

TB MONITOR™

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March flowers, April showers

March saw the introduction in Congress of two long-awaited TB appropriation bills, one calling for a big increase for TB control at the CDC and the other urging that the United States lead the world in assembling a NATO-like funding pot to fight global TB. That good news was tempered in April, when President George W. Bush submitted a budget that eliminates line-item spending for TB and calls for yet another year of flat funding Cover

Sudanese refugees trekking to Omaha

The capitol city of Nebraska, a sparsely populated state that's generally enjoyed minimal TB rates, is trying hard to adjust to the presence of the biggest Sudanese community in the nation. The Sudanese, for their part, are a tight-knit community whose customs often place them at odds with the neighbors in their adopted homeland. TB controllers say they are finally starting to make inroads and gain the newcomers' trust — but no one is claiming it's been easy 56

Cross-border dilemma bedevils immigration docs

When a criminal alien slated for deportation is found to have TB, it's tough to convince him that he needs to go back into custody while undergoing treatment for his disease. The trouble is that many deportees slip back across the border after they're sent home, still untreated and still liable to expose Americans to disease. So far, there seems to be no legal means to prevent this scenario from occurring, but one immigration physician is trying hard to find a way. 57

Somali TB patient caught between two worlds

A 29-year-old Somali man with MDR-TB resistant to seven drugs has been responding well to treatment at A.G. Holley Hospital in Lantana, FL. The problem is that after Mohamed Hashi finishes treatment, he'll likely be sent home — to a land where there is no functioning government, let alone a chance for the lengthy follow-up he'll need. The young man's physician has gone to bat for him, but acknowledges the case is difficult 59

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New Bush budget sets ominous tone for future funding

Still, TB's higher profile could help, say experts

The 2002 federal budget that President George W. Bush submitted to Congress in April would eliminate line-item funding for TB and would hold TB funding to flat levels, policy experts say. Eliminating line-item funding potentially sets the stage for a return to block grants, a funding mechanism opposed virtually across the board by U.S. TB experts.

In the budget Bush submitted, TB funding at the Centers for Disease Control and Prevention (CDC) in Atlanta is shown bundled together with money for sexually transmitted diseases and for HIV.

Lobbyists and policy experts at the American Lung Association (ALA) say they've seen other signals that the new administration would like to return to block grants. "In the theme document" — the blueprint for the proposed budget which the president released in February — "there was language suggesting they want to move back to block granting," says Gary Ewert, a media spokesman for the Washington, DC-based ALA.

At the CDC, Ken Castro, MD, head of the Division for the Elimination of TB, was terse in his reaction to the budget news. "The proposed budget represents an effort to simplify administration of divisions at the CDC," he says. "It will be very important to keep track of resources appropriated for TB by Congress."

A start, not an ending

Still, the proposed budget is no more than a wish list, Hill-watchers say. Increased funding for TB "has never appeared in the President's budget before; that's something we've always gotten during the appropriations process," notes Ted Miller, press secretary to Congressman Sherrod Brown (D-OH), who

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AIDS drug debate drags DOTS into the ring

In the midst of an impassioned debate about developing countries' lack of access to triple-therapy drugs for AIDS, public-health experts ponder how the drugs can be safely administered. Topping the list of their concerns are the prevention of drug resistance by managing side effects and averting noncompliance. Some experts say a DOTS-like strategy, incorporating direct observation and community health workers, is the best available tool and should be given a try. Others claim that DOTS may be too cumbersome and that better means of delivery must be found 60

Atlanta jail reforms finally under way?

