in the Pacific Northwest have similar rates of unemployment, marriage, median income, and percentage of population earning below $10,000. Both communities have a substantial white majority (though Vancouver has a larger Asian population and Seattle a larger Black population). These two communities differ in that Vancouver has far more restrictive handgun laws, fewer handguns and fewer handgun owners. In the population as a whole, the higher rate of handgun suicide in Seattle (5.7 times higher) was completely offset by a 1.5 fold higher rate of suicide by other means in Vancouver. However, among young adults (15 -24 years of age), the overall suicide rate in Seattle was 38% higher than in Vancouver, with virtually all of this increased risk attributable to a nearly ten-fold greater risk of suicide by handguns.

**US studies**

(a) Individual Level

Seven case-control studies in the U.S. have found that a gun in the home is a substantial risk factor for suicide. Five studies by one research team focused on adolescent suicides in western Pennsylvania, comparing adolescents who killed themselves to other groups of adolescents from the same area. Controls included adolescents who were psychiatrically ill and had attempted suicide; who were psychiatrically ill and had not attempted suicide; who had a lifetime history of affective disorders; and who had no psychiatric history.

One of the studies compared 47 adolescent suicide completers from a community sample with two psychiatric inpatient control groups, 47 who had attempted suicide and 47 who had not. Guns were in the homes of 72% of the completers compared to 37% and 38% of the controls.

<table>
<thead>
<tr>
<th></th>
<th>Gun Suicide</th>
<th>Non-gun Suicide</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>0.49</td>
<td>0.35</td>
<td>0.84</td>
</tr>
<tr>
<td>Non-U.S.</td>
<td>0.05</td>
<td>0.35</td>
<td>0.41</td>
</tr>
<tr>
<td>Ratio</td>
<td>10-1</td>
<td>1-1</td>
<td>2-1</td>
</tr>
</tbody>
</table>

Another case-control study indicated that the danger of having a gun in the home applied to all adolescents in the community—and not just to those with known psychiatric or drug abuse problems.14

Two large case-control studies included adults as well as adolescents. One study had 438 suicide cases that occurred in the homes of victims in two urban areas—the counties that include Memphis, TN and Seattle, WA. Controls were randomly drawn from the same neighborhoods. Sixty-five percent (65%) of victims had a firearm in the home, compared to 41% of controls (Table 4).15 In homes with firearms, 86% of suicides used a firearm; in homes without firearms, 6% of suicides used a firearm. After controlling for several variables including alcohol, illicit drug use and depression, the presence of a gun in the home was still associated with a large increased risk of suicide. Restricting the analysis to those suicides without a history of mental illness or depression revealed that a gun in the home was even more strongly associated with suicide.

A second large case-control study analyzed whether the purchase of a handgun from a licensed dealer was associated with an increased risk of suicide, whether or not the suicide took place in the home. Data on gun ownership came not from asking people about the presence of a gun in their homes but rather from the state’s computerized database of all handguns purchased from a licensed dealer. Cases were 353 suicide victims who were members of a large HMO in Washington State; controls were members of the same HMO matched on age, gender and zip code. Over the 12-year study period, suicide was twice as likely among persons in families that had purchased a handgun, compared to rates in families that did not purchase a handgun.16

(b) Area-wide

Many studies have examined whether geographical areas with higher levels of gun ownership have higher rates of suicide. Studies have looked across census regions, states and cities. Across regions, even with a small sample size (n=9 census regions), some studies have found a statistically significant relationship between levels of household gun ownership and suicide rates.17 A more recent regional analysis for 1979-1994 found a statistically significant relationship across regions, which held for young people and the elderly, even after controlling for levels of divorce, education, unemployment and urbanization.18

A limitation of state and city studies has been the lack of reliable data on gun ownership levels. Crude proxies have been used (e.g. the accidental death rate from firearms,
and subscriptions to gun magazines). Nonetheless, studies consistently find a positive association between gun ownership levels and suicide, and many find a statistically significant relationship.\textsuperscript{19-21}

Recent analyses of state level data for 1988-1997 also find a strong, statistically significant relationship between measures of and proxies for levels of household gun ownership and suicide rates.\textsuperscript{22} The proxy used in this study was validated against survey-based gun ownership levels at the international, regional and state levels (correlation coefficients were all >0.8). The relationship between gun availability and suicide rates could be seen in both genders and for every age group.

A variety of studies have also examined the relationship between the strictness of gun control laws and suicide rates. Many of these studies are cross-sectional in nature and are therefore subject to confounding by cultural, social and economic differences that are difficult to take into account. Nevertheless, most cross-sectional studies find that strict state gun control laws are significantly associated with lower levels of suicide Lester & Murrell 1986.\textsuperscript{23-27} For example, cross-sectional studies find that suicide rates in 1970,\textsuperscript{28} 1980 and 1985 (Boor and Bair 1990) were significantly lower in those U.S. states with stricter gun control laws.\textsuperscript{29,30}

Time-series studies in the US and Canada also find a significant reduction in suicide rates after enactment of strict gun control laws.\textsuperscript{31,32} In 1978, for example, Canada imposed tighter restrictions on gun ownership, virtually outlawing handguns; a nationwide educational campaign about safe use and storage of the firearms was also undertaken. It appears the law led to a one time drop in both the firearm and total suicide rates, but not the non-firearms suicide rate (Lester and Leenaars 1993, 1994).\textsuperscript{33-35} In 1976, the District of Columbia adopted a very restrictive handgun law.

A time-series analysis covering the years 1968-1987 found that the adoption of the law coincided with an abrupt and sustained 23\% decline in the suicide rate by firearms. There were no parallel increases in suicide from non-firearm methods, nor were similar declines in firearm suicide rates seen in adjacent metropolitan areas of Maryland or Virginia, to which the legislation did not apply.\textsuperscript{36} Despite the limitations inherent in these approaches, a recent review of the impact of gun control legislation on suicide concluded that restricting access to firearms through gun control legislation diminishes suicide rates, and substitution of other means does not appear to offset the benefits of restrictions (Lambert and Silva 1998).\textsuperscript{37}

<table>
<thead>
<tr>
<th></th>
<th>Suicide Cases</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firearm In Home</td>
<td>65%</td>
<td>41%</td>
</tr>
<tr>
<td>Handgun In Home</td>
<td>50%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Table 4: Case Control Study of Firearm ownership in Memphis and Seattle. (438 cases), Kellerman, et al. and Case Control study of Handguns purchased from licensed dealers in Washington State. (353 suicide victims) Cummings P, et al.
Summary

Case-control studies provide strong evidence that suicide risk is heightened where guns are more readily available. The results of these studies are compelling, in part because all of their ancillary findings correspond to current knowledge about risk factors for suicide, and in part because these studies hold constant many important characteristics correlated with suicide. The results from these studies consistently indicate that a gun in the home is significantly associated with a higher risk of suicide, especially among youth.

That firearms may pose a higher suicide risk to teens than to older adults is consonant with the notion that adolescents are particularly likely to act impulsively and therefore are more likely to be affected by availability of the means at hand (Rich, Young, & Fowler, 1986). Several cross-national studies have found similar results and lend credibility to the notion that availability of weapons matters, especially among impulsive individuals.

Ecological studies provide less compelling evidence linking guns to overall suicide rates, in part due to the difficulty in accounting for cultural differences between comparison groups. Another major limitation of these studies is the lack of reliable data on firearm availability. Nevertheless, it is remarkable that despite poor measures of firearm availability (which should make it harder to see effects even if they exist) many ecological studies, particularly in the United States, still find that firearms are a risk factor for overall suicide rates.

Taken as a whole, the preponderance of current evidence indicates that gun availability is a risk factor for suicide, especially among youth. This is precisely the conclusion reached by the American Association of Suicidology in their consensus statement on youth suicide, which provides a fitting conclusion to our review as well: “There is a positive association between the accessibility and availability of firearms in the home and the risk of youth suicide. Guns in the home, particularly loaded guns, are associated with increased risk of suicide by youth, both with and without identifiable mental health problems or suicidal risk factors.”

ENDNOTES

2. NCHS 1998 mortality data
3. Ibid.
6. Chapdelaine et al. 1991
10. Johnson GR, Krug EG, Potter I.B. “Suicide
among adolescents and young adults: a cross-national comparison of 34 countries.” *Suicide and Life Threatening Behavior*, 2000; 30:74-82.


28. Medoff and Magadino 1983

29. Yang and Lester 1991

30. Boor and Bair 1990


33. Ibid.


36. Lostin et al. 1991
37. Lambert and Silva 1998

References

Birckmayer J, Hemenway D. Suicide and gun prevalence: Are youth disproportionately affected? Suicide and Life Threatening Behavior. In press
Johnson GR, Krug EG, Potter LB. Suicide among adolescents and young adults: a cross-national comparison of 34 countries. Suicide and Life Threatening Behavior. 2000; 30:74-82.
Lester D, Musrell ME. The preventive effect of strict gun control laws on suicide and homicide. Suicide and Life Threatening Behavior. 1982; 12:13140
Markus R, Bartolucci A. Firearms and suicide in
Linking Data to Save Lives: Recent Progress in Establishing a National Violent Death Reporting System

Deborah Azrael, Ph.D., Catherine Barber, MPA, and James Mercy, PhD

The quality and scope of research on U.S. homicides and suicides has been hampered by the paucity of information about the characteristics of these events that can be derived from publicly available data. Researchers attempting to evaluate policies aimed at reducing violence or better understanding its etiology have generally relied on the limited outcome data that are available from the National Vital Statistics Mortality System and the Federal Bureau of Investigation’s Uniform Crime Reports (UCR) or on costly case control studies with limited generalizability. As a consequence, public discourse on violence prevention often takes place in an information vacuum and the development of effective prevention programs and policies has been inhibited.

In many other public health arenas, researchers rely on surveillance systems to provide them with rich data with which to characterize the epidemiology of particular conditions and to assess the effectiveness of interventions in ameliorating problems. Such surveillance systems are at the very heart of the public health enterprise, yet the U.S. currently lacks a state-based, national surveillance system for this leading cause of death.1

Establishing a National Violent Death Reporting System

The enormous benefits of a state-based, national reporting system to track the incidence and characteristics of health conditions have been well-established in other areas, such as infectious disease and motor vehicle safety. For example, the National Highway Traffic Safety Administration’s Fatality Analysis Reporting System (FARS) collects over 125 pieces of information on each of the approximately 40,000 motor

Deborah Azrael, Ph.D., and Catherine Barber, MPA, are co-directors of the National Firearm Injury Statistics System at the Harvard School of Public Health. James Mercy, Ph.D., is the Associate Director of the Science Division of Violence Prevention, Center for Injury Prevention and Control, CDC.
vehicle-related fatalities that occur annually— including features of the crash, the vehicles involved, the road and weather conditions, and the people involved. FARS has been used to evaluate the effectiveness of speed limit laws, minimum age drinking laws, air bag and seat belt effectiveness, and numerous other state and federal initiatives over the past 3 decades.\textsuperscript{2-23} Our ability to maintain, refine or change policies based on the results of these analyses is clearly one of the reasons that the U.S. motor vehicle fatality rate has fallen dramatically over the past 20 years.

The utility of FARS and other surveillance systems has led many to call for the creation of a comparable reporting system for violent deaths. In 1999, for example, the Institute of Medicine (IOM) called for a national data system for homicides and suicides to provide objective data with which to monitor trends and evaluate the effectiveness of prevention programs and policies.\textsuperscript{24} These calls have not gone unheeded: in his recent \textit{National Strategy for Suicide Prevention: Goals and Objectives for Action}, the Surgeon General set as an objective “\textit{implementation of a national violent death reporting system that includes suicides and collects information not currently available from death certificates.”}\textsuperscript{25}

\textbf{Preliminary Efforts to Establish a National Reporting System}

Efforts to establish a national reporting system for violent injuries have a history going back more than 10 years. Beginning in the mid 1990’s, CDC, which had started to focus on violence as a public health problem, supported the development of violence-related injury surveillance systems at the national, state, and local level, culminating in their funding 7 states to conduct local surveillance in 1994.\textsuperscript{26}

In 1999, convinced that basic data collection was a federal responsibility, but aware that federal efforts to establish a national surveillance system were stalled, 6 private foundations (under the leadership of the Joyce and Soros Foundations), funded the Harvard Injury Control Research Center (HICRC) at the Harvard School of Public Health to establish the National Firearm Injury Statistics System as a method of jump-starting the federal initiative. Originally conceived as a firearm injury surveillance project, the scope of the pilot was soon expanded to include all violent deaths (homicides and suicides by any means, and unintentional firearm injuries) and renamed the National Violent Injury Statistics System, NVISS.

\textbf{The NVISS Pilot}

NVISS is working with 13 state and local grantees to design and pilot this reporting system, which in many respects mirrors the Fatality Analysis Reporting System (FARS) for motor vehicle-related deaths. The NVISS model builds on models developed by the Medical College of Wisconsin and other sites and links information from four major reporting sources: death certificates, coroner/medical examiner reports, police Supplementary Homicide Reports (and, in some jurisdictions, incident reports), and crime laboratory data. The system serves to combine previously collected but unlinked data from these sources and thus provides rich, heretofore unavailable, information about the circumstances of suicides and homicides (includ-
ing those that are school-related, domestic violence-related and drug-related). For example, information is collected about the relationship between victims and suspects in violent crimes, and about characteristics of the events. These include where they took place, whether or not the victim was intoxicated, and if the victim or perpetrator was a minor, whether or not their access to a weapon was authorized. The heart of the linkage is a set of uniform data elements used by all pilot sites to collect over 50 pieces of information about each incident in their jurisdiction that results in a violent death.

NVISS funds programs conducting statewide surveillance in Connecticut, Kentucky, Maine, Maryland, Michigan, Utah and Wisconsin and local surveillance in Allegheny County and Bethlehem, Pennsylvania; Miami-Dade County, Florida; metropolitan Atlanta, San Francisco and Youngstown, Ohio. Together, the programs developed uniform data elements for fatal violent injuries that are outlined in a detailed manual, and NVISS has developed incident-based relational software for the system. The sites are currently piloting the fatality reporting system, collecting data on an estimated 4,000 violent deaths in 2001.

The Expert Meeting on Firearm Injury Reporting

The system being developed and tested by NVISS has served as a useful starting point for planning a national violent death reporting system, a process that was moved significantly forward in May of 2000 when the Joyce Foundation and the Harvard School of Public Health co-sponsored an Expert Meeting on Firearm Injury Reporting in Washington, DC, to discuss the development of a national reporting system for firearm injuries. The goal of the Expert Meeting was to move the federal government toward implementing a firearm injury reporting system by bringing together key representatives of the federal agencies concerned with firearm and other violence-related deaths, the fields of injury and surveillance, and public health and public safety.

A key outcome of the meeting was a consensus document outlining a set of 10 core principles of a national reporting system for violent deaths. Among the principles agreed upon at the meeting was that the system should be state-based and administered at the national level by the CDC. Participants also agreed that the scope of the system should include all violent deaths (as well as unintentional and undetermined firearm deaths), with data coming from multiple criminal justice and public health sources at a level of detail comparable to that available through the FARS system.

The National Violent Death Reporting System

Galvanized by the Expert Meeting, the CDC empanelled a working group on creating a violent death reporting system which has now developed a plan for a National Violent Death Reporting System. Based substantially on the ongoing HICRC pilot, the proposed NVDRS is intended to provide a census of violent and other firearm-related deaths that occur within the United States, including all homicides, suicides, legal intervention deaths, unintentional firearm-related deaths, and deaths of unde-
determined intent occurring within the United States.

Conclusion

With data from the NVISS pilot, over the next five years we will be able to answer questions we are currently unable to answer from existing data sources, including: Where do youths obtain the weapons they use in acts of violence? How often do murder-suicides occur? What proportion of suicide victims are intoxicated at the time they kill themselves? What are the most common circumstances leading to accidental gun deaths among children?

After years of limited progress, and following a remarkable collaboration between foundations, researchers, state and local partners, and federal agencies, we appear to be poised on the verge of establishing a truly national violent injury surveillance system. This national system will be capable of answering the epidemiologic, programmatic, and public-policy related questions whose answers could be enormously useful to front line public health and public safety workers, policy makers, and researchers concerned with America’s continuing and disproportionate problem of violent death. Federal efforts to establish such a system should be commended and actions to implement such a system encouraged.