Lawyers who've brought suit on behalf of prisoners in Atlanta's DeKalb County Jail say conditions may finally begin to improve there in respect to TB and HIV care. It's been an uphill battle, with lots of diversions along the way, including inmates subjected to physical threats, a health care contractor in bankruptcy, and the apparent assassination of a sheriff bent on reforming the county's corrupt correctional system. A court settlement calls for outside monitoring, a TB control plan, screening, treatment, and construction of respiratory isolation rooms — a good start, attorneys say. Now, if only the jail can pull it off 61

OSHA TB standard hanging fire

The long-disputed TB standard proposed by OSHA is going nowhere fast these days, thanks to a directive that placed on hold all pending government regulations. That means there's plenty of time to place bets and try to decide what the new Secretary of Labor, Elaine Chao, will make of the TB rule once she gets de-briefed. Chao is known as a temperate conservative who tries to maintain cordial relations with labor 62

Bill Gates: Public-health funder for Planet Earth

The former CEO of Microsoft handed the World Health Organization \$10 million the other day, a sum the organization will use to develop better diagnostic technology for use in low-income settings. Taken altogether, Gates' largesse over the past year equals about a quarter of what the world devoted to public health in the same time period. Luckily, Gates has made clear that his commitment to better health for developing countries isn't going away anytime soon 63

COMING IN FUTURE ISSUES

- The Russian experience with DOTS
- Coverage of the American Thoracic Society convention
- Progress in the CDC's TB Trials Consortium
- Global Alliance grants announcements
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recently introduced two bills that would substantially increase funding for TB at home and abroad. "There are going to be changes in that budget."

Ewert agrees: "Spending levels for health care overall [in the proposed budget] are below what's needed to get a bill out of Congress," he says. "I think [Congress] will add something — but whether it'll be something at the margin or something significant, I don't know."

In the Bush proposal, the "bundle" composed of TB, HIV, and sexually transmitted diseases (STDs) would get only a modest funding increase of \$24 million, of which little or even none seems intended for TB, says Ewert. "The text implies that \$20 million of the \$24 million increase would go to domestic and international HIV prevention," he says. That would leave just \$4 million for the STD and TB divisions at the CDC to scrap over — unless the \$4 million is intended as money to run the HIV programs. At many points, including that one, the Bush budget language simply isn't clear enough to see what's meant, say several ALA lobbyists.

Will block grants push TB rates higher?

Block-granting, also known as non-categorical funding, gives states much more discretion in how they use federal money.

"We've got solid evidence from the past that when there is block granting, funding for TB goes down, and TB goes up," says Ewert. **Lee Reichman**, MD, MPH, director of the National TB Center at the New Jersey Medical School in Newark, emphatically agrees. "I thought we'd learned our lesson," Reichman says. "If this [goes through,] we could all be in business a lot longer than we'd intended."

Clearly, the Bush proposals signal that a tough fight lies ahead, says Ewert. "For the last eight years, we had the Clinton administration," he says. "The endgame strategy there was that Republicans would send in a budget well below what was needed. Then the President and the [Democratic] leadership would hammer out some compromises, and we'd see huge increases at the end. Now we've got a new set of rules."

Certainly, it's time for TB advocates to roll up their sleeves and get to work, adds Miller. "There is some urgency for people who feel these programs are important to let their Congresspeople know about it," he says.

The budget news cast a pall over earlier, much more positive developments.

On World TB Day in March, Brown introduced the two long-awaited bills, which were crafted chiefly by the Washington, DC-based National Coalition to Eliminate Tuberculosis and the ALA. Acting as co-sponsors for the two bills are Democrat Henry Waxman of California and Republicans Connie Morella of Maryland and Greg Ganske of Iowa.

The strong bipartisan support the bills have garnered should certainly help TB's shot at leveraging more funding, say Miller and Ewert. "The fact that we've got people on both sides of the aisle supporting this bill certainly helps," Ewert says.

Policy-makers taking notice of TB

It also helps that policy-makers and the public are far more aware of TB-related issues now than they were four years ago, TB experts add. "I've been visiting Washington, DC, for years talking about TB, and this [year] is the first time that people went out of their way to meet and talk with us," Reichman says. "It wasn't just courtesy visits with junior staff. These were Congresspeople and senior staff."

Originally conceived as an omnibus-style package that would incorporate both international and domestic proposals, the TB bill was later split into two pieces in hopes of increasing chances for passage by preventing it from having to work its way through multiple committees. The international bill will be referred to the Foreign Affairs Committee; the domestic bill, to the Energy and Commerce Committee. Brown, a long-time supporter of TB control and other health-related issues, is the ranking Democrat on the Commerce Committee's Health Subcommittee.