Endnotes

11. Evans L. Airbag effectiveness in preventing fatalities predicted according to type of crash, driver age, and blood alcohol concentration. Accid Anal Prev 1991 Dec;23(6):531-41
15. MMWR Motor-vehicle occupant fatalities and restraint use among children aged 4-8 years—United States, 1994-1998. MMWR Morb Mortal Wkly
Confronting the Global HIV Epidemic: A Call for Equity

Laura Tarter and Paul Farmer, MD

The dimensions of the global HIV crisis are such that predictions termed “alarmist” a decade ago are now revealed as sober projections.1 In 2000, HIV overtook tuberculosis as the world’s leading infectious cause of adult death. HIV has, in fact, overtaken the 1918 influenza epidemic as the most devastating communicable cause of adult death since the bubonic plague of the 14th century.2 With each passing year, HIV is becoming increasingly concentrated among the poor; at this writing, HIV incidence is declining in wealthy countries and more than 95% of new infections occur in the developing world (Figure 1).3 Close to 80% of cumulative AIDS deaths to date have occurred in Africa, the world’s poorest continent.4 While the virus is tearing through poor communities at a frightening pace, life-saving therapeutics are not following suit. At the same time that AIDS mortality has dropped precipitously in affluent countries, in large part because of access to highly-active antiretroviral therapy (HAART), the death toll mounts in the so-called developing world, where treatment is deemed “unsustainable.”5 6 7 We argue that it is not the treatment of the destitute sick that is unsustainable, but rather the ever-widening global outcome gap that prohibits the fruits of science from reaching those most in need of them.

Here in rural Haiti, where we have been treating people infected with HIV/AIDS for several years, it wasn’t long before patients began asking for one of the latest scientific developments, antiviral “cocktails.” Adeline Merçon did not ask for the medications, even though more than a decade of battling with HIV had worn her down to less than 80 pounds; her father asked instead for money for a coffin. He could see by November 1999 that Adeline wasn’t going to last much longer (Figure 2). Instead of a coffin, however, we gave Adeline a three-drug cocktail of anti-HIV drugs. And between November 29th, when she began therapy, and January 2000, she gained 26 pounds (Figure 3). Adeline is aware of the debates surrounding the use of these agents in what are euphemistically termed “resource-poor settings.” She is now devoting her time to the “HIV Equity Initiative” based not far from her home village.
“If the drugs cost a lot, there must be a reason,” she commented in a recent meeting. “Science made them, so science will have to find a way to get them to poor people, since we’re the ones who have AIDS.”

Examining global trends in confronting the epidemic might not bolster Adeline’s optimism. And no wonder: globally, billions of dollars have been invested in AIDS prevention and treatment, but the epidemic marches on. AIDS-prevention efforts have failed in precisely those areas where they are needed most. And yet in these very areas - poor communities in developing countries - we are encouraged to restrict our “AIDS-related activities” to prevention alone. Take, as an example, the world’s largest pot of AIDS funding targeted to the developing world. The hundreds of millions of dollars disbursed by USAID through Family Health International have until now gone almost exclusively for prevention, even though the efficacy of these interventions is difficult to demonstrate. The exception more recently has been to fund palliative care (sometimes under the euphemism “community-based care”) or low-cost prevention of certain opportunistic infections.

By this point, readers may conclude that we are making an attack on prevention or public-health approaches to HIV, but this is simply not true. We are calling instead for a redoubling of our efforts to improve prevention, including vaccine development and educational tools. Prevention, however, will be most effective as part of a comprehensive plan to meet widespread demands for treatment and health equity in general. It is high time to admit the limitations of existing prevention strategies.

Prevention is cheap, compared to therapy.
for people already infected with the disease. But what is the cost of focusing solely on prevention, given our current limitations? First, we fail to represent the aspirations of those already infected or sick. They will number, soon enough, more than 100 million. This large number represents parents, farmers, doctors, teachers, factory workers - the very fabric of a society as we know it. Second, letting HIV disease run its course in high-burden countries will mean - and has already meant - significant reductions in life expectancy with many drastic social consequences, even if new infections were to cease immediately. The number of AIDS orphans grows, with sober projections of 40 million orphans by 2010 on the continent of Africa alone (Figure 4). Many children left to fend for themselves will eventually turn to sex work, crime, or will perhaps become soldiers in local conflicts. They will almost certainly live out their lives in poverty. And if little is done, they too are likely to die of AIDS, which is already causing ten times as many deaths in Africa as war. Third, other diseases will emerge. Throughout sub-Saharan Africa and beyond, HIV is driving the frightening rise in tuberculosis incidence. The wealthy country of South Africa shows rates of TB to be two or three times higher than those registered in far poorer countries where HIV is not a ranking problem.

Fourth, by focusing solely on prevention, we fail to fully engage the medical and scientific community as partners in responding to this cataclysmic epidemic. The medical and scientific community finds itself un-equipped to participate in the arena of primary and secondary prevention. By asking clinicians and bench scientists who wish to work in or on behalf of poor countries to

Figures 2 (l) and 3 (r): Adeline Merçon in November 1999 (left) and in January 2000 (right).
put all of their weight behind “information, education, and communication,” we are undermining the potential contribution of a highly skilled sector eager to help. This denies us of sorely needed clinical and scientific abilities.

Fifth, we fail to recognize that existing AIDS-prevention strategies have their limitations. The most eloquent rebuke to optimism regarding their efficacy is the rapidly rising HIV incidence in many nations. We are finally beginning to acknowledge this failure with honesty - fully 20 years into the epidemic. In some settings, paradoxically, “the presence of health-education materials seemed to lead to lower frequency of condom use.”14 A recent candid review notes, “Somewhat surprisingly, towards the end of the second decade of the AIDS pandemic, we still have no good evidence that primary prevention works.”15

We undermine faith in medicine and public health whenever we make unreasonable, excessive, or propagandistic claims. Arguing, for example, that “education is the only vaccine” is neither accurate nor wise; since we cannot show that cognitive interventions have been highly effective in preventing HIV infection among the poor - the global risk group - it is surely unwise to rely exclusively on such methods.

Finally, we also ironically ignore a powerful means of prevention: treatment. The burden of stigma varies proportionally with perceived fatality. As more effective therapies have been developed, the degree of AIDS-related stigma in industrialized countries seems to have lessened. Wherever HIV disease is termed “untreatable” for whatever reason, AIDS has remained a stigma-
tized disease, with obvious implications for prevention.

Having staked these claims, allow us to make several assertions that spring from the argument that we must move beyond weak prevention programs to develop a global HIV strategy which encompasses meaningful prevention efforts and treatment of those already afflicted.

1. Treatment cannot be regarded as solely the province of wealthy countries.

There are many reasons for this, some of which will be examined below. But here we will underline the painful fact that, as AIDS deaths drop in North America and Europe, they continue to climb in Africa and in most other settings in the world. Good but prohibitively expensive therapies can only heighten this trend of concentration unless global health equity becomes more than a slogan.

How are we to respond? One of the first things we should do is listen to those infected with HIV. They are 40 million strong and growing, and they are not telling us to concentrate all of our AIDS activities on prevention. They are not reminding us that antiretroviral therapy is not cost-effective. They are not arguing that costly therapeutic interventions are not “sustainable” in poor settings, not “appropriate technology” for low-tech areas of the globe. Often enough, they are saying just the contrary because the destitute sick remind us that sacrosanct market mechanisms will not serve the interests of global health equity. 

Show us the data to support the assertion widespread in international financial institutions, that the neoliberal economic policies now in favor will ever serve the interests of those living, already, with HIV. Show us the data to suggest that declining HIV incidence - and declining AIDS deaths - in wealthy countries will not be followed by decreasing investment in the basic research necessary for new drug and vaccine development. No such data exist. If they did, new antituberculosis agents, also sorely needed, could not be termed “orphan drugs” - a great irony, since TB remains, along with AIDS, the leading infectious cause of adult death in the world today (Figure 5). 

2. Cost-effectiveness cannot become the sole gauge by which public health interventions are judged.

Market utilitarianism is a strange beast, since it seems to permit all sorts of inefficiencies as long as they benefit the right people - namely, the privileged. But if the goal is to heal or to ease the suffering of the destitute sick, there are enormous obstacles in the way of financing what was once felt to be a public good. Show us the data to suggest that any costly interventions serving the destitute sick will find favor in a world in which corporate welfare goes unquestioned, but chiding rebukes follow the introduction of antiretroviral therapy to poor communities.

3. AIDS research in developing countries must include a social justice component.

It is clear that many in the community...
of researchers would just as soon ignore poor people’s bitter criticisms of most existing program priorities. But what do we expect when we provide first-world diagnostics (viral-load and genomic testing, which are used to contribute to data collection) and third-world therapeutics (treatment of certain opportunistic infections or sexually transmitted diseases, leaving HIV to progress unhindered) within the same research project? If the press for cheaper - or even free - medications for HIV has had resonance, it is surely because something inside all of us recognizes the fundamental unfairness of this situation. Asking the destitute sick to wait for research to pay off is also unfair. The need for reciprocity is widely acknowledged in international public health, but it rings hollow to call poor people to participate in research for the greater good when they will rarely benefit from research outcomes.

A central point to keep in mind is that more and more people sick with AIDS need effective treatment now. Which groups have led this charge? Sadly, not the international health experts and responsible officials, but rather the AIDS activists and the non-governmental organizations. The fundamentally remediative nature of their work is more appropriate to this problem because it addresses widespread demands for social justice. If we are embarrassed by this term, then perhaps we should invent another. But show us the data to justify an absence of social justice initiatives in even the most basic research, since social justice is a dimension that must be built into all human research that involves drawing blood - or sweat or tears - from the destitute sick.

4. We need more effective prevention strategies.

The countless “Knowledge, Attitudes, and Practices” surveys and AIDS educational interventions derived from them have not achieved their aim, and to say so is not to object to AIDS education. On the contrary, educating everyone, and especially the young, is our civic duty and is part of being human. But show us the data to suggest that, in settings where social conditions determine risk for HIV infection, cognitive exercises can fundamentally alter risk. We know that the risk of acquiring HIV does not depend on knowledge of how the virus is transmitted, but rather on the freedom to make decisions. Poverty is the great limiting factor of freedom. Indeed, gender inequality and poverty are far more important contributors to HIV risk than is ignorance of modes of transmission or “cultural beliefs” about HIV. We can already show that many who acquire HIV infection do so in spite of knowing enough information to protect themselves, if indeed cognitive concerns were ever central to preventing HIV among the poor. Until we have effective, female-controlled prevention, whether a microbicide or something else, and an effective vaccine, nothing we do should suggest that education can substitute for, or remove the necessity of, effective therapy for AIDS. These truths are just now beginning to be acknowledged, and they are late in coming.

5. We can no longer accept whatever we are told about “limited resources.”

We keep hearing that we live in “a time of limited resources.” But how often do
physicians, anthropologists, and other researchers, or public-health specialists challenge this slogan? The wealth of the world has not dried up, it has simply become unavailable to those who need it most. Show us the data to prove that there are fewer resources than in previous decades, when we did not have effective therapies for many diseases. The struggle for social and economic rights for the poor must become central to every aspect of AIDS research and treatment.

Our challenge, therefore, is not merely to draw attention to the widening outcome gap, but also to attack it, to dissect it, and to work with all our capacity to reduce this gap. One way to do this is to let it be known that the community of those concerned with preventing and treating HIV - and with making the plight of the sick a common cause - is not willing to stand by idly as wealth becomes ever more concentrated. Even a doctor without formal economic training soon starts to wonder if the neoliberal agenda of the international financial institutions might be driving up HIV risks while these institutions slap the hands of those who dare to treat the destitute sick.22

Another challenge is to "harmonize" a global research and treatment ethic rather than to maintain the pretense that rich and poor live in two different worlds. There is no wall between the worlds, as any honest assessment of either microbial traffic or capital flows will show. Our imperative is to develop treatment components for all research or prevention programs that in-
volve HIV testing. As Wood and colleagues note, even “limited use of antiretrovirals could have an immediate and substantial impact on South Africa’s AIDS epidemic.”

To unite treatment and research in this way, we need drugs, diagnostics, and increased investment in health infrastructures. We need to forge novel alliances. We need to have easier access to drugs, especially those developed with public funds.

Finally, we also need pilot projects to pioneer the use of antiretroviral therapy in settings with a heavy burden of HIV but without laboratories capable of performing CD4 counts or viral loads. We need to think ahead, to pioneer the use of new agents where they are needed most. On the basis of our experience of developing directly-observed therapy for tuberculosis, we have developed such a program in one of the poorest parts of rural Haiti, the poorest country in the Western hemisphere. We are using three-drug regimens that are slightly more complicated than short-course chemotherapy for TB; other, simpler regimens will soon be available. Our “HIV Equity Initiative” in rural Haiti has not replaced our prevention efforts. Rather, it has helped to revive them. At this juncture, facing catastrophe in Africa and beyond, we are asked to choose between treatment and prevention. But we cannot make this choice. We remain squarely behind efforts to prevent transmission - from vaccine trials to improved educational interventions - but believe that prevention and treatment are intimately linked. They belong together as planks of a single platform to halt AIDS.

So why is treatment not central to AIDS policy in resource-poor settings? Because we are told it is “not sustainable.” Why? The response to this question has long been that the drugs are too expensive. Yet the recent and precipitous drop in drug prices augured by the development of generic drugs has not lead to a concomitant scaling up of treatment efforts. Rather, as the financial barrier has fallen, the response to a potential increase in access has been to turn to a new set of excuses: two problems often cited are patient “non-compliance” and the resulting acquisition of antiretroviral resistance, and the lack of requisite health infrastructure in developing countries. Recently, for example, influential voices in the U.S. government have argued that Africans have a “different concept of time” and are thus unlikely to adhere to the complex dosing schedules required for HAART. These and other objections to treatment are interrogated by our experience in rural Haiti, which is notable for both high rates of HIV and poor health infrastructure. In a subset of patients receiving triple therapy at our clinic whose viral loads were tested, approximately 80% had no detectable virus in peripheral blood. Of note, this initial finding suggests that therapy in this project is quite effective, since most US based studies demonstrate viral suppression in only about 50% of patients (or fewer) at the end of one year.

Only by coupling prevention with treatment can we hope to halt the global HIV epidemic and prevent wide-scale social catastrophe in Africa and elsewhere. Any other response to the greatest public health emergency in over 600 years is not morally sustainable, intellectually sustainable, epidemiologically sustainable, or socially sustainable. If unequal standards are to be accepted as a fact of life, then why do we feel uncomfortable that, in order for medical students from Harvard to do summer research projects in places like Haiti, they are now required to travel with doses of
“triple therapy” on the off chance that they might be exposed to HIV? Why do we feel uncomfortable that researchers from the same institutions dismiss as “utopian” the possibility of treatment for locals who are already sick? How sustainable is that? 

References

8. “AIDSCAP interventions were built on three strategies for reducing HIV transmission: communication to encourage people to avoid behaviors that put people at risk of infection, improving treatment and prevention of other sexually transmitted diseases (STDs), and increasing access to and correct use of condoms. These central technical strategies were supported by policy development, behavioral research, evaluation, gender initiatives and capacity building” (Family Health International, Making prevention work: global lessons learned from the AIDS control and prevention (AIDSCAP) project 1991-1997. Arlington, VA: Family Health International and AIDSCAP, October 1997). There have been calls to expand the FHI portfolio to include treatment, and an “HIV Care Coordinator” was recently appointed (Eric von Praag, personal communication).
9. Do the math. As of end-1999, an estimated 34.3 million adults and children were infected with the HIV virus; 1999 alone saw 5.4 million infections, at a rate of 15,000 new infections per day (Joint United Nations Programme on HIV/AIDS, 2000).
10. The latest projections are staggering: in Botswana, where an estimated 36% of adults are infected with HIV, impressive gains in life expectancy over the past 40 years have been dramatically reversed in the past decade: life expectancy had plummeted to 47.4 years by 1997, a 14% drop compared to 1975 (United Nations Development Programme, Human Development Report, 1999. New York: Oxford University Press, 1999). In countries with adult HIV prevalence rates of 15% and above, current projections suggest that more than one-third of boys now aged 15 will die of AIDS; in even harder-hit countries, such as those in southern Africa, this proportion may exceed two-thirds (Joint United Nations Programme on HIV/AIDS, 2000). See also Boerma JT, Nunn AJ, and Whitworth JAG. Mortality impact of the AIDS epidemic: evidence from community studies in less developed countries. AIDS 1998; 12 (Suppl 1): S3-S14; Stover J and Way P. Projecting the impact of AIDS on mortality. AIDS 1998; 12 (Suppl 1): S29-39.
13.2 million, with over 90% of these children living in sub-Saharan Africa (See Joint United Nations Programme on HIV/AIDS, 2000).

12. In 1998, 200,000 Africans died in war, while more than two million died of AIDS (Joint United Nations Programme on HIV/AIDS, 2000).

13. Relatively prosperous South Africa has one of the highest rates of HIV infection in the world. In 1998, the TB case notification rate was 326 per 100,000 population (World Health Organization, 2000a); true incidence is estimated at over 500 per 100,000 population (Weyer K, Fourie PB, and Nardell E.A. “A noxious synergy: Tuberculosis and HIV in South Africa.” In: Program in Infectious Disease and Social Change. The global impact of drug-resistant tuberculosis. Boston, MA: Harvard Medical School and the Open Society Institute, 1999; pp. 127-148.). In contrast, poorer Senegal, where 1.77% of the adult population is HIV-positive, had a TB case notification rate in 1998 of 94 per 100,000 population (Joint United Nations Programme on HIV/AIDS, 2000; World Health Organization, Global tuberculosis control: WHO report 2000. Geneva: World Health Organization, 1999.). One candid review of drug development notes that “few developments are need-driven”— the average cost of bringing a new drug to market is approximately $224 million, costs that pharmaceutical companies argue would not be recouped for diseases endemic in poor countries with few resources and no property rights laws to prohibit far cheaper generic products from entering the market (Trouiller and Olliaro, 1999, p.164).


16. The market fails when it comes to research and development— in the case of tuberculosis, for example, the last novel treatment was developed over 30 years ago (t’Hoen E. Statement from Médecins Sans Frontières at the Health Issues Group DG Trade; Brussels, 26 June 2000.). Over the past two decades (1975-1996), less than 1% of over 1,200 new molecular entities sold worldwide were earmarked for tropical diseases (Trouiller P and Olliaro PL. Drug development output: what proportion for tropical diseases? Lancet 1999; 354(9173): 164).— this despite the fact that infectious diseases remain a major cause of mortality throughout the world: in 1998, infectious diseases accounted for 25% of deaths worldwide and 45% of deaths in low-income countries (World Health Organization, Removing obstacles to healthy development. Geneva: World Health Organization, 1999.). One candid review of drug development notes that “few developments are need-driven”— the average cost of bringing a new drug to market is approximately $224 million, costs that pharmaceutical companies argue would not be recouped for diseases endemic in poor countries with few resources and no property rights laws to prohibit far cheaper generic products from entering the market (Trouiller and Olliaro, 1999, p.164).


19. Organizations such as Médecins Sans Frontières have been at the forefront of the movement to gain equal access to effective therapies for the poor (t’Hoen, 2000). One MSF spokesman argued recently: “The global HIV/AIDS-crisis has provided us with a magnifying glass under which the inequity in access to treatment became painfully clear... Medicines cannot be treated as mere commodities. Often access to medicines is a question of life and death. Yet in international trade they are regulated very much the same as any other consumer good” (t’Hoen, 2000).

20. For a review of the data supporting this claim, see Farmer P, Connors M, and Simmons J (eds.), Women, poverty, and AIDS: sex, drugs, and
structural violence. Monroe, ME: Common Courage Press, 1996, which reviews over 1000 studies and papers relevant to both HIV transmission and disease progression among women.

21. “Failure to use STD and HIV incidence as the outcome measure constitutes a major weakness in the behavioral-intervention area. Another important weakness is our failure to evaluate basic social structural interventions. We cannot know the effectiveness of interventions that have not been addressed. There is overwhelming evidence that oppression contributes to STDs and many other maladies” (Aral SO and Peterman TA. Do we know the effectiveness of behavioral interventions? Lancet 1998; 351(Suppl III):33-36, p. S35). In a randomized control trial of over 12,000 adults in Tanzania assessing the impact of treating STDs as a means of preventing HIV transmission, Gilson and colleagues found that treating STDs reduced transmission of HIV-1 by about 40%. They conclude: “From a societal standpoint, therefore, the cost of the intervention is likely to be substantially less than the cost of not intervening” (Gilson L, Mkanje R, Grosskurth H, et al. Cost-effectiveness of improved treatment services for sexually transmitted diseases in preventing HIV-1 infection in Mwanza region, Tanzania. Lancet 1997; 350:1805-1809, p. 1808).


23 Wood E, Braitstein P, Montaner JSG, et al. Extent to which low-level use of antiretroviral therapy could curb the AIDS epidemic in sub-Saharan Africa. Lancet 2000; 355:2095-2099, p. 2095. One model of the impact of antiretroviral use on the AIDS epidemic in South Africa projected that the use of short-course prophylaxis would reduce perinatal transmission by 40%, preventing 110,000 Infant HIV infections by 2005—at a cost of less than 0.001% of the per-person health expenditure. In a more costly scenario, 25% triple-combination treatment for the HIV-1 positive population would prevent both 430,000 incident AIDS cases and a 3.1-year decline in life-expectancy (Wood, Braitstein, Montaner, et al., 2000).

24 For example, AZT and to a lesser extent 3TC have been developed with federal research dollars. See also comments in t’Hoen, 2000.

25 For more on our program, as well as the clinical algorithms for the management of HIV disease in resource-poor settings which we are developing, see Farmer P, Leandro F, Mukherjee JS et al., Community-based approaches to HIV treatment in resource-poor settings. Lancet 2001;358:404-409.

26 Within months we will have a triple nucleoside RT inhibitor pill—AZT, 3TC and abacavir, the most potent NRTI. Such a fixed-dose combination would be easier to use and would preserve both protease inhibitors and non-nucleosides for cases of resistance. Using a non-nucleoside (e.g., nevirapine) in a three-drug regimen may be more risky than using a protease inhibitor because a single mutation confers resistance to the entire class of drugs as opposed to resistance to nucleoside analogs and protease inhibitors in which it takes multiple mutations to confer clinically meaningful resistance. (For more on readily-induced nevirapine resistance, see Becker-Pergola G, Guay L, Mmiro F, et al. Selection of the K103N Nevirapine resistance mutation in Ugandan women receiving NVP prophylaxis to prevent HIV-1 vertical transmission (HIVNET-006). Abstract of the 7th Conference on Retroviruses and Opportunistic Infections, San Francisco: Jan 30 - Feb 2, 2000.)


Malaria: Its Human Impact, Challenges, and Control Strategies in Nigeria

Arese Carrington, MD, MPH

Malaria is one of the most serious health problems facing the world today. The World Health Organization estimates that over 300 million new cases of malaria arise a year, with approximately two to three million deaths resulting from contraction. Malaria is endemic in tropical Africa, with an estimated 90% of the total malaria incidence and deaths occurring there, particularly amongst pregnant women and children. More specifically, malaria is causing various problems in Nigeria. Malaria is the only vector borne disease to be placed on World Health Organization’s Disability Adjusted Life Years (DALYS) list. It is important to look at health problems like malaria that grossly affect the morbidity and mortality rates, as well as the economy of a developing country, such as Nigeria. Nigeria has a population of about 123.9 million people [1]. A large percentage of its population lives in extreme poverty in rural areas, without access to potable water and adequate healthcare. Nigeria is also a low-income country already saddled with a huge foreign debt burden. It risks sinking further into debt as it struggles with a sick populace whose good health is essential for its economic growth.

Traditionally, Chloroquine was a common treatment for Malaria. However, with the increase in chloroquine resistant malaria, additional methods of control must be employed. A multidimensional approach should be used in the control strategy, such as good management of clinical malaria, the use of insecticide-treated bed nets (ITBN), education and training programs in malaria prevention, vaccine research and the use of insecticide spraying such as DDT on breeding sites. It is also necessary to explore the use of indigenous natural mosquito repellant plant species. Pharmaceutical companies should study local anti-malarial herbs to determine their efficacy on malaria and effective and safe dosages should be found. The answer to malaria control may lie within local communities. Policies pertaining to the use of impregnated (soaked in insecticide) bed nets would be doubly advantageous and economical in rural areas. Culturally, the two most susceptible groups of people, pregnant mothers and infant children, tend

Arese Carrington, MD, MPH, is an Associate Director of the Harvard School of Public Health’s AIDS Prevention Initiative in Nigeria Program.
to sleep together. Walls of mud huts in rural areas should be white washed to avoid attracting mosquitoes. Cracks and crevices where stagnant water can collect should be sealed.

Partial funding for malaria control projects could be generated internally if the Nigerian government collected a levy from companies that are involved in activities that pollute the environment. Oil companies working in the Niger Delta areas, where there are many marshy swamps and a high prevalence of malaria, should also be asked to contribute to a general malaria control fund.

The Issue of Malaria

Malaria is caused by four different protozoa in the plasmodium genus: either Plasmodium Vivax, which is more prevalent in low endemic areas, Plasmodium ovale, Plasmodium malaria, and the Plasmodium falciparum, the most dangerous of the four. The Plasmodium falciparum has a life cycle in the mosquito vector and also in the human host. The anopheles gambiae mosquito is the vector responsible for the transmission of malaria. The prevalence of malaria is dependent on the abundance of the female anopheles species, the propensity of the mosquito to bite, the rate at which it bites, its longevity and the rate of development of the plasmodium parasite inside the mosquito. When the female mosquito bites and sucks the blood of a person infected with malaria parasites she becomes infected; she then transmits the parasites to the next human host she bites. Malaria incubates in the human host for about eight to ten days.

The spread of malaria needs conditions favorable to the survival of the mosquito and the plasmodium parasite. Temperatures of approximately 70 - 90 degrees Fahrenheit and a relative humidity of at least 60 percent are most conducive for the mosquito [2]. The development of the malarial parasite inside the mosquito is more rapid as the temperature rises and ceases entirely below 60 degrees Fahrenheit [3]. Increased rainfall and stagnant pools of water or surface water provide hospitable breeding grounds for the mosquito.

It is important to understand how malaria transmission is affected using the “basic reproduction number.” In an entirely susceptible host (non-immune) population from each primary malaria infection arises a varying number of secondary infections, referred to as the Basic Reproductive Number. That number is directly proportional to the populations’ risk for contracting malaria and can be increased by the following factors: an increase in the abundance of mosquitoes relative to the human population, an increase in the propensity of the mosquito to bite its human host, an increase in the proportion of the infective mosquito bites, an increase in the length of illness and an increase in survival rates or longevity of the mosquito [4].

The Burden of Malaria

As malaria’s incidence increases, so too will morbidity and mortality rates. Malaria is endemic in Nigeria, and the population at highest risk includes children, pregnant women, and the non-immune.

Along with malarial morbidity and mortality come economic losses. Social and economic consequences are directly related to the severity of the malaria’s increased morbidity and mortality. As a result of malaria, children spend days away from school and adults lose workdays. Age distribution of the popula-
tion also has an effect on the burden of disease. In highly endemic areas, the older population develops some collective immunity to malaria so the severity of malaria attacks is less than in children under five. *Plasmodium ovale* is less fatal than *Plasmodium falciparum*. Since *Plasmodium ovale* is more prevalent in non-endemic areas, in these areas the burden of disease is less than in endemic areas where malaria is due to the fatal *Plasmodium falciparum*. Currently, studies show that any increase in the disease burden of malaria as expressed in terms of DALYS is an unsustainable development.

The level of socio-economic development in a country usually affects how much is invested in health care, which in turn affects the health outcomes and severity of diseases like malaria. Like a vicious cycle, the health outcomes affect income and capital, which in turn affects the economic development of the country. Nigeria's 6% allocation of its annual national budget to the healthcare sector is low and has resulted in poor health outcomes and an increase in the severity of diseases like malaria. These poor health outcomes are partially responsible for its low gross national income per capita (GNI) of US$260. [5] In the cause and effect relationship between malaria and economic growth, it is also possible that the severity of malaria leads to poor health outcomes which in turn leads to a low gross national income and poor economic growth.

Risk Control strategies; Implications and Cost Effects

Policy makers need to aggressively pursue malaria control strategies because malaria infections are attacking Africa's most populous country, Nigeria, at an alarming pace. Factors that are also responsible for the increase in the resurgence of malaria must be addressed in malaria transmission control. These factors include the large-scale resettlement of people usually associated with ecological changes, increasing urbanization disproportionate to the infrastructure, drug resistant malaria, insecticide resistant mosquitoes, inadequate vector control operations and public health practices.

Vector control is significant in the light of increasing drug resistant malaria, as well as for cost effective reasons. Insecticide treated bed net trials are being conducted in some parts of Nigeria and the results so far have been promising for the reduction in severity and prevalence of malaria in children. The cost effectiveness of using insecticide treated bed nets in reducing pediatric admissions also reduces the personal costs that family and friends bear during a hospital admission. Such costs include out of pocket expenses, travel, family input into treatment, and productive time lost by mothers who have to take their children to the clinic or stay with them in hospital.

A trusted method of controlling the mosquito is spraying breeding sites with insecticide such as DDT. Although some studies have reported the presence of DDT resistant mosquitoes, it is still one of the most effective and economical forms of insecticide in the control of malaria. The use of DDT was partly responsible for the reduction of malaria in areas where it is now mainly eradicated.

Environmental laws are leading towards the total ban of the use of DDT. Due to its persistence in the environment and its effect on the ecosystem, it is regarded as a persistent organic pollutant. A total ban on the use of DDT, however, could prove
disastrous to poor countries that still rely heavily on its use for malaria control.

A more widely agreed upon solution is that there should be mass campaigns for education training in malaria prevention. In addition, research for a vaccine for malaria would be a noble gift to Africa and other areas where malaria is endemic and should be intensified.

At the April 2000 Malaria Summit hosted in Nigeria, a pledge was made by African countries to reduce or waive taxes and tariffs for mosquito nets, insecticides, anti-malarial drugs, and other tools used for malaria control. Since Nigeria is the most populous country in Africa, the success of its malaria control programs will have a significant impact on the overall control of malaria in the region. Because a large proportion of the population in Nigeria’s rural areas lives in poverty, a control plan focused on those areas should be initiated.

A Summary of Problems Affecting Malarial Control in Rural Nigeria

Most of the rural areas do not have access to good health care systems. Usually there are no accessible roads to the health centers, which in turn are poorly equipped and have inadequate drugs for malaria treatment. Drug resistant malaria is common and anti-malarial drugs are becoming less effective as the plasmodium parasite develops resistance to affordable drugs. This poses a serious threat to clinical management and treatment of malaria. People cannot afford anti-malarial drugs so they tend to self medicate with local herbs. Children wear little clothing during the day and at night due to heat and humidity, thus leaving their bodies exposed to mosquito bites. Rural dwellers cannot afford to purchase bed nets. Mud houses are poorly constructed and are surrounded by bushes. Water is collected from streams and wells and left standing in open clay pots since there are usually no running taps.

Recommendations to Control Malaria in Rural Nigeria

Within the control strategy for malaria, a multi-dimensional approach is needed. Resources collected for a general malaria control fund could be used to implement some of these strategies.

1. Management of clinical malaria:
   - Accessibility to primary health care centers and affordability must be guaranteed. Units within primary health care centers should be set up to diagnose, treat and monitor malaria cases. These centers will need the basic equipment required to check blood films for malaria parasites and a full blood count. All drug resistant cases should be reported and referred to tertiary health centers where alternative lines of management, such as radical drug treatment combinations, can be established.

2. Surveillance
   - Epidemiological surveillance is highly essential in any control strategy, and is an essential guide in developing a multi-dimensional approach. The malarial control units set up should keep data on the
epidemiological surveillance and the information should be sent to the national malaria control center.

3. Chemoprophylaxis

- During seasonal outbreaks anti-malarial prophylaxis should be provided for children under five and pregnant mothers.

4. Vector control using the barrier method

- If the mosquito cannot bite its human host it cannot transmit malaria. Thus, people should be advised and encouraged to wear light-colored protective clothing that covers their whole body. Mosquitoes are attracted to the dark and likewise to people in dark clothing.
- Bed nets act as a mechanical barrier and prevent the mosquito from biting humans and transmitting the opportunistic plasmodium parasite.
- Bed nets that have been impregnated with an insecticide have been shown to be highly effective in the control of malaria and reducing the severity of malaria in children. In rural areas, they will prove to be very valuable because pregnant mothers and mothers in general tend to sleep on the same bed with their young children. Insecticide treated bed nets should be gradually phased in starting with mother and child. President Olusegun Obasanjo of Nigeria recently announced a policy trust for the provision of free insecticide treated bed nets for children under five and pregnant women.
- Rural health workers need to be properly trained on how to treat the bed nets with insecticide and also to teach people how to treat the bed nets every six months. It is important that people are also taught how to use the bed nets, when to place them in the evening and how to store them during the day so they don’t get torn. Most mosquito bites usually occur between dusk and dawn.
- Compliance is highly essential and this should be stressed. Impregnated bed nets not only protect individuals from mosquito bites, there is also a high probability that the mosquito will be killed when it rests on the impregnated bed nets.

5. Vector control using the direct attack method: Use of DDT

- Workers should be trained how to spray the various sites such as inner walls of houses and the surrounding environment around the houses properly. They should also wear protective clothing and nose masks. They must be taught all the necessary safety precautions that should be taken when on a spraying mission.
- Residual spraying of DDT should be used on the inner wall of houses. In rural areas most of the houses are made of mud and this dull color tends to attract the female anopheles mosquito. The anopheline mosquito after feeding tends to rest on the walls and if it rests on one that has residual spraying it is most likely that it will be put to rest permanently. Since some mosquitoes do not rest on walls after feeding, it is important to also spray the surrounding environment.
- Residual spraying should be done at least
every six months. Currently, residual insecticide spraying with DDT is still the most effective and economical means of control. However due to the persistent harmful effect of DDT in the environment and on human health it is important to start testing insecticides locally produced from herbs.

6. Housing

• Mud houses should be plastered and painted white. This will prevent water from being collected in the walls and will prevent mosquitoes from being attracted.