The domestic bill, dubbed the Comprehensive Tuberculosis Elimination Act of 2001, seeks \$240 million for the National Institutes of Health (NIH), a sum that would double the amount of money currently targeted for TB-related research at the NIH.

Bush's proposed budget allots an additional \$2.8 billion overall for NIH research. In order for part of that increase to be earmarked for TB, the amount named in Brown's bill would first have to be authorized; then specific dollar amounts would have to be approved in a separate appropriations bill.

Brown's domestic bill also seeks authorization to appropriate an additional \$400 million for TB at the CDC. The current TB budget at the CDC is \$126.5 million. The increase Brown's bill names is intended to implement recommendations contained in an Institute of Medicine report on how to eliminate TB in the United States by means including the targeting of high-risk populations and by giving the CDC an expanded role in training and educational outreach to medical professionals and others who serve high-risk populations.

The Stop TB Now Act — the international bill Brown introduced at the same time as the domestic bill — seeks to authorize \$200 million for TB control activities of the U.S. Agency for International Development (USAID). This year, \$60 million was appropriated for TB at USAID; just four years ago, the amount stood at zero.

TB experts at WHO say that if appropriated, the increase for USAID would help catalyze the huge multinational commitment needed to trim TB deaths worldwide by half. TB experts at WHO say that would take a billion dollars a year for 10 years. "If the U.S. [does its part,] we can assemble that \$1 billion internationally in a NATO-like plan that we can lead and put together," Brown says.

Global TB Drug Facility to get a slice of the pie

Most of the \$200 million the Stop TB Now Act requests for USAID would go toward expanding TB control programs. The rest would be channeled to the Global TB Drug Facility, a newly created multinational organization housed at WHO and intended to provide a reliable supply of high-quality TB drugs to developing countries.

Canada has already pledged \$11 million to the global drug facility. WHO officials say the drug facility — which is a "virtual" facility, not a true warehouse for drugs — needs \$250 million in pledges from the United States between 2001 and 2005 to meet global treatment targets.

The increased U.S. commitment to fighting TB in low-income settings has already helped rally international support for fighting TB, says Brown. When he was visiting the recent Chicago conference of the International Union Against TB and Lung Disease, Brown says he listened to one international TB expert after another talk about that impact. "They say now that the U.S. is involved, it's bringing on other countries around the world to be part of this whole effort," he says. ■

Sudan meets Omaha: Bridging the TB gap

Building access one step at a time

Over the past three years, Omaha, NE, has become home to the biggest settlement of Sudanese refugees and immigrants in the United States. Building a bridge to the community of newcomers so as to enable effective TB control hasn't been easy, says **Carol Allensworth**, MT (ASCP)SM, division chief of health, data, and planning for the Douglas County health department.

With a cornucopia of Latinos, Asians, and Russian Jews, the city isn't the WASP-y, white-bread capitol many would think, Allensworth says. Still, the impact of an influx of 5,000 Sudanese in a city of 390,000 has been substantial. Statewide, Nebraska's TB rate last year was 1.1 per 100,000; among southern Sudanese, the TB rate is about 211 per 100,000.

Adapting to the change has been work, says Allensworth. "Has it taken a lot of our time? Yes," she says. "Are we putting a lot of resources into it? Yes. Are we frustrated? Yes." And yes, she might have added, all the work is finally starting to pay off.

Access to good health care draws immigrants

The Sudanese began arriving three years ago, Allensworth says. At first they gravitated to a single apartment complex, and then a second; now they fill five. Among the factors that drew them were plentiful jobs; the presence of relatives and friends; a strong community-based advocacy group run by a local attorney; and — because the city boasts two university medical schools — good health care.

Soon, not only Sudanese refugees from Africa were coming to Omaha, but also immigrants who'd already settled in other states.

Right from the start, the group posed cultural and public health challenges, says Allensworth. Because Sudanese traditionally eat from a common dish, using their hands and eschewing utensils, there were outbreaks of shigella and other gastrointestinal complaints.