7. Control through local vegetation: Anti-mosquito plant species

• Some local herbs may contain mosquito repellant properties when burnt. Some plants may produce natural chemical substances against insects such as the mosquito. The diverse and dense savannah and rainforest regions could hold the key to malaria control. It may be time to start looking within communities for measures to use to fight the mosquito. More research needs to be done on indigenous plants and trees which local people claim contain anti-mosquito properties.

8. Health education

• Mass health education campaigns and training in malaria prevention are important. People should be educated on the importance of not providing conducive dwelling and breeding places for the mosquito. Refuse dumps should not be located near houses. Collection of rainwater in discarded waste such as old tires and empty cans should be prevented. Draining all stagnant water, clearing bushes around the house and eliminating pot holes on the roads are methods of depriving mosquitoes of their breeding grounds. Domestic water should be stored in containers that can be covered and should not be left open. Self-medication with local herbs is commonly practiced. The dangers of inadequate self-treatment within a population should be emphasized and people should be told to go to the health center when they have malaria symptoms such as fever, body aches and generalized poor health.

Conclusion

No single individual method can be used to achieve a successful malaria control program. Due to the vast differences in geographical climate and landscape in the various locations of rural areas within Nigeria, it is useful to concentrate on combinations of control methods that have proven effective in similar conditions. Strategic control methods must involve some combination of effective clinical control, vector control, reduction in contact of the mosquito with its human host, improved sanitation, and better health education and malaria prevention programs.

Limitations on control methods include: inadequate healthcare infrastructure in the rural areas, poor drug distribution, increases in drug resistant parasites, increases in insecticide resistant mosquitoes, poorly constructed rural dwellings with cracks and crevices, and individuals’ non-compliance with the control program.
To avoid non-compliance, it is important that people are sensitized and mobilized prior to the initiation of the program. Acceptance of the various malaria control strategies by the community is important; therefore local chiefs, community leaders, and women should be involved in education and mobilization campaigns.

The cost of controlling malaria, as expensive as it may be, cannot outweigh the benefits when morbidity, mortality, pain and suffering, and the economic consequences of malaria are taken into consideration.

Endnotes

1) World Development Indicators, July 2000
2) Martens Pim. “How will climate change affect human health,” American Scientist; Research Triangle Park; (Nov/Dec 1999)
3.) Ibid.
5.) World Development Indicators, July 2000
6.) Mengestu Woube. “Geographical distribution and dramatic increases in incidences of malaria: Consequences of resettlement scheme in Gambela, SW Ethiopia.”
10.) Martens (1999)
12.) Steve Steinberg 1999. “Mosquito nets in Africa could save 250,000 lives.” USA Today 2744-69
Eradicating Malaria: High Hopes or a Tangible Goal?

Ilana Brito

Malaria is a disease known well by name, but not by face. Most persons living in an industrialized country have never had, nor seen this serious disease. During the rainy season in malaria-endemic regions, individuals can receive as many as 300 mosquito bites per month. In such tropical areas, it is normal for ten percent of all mosquitoes to carry Plasmodium, the single-celled parasite that causes malaria. In Africa, where over eighty percent of malaria cases occur, Anopheles mosquitoes (the vector responsible for transmitting the malaria parasite) make up the bulk of the entire mosquito population. After calculation, the odds of being infected with plasmodia are practically all to none. Once transmitted, Plasmodia first hide in the liver and eventually invade and attack red blood cells, causing fevers, shakes, comas or convulsions, and occasionally, death.

Today, malaria continues to plague children and adults throughout the world. Those without any built-up immunity to malaria, i.e. young children and tourists visiting malaria-endemic regions, face the highest risks of dying. While tourists can take prophylaxis to prevent contracting malaria, children are completely exposed once the short-lived immunity inherited from their mothers wears off.

Each year in undeveloped nations, malaria takes the lives of more than 1.2 million children, at an average of 2,800 deaths per day. This daily death toll is thirty times that of the entire 1995 outbreak of the Ebola virus in Zaire. Five hundred million people, just fewer than ten percent of the world’s population, suffer from malarial fevers. In addition, malaria collectively drains national economies of more than $13 billion per year.

The Threat of Malaria

The threat of malaria continues to grow over time. Initial efforts to eradicate malaria by using insecticides were unsuccessful, merely resulting in insecticide-resistant strains of mosquitoes. Now, cheap and easily available drugs that were once effective against malaria often fail. Changing climates and increasing long distance travel can increase the population at risk. The resources once used to control malaria are no longer effective.

In the early 1950s, scientists, policymakers and doctors thought they had the solution to control malaria, a disease that first appeared before Hippocrates’ time. The World Health Organization (WHO) initiated a program to globally eradicate
malaria by using a new chemical against *Anopheles* mosquitoes: dichloro-diphenyl-trichloroethane, commonly known as DDT. The objective seemed clear: simultaneous extermination of the vector for the disease and the parasite. Despite political debates about the use of insecticides after the 1962 publication of Rachel Carson’s book, *Silent Spring*, DDT provided the single greatest hope for defeating this disease that, at that time, was one of the top killers in the world.

For more than ten years, the WHO’s Global Eradication of Malaria Programs spent more than one billion dollars on spraying fields throughout malaria-endemic regions and coating pools of standing water where *Anopheles* mosquitoes lay their eggs; but the program was finally abandoned in 1972. The program succeeded in some areas, such as Sri Lanka, where malaria deaths went from 1 million cases per year to a mere 17. However, the persistent use of DDT had artificially selected mutant mosquitoes that were resistant to the insecticide. A parasitic species that had evolved over more than three or four thousand years was not going to die out that simply. Other attempts at controlling mosquito vectors have been made using *Bti*, a bacteria capable of destroying mosquito larvae, but whether it is ecologically feasible remains questionable. Pesticides alone could not solve this age-old problem. Even if mosquito populations are severely reduced for a short period, it may not prevent malaria from reemerging. After all, malaria parasites normally survive months of unsuitable conditions during the dry season and then reappear when the rain returns.

That was the last notable malaria eradication effort. Wiping out malaria seemed too difficult a task, so more achievable goals were set in its place. Reducing the malaria caseload became the international objective. People were encouraged to use insecticide-treated bed-nets and to spray insecticides around their homes. Women were encouraged to take prophylaxis during their pregnancies to prevent infection. Control increasingly relied on medication rather than controlling mosquitoes.

Unfortunately, medication could no longer protect individuals either. Parasites throughout the world independently developed resistant strains to our most effective medications. Although quinine, an extract from the bark of the Peruvian cinchona tree, was used to effectively treat malaria for more than 350 years, it was difficult and costly to extract, caused severe side effects and, at one point in time, its production caused the near extinction of the cinchona tree. Instead, almost immediately after, chloroquine, a substance sharing the same basic chemical structure to quinine, was synthesized in 1943. It was put to use because of its low manufacturing costs. Its misuse led to the independent emergence of drug-resistant strains of *Plasmodium falciparum* parasites throughout the world as early as 1965. Overusing chloroquine, using poorly manufactured chloroquine, failing to take the complete cycle of treatment, or using chloroquine alone in one given region has allowed plasmodium to develop resistance mechanisms. In some parts of Africa and Southeast Asia, over fifty percent of malaria cases are caused by resistant strains.

While other drugs do exist, they are often too expensive to manufacture and distribute to the developing world. The only other cheap, available treatment is Fansidar, a mix of pyramethamine and sulfadoxine, but parasites have developed resistance mechanisms against it as well. The lack of practical medications has made malaria vir-
tually uncontrollable in many parts of the world.

Over ninety countries are now hotspots for malaria, with 2.4 billion people at risk (40 percent of the world’s population). That number is likely to grow with the onset of global warming. Climates once unsuitable for Anopheles mosquitoes now permit the growth of mosquitoes and their guests, the malaria parasites. The southwest United States is currently experiencing such changes. Intercontinental travel increases the chances of bringing infected mosquitoes to untouched sections of the globe. The appearance of West Nile encephalitis in the New York metropolitan area and Florida are other key examples.

Reconsidering Third World Problems

Contrary to other widespread killers, such as cancer, the pathology of malaria is well known and yet, it persists. Malaria existed in the United States from colonial times into the 1950s, but with eradication efforts, improved medical care, available drugs, and higher standards of living, malaria disappeared. Likewise, malaria was eliminated from many industrialized nations, including the Soviet Union, Italy and Canada. Unlike AIDS, which plagues the entire world, malaria is now strictly a developing world disease, and, consequently, no longer receives the funding needed for its control. For example, in 1993, $84 million was spent to fight malaria, while forty times this amount was spent on cancer. As of 2000, New York alone has spent more than $30 million trying to control the outbreak of West Nile encephalitis during which 7 people died and 62 people became ill. One can imagine that if the problem of malaria had been addressed earlier, the disease might have been eliminated from a larger section of the globe or a vaccine might have already been made available. Perhaps with the growing danger of malaria to the populations of industrialized countries, they too will begin to take notice.

Fresh efforts aimed at controlling the disease have recently been adopted, such as cheaper, faster diagnostic tests, new drug options, education efforts, and prevention campaigns supporting the use of bed-nets to keep out mosquitoes. Some programs start early in people’s lives - educating them in attempt to dispel local folktales about a bird that steals the breath away from sleeping children and is responsible for the shakes, convulsions, and comas caused by severe forms of malaria. Countries have begun collaborating to combine research efforts and to support international malaria prevention campaigns. Examples include the World Bank’s Roll Back Malaria program, which aims to cut the number of worldwide malaria cases in half by 2010, the Bill and Melinda Gates Foundation’s Malaria Vaccine Initiative, Multilateral Initiatives on Malaria, and the World Health Organization’s Medicines for Malaria Venture.

Without reliable vector control or medication, what hope remains for controlling the disease aside from individual and local efforts? With more money now going to scientific research on malaria, innovative solutions are close at hand. A vaccine is more possible now than ever before - scientifically and financially.

Viability of a Vaccine

Malaria has momentarily been eliminated
from certain regions, but is it possible to completely eradicate malaria? Eradication, in its purest definition, means to permanently reduce the worldwide incidence of the disease to zero, while elimination signifies a reduction within a defined geographic area. Elimination requires continued efforts to contain the disease and prevent its reestablishment within the given area. So far, smallpox has been the only disease eradicated by human efforts.

Eradicating a disease is considered impractical if any of the following conditions exist: 1) there is an animal reservoir that persists independently from humans; 2) the parasite has a relatively long infectious state; 3) detecting the infection is difficult, costly, or timely; 4) the political or social will to proceed with an effective vaccination, treatment, or prevention program is weak; or 5) there is no effective vaccine and/or cure. For a vaccine to be effective, it must affect all strains of the parasite. In the case of malaria, all five conditions exist.

Vaccines work by introducing antigens (derived from proteins that come from the surface of the parasite) into the human’s immune system, stimulating the body to naturally produce antibodies against the parasite. The vaccine’s effects must be long-lasting or there must be an effective booster, or else the body will stop producing antibodies. In the case of malaria, it is vital for the vaccine to be cost-effective and non-degradable in tropical climates. Without a vaccine, eradication, or even elimination from malaria-endemic areas will be unlikely, if not impossible.

The complicated lifecycle of the Plasmodium is one factor that makes vaccine development difficult. Plasmodia are ingested and expelled when a mosquito bites a human. After getting bitten, the parasite, then called a sporozoite, goes dormant in the human’s liver cells for anywhere from one week to several months. This varying period of time in the liver makes detection quite difficult. After inconspicuously multiplying, the parasites burst out of the liver cells as merozoites. Immediately, they invade red blood cells where they continue to multiply and eventually rupture the cells. This mass destruction of red blood cells causes intense fever and anemia. When infected red blood cells stick to each other, they can block capillaries, which can cause convulsions or comas if blockages occur in the brain. Some of the merozoites leave the red blood cells as sexual forms, which are then taken up by another mosquito during its bloodmeal, and fuse together within the mosquito to continue the cycle. With its hide-and-seek lifestyle, the parasite is able to escape immune responses at each of its life phases.

Unlike immune responses to bacteria or viruses, the immune response to Plasmodia is partial – occurring in multiple steps but only lasting for a short period of time. During a normal immune response to malaria, different antibodies are produced each time the parasite, is exposed to the blood. Antibodies target specific proteins found on the surface of the parasite. Each time a person is exposed to malaria, he produces more antibodies. It was discovered in the late 1970s that injecting people with irradiated sporozoites prevented subsequent infections for a period of time. After 3 to 4 bouts of malaria illness, the body is capable of limiting the growth of parasites in the blood and preventing severe malaria symptoms, such as severe anemia or cerebral complications. If the patient has enough built-up immunity, he can succeed in completely eliminating the parasite from his blood.

Thus, scientists can use the parasite’s com-
complicated lifecycle to their advantage. Many vaccines are being developed, each trying to imitate the different antibodies’ responses. Ideally, a vaccine would be able to imitate the antibodies produced at various stages of the parasite’s lifecycle to prevent the disease from developing any further.

If a vaccine is able to invoke an immune response against the sporozoite, or pre-liver stage, it will be able to prevent infection - the parasite will never get the chance to multiply and develop within the liver, and patients will never accumulate parasites in their blood. A vaccine that is able to invoke an immune response against the merozoite stage will prevent the disease - merozoites that are unable to attack red blood cells will be incapable of causing any clinical symptoms. Finally, if a vaccine can block sexual differentiation, kill the sexual forms of the plasmodia, or prevent the fusion of the sexual forms, it may be possible to block the transmission of the parasite to mosquitoes and thus reduce communicability.

**Hopeful First Attempts and Continued Efforts**

The first promising malaria vaccine was introduced in 1987. This SPf66 vaccine, using both proteins from the sporozoite and merozoite phases of the parasite, was tested in Tanzania and the Gambia. It showed mixed results in different trials, but maximum efficacy never surpassed 31 percent. The second vaccine was based on one antigenic protein found on the surface of the sporozoite that is most likely involved in the parasite’s ability to enter human liver cells. This vaccine provided only marginal benefits.

After these attempts, scientists put greater confidence in vaccines that targeted multiple stages - ones that prevented infection, halted the onset of disease symptoms, and blocked transmission. Scientists feared that using vaccines that target single stages would select resistant parasites that may have developed covert mechanisms to avoid immune responses. By targeting multiple stages, mutant parasites could be better controlled.

The vaccine, NYVAC-Pf7 incorporated 7 proteins from all three stages: the sporozoites, the merozoites, and the sexual stages. It passed phase I and IIA trials ensuring safety and preliminary positive results. Ongoing trials are testing efficacy.

This latest vaccine is being tested in Mali, Kenya, and Thailand. It features a specific antigenic protein from the merozoite stage, intending to stop the plasmodia from invading red blood cells to interrupt their lifecycle. Initially, the vaccine may only protect against the clinical manifestations of the disease, allowing plasmodia to enter the bloodstream and pass through the liver stages. The vaccine is expected to come out strong; this protein is the most documented, there are as few as three strains of this protein, and the genes coding for the protein have already been sequenced. These trials, like the others, are bringing together support from different foundations, pharmaceutical companies, the US army, research universities, governmental funding, and local on-site resources.

Despite the progress, a set of ongoing obstacles still hinders vaccine development. While two of the 14 chromosomes of *Plasmodium falciparum* are already sequenced, there is high genetic variability between different strains. The vaccines have met difficulty in covering all plasmodia strains without leaving holes in the coverage. Secondly, the specific functions of the proteins used in the
vaccines are not well characterized, making it difficult to predict its efficacy. It is not known whether the antibodies will be sufficient to ward off new infections. So far vaccines have shown only partial immunity that dwindles over time. Finally, the vaccine must be cost-effective and appealing to the governments of developed countries and international pharmaceutical companies that will invest in the production and distribution of these vaccines.

Two other high-tech possibilities have been suggested. The first is a type of vaccine that works by injecting DNA into host cells to stimulate the ongoing production of antibodies. The technology is relatively new and it holds many risks, including the possibility of activating or deactivating the wrong genes. This type of vaccine could potentially overstimulate the production of antibodies, which, in theory, could provoke an autoimmune response.

The second possible intervention is actually engineering a new mosquito that rejects Plasmodium, by forbidding the parasite to develop within it. The altered mosquitoes would then be released in nature and naturally compete with other mosquitoes.

Conclusion

Malaria is expected to go from 11th in 1990 to 24th in 2020 on the list of worldwide reductions in DALYs (Daily Adjusted Life Years - a measure that inversely accounts for both morbidity and mortality), but important steps must be taken before getting there. Enormous progress has been made and, thanks to increased research efforts, a vaccine now seems achievable. The implications of a malaria vaccine are immense, including longer life expectancies at birth and more productive national outputs. However, due to the long process of conducting vaccine trials, it may be more than ten years before a functional, effective vaccine is available and ready for international distribution. Before that time, nations can continue working together to reduce infection rates, and appeal to international aid organizations for support. Even with a vaccine, which will result in many saved lives, elimination or eradication of a disease will not happen overnight. It will take a strong financial backing, global coordination and infrastructure, and a constant, widespread effort. If there is hope in extinguishing the threat of malaria, it will take shared commitments from a collection of nations, rich and poor.

Endnotes

Desowitz, Robert S. “Malaria capers: More tales of parasites and people, research and reality.” W.W. Norton & Co., 1993
Once in a great while, a scientific discovery is made that can transform both science and society. Humankind's newly acquired ability to map and ultimately alter its own genetic traits may well be one such epochal discovery. While recent advances in genetics are the work of thousands of scientists in dozens of countries, the most prominent symbol of our newfound mastery of the gene was the announcement in June 2000 that two vast teams of scientists had determined the DNA sequence of the human genetic code. No movie star ever had better timing than this discovery, which arrived at the perfect moment to symbolize the end of a century of physics and the beginning of a century of the gene.

The most immediate use of the data from sequencing the genome will be to increase our understanding of the links between genetic traits and disease. Medicine has already benefited from the first trickle of what will soon become a flood of new discoveries about the links between genetic mutations and particular diseases.

One well-known example of such a link is the correlation between a mutation in two genes, BRCA1 and BRCA2, and an elevated risk of breast and ovarian cancer. The benefits of a test for mutations in these genes were recently illustrated by a large-scale study showing that women with the mutation significantly increased their life expectancy by undergoing prophylactic mastectomy. One in eight of the women who tested positive for mutations in one of the two genes, but did not undergo mastectomy, developed breast cancer within three years of the study, whereas all the women who underwent the surgery remained cancer-free.1 Clearly, undergoing a prospective mastectomy is a step that few women would undertake without a compelling medical reason to do so. One message of the study is that testing positive for a BRCA mutation may provide such a

David Bowen, Ph.D., is currently a Visiting Fellow at the Department of Health Care Policy at Harvard Medical School, and serves as an advisor on health care policy to the Senate Committee on Health, Education, Labor and Pensions. Nancy Segal is the Legal Director of the Program on Gender, Work and Family, Washington College of Law, American University.

---

1 Bowen and Segal: Genetic Discrimination

The DNA Code Meets The United States Code: Legal Protections Against Genetic Discrimination

David C. Bowen, Ph.D. and Nancy Segal, JD
reason. If used to guide medical decision-making, the BRCA test can thus be an extraordinary boon to women in evaluating a treatment that could save their lives.

Yet this new understanding of the genetic basis of disease holds risks as well as benefits. The knowledge that a woman carries a BRCA mutation can be used to inform medical decision-making. But an employer might view that same information to mean that a woman was ordained inevitably to contract cancer. Such is the power of genetics that many non-specialists regard the presence of a genetic mutation as an unalterable prediction that a person will express a disorder that has been associated with that mutation. Thus, a person’s genetic signature is not seen as one of many factors affecting his or health, but rather as the determinative factor. With these misconceptions so prevalent, employers may increasingly come to rely on genetic testing to “weed out” those employees who carry genetic traits associated with undesirable characteristics. Similarly, genetic traits may come to be used increasingly by insurance companies to deny coverage to those who are seen as “bad genetic risks.” Enabling employers, insurers and others to base decisions about individuals not on their actual characteristics, but rather on the characteristics that are assumed to be their genetic destiny would be a truly dystopian outcome of our vast national investment in genetic research.

The challenge lawmakers must face is in harnessing the great potential benefits that come from understanding the human genome while preventing undesirable uses of genetic information. This essay reviews the current legal protections against genetic discrimination and previews Congressional action likely to occur on this issue in the near future.

**Public Concerns about Misuse of Genetic Information**

Genetic information and its applications offer great opportunities to save lives and prevent the onset of disease. However, the medical progress made possible by genetics studies, such as those on BRCA, is dependent on the willingness of study volunteers to undergo genetic testing. Such willingness may be increasingly hard to come by. Fears surrounding possible misuse or unauthorized disclosure of genetic data have increasingly come to affect the willingness of individuals to participate in genetic research. A national telephone survey of more than 1,000 people on this issue found that 63% of respondents said they would not take genetic tests if health insurers or employers could get access to the results. Even when patients do volunteer for research, they or the investigators conducting the research may conceal identifying information out of fears of genetic discrimination.

These fears extend to clinical practice. Genetic counselors report that fears about breaches of privacy and improper use of genetic data are widespread among their patients, who often agonize about the decision to take a genetic test. These reports are substantiated by a growing body of evidence documenting reluctance among at-risk populations to undergo genetic testing. For example, only 43% of those at risk for hereditary colon cancer participated in a genetic testing program and the same percentage of women at risk for breast cancer participated in a genetic test for that disease.

More broadly, the public at large rou-
tinely expresses a strong desire to keep genetic data private. In a 1995 Harris poll, 85% of respondents indicated that they were either “very concerned” or “somewhat concerned” that insurers and employers might gain improper access to their genetic data. In a Gallup poll, 93% of respondents stated that government researchers should not be allowed to study an individual’s genetic information without consent. Fears about the possible misuse of genetic knowledge have translated into a deep-seated mistrust of genetic research. In a survey taken at the time the human DNA sequence was announced, 46% of respondents said they expected harmful results to occur as a result of the research, while 41% viewed the genome project as morally wrong.

Despite this widespread concern about misuse of genetic data, there is no comprehensive federal law protecting either the privacy of genetic information or prohibiting the use of such data to deny insurance coverage or affect employment status. Instead, there is a patchwork of often weak or incomplete protections, based on other laws that were not designed for this purpose. While some states have enacted protections against genetic discrimination, they vary widely in effectiveness and scope.

Federal Law on Genetic Discrimination in Insurance

HIPAA and Insurance

In health insurance, the Health Insurance Portability and Accountability Act (HIPAA) affords some protection against discriminatory practices based on an individual’s genetic traits. HIPAA ensures that individuals who change insurance carriers (usually after switching jobs) do not have their coverage denied or unduly restricted because of preexisting medical conditions. HIPAA also prohibits an insurance carrier from charging one individual within a group, higher rates than other “similarly situated” individuals in the same group.

Since HIPAA includes genetic information as part of its definition of a preexisting medical condition, the Act might at first glance appear to protect against genetic discrimination in insurance. However, HIPAA, has several important blind spots. First, HIPAA applies only to the group insurance market. Under HIPAA, it is still entirely legal for carriers selling insurance in the individual market to deny coverage or to charge exorbitant rates to individuals based on genetic traits, regardless of whether those traits affect a person’s current health status.

Second, violations of HIPAA are subject only to relatively weak administrative sanctions. Under the Act, individuals who have suffered discriminatory treatment have no recourse to litigation to address their grievances. Rather, they must rely on a sometimes cumbersome system of administrative enforcement through the federal Department of Health and Human Services (HHS). Even if an HHS review finds that an insurance carrier has engaged in discriminatory practices, the company may be fined only a maximum of $100 per day — a tiny sum in the multimillion dollar world of insurance.

HIPAA and Privacy

In addition to its provisions on insurance coverage, HIPAA also deals with the privacy of medical records. It comes as a
surprise to many citizens to learn that there is as yet no functional comprehensive federal regulation protecting the privacy of medical information. HIPAA, which passed in 1996, stated that if Congress failed to enact a comprehensive law on medical privacy by August 21, 1999, then the Secretary of HHS would be required to issue privacy regulations. To cut a long and bitterly contentious story short, Congress was unable to enact a privacy law by the required deadline, so HHS issued regulations on medical records privacy in December 2000 that are scheduled to go into effect for large businesses in April 2003 and for small businesses the following year.\(^\text{10}\)

These HHS medical privacy regulations are of obvious relevance to the debate on genetic discrimination. While people fear discriminatory action based on their genetic traits, they also fear the unauthorized disclosure of genetic information. Here again, HIPAA appears at first glance to protect against improper practices, but on closer inspection is found wanting.

While the HHS privacy regulations are comprehensive in many respects, they are limited by the underlying statutory framework of HIPAA, which applied only to three named categories of businesses: providers (i.e. doctors' offices), payers (i.e. insurance companies) and information clearinghouses. However, medical information is increasingly becoming dispersed beyond these “covered entities”. For example, a bank may provide insurance coverage for its employees. The insurance arm of the company would thus gain access to the medical records of its enrollees. It does not take a vast stretch of the imagination to believe that this information might find its way into the hands of the employer's personnel department or even into bank's mortgage lending department.

Due to the underlying statutory constraints of HIPAA, the new HHS privacy regulations cannot directly affect employers or other non-covered entities. Instead, the regulations require any non-covered entity to enter into a contract with a covered entity promising that it will respect the privacy of information transmitted from the covered entity to the non-covered entity.\(^\text{11}\)

If this all sounds a bit convoluted, that’s because it is. Many have argued that a more straightforward system that protects medical information directly — wherever it is and whomever controls it — would be a smoother and more effective system of regulation.\(^\text{12}\)

The need to protect the privacy of medical information is particularly acute for genetic information. While knowledge that a person has hemorrhoids or herpes may be embarrassing to that individual, knowledge about genetic traits may be damaging not only to an individual but also to siblings or children. Due to the extreme sensitivity of genetic information and the possibility that improper disclosures may harm more than one individual, many proponents of legislation on genetic discrimination have sought to include privacy protections that directly protect the genetic information itself, rather than relying on the indirect protections established under the HIPAA regulations.

Federal Protections Against Genetic Discrimination in Employment

Federal Constitutional Protections

Employees of the federal government and federal contractors have additional guarantees under the U.S. (and some state consti-
tutions) that may protect them from genetic testing and discrimination on the basis of genetic information. If genetic testing is conducted without their knowledge and consent, they may claim that the testing, as well as the misuse of such information, violates their equal protection and privacy rights under the United States Constitution. If similar constitutional protections exist under the applicable state constitution, state constitutional claims may be brought as well.

Two federal employment laws, the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 (Title VII), provide limited or uncertain protections against the discriminatory use of genetic information in the workplace.

**Title VII of the Civil Rights Act of 1964**

Title VII of the Civil Rights Act of 1964 makes it illegal to “discriminate against any individual ... because of such individual’s race, color, religion, sex, or national origin.” While this legislation provides robust guarantees of equal treatment in the workplace, its applicability to genetic discrimination may be limited. Clearly, the language of the statute provides no direct protection against genetic discrimination. However, Title VII may indirectly offer some protections against discrimination on the basis of a person’s genetic traits when that discrimination disproportionately affects individuals on the basis of one of the characteristics named in the Act.

For example, the genetic mutation associated with Tay-Sachs Disease is found most commonly in persons with an Eastern European Jewish ethnic background. If an employer were to selectively refuse to hire carriers of the Tay-Sachs mutation, this action would have a disproportionate effect on people with a specific national or ethnic origin. In this limited circumstance, the individuals experiencing this discrimination might have a claim under Title VII.

**The Americans with Disabilities Act**

With regard to genetic discrimination, the ADA provides almost the inverse of the protections afforded under Title VII. While the protections of Title VII are well established but limited in scope, the protections of the ADA are potentially broad but extremely uncertain.

On its face, the ADA provides comprehensive protections to persons experiencing workplace discrimination on the basis of an actual or perceived disability. The statute establishes a broad, three pronged definition of disability. Under the ADA the term “disability” means:

A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual;  
B) a record of such an impairment; or  
C) being regarded as having such an impairment.

It is this third “prong” of the definition that might reasonably be read to provide protection for persons who are denied jobs or promotions based on their genetic traits. After all, a person who is denied a job because an employer thinks they may get sick or become disabled is, in effect, being “regarded as” disabled. The Equal Employment Opportunity Commission (which is responsible for enforcing and providing guidance on the employment provisions of the ADA) adopted this reading of the statute in an interpretive guidance that it issued
in 1995. In this guidance, EEOC declared that it considered the ADA to cover discrimination based on “genetic information relating to illness, disease or other disorders.” Such guidance does not have the force of law, however, and may be disregarded by courts.

There is increasing evidence, however, that the Supreme Court does not share the EEOC’s expansive view of genetic discrimination under the ADA. The case that bears most directly on the Court’s views in this area may well be *Bragdon v. Abbott*. Sidney Abbott was an HIV-positive woman who sought dental treatment from Randon Bragdon. He essentially refused to provide such services and Abbott sued, citing the ADA’s protections against discrimination on the basis of actual or perceived disability. One possibility open to the Court was to determine that Abbott had suffered discrimination because she was “regarded as” being disabled by Dr. Bragdon, and would thus qualify as disabled under the third prong of the ADA definition.

Instead, the Court held by a 5-4 majority that Abbott was actually disabled under the first prong of the ADA definition despite the absence of any clinical symptoms of AIDS. In its decision, the Court described in microscopic detail the cellular effects of HIV infection to conclude that Abbott was disabled *on a cellular level* by her HIV infection, despite the absence of any macroscopic symptoms of AIDS. The Court further held that since HIV can be transmitted from mother to child, Abbott was effectively limited in the major life activity of reproduction. In arriving at this conclusion, the Court established the theory that a person did not have to be physically unable to perform a “major life activity” in order to be “substantially limited.” Clearly, HIV-positive women can and do bear children, yet the Court found that the risk of maternal HIV transmission was of sufficient magnitude as to constitute a “substantial limitation” to Sidney Abbott’s ability to reproduce.

In many ways, a genetic mutation that has not resulted in any macroscopically observable symptoms of disease would fall squarely within the type of reasoning that Court used in the *Bragdon* case to determine that Abbott was actually disabled. Like an HIV infection, a genetic mutation may produce no macroscopically observable symptoms for many years—or indeed forever. Yet even in the absence of symptoms of disease, a mutated gene usually results in a mutated protein product of that gene, which can in turn cause abnormalities of cellular function. Most people would probably not think of these microscopic abnormalities as a “disability”, yet this is precisely what the Court decided they were in the *Bragdon* decision. Since a genetic mutation has a 50% chance of being transmitted from parent to child, one might plausibly argue that if Sidney Abbott is limited in her major life activity of reproduction by HIV infection, then so too is anyone with a genetic mutation that might lead in future to disease. Thus, in deciding *Bragdon* the way it did, the Court may have opened the door to an expansive treatment of genetic discrimination as a violation of the ADA under the “actual” disability prong.

Chief Justice Rehnquist appears determined to slam that door shut. In a dissenting opinion in the *Bragdon* case, Justice Rehnquist explicitly recognized that the Court’s reasoning “taken to its logical extreme, would render every individual with a genetic marker for some debilitating disease ‘disabled’ here and now because of
some possible future effects. This conclusion comes amid an extensive argument faulting the Court’s reasoning in the case. It seems clear that the Chief Justice would in no way support the idea that having a genetic mutation in the absence of macroscopically observable symptoms constitutes an actual disability under the terms of the ADA.

In addition, since Bragdon, the Supreme Court has taken a less, rather than more, expansive reading of the ADA. In 1999, the Supreme Court adopted an extremely narrow reading of the ADA definition of disability in three decisions that were issued simultaneously: Sutton v. United Airlines, Murphy v. United Parcel Service, and Albertsons v. Kirkengburg. These decisions excluded many individuals, in particular those who utilize measures that mitigate the effect of a disability, from the protections of the ADA.

As a result of the Supreme Court’s trend toward contracting, rather than expanding, the definition of disability under the ADA, it is extremely uncertain whether courts will find that genetic discrimination is prohibited by the ADA.

Finally, earlier this year, the EEOC and the Brotherhood of Locomotive Engineers challenged Burlington Northern Railroad’s genetic testing of employees who had sought workers compensation for carpal tunnel syndrome. A settlement was reached, which interestingly included Burlington Northern’s agreement to support legislation limiting the use of genetic screening in employment decisions.

State Law on Genetic Discrimination

To fill the void created by the absence of clear protections at the Federal level, many states have enacted laws that seek to prohibit genetic discrimination in insurance and/or employment. To date, 28 states have passed laws on genetic discrimination in employment and 34 have prohibited insurance discrimination. These laws cover the legal waterfront from comprehensive and far-reaching protections to uncertain and ineffective prohibitions.

Among the former category is the Massachusetts law against genetic discrimination enacted last year, which added genetic information as a prohibited basis for discrimination under its general state civil rights law. An even more expansive view of citizens’ rights to control their genetic information was enacted in Oregon, where individuals now have an explicit property right to their genetic information. Thus, the improper disclosure of genetic information becomes not a violation of some complex genetic discrimination statute, but rather a straightforward misdemeanor that can result in a year in the county jail.

However, most state laws on genetic discrimination are much less far-reaching. Some states cover insurance but not employment, while others do the reverse. Many states exclude family medical histories from their definition of genetic information or include only the results of tests that are performed with announced intention of detecting genetic mutations. Regardless of the technical aspects of any particular state law, there is necessarily a significant gap in any state’s ability to deter genetic discrimination. Although the regulation of insurance is generally a state responsibility under the 1948 McCarran-Ferguson Act, employer-purchased plans were exempted from state regulation by the Employee Retirement Income Security Act of 1974. Under this Act, no state may regulate the type of insurance plans typically used...
by employees of large corporations. The responsibility for a truly comprehensive law on genetic discrimination lies, therefore, with the Congress in Washington.