Other Sudanese customs proved hazardous as well. Sudanese mothers who left their children alone while they ran out to do errands, for example, found that child protective services could

charge them with abandonment and take their children away. Sudanese men learned that beating their wives was not acceptable in their adopted homeland. To the distress of the Sudanese community, the local newspaper embarked on a series in which such differences were aired and debated, says Allensworth.

From the perspective of TB control, the biggest headache was what to do about widespread latent TB infection among Sudanese children. Not surprisingly, screenings at the university clinics had turned up high rates of latent TB. Soon, a pediatrician with over 300 Sudanese children in her practice began insisting that TB controllers provide directly observed preventive therapy (DOPT) for every child, Allensworth says.

Possible epidemic loomed large in Omaha

"She was very gung-ho, very dedicated, and very insistent," she says. "She warned that without DOPT, we'd soon have an epidemic on our hands."

Despite the fact that the contractors were charging \$120 per child visit, Medicaid actually did pick up the cost of the DOPT for a short time. But once it was determined that the long-term costs would run to \$1.9 million, Medicaid officials did an about-face, and coverage ceased. At about the same time, three Sudanese infants, as prophesied, came down with active TB. "That just added fuel to the fire," says Allensworth.

To top things off, an outbreak occurred among adults living in one apartment complex. An outreach worker tending to a TB case in another complex uncovered a Sudanese man with undiagnosed, full-blown TB; he'd gone to an emergency room months earlier, been misdiagnosed with pneumonia, and was sent home with a prescription for antibiotics.

Business as usual wasn't going to cut it, TB experts began to realize. For one thing, language and cultural barriers loomed large. Almost no one in the community of newcomers spoke fluent English, and interpreters were in short supply for both Nuer and Dinka, the languages of the two tribes most widely represented — which, as it turns out, are bitter enemies back home.

Concentric circles? Forget it, says Allensworth. "For one thing, when someone is sick, everyone goes to visit you, whether or not they know you," she says. In addition, custom dictates that when newcomers arrive, they stay two weeks in one apartment, then two weeks in another — a process

that continues for up to two months, by which time the new arrivals have their own job and apartment and are ready to take in house guests of their own.

At length, TB controllers decided they needed to go to the apartment complexes and screen every single Sudanese for TB, Allensworth says. Public health experts pulled together a group of Sudanese, along with representatives from the community-based agency, and asked them how best to proceed. "We asked them whether they thought we could do this and how we could gain the trust of the community," says Allensworth.

The group advised them to start with the one group the Sudanese already trusted: their health care providers at the medical school clinics. In short order, letters signed by these providers went out to every Sudanese household, telling them that all family members must be screened for TB and warning that "if you don't, TB could be transmitted to a child, which could cause death."

TB workers rely on improved trust

Remembering the three infants desperately ill with TB, the community listened, Allensworth says. Soon, trust between TB controllers and the Sudanese community improved to the point that public health workers began going door to door in the apartments. In addition, an agreement was struck with the public schools whereby children over five years old began getting their preventive medication from school nurses, leaving only kids under five needing DOPT at home.

TB nurses, accompanied by translators obtained from the community-based agency, began slowly working their way through one family. Outreach workers doing DOPT spooned medication-laced applesauce into tiny mouths, surrounded by a half-dozen other youngsters begging for a taste. "Doing DOPT on a 12-month-old or a 17-month-old is a trick," laughs Allensworth. "You put the medication into juice or yogurt, and after about three days they've figured out what's happening. Meanwhile everyone else in the family is crawling all over you, clamoring for the juice or the yogurt. The outreach workers are absolute saints."

All the while, the public health department took care to go about its business quietly, Allensworth says. "We had heard from the Sudanese that they didn't enjoy being a spectacle and that they didn't want this to be in the newspapers," she says. The

Sudanese also needed lots of reassurance that public health officials, though part of the county government, weren't going to take Sudanese children into custody or otherwise make life difficult. "We had to put out the message that we want to work with you, not against you," she adds.

Collaboration facilitates control efforts

At length, TB controllers decided that combing through the apartment complexes was simply too time- and labor-intensive. Recently, they managed to convince one of the medical schools and state TB control to collaborate in funding a special clinic just for Sudanese; now the hope is to begin transporting Sudanese directly to the special clinic. "The cost for translation services is killing us, and it's taking so long this way," says Allensworth.