Competing Views on National Protections

Legislation on genetic discrimination has been introduced into both chambers of Congress. Senator Tom Daschle of South Dakota has introduced a bill to prohibit genetic discrimination in health insurance and employment, and similar legislation has been introduced in the House by Representative Louise Slaughter of New York.28

The Daschle and Slaughter bills consist of four major elements. First, they prohibit the use of genetic information in setting rates or establishing criteria for eligibility in health insurance. Second, they ban the use of genetic information in setting conditions of employment. Third, the legislation prohibits unauthorized disclosure of genetic information. Finally, the two bills establish new procedures for enforcing the protections contained in the legislation. In addition to existing mechanisms of administrative enforcement, the legislation permits persons whose rights have been violated to seek redress in the courts.

A bill introduced Senator Olympia Snowe of Maine and Senator Jim Jeffords of Vermont provides an alternate approach to genetic discrimination legislation.29 The Snowe-Jeffords legislation covers discrimination in health insurance, but not employment. Rather than providing privacy protections for genetic information in statute, the Snowe-Jeffords bill relies on holders of that information to adopt and abide by their own privacy protection policies. Finally, the

Snowe-Jeffords legislation relies solely on administrative action for enforcement rather than establishing any individual right to sue.

Although it may seem that proponents of the two competing bills sit rigidly on opposite sides of an unbridgeable chasm, the political reality is far more fluid and the chasm may prove to be a far narrower gap than it appears.

Outlook for Future Action

The political profile of genetic discrimination legislation has risen steadily in recent months. After Senator Daschle became Majority Leader of the Senate in May, he used his first full press conference to urge action on his genetic non-discrimination legislation. President Bush spoke on the need for new legal protections against genetic discrimination in insurance and employment in a radio address the following month, while a steady stream of hearings on the issue have put genetic discrimination on the political front burner in both the House and the Senate. The heat from that burner may be enough to provoke a search for compromise between the supporters of the competing bills on genetic discrimination now before the Congress. Agreement is needed in four areas.

First, differences in the scope of the two bills must be resolved. The Daschle legislation deals with both health insurance and employment while the Snowe-Jeffords legislation addresses only insurance. The scope of the Snowe-Jeffords legislation was confined to health insurance largely due to the belief that the ADA already protects against genetic discrimination in employment. However, recent Supreme Court decisions have so eroded confidence that there is a growing consensus that explicit legal pro-
tections against genetic discrimination in the workplace are needed.

Second, the Daschle and Snowe bills differ in the way they protect the privacy of genetic information. The former provides explicit protections while the latter relies on adherence to companies’ own policies. However, the recently issued HHS rules on medical records privacy provide – for the first time – national protections for medical privacy, although they cover employers and other holder of medical information only indirectly. Significantly, the new regulations provide a commonly – if grudgingly – accepted privacy standard. Applying these regulations directly to employers and other holders of genetic information might serve as an acceptable middle ground between the two positions.

Third, the bills differ in their definitions of just what is “genetic” information. At the heart of these differences is the fact that a genetic mutation can be detected not only by directly analyzing the DNA sequence of a gene, but also by examining the protein product of that gene or even by testing for an alteration in its function. Drawing a mutually acceptable boundary between what is and is not genetic information deserving of legal protection will be a complex and painstaking process – but one that is central to effective legislation.

The two sides are farthest apart on the issue of how to enforce the protections established by the legislation. The Snowe-Jeffords bill relies on administrative action by Federal agencies to enforce its provisions, while the Daschle and Slaughter bills provide a right to individual legal action. There is no easy middle ground between these two positions, although the many state laws on genetic discrimination provide possible models for discussion.

While the differences between the two positions might ordinarily be grounds to administer last rites to a bill, there are distinct signs of life coming from the genetic discrimination legislation. A desire for action has been voiced strongly by the President, the Majority Leader of the Senate and the Chairman of the Senate committee of jurisdiction. In the House, a majority of members have agreed to cosponsor Rep. Slaughter’s bill. This rare alignment of the political stars has created a climate in which there is considerable pressure to reach a mutually acceptable legislative solution to the problem of genetic discrimination. What that solution will be (or even whether it will materialize) is hard to predict with any confidence at present. But it’s safe to say that the issue of genetic discrimination will remain at the forefront of the Congressional agenda for some time to come.

Endnotes


2 Results reported by national human Genome Research Institute and displayed at http://www.nhgri.nih.gov/HGP/Reports/genetics_workplace.html.


5 Lerman et al. “BRCA1 testing in families with hereditary breast-ovarian cancer. A prospective study of patient decision making and outcomes.” *JAMA* 275:1885-1892. (1996) Study subjects were administered the test and the rate at which they accepted or declined to learn the
results were quantified.


7 “Public Attitudes Toward Medical Privacy” Submitted to The Institute for Health Freedom September, 2000 by The Gallup Organization, 47 Hulfish Street Princeton, New Jersey 08542

8 Results displayed at http://www.cnn.com/2000/HEALTH/06/26/human.genome.05/


10 Synopsis provided at http://www.hcfa.gov/medicaid/hipaa/adminsim/privacy.htm


12 For example, see Hodge, J., Gostin, Jacobson, P. “Legal issues concerning electronic health information.” JAMA 282:1466-1471; (1999)

13 Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260, 1271 (9th Cir. 1998).

14 Ibid.

15 Text of Title VII of the Civil Rights Act displayed at http://www.eeoc.gov/laws/vii.html

16 Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F. 3d 1260, 1272-73 (9th Cir. 1998).

17 Text of the ADA displayed at http://www.eeoc.gov/laws/ada.html


19 Opinion of the Court Supreme Court of the United States, No. 97–156.


24 Prior to the Sutton trilogy, a federal appellate court held that the ADA did not limit the pre-employment genetic testing conducted by the employer in that case and that the genetic tests were conducted in compliance with the ADA’s restrictions on disclosure and use. See Norman-Bloodsaw v. Lawrence Berkeley Lab., supra., fn. 17.


26 Oregon Revised Statutes, 1999 Edition Chapter 659 Section 715; displayed at http://landru.leg.state.or.us/ors/659.html

27 ibid. Section 990.

28 Daschle bill is S. 318; Slaughter bill is H.R. 608; text of legislation available at http://thomas.loc.gov/

29 Bill is S. 382; text of legislation available at http://thomas.loc.gov/

TV, Drugs, and Health Care: Evaluating and Combating the Influence of Direct-to-Consumer Advertising on the Prescription Drug Market

Gwyneth Card

The recent increase in direct-to-consumer advertising of prescription drugs is something of a controversy amongst physicians, managed care organizations, and consumer groups. The skepticism of these groups is compounded by the fact that prescription drug costs are skyrocketing, and evidence suggests that the marketing of brand-name drugs to consumers is playing a large role in this increase in drug spending.

Whether or not prescription medication should become a market commodity is a question that it may be too late to address. But what policies and market structure will be established to ensure that the correct medicines are taken by patients at an affordable price still remain to be determined. This paper examines the role of direct-to-consumer (DTC) advertising in the current crisis of rising healthcare costs. While many are clamoring for federal intervention with price controls, an equally important mechanism for lowering drug prices and providing patients with the best medical treatment is providing consumers and physicians with more comprehensive and digestible information on the wares of the emerging drug market. If we are going to treat patients as consumers, as many insurance companies and HMOs already do, we must help them to be empowered and informed consumers.

Rising Costs

There is no denying the economic truth that healthcare costs are on the rise. A 1999 report from the Health Insurance Association of America (HIAA) estimated that, while 1999 healthcare expenditures would exceed

Gwyneth Card graduated from Harvard College in 2001. She is currently a graduate student in neurobiology at the University of Cambridge.
DATA FROM THE HEALTH CARE FINANCING ADMINISTRATION (Table 1) INDICATE THAT SPENDING ON PRESCRIPTION DRUGS NEARLY DOUBLED FROM 1993 TO 1998 (FROM $50.6 BILLION TO $93.4 BILLION SPENT), AND THAT DRUG SPENDING CONTINUES TO INCREASE RAPIDLY. A SEPTEMBER 1999 HIAA STATEMENT REPORTED THAT THIS INCREASE IN DRUG SPENDING WAS OUT OF PROPORTION WITH OTHER HEALTH COSTS SUCH AS HOSPITAL AND PHYSICIAN SERVICES, WHICH INCREASED ONLY 3-5% ANNUALLY (1995 THROUGH 1999) WHILE PRESCRIPTION DRUG EXPENDITURES INCREASED 10-14% PER YEAR.6 MORE RECENT ESTIMATES FROM REPORTS JUST A YEAR LATER INDICATE THAT PHARMACEUTICAL SPENDING WILL CONTINUE TO HAVE DOUBLE-DIGIT PERCENT GROWTH OVER THE NEXT DECADE.7 BY 2008, HIAA PREDICTS PRESCRIPTION DRUG EXPENDITURES COULD REACH $243 BILLION AND REPRESENT 12.6% OF TOTAL NATIONAL HEALTH EXPENDITURES IN THIS COUNTRY—MORE THAN DOUBLE THE 6.1% REPRESENTED A DECADE AGO IN 1990.

WHY ARE THE COSTS OF PRESCRIPTION DRUGS RISING SO RAPIDLY? HIGH COSTS ARE LIKELY INDICATIVE OF THE “VALUE” PLACED ON NEW MEDICINES. PHARMACEUTICAL COMPANIES ARGUE THAT HIGH PRICING IS NECESSARY TO RECOVER EXPENSIVE RESEARCH AND DEVELOPMENT COSTS, AND TO PROVIDE INCENTIVE FOR FURTHER INNOVATION. PhRMA REPORTS THAT IT CURRENTLY TAKES 12-15 YEARS TO BRING A NEW DRUG TO MARKET, AT AN AVERAGE COST OF $500 MILLION DOLLARS.8 HOWEVER, THE COST OF RESEARCH IS MORE THAN MATCHED BY THE DOLLARS THAT THE DRUG INDUSTRY SPENDS ON MARKETING AND ADMINISTRATION. PUBLIC CITIZEN, A NOT FOR PROFIT CONSUMER ADVOCACY GROUP, FOUND THAT IN 1997 TWO OF THE TOP 10 DRUG FIRMS, MERCK AND PFIZER, PUT AN AVERAGE OF 11% OF REVENUE INTO R&D, AND 29% INTO MARKETING AND ADMINISTRATION. MOST STUDIES THAT HAVE EXAMINED MARKETING FIND THAT INCREASING SPENDING ON DIRECT-TO-CONSUMER (DTC) ADVERTISING IS ONE OF THE PRIMARY CAUSES OF ESCALATING DRUG COSTS.

CAUSES OF INCREASING DRUG COSTS

THE FOLLOWING REASONS ARE OFTEN CITED AS CAUSES OF INCREASING EXPENDITURE ON PRESCRIPTION DRUGS:

- NEW MEDICINES. PhRMA REPORTS THAT 40 NEW

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription drug expenditures($B)</td>
<td>$50.6</td>
<td>$55.2</td>
<td>$61.1</td>
<td>$69.1</td>
<td>$78.9</td>
<td>$93.4</td>
</tr>
<tr>
<td>Percent increase over previous year</td>
<td>8.7%</td>
<td>9.0%</td>
<td>10.6%</td>
<td>13.2%</td>
<td>14.1%</td>
<td>18.4%</td>
</tr>
</tbody>
</table>


$1.1 trillion, almost 14% of the gross domestic product (GDP), by 2008 healthcare expenditures would double to $2.2 trillion, or 16.2% of the GDP.1 No other country spends this much on health care. Furthermore, studies by the Health Care Financing Administration (HCFA), Blue Cross Blue Shield Association (BCBSA), the National Institute for Health Care Management (NIHCM), the Access and Affordability Monitoring Project (AAMP), and the Pharmaceutical Researchers and Manufacturers of America (PhRMA) are all in agreement as to where to place much of the blame for these rising costs: the escalating costs of prescription drugs.2,3,4,5

Why are the costs of prescription drugs rising so rapidly? High costs are likely indicative of the “value” placed on new medicines. Pharmaceutical companies argue that high pricing is necessary to recover expensive research and development costs, and to provide incentive for further innovation. PhRMA reports that it currently takes 12-15 years to bring a new drug to market, at an average cost of $500 million dollars.8 However, the cost of research is more than matched by the dollars that the drug industry spends on marketing and administration. Public Citizen, a not for profit consumer advocacy group, found that in 1997 two of the top 10 drug firms, Merck and Pfizer, put an average of 11% of revenue into R&D, and 29% into marketing and administration. Most studies that have examined marketing find that increasing spending on direct-to-consumer (DTC) advertising is one of the primary causes of escalating drug costs.
treatments were introduced to market in 1999 alone. Moreover, the FDA has lowered drug approval times significantly over the past decade. It is possible that rather than merely increasing healthcare expenses, new drug treatments may actually reduce overall expenditures on health care by reducing or eliminating need for lengthy hospital stays or invasive surgery. However, at least one study by NIHCM has indicated that physician and hospital costs continue to rise along with drug costs.9

- **Increased drug prices.** New medicines are also frequently more expensive. NICHEM (1999) reported that “new” drugs introduced after 1992 cost, on average, twice as much as older drugs.10 The retail price of these new drugs was also increasing at a higher annual rate than old drug prices, contributing to the trend of increasing drug expenditure.

- **Increased utilization.** As medication becomes available to treat a wider variety of medical conditions, prescription drugs are increasingly becoming the treatment of choice, reflecting a shift away from hospitals and other services. Thus, while there were 1.9 billion prescriptions filled in 1993, there were a startling 2.5 billion prescriptions filled in 1998. In some therapeutic categories, such as antidepressants, cholesterol reducers, and oral antihistamines, the number of prescriptions more than doubled in this 5-year span.11 The demographic trend toward an older population is also seen as a cause of increased drug utilization, as the elderly are more at risk for conditions requiring prescription medication.

- **Distanced consumers.** The shift to managed care structures with low co-payments for doctors visits and medication, has insulated many patients from the actual costs of care. Therefore, patients are more likely to accrue large costs by making frequent physician visits or choosing costlier drugs that are not necessarily more effective. The introduction of multi-tier pricing schemes which charge patients a higher co-payment for brand name or non-formulary drugs is a recent and growing effort to make consumers more price sensitive when choosing drugs.

- **Intellectual property rights.** Patents on new brand-name drugs give pharmaceutical companies a temporary monopoly on their product for the first few years after FDA market approval.

- **Direct-to-consumer advertising.** The introduction of direct-to-consumer (DTC) advertising in the mid-eighties and its rapid growth in the late nineties, of course, have intensified the dramatic increases in almost all of these factors.

## DTC Advertising

**A brief history**

Before the 1980s, direct-to-consumer advertising of prescription pharmaceuticals was basically non-existent and drug companies invested in detailed promotion of their products to physicians and healthcare professionals instead of patients. Under the 1938 Federal Food, Drug, & Cosmetic Act, the Food and Drug Administration (FDA), a federal agency under the Department of Health and Human Services, regulated labeling of prescription products, including all packaging, inserts, brochures, and toll-free hotline information. In 1962, new legislation called the “Drug Amendments,” gave the FDA jurisdiction over advertising of prescription drugs as well (over-the-
counter advertising still remained under the scrutiny of the Federal Trade Commission (FTC). Under these early FDA regulations, drug labeling was considered inappropriate if it was “false or misleading” and was required to include a “brief summary” of drug side effects, contra-indications, and effectiveness as approved by the FDA during clinical testing.

Under these rules, “product-claim” ads that advertised both a brand-name drug and the medical condition for which it was appropriate were required to include all labeling information, including a “brief summary” in which a “fair balance” of drug benefits and risks had to be presented. Pharmaceutical companies could get around the cumbersome requirement of including lengthy fine print “summaries” by advertising either their brand name alone, with no connection to the condition it treated, or the medical condition alone, without mention of their brand-name. Needless to say, these measures heavily discouraged DTC advertising since including “brief summary” information added costly pages to print ads and was virtually impossible to present in a 30 second TV or radio promotion, and advertising either brand name or medical condition alone left consumers confused.

Still, early direct-to-consumer print advertising in the early 1980s proved to be so successful that the FDA was forced to call a voluntary moratorium on the growing number of DTC ads in 1983 until the effect on consumers could be studied. The consumer surveys conducted by the FDA found that most consumers were eager for more drug information and would regard DTC ads from pharmaceutical companies favorably. In 1985 the moratorium was lifted and DTC ads proliferated but were still limited mostly to print since regulations made advertising in other media troublesome.

In August of 1997, in response to growing complaints from drug advertisers and the generally positive response of the public to DTC ads, the FDA drafted new guidelines for direct-to-consumer broadcast advertisements. Finalized in August 1999, these new guidelines significantly relaxed the old restrictions by allowing advertisers to satisfy the “brief summary” requirement with a “major statement” of the most important risks involved in taking their product along with “adequate provision” for conveyance of approved product labeling, usually fulfilled with a toll-free phone number or web address.

The explosion in DTC advertising was immediate. The NIHCM reports that after the relaxed FDA regulations, spending on DTC ads had increased from $55.3 million in 1991 to $1.3 billion in 1998, a 20-fold change. A Blue Cross and Blue Shield Association report adds that DTC spending increased another 40% in 1999, reaching $1.8 billion in total advertising costs. The increase in direct-to-consumer advertising is a direct result of FDA regulation relaxation allowing DTC ads to move into television media. In 1996, for example, right before the new guidelines, TV ads constituted 11.2% of the pharmaceutical industry DTC spending. By 1999, TV ads had increased to 61% of total DTC costs.

How DTC advertising contributes to increasing drug costs

• New medicines. To get the most return on their investment, pharmaceutical companies often focus DTC ads primarily on new medicines early in their patent life.
A FDA study of 1,081 consumers indicated that DTC is a successful means of creating demand for these new medicines. 25% of those who had seen an ad, for example, reported asking their doctor about a medical condition for the first time as the result of the advertisement, and 13% of those asked for the drug by name, with over 6% actually receiving prescriptions for their request. 85% of those surveyed also said that seeing an ad had made them aware of new available drugs.

- **Increased drug prices.** Direct-to-consumer advertising increases drug prices by increasing demand for brand-name drugs that are not necessarily more effective than their generic counterparts, but are usually more expensive. Among oral antihistamines, for example, the heavily marketed brand-name drugs Claritin and Allegra controlled over 70% of the market in 1998, and Claritin oral cold preparations alone constituted 78.9% of the market in decongestants, despite being over 280% more expensive than older treatments.15

- **Increased utilization.** Not only has DTC advertising been shown to create a market for new medicines and thus increase utilization of medication via treatment of new conditions, direct-to-consumer advertising has increased the consumer base for previously available treatments by encouraging patients to go and see their doctors. According to data from the Scott-Levin marketing study presented by NIHCM in July 1999, patient visits for heavily advertised conditions increased by 11% between January and September 1998, while the number of total office visits rose only by 2%. Specifically, visits for an elevated cholesterol level increased by 19% and visits concerning hair-loss treatment increased by 30% in this time period.

The degree of growth in these two figures mirrors the degree of advertising spending on drugs related to these conditions. Lipitor, a cholesterol-reducing drug, was promoted with $55.5 million in 1999, making it the 6th most promoted drug of that year. Propecia, a medication for male-pattern baldness, cost $71.1 million to promote and was the 4th most promoted drug of 1999. Furthermore, studies indicate that DTC advertising targets chronic illnesses that are likely to involve prescriptions with ongoing refills (the allergy medication, Claritin, for example, topped the list as 1999’s most heavily promoted drug, accounting for about 9% of all DTC spending for that year). Many of these drugs treating chronic illnesses, such as arthritis or osteoporosis medications, will be required by a disproportionately large number of elderly patients. As already mentioned, the American population on average is getting older as the “baby boom” generation ages, thus leading to greater drug utilization by increasing the number of patients at a high risk for well-advertised drugs.

- **Distanced consumers.** DTC advertising and promotion of brand-name drugs play off the lack of consumer price-sensitivity. Faced with the same co-payment of $5 or $10 to pay for a prescription of a well-marketed and familiar brand-name drug or a generic equivalent, few patients would choose the less familiar option. Yet savings from generic drug substitution could save third party payers 30-60%. Some health care insurers have moved to a three-tier prescription drug co-payment
system in which patients pay more, say $25, for the most expensive brand-name drugs, according to drug price. However there is still no evidence to suggest that such schemes provide enough incentive to the patient to significantly reduce prescription drug spending. Even though generic drugs must all be approved by the FDA and are only marketed if declared "bioequivalent" to brand-name drugs in active ingredient, dosage (bioavailability measured by blood plasma content after a certain time period following drug administration), and major side effects, there is still wariness of generics among consumers.

Consequences of DTC Advertising—Who Benefits and Who Pays

The burden of mounting healthcare costs associated with increased spending on prescription drugs has fallen squarely on the shoulders of employers and health insurance providers. From 1992 to 1997, third-party drug spending increased 123% from $18 billion to $40 billion, while consumer spending increased only 13% from $20 billion to $23 billion.16

Drug plans with high percentages of retirees were hit especially hard, and in 1999 paid out 30% of their total benefits in prescription drug subsidies. This was much higher than the 13% paid for drugs by organizations insuring younger populations. Senior citizens are the consumer group most affected by rising drug costs as they are the largest users of prescription drugs. For example, a physician visit results in a drug prescription nearly 70% of the time for patients over 65, compared to 54% for 15-44 year-old patients (Study Examines Prescription Drug Data, Employee Benefit plan review, 1992).17

After an AARP study found that elderly consumers are less savvy interpreters of prescription drug ads than the general population (e.g. less likely to understand that the product is only available by prescription and less likely to notice "small print" warnings), the AARP declared that a "medication information gap" was left unfilled by DTC ads, and that such ads were of "limited educational value for customers, especially older consumers."18

PhRMA defends drug ads, saying that, while they are not meant to be a consumer’s only source of information, they benefit all patients by increasing awareness of new treatments and stimulating conversation with physicians or other healthcare providers who still must act as intermediaries between the patient and the drug. As mentioned previously, consumers who have seen an ad are more likely to ask their doctor about a drug during a check-up or to schedule an appointment about a new treatment. The AARP found, however, that only 54% of consumers talked to their doctor about risks and side effects when getting a prescription and that this problem is exacerbated among elderly patients. So healthcare professionals are not, in the majority of cases, providing additional information to balance pharmaceutical companies’ presentation of their product. Furthermore, rather than providing a safety barrier between patient and drug, many doctors are eager to please the patients by prescribing the drug requested. In 1997, for example, 86% of Claritin requests were honored according to a Prevention Magazine study. Also, in cases of over-prescribed drugs where a specific treatment for a patient can be considered unnecessary,
doctors most often cited patient pressure as the cause of over-prescription. Despite high levels of compliance with patient requests for advertised prescription drugs, BCBSA reports that most physicians are still distrustful of DTC advertising, and a 1998 IMS Health survey of 2,000 physicians found that 64% wanted to see a decrease in DTC advertising.

Proposed solutions from the main players

One reason prescription drug price control has been so difficult to achieve is that there are numerous sides to the issue, each with a different agenda. The “main players” affected by and/or involved with the cost of prescription drugs include consumers (different segments of which are represented by consumer interest lobby groups such as the AARP), pharmaceutical companies (whose interests are expressed by PhRMA), employers and HMOs paying third-party costs (the most vocal of which has been Blue Cross and Blue Shield), and finally the government (primarily the FDA). Each of these groups has a different perspective on how they would like to see the market for prescription drugs changed.

• Consumer groups. The main concern of these groups is protecting consumers from misinformation that could lead to harm or drug costs so high that they prevent patients, especially the uninsured, from obtaining the medication they need for a healthy, comfortable lifestyle. The AARP’s main focus is in obtaining a drug benefit through the Medicare coverage provided by the government to all senior citizens. The AARP sees this legislation as not only an ethical requirement to ensure that those who need prescription drugs most can afford them, but also as a good way to cut down on drug costs by obtaining wholesale government prices for the largest prescription drug consumer group. Public Citizen, a lobby group for the AARP, claims such a benefit would reduce drug company revenues by only 3.3 percent. By contrast, Affordable Medication for Americans (AMA), another lobby group for consumers, thinks that change should come from international treaties that would more fairly share drug costs between wealthy nations, including Canada and European countries.

• Pharmaceutical companies. The main lobbying effort by pharmaceutical companies has been against the implementation of federal price controls. PhRMA argues that our American healthcare system, “one of the best in the world,” is wedded to free market principles. The stated goal of most companies is to provide high-quality, effective drugs to the patients that need them, but they argue that they can only continue to produce some of the best prescription drugs in the world in an environment where their industry remains profitable.

• HMOs and health insurance providers. Managed care organizations have paid the bulk of the increasing costs in the first few years of what Blue Cross and Blue Shield has called a “healthcare crisis.” These organizations are in favor of reducing costs by whatever means necessary. Many have already altered drug benefit plans since 1997. According to a report called “Prescription Drugs: Cost and Coverage Trends” from the Health Insurance Association of America (HIAA), in 1998, 35% of large employers (500+ workers) changed their drug benefits, 18% of those...
increased cost-sharing with employees and 9% modified the list of drugs they would cover. In addition, large HMOs such as BCBS have been vocal supporters of government intervention. In a letter to the Desk Officer of the Federal Trade Commission, the BCBS Office of Policy and Representation expressed strong support of FTC investigation into current practices that may unfairly slow the entrance of generic competitors into the market. Specifically, they “support the FTC's efforts to re-examine the affect of the 30-month stay and 180-day marketing exclusivity provisions of the Hatch-Waxman Act [a law credited with the creation of a viable generic drug market] on the prescription drug market,” and “FTC’s effort to gather information about potentially anticompetitive abuses of the citizen petition process.”

• The government. Government policy develops slowly and has a tendency to change with each new administration. Recent legislation, such as the 1997 FDA Modernization Act, seems to have favored the pharmaceutical companies by expediting FDA approval processes so as to lengthen the market time for a new drug while still under patent. Key decisions still need to be made, however, on whether to extend Medicare benefits and/or patent limits. One recent step in the right direction was a 1999 FDA regulation to simplify and standardize drug labeling of both over-the-counter (OTC) and prescription drugs. Under the new regulation, OTC drug labels must simplify words such as “indications” to “uses,” use larger print, and follow a standardized format for presenting required information - much like the changes recently made to nutrition labels.

Seeking Consumer-Centered Enlightenment

All players share the goal of getting the appropriate, high-quality drugs into the hands of those who need them, but no group offers an ideal solution to the critical challenge of helping patients make informed choices about prescription drugs. With “bioequivalent” generic drugs already on the market at 30-60% lower price for over half of the brand-name products, the means to control drug prices through competition rather than through direct federal regulation already exists. What is missing from this “free market” is consumer awareness. Both the reduction of out-of-pocket costs due to managed care and the lack of information sources beyond drug company DTC ad campaigns have created an insulated consumer who is aware that he has choices to make concerning his own health care, but who is unaware of all the options, risks, and benefits facing him.

Missing from the current prescription drug scene are comprehensive objective sources of comparative information. Joanne Lynne, the director of RAND Center for Care of the Dying and well-known expert on end-of-life care, has argued that a new way of thinking about quality care for chronically ill and dying patients is to treat the profile of healthcare needs for each patient, rather than merely to treat his or her disease. She has identified four different profiles which ranged from acute care only at the end of life to daily care-taking. Along these lines, the FDA might consider drug labeling that addresses patients’ medical conditions and that is sensitive to the health profiles of consumers. In addition, it would be invaluable for patients to have an easily accessible source of comparative infor-
information on prescription drugs. Perhaps such comparative information might be included on labels as well.

To further target drug spending reductions, HMOs and employers that are already spending millions in lobbying the government might find it worthwhile to conduct specific education campaigns among those for whom they provide benefits. Market research shows that pharmaceutical DTC advertising campaigns are concentrated mainly in a select number of drugs from only a few therapeutic areas. For example, in 1999, the top 25 most heavily advertised drugs were responsible for 77% of all prescription drug mass media spending, and these same top 25 drugs accounted for 40.7% ($7.2 billion dollars) of the total increase in 1999 drug spending. Drug spending over the five preceding years (1993-1998) was also concentrated among only a few categories, with 30.8% of the increase in spending from 1993-1998 due to sales increases in oral antihistamines, antidepressants, cholesterol reducers, and anti-ulcerants. These four categories included 7 of the 10 most-advertised drugs during that period: Claritin, Zyrtec, Allegra, Prozac, Zocor, Pravachol, and Prilosec, two of which (Claritin and Prilosec) were the two most heavily advertised drugs in the following year, 1999.

This concentration of advertisement and spending suggests a strategy for a counter campaign that targets only the four most costly therapeutic areas to third-party payers. Providing their beneficiaries with further information on treatments for allergies, depression, high cholesterol, and ulcers at best could reduce costs to HMOs by informing some customers about alternatives that exist. Introducing multiple treatment options should stimulate further discussion between the patient and physician to evaluate what is in that particular patient’s best interest. This would balance out the potentially manipulative effects of DTC ads on uninformed consumers. Ideally, patients would continue to benefit from advertisements that raise their awareness about treatment options while clarifying information sources provide comparative information on the drugs’ effects and help patients to make informed choices about alternative treatment options.

Conclusions

Healthcare costs are on the rise, due in large part to increased expenditures on prescription drugs. Evidence from multiple studies indicates that the rise in use and price of prescription drugs can be linked to the proliferation of television and other direct-to-consumer ads that raise consumer awareness about medical conditions and new treatments, and thereby increase consumer demand. Managed care organizations and insurance providers have been the groups most affected by these rising costs, although they will inevitably pass on the financial burden to consumers. Elderly patients, who are the largest group of prescription drug users, have also suffered from rising costs, creating further pressure for the addition of a drug benefit to the federal Medicare package. Although different interest groups look to the government, especially the FDA, to effect change through legislation that would either directly control prices or, as the drug companies hope, permit renewal of patents, the real power of the FDA to aid consumers is in continuing the improvement of objective, standardized information about all available medications in the market today. Specifically, the FDA should use its power to create a forum for consumer education that is “condition-based,” providing comparative information about available drugs to treat the patient’s illness, rather than the current “drug-
based” information, which does not provide the consumer with a useful means to evaluate the appropriateness of a particular medication for his/her condition. As generic drug alternatives are already on the market for many brand-name drugs, more informed consumers should help reduce spending on prescription drugs, especially if nominal incentives such as tiered co-payments are maintained. HMOs or insurance companies who wish to further combat the effect of DTC advertisements can provide their members with comparative information similar to that suggested for labeling purposes for the four most advertised and most costly therapeutic areas: allergies, depression, cholesterol control, and ulcers. Costs to the government and HMOs simply consist of compiling and standardizing information that already exists. Hopefully enlightened consumers could both make better decisions about their own care and help to reduce wildly escalating prescription drug costs.

Endnotes

6. “Prescription Drugs: Cost and Coverage.”
8. “Why do prescription drugs cost so much…and other questions about your medicines.”
15. “Factors Affecting the Growth of Prescription Drug Expenditures.”
17. “Factors Affecting the Growth of Prescription Drug Expenditures.”
20. “Why do prescription drugs cost so much…and other questions about your medicines.”

References

Physicians’ Asthma Prescribing Habits: Challenges to Popular Therapeutic Narratives of Racial Disparities in Asthma Morbidity

Jennifer Clark

“Black children are three times as likely as whites to be hospitalized for treatment of asthma...blacks are rushed to emergency rooms for asthma attacks at more than four times the rate (19.1 visits per thousand population) than whites (4.5 per thousand) or those of other races (3.9 per thousand).”

In the early 1990’s, partly in response to increased media and political attention to public health and diversity, a series of unrelated epidemiological studies attempted to verify and quantify newly perceived disparities between black and white health outcomes. The results of several surveys demonstrated significant disparities in health outcomes of diseases that included kidney disease, cancer, heart disease, obesity, diabetes, and childhood asthma. Statistics on childhood asthma seemed to particularly capture the media’s interest. The medical community had witnessed a disturbing 61.2% increase in asthma prevalence since the early 1980’s and an almost twofold increase in deaths due to asthma attacks. At the same time, the gap between the prevalence of asthma in whites and blacks widened, with blacks eventually making up only 12.7% of the population but 22% of asthma patients.

At first, these compelling statistics alone made up the content of most media citations on asthma. But in the last few years journalists, health advocates, and medical researchers have taken a particular interest in explaining the sources of these health outcome disparities via paradigms that diverge from the purely biomedical. This paper examines the narratives that have been developed in such articles, and uses data from the 1998 National Ambulatory Medical Care Survey to challenge widely held beliefs about the source of racial discrepancies in asthma morbidity. Explanations

Jennifer Clark is an undergraduate at Harvard College.
of elevated black asthma morbidity take one of three forms. The least politically popular narrative seeks ethnic variation in genetic predisposition to or experience of asthma to portray asthma as a disease similar to sickle-cell anemia in its ethnically unequal distribution. Other accounts seek to correlate asthma morbidity to another condition or situation which is distributed unequally among blacks and whites – accounts in this vein, in general, seek to explain a great degree of minority health disparities in one illness by pointing out that the difference actually reflects a disparity in another statistical reality or condition that has a nearly 1:1 comorbidity relation to asthma.

Accounts in the third vein identify culturally motivated patient noncompliance and/or physicians’ unwitting ethnic insensitivity as the source of discrepancies in the experience of asthma. The strategy of narratives in this category is to identify a particular cultural practice among black children or their parents that leads to noncompliance with therapy and then provide some judgment of how the cultural practice can be adjusted to be more in line with biomedical practice. Two oft-cited strategies are educational programs for minority families and cultural competency training for physicians. This latter narrative is capturing public imagination and discourse and gradually overshadowing earlier comorbidity and ‘ethnic genetic variation’ narratives to become the focus of political and medical programs to eliminate racial health outcome disparities.