Meanwhile, social workers and visiting nurses are forming women's groups and men's groups in the community, trying to put out the word about American customs. The groups seem to be having an effect, Allensworth adds: "Some of the women are becoming more independent," she says. "There seems to be a shift taking place." ■

Border criss-crossers pose dangers on both sides

They can't legally be forced to stay and be treated

Consider the following circumstances: A resident of another country enters the United States, commits a minor crime, and is sentenced to a few months' jail time. Perhaps because the county jail where he is serving his sentence has slipshod TB screening procedures, the man's TB goes undetected.

The man is released from jail, and an immigration judge orders his deportation. At an immigration service processing center, he undergoes a routine health screening. He is found to have multidrug-resistant TB.

Because the man has a criminal record, he cannot be released back into the community to undergo TB treatment. Instead, he must re-enter custody. Physicians at the immigration processing center try their best to convince him to stay and be treated, but he wants out. A few months after he is deported, the man slips back across the

border again, exposing American citizens to a potentially fatal disease.

The scenario is not especially frequent. But when it does occur, it causes trouble all out of proportion to its incidence, says **Abraham Miranda**, MD, a physician who works for Immigration Health Services at the Immigration and Naturalization Service processing center in Port Isabel, TX. Worse, under current immigration law, Miranda says there appears to be no way to prevent it from happening.

"In virtually 100% of these cases, these people demand to go home," Miranda says. The usual arguments for undergoing TB treatment carry almost no weight under such circumstances, he adds.

Criminals prove especially recalcitrant

"As a physician, I've figured out over the years which buttons to push," Miranda explains. "I talk about the person's children, and how they can get infected more often, how they get meningitis more often, how they could die." None of it makes any difference, he says. "These people don't care — not if their family suffers, not if they suffer. Perhaps it's part of the criminal mentality."

More often than not, the TB that such people carry is resistant or even multidrug-resistant, Miranda adds. "MDR-TB is almost a marker for this kind of situation," he says. "These people have already been bounced back and forth across borders, they've been in the criminal system back home, and they're noncompliant with their medications. They have a higher risk of homelessness, drug abuse, and criminal behavior, and until they start feeling sick, TB treatment is very low on their list of priorities. It all makes a bad problem doubly problematic."

There are no data on how often such episodes occur, Miranda says. "I'd say they're relatively rare, but they cause a lot of problems when they do occur," he says.

Recently, Miranda encountered a man with untreated MDR-TB from a country in Central America. He'd been deported once, had slipped back into the states, had been re-apprehended, and was scheduled for deportation a second time.

When Miranda asked him to consider remaining in INS custody for treatment, the man became extremely upset. "He started screaming about human rights and civil rights," Miranda says. "It

was only by force of sheer will power that I convinced him to stay. I used some carrots; I used some sticks. It was not easy."

It's not that the governments who agree to take their citizens back are intentionally irresponsible or negligent, he adds. "A lot of them would probably argue that they care very deeply about providing good TB treatment," he says. "The problem is that whereas we go to great lengths to provide directly observed therapy, they don't approach treatment in the same way. They'll tell me, 'Write up a summary letter and have him stop by the Ministry of Health,' and that's it. It's the discrepancy between the way we approach TB care and the way most other governments do that makes me uncomfortable."

Fortunately, Mexico is an exception to this rule. Thanks to agreements between that country and the United States, a handful of highly successful cross-border TB projects exist that track and treat TB patients who regularly cross the border or who are bound back to Mexico. Unfortunately, the United States has no such agreements or transnational programs in place for any other countries.

Luckily, too, criminal aliens who have served time in a U.S. prison (instead of a jail) have been screened for TB — "almost ad nauseam," notes Miranda. At the time these aliens are due for deportation, they're not likely to present with active TB.

U.S.-Mexico agreement difficult to replicate

Miranda admits that it's hard to imagine what it would take to ease the present predicament. "Our recommendation to INS would be simply, don't deport this person — hold onto him," he says. But that's easier said than done, he admits. The prospect of negotiating TB agreements with every country in the world like the one between the United States and Mexico is daunting.