The popular explanation for differing rates of asthma morbidity focuses on cultural and social factors leading to disparate patient reactions to uniformly administered medical care. If this narrative accurately portrays the patient/doctor/society interaction that leads to increased asthma morbidity in black children, then statistical surveys from the late 1990’s should show physicians providing relatively equal medical care to both black and white patients (especially when controlled for certain socioeconomic factors). Analysis of self-reported data on the prescribing habits of physicians who participated in the 1998 National Ambulatory Medical Care Survey, however, indicates large disparities in the primary drugs prescribed for asthma patients. Black asthma patients are routinely given fewer prescriptions that white asthma patients. Surveys previously interpreted to indicate patient non-compliance or voluntary underuse of medications may actually have been recording differences in the type and number of drugs prescribed to white and black asthma patients. The source of explanatory theories of these discrepancies – that is, medical and public health researchers – may be largely responsible for the failure to yet turn the statistical eye on physician behavior or consider the possibility that, even in the 1990’s and today, medical care might be provided unequally to black and white asthma patients.

**Genetic Variation Narratives**

The number of studies which have seemed to show statistically significant variations in genetic predisposition to asthma are few, although such studies continue to be scientifically popular to the present despite their politically incorrect implications. Notably, a May 2000 study in *Chest* concluded, based on a variety of genetic tests, that black children could be genetically predisposed to develop asthma. A recent study by Xu et
al. supports this data, demonstrating small but statistically significant differences in asthma susceptibility across families and ethnic groups. In general, however, politically popular scientific narratives that seek to show greater genetic variation within, rather than across, racial groups are fairly successful in demonstrating that genetic differences between races can account at most for only a fraction of disparities in health outcomes.

Comorbidity Narratives

Comorbidity is a medical term that refers to certain illness contributing to or being partially caused by other illness – for example, diabetes, heart disease and obesity are all considered comorbid conditions. In the case of racial disparities in asthma morbidity, the comorbid conditions may be either medical or socioeconomic/geopolitical conditions. Arruda et al., in their review of cockroach allergens and asthma, ascribe heightened asthma morbidity to cockroach allergen exposure within the first three months of life, postulating that poorer housing conditions among African Americans is the true source of discrepancies in asthma morbidity. Brooks et al. report a strong correlation between very low birth weight and severe asthma symptoms, pointing to a greater prevalence of very low birth weight babies among blacks as a major determinant of disparity.

Popular media coverage often exaggerates the extent to which such studies invalidate discrimination or substandard care hypotheses. For example, studies throughout the 1990’s, including an early study by Weitzman et al. and a recent study by Fagan et al., have reduced or eliminated racial disparities in asthma prevalence by controlling for socioeconomic status. A May 1999 survey published in The Journal of Asthma examined the distribution of asthma hospitalizations in New York state by zip code and concluded that “rates of hospitalization because of asthma were generally higher in the zip codes with higher proportions of poverty, unemployment, poorly educated residents, African-Americans, and Hispanics.” The New York Times’ take on this study, however, places the authors in opposition to the earlier literature cited in their article and suggests that the authors are dismissing earlier theories on substandard minority care, lack of access to care, and environmental factors due to lack of evidence. The concentration of hospitalizations in poor zip codes of New York City is presented as data that explains away the results of earlier studies, rather than as data that contributes to a more complete understanding of the dynamic of asthma morbidity (the authors’ stated intent).

Similarly, in a fall 2000 study with similar methodology, lead author Andrew Aligne specifically stated that he hoped to challenge public perceptions “that asthma is something that’s related to race, in the way sickle cell anemia is” but the lead-in of the same article in which this comment appeared gave a much more simplified view of the dynamic:

Federal studies have found a 20 percent higher incidence of asthma in black children than in whites. But a new study suggests that this may be missing the point.

Again, the purpose of the study moves from clarifying and enhancing earlier studies of race and asthma to dismissing them as beside the point.

Studies on asthma prevalence by zip code led to hypotheses that location of resi-
Evidence was a greater risk factor for asthma than socioeconomic status. A September 2000 study by Aligne et al. revealed that both urban poor and urban non-poor children were at a greater risk of developing asthma than were non-urban poor children. Data from Lamphear et al.’s March 2001 Pediatrics article seems to support Aligne’s theory. It is important to note that these studies all focus on eliminating racial disparities in prevalence by controlling for socioeconomic or geopolitical factors. However, equalizing prevalence does not necessarily equalize the burden of disease. Within socioeconomic and geopolitical groups, blacks are more likely to have acute asthma attacks, more likely to be hospitalized for asthma, and more likely to die from a severe asthma episode. In order to account for this unequal burden of disease, explanatory narratives must move beyond simple comorbidity explanations of disparities in prevalence.

The Compliance Narrative

Compliance narratives generally take the forms of inquiries into cultural or ethnic differences that may serve as barriers to appropriate medical care. In medical literature, this quest has often taken the form of discussion of ‘cultural competence,’ the underlying idea of which is that noncompliance is largely motivated by cultural differences between physicians (and biomedicine in general) and patients. The idea of cultural differences affecting the way patients react to the self-care demands of biomedicine is a theme that seems to have captured public and professional imagination recently. Anne Fadiman’s The Spirit Catches You And You Fall Down, a text chronicling the epilepsy experienced by a Hmong child constantly slipping through what Harvard professor Mary Jo Good has called the “biomedical embrace” – and perhaps one the first and longest media investigations into cultural competency – has enjoyed widespread popularity and is in large part responsible for bringing issues of cultural barriers in medical care to public attention. Medical societies, medical schools and hospitals across the country have been rushing to establish committees on cultural competency and to investigate and inform the extent to which physicians are delivering culturally competent care. The AMA’s extensive investigations and reports on cultural competency clearly attest to this popularity. The purpose of these committees, however, is not to advise physicians on how to better or more equitably deliver biomedical care, but how to structure their dialogue with patients to elicit desired reactions and compliance. In other words, the patients are portrayed as mixed up or chronically misinformed and physicians are trained in how to mediate this issue.

As early as 1993, researchers were investigating potential ways that black patients’ attitudes toward asthma might contribute to their increased rates of acute asthma episodes. Although the study in question was more interested in correlating attitudes with socioeconomic and other factors, later studies became more specifically focused on identifying black patients’ (and their parents, in the case of children) misperceptions as the source of asthma disparities. An early 2000 study sought to explain higher functionality morbidity in black asthma patients in terms of “caretakers [overestimating] the level of adolescent involvement in asthma self care.” In this study, and in an earlier study on perceived control of asthma, black patients were portrayed as ignorant of or
unable to adhere to the advice and information physicians had clearly provided.  

The attitudes toward racial disparities presented in these studies carry over into the media investigations of disparities in health outcomes. Articles constantly stress the difficulty of teaching black patients how to manage asthma:

Two years ago, federal health officials recommended the daily use of inhaled corticosteroids to control asthma in people with moderate or severe disease. Experts say the medicines can reduce emergency room visits, hospitalizations and deaths. But only half the eligible patients use them.

The implication here is that all eligible patients are being prescribed inhaled corticosteroids, but that not all carry through the physicians’ orders to fill the prescription or use the medicines regularly. Although the article goes on to briefly suggest that not all physicians may have accepted the idea of long-term asthma management (and thus may in general prescribe short term over long term therapies), the remainder of examples cited portray black parents who, for a variety of imputed reasons, did not buy recommended medicines and continue to treat their children’s asthma through acute care and hospitalization.

Other articles on recent increases in asthma point to the slow adoption of new standards expressed in a 1997 federal document on asthma management which portray the disease as chronic rather than as a string of acute episodes: “what we don’t want is for families to have to go to the emergency room and hospital.” Some articles focus on success stories - tales of individual parents whose children once had their asthma treated through emergency room visits but who were educated on the correct way to manage asthma. These accounts seem to suggest a sort of stubbornness or latent skepticism in the patients and their guardians. A mid-1999 Washington Post article cites one recommendation of such an educational program, and then proceeds to describe the parent in question clearly ignoring this recommendation, sending her child outside on a “bad air day.”

The most recent in a spate of similarly veined articles was published in the New York Times on May 13, 2001. The article, “Breathless,” touches on a variety of potential triggers for asthma - including indoor pollution, cockroaches, and the stress of inner-city living - before settling on its most important issue: compliance.

All too often, parents treat asthma as an acute, not a chronic, problem. Children gasp, parents want to help, and an emergency room visit works...How to make sure patients keep taking their anti-inflammatories comes up often in talking to doctors in East Harlem. ‘If they would take their medicine, they wouldn’t need to go to emergency rooms, and they wouldn’t get sick.’

The attitudes expressed in this article may have been due in part to a mid-2000 study of medication use among asthmatics in East Harlem. The study surveyed parents of asthmatic children (as identified through school programs) regarding the medications their children took on a regular basis. Not surprisingly, the study found that black patients were more likely to be hospitalized for acute asthma episodes and less likely to use anti-inflammatory medicine on a regular basis. The explanation for this difference, however, was that social and cultural factors were preventing these patients either from getting to a physician for regular asthma care or from taking anti-inflammator...
tory medications on a regular basis. As before, the “blame” for differences in asthma morbidity is placed on factors in patients’ lives, and the solution is education or greater sensitivity to prevailing cultural factors or folk beliefs on asthma care.

“Cultural competency” has become a significant buzzword within the medical community; the typical description of the problem is similar to the following quote from the abstract of a review of current opinion on pediatric asthma:

“[Black children] continue to misuse health care and medications because of lack of access to culturally sensitive pediatricians who understand their needs and barriers.”

The AMA in particular has invested a significant amount of time and effort, as well as several other organizations, into developing and sponsoring programs on providing culturally competent care. But there are several inconsistencies in certain studies that suggest complications to such a narrative. A September 2000 study reported that 18% of black parents identified their health care provider as a barrier to adequate care for their children – in the context of the study, the parents were essentially reporting perceived discrimination by their physicians. But in later studies this same statistic was referred to as a product of differences in health beliefs between patient and physician. This restructuring of the statistic to fit a popular narrative of racial disparities in health care completely repositions the issue – it is no longer a case of the black patient accusing the physician of being a barrier to care, but rather of the medical establishment pointing out the black patient’s culturally ‘different’ health beliefs.

Similarly, a study on implementation of the 1997 Federal guidelines on asthma management revealed that low outcome expectancy (i.e. physicians did not believe their advice would or could be followed) was a barrier to implementing the guidelines, but more importantly showed that physicians’ predictions of patient compliance directly shape their prescribing habits. Later citations of this study mentioned only the first statistic, without reflecting on the implications of a physician population that decides prescriptions based not on presentation of the disease but on subjective assessments of compliance informed by a body of medical literature that considers black patients’ noncompliance to be common knowledge. This study, in combination with black patients’ scattered reports of discrimination, suggests that physicians might have preconceptions about black versus white compliance that create disparities in their prescribing habits for these groups.

Methodology

The purpose of this cursory analysis is to test the validity of the common therapeutic narrative for asthma that identifies cultural factors or differences in access to care as the source of racial disparities in asthma morbidity. The data comes from the 1998 National Ambulatory Medical Care Survey, consisting of a total of 23,339 patient records from 1,226 participating physicians. The survey is conducted yearly in a nationwide sampling of physician offices. Hospital and other acute care settings are not included in the survey data. Data collected includes standard information on patients – age, sex, race, etc. – as well as a wealth of physician reported diagnostic, prescriptive, and advisory information.

This cut of the NAMCS data examines self-identified prescribing habits of physicians who treat black and white asthma
patients. Physicians’ prescriptions of a variety of branded and generic acute and long-term asthma care therapies were analyzed against data on the number of visits with asthma diagnoses. To counter earlier narratives that explained disparities in terms of urban and non-urban residency, the sample was restricted to physician office visits made in metropolitan areas. Analysis was limited to what physicians identified as the primary diagnosis and the primary medication prescribed; the fields are not cross tabulated – avoiding cross tabulation allows cases in which physicians diagnose a comorbid condition (for example, pneumonia, which would not be recorded as a primary asthma diagnosis) resulting from asthma but prescribe an asthma medication as the primary therapy. In general, in cases where asthma may have led to an additional illness such as a respiratory ailment, the primary medication listed should correlate to this additional illness, and a secondary prescription should theoretically go along with the secondary diagnosis of asthma. An early analytical design that examined secondary and tertiary diagnoses and attempted to correlate them with the six available prescription fields was discarded based on concerns that it would become a microanalysis of prescribing habits and might obscure trends in physician attitudes toward black and white patients.

The list of drugs for the analysis was drawn from the 1997 Federal Guidelines and from the studies cited earlier in this paper. Short-term medications included generic albuterol, Proventil and Ventolin (branded forms of albuterol), and Maxair; long term medications included generic triamcinolone, prednisone, and theophylline in addition to Vanceril, Pulmicort, Aerobid, Serevent and Medrol, as well as new anti-inflammatories like Cromolyn (generic). Prednisone is prescribed for a variety of other conditions besides asthma; to account for this variation, statistics on Prednisone prescriptions were reduced by two-thirds. All other medications are prescribed almost solely for asthma to the extent that adjustments were not considered necessary. Results were expressed in terms of the rate per 100 asthma visits by race. Data for Asian and Hispanic respondents was not included, both due to the size of the sample and the focus of popular media investigations on mainly black/white disparities.
Results

Whites were 79% more likely than blacks to receive prescriptions for asthma medications. Far more primary prescriptions for asthma therapies were reported than were primary diagnoses of asthma (164.1 prescriptions per 100 asthma diagnoses) suggesting that, at least in the case of white patients, physicians identify asthma control as the primary means of controlling the diseases that may have taken therapeutic primacy over asthma. On the other hand, even ignoring the possibility that physicians use this practice to some degree with their black patients, not all black patients whose primary diagnosis was asthma appear to have received a prescription for their illness.

Breaking down prescriptions into acute and long-term therapeutic strategies yields even more divisive results. Prescribing patterns for white patients reflect the recent Federal Guidelines’ emphasis on long-term maintenance medications that work to reduce the inflammation that can cause asthma attacks. Whites were 17% more likely to be given a primary prescription for long-term rather than fast-acting anti-inflammatories. Blacks on the other hand, in addition to being prescribed less of each category, were slightly less likely to receive long term medications as their primary therapy. Though they were 62% as likely as whites to receive prescriptions for acute therapies, blacks were almost half as likely as whites to receive prescriptions for long-term medications. Surveys that pick up on blacks’ focus on acute care for asthma may not be illuminating cultural preferences but may be reflecting differences in the ways physicians present asthma care to whites and blacks.

A breakdown of prescriptions by drug branding gives a fuller picture of physician prescribing patterns, although it does little to elucidate potential reasons for these differences. The only area in which blacks and whites seem to be prescribed equally is generic acute care, which consists mainly of albuterol, a standard in acute asthma care for many years. Blacks are more than half as likely to receive prescriptions for branded short-term therapies. In the case of long-term care, this pattern is reversed – in generic long-term-care whites receive over twice as many prescriptions as blacks, while the under-prescribing of medications to blacks is slightly less drastic in branded long-term therapies. This particular cartography of prescribing habits suggests a complex pattern of discrimination against black patients, not easily explained by a simple story of physician perceptions on the socioeconomic status of black patients or differences in the way physicians present asthma to patients. Although black asthma patients are prescribed fewer medications than white patients and are prescribed in a way that does not seem to favor long term therapy over short term, this does not necessarily mean the explanation is as simple as identifying and correcting one misperception on physicians’ parts. One hypothesis might focus on the new popularity of long-term anti-inflammatories and recent patent expirations as the source of the peak in generic prescribing to whites. The fact that this dynamic seems to do little to affect the fact that black patients are prescribed more generic compounds than branded ones suggests a sort of dissociation between new medical knowledge in mainstream biomedicine and prescribing habits to minority patients.

Hypotheses such as this would require a much more detailed inquiry into the factors that affect physician decisions on prescrip-
tions. However, it is clear from even this cursory analysis that there are significant disparities in drugs prescribed to black and white asthma patients, even when urban residency and medical care setting are controlled.36 Although discussions of other racial disparities have addressed physician discrimination in the past several years, discussion of the sources of racial disparities in asthma morbidity have avoided turning the microscope on physician practice. Evidence that black asthma patients use fewer long-term anti-inflammatory medications has been interpreted to mean that black asthma patients choose to use fewer long-term anti-inflammatory medications that physicians prescribe. Hopefully, this and subsequent analyses can direct some attention to the possibility of disparities in the quality of care provided to black and white asthma patients as yet another factor in the complex calculus that leads to variations in asthma morbidity among racial groups.

References

7 “Focus: Asthma”. A.L.A.
8 Ibid.
9 I assume here that narratives developed by popular media authors do not represent separate ‘folk’ beliefs on the sources of these discrepancies, but were informed by (and informed) medical narratives on this topic.
**HEALTH HIGHLIGHTS**


20 Nagourney. “Childhood Asthma.”


36 This data concerns only those patients who receive care in an ambulatory medical care setting – therefore controlling to some extent physicians’ outcome expectancies. In an acute medical care setting the fact that asthma was treated with an emergency room visit can be expected to color physicians’ expectations of compliance with long-term asthma therapy.