For now, Miranda is working with others (including a group at the Advisory Council to Eliminate Tuberculosis and with the Centers for Disease Control and Prevention) to get a sense of the extent of the problem and to see what diplomatic or legal mechanisms might be available.

An INS spokeswoman says she's surprised to hear about Miranda's complaint. Why, asks **Karen Kraushaar**, would a foreign government willingly accept someone with a communicable and potentially fatal illness? Deportation is a lengthy and complex process, she adds. Presumably, there are

many steps along the way where the process could be delayed or halted. “It’s not something that happens in the twinkling of an eye,” she notes.

For example, the Justice Prisoner Air Transportation System can refuse to carry someone with a communicable disease. Before final orders of removal can be issued, an immigration judge must approve the order, she notes; “and judges, of course, can do whatever they want, within reason,” she adds.

Kraushaar cites a recent case in Los Angeles in which the judge ruled against deporting a child enmeshed in a prostitution smuggling scheme, even though the youngster’s grandparents have petitioned for her to be sent home and placed in their care. First, the judge ruled, the child must undergo medical treatment in the United States.

The trouble is that’s not the way it usually works out in practice, Miranda says. Perhaps to save face, foreign governments rarely refuse to take back one of their own, he says. Plus, by the time an immigration service processing center has uncovered a case of TB, orders for deportation have generally already been issued, he adds. ■

Immigration dilemma: Deportation equals death

Somali man needs three years of follow-up

Mohamed Hashi, a 29-year-old Somali man suffering from multidrug-resistant TB, has spent the last two years trying to get to the United States. Now, TB experts in Florida are afraid that once he finishes treatment he will have to go home — to a war-torn land where it will be virtually impossible for him to get the follow-up care he needs.

“We’re on a slippery slope here,” says **David Ashkin**, MD, medical director of the state TB control program and Hashi’s physician for the past year. “Legally, there is an obligation to return him to the Immigration and Naturalization Service. From a humanitarian and public-health standpoint, it’s another matter.”

The case in some ways resembles others that immigration health experts say are troubling — cases in which untreated or undertreated patients with TB ping-pong back and forth across borders,

subject to laws that don’t fully account for the vagaries of life as a refugee or immigrant. (**See related article, p. 57.**) If Hashi is deported once his treatment is technically completed, Ashkin is convinced he risks death by staying in Somalia. If, on the other hand, he manages once more to return to the United States, he will expose Americans to a strain of TB known to be resistant to seven drugs.

In Somalia, “many people have TB,” says Hashi, speaking through an interpreter; but there are no public clinics or TB sanitariums in his anarchy-ridden homeland. “If you have money, you can go to the pharmacy to buy medications, and perhaps you can cure yourself,” he says.

No money, no family, and no TB care

Born in Mogadishu, Hashi and his family fled fighting in the capitol when he was young, he says. Then came more fighting, and Hashi’s family members scattered. Now, he says, he no longer knows where most of them are.

He fled north to the United Arab Emirates, where he sought the help of friends and relatives. For two years, he wound his way through northern Africa, traveling from one Arab country to another; eventually, he obtained a tourist visa to America. By that time, Hashi knew he had TB. He has no idea where or when he got it.

By Ashkin’s account, the young man spent the plane trip to the United States wracked with violent coughs, his coat pulled over his head. By the time the aircraft touched down in Miami International Airport, he was so weak he had to be carried off the plane. He was taken into custody by the Immigration and Naturalization Services (INS). At Krome Detention Center in Miami, physicians took chest X-rays and told him he had TB. In INS custody, he was sent to a local hospital for treatment.

But the disease had progressed too far for the hospital to be able to treat it. Hashi’s left lung was almost entirely obliterated by a cavity and infiltrate. He was emaciated and unable to eat, and he suffered from severe hemoptysis. In addition, he was resistant to seven anti-TB drugs.

The decision was made to release him from INS detention, place him in the custody of the state, and admit him to A.G. Holley Hospital, the TB sanitarium in Lantana, FL. At Holley, once doctors succeeded in getting Hashi culture-negative, they removed his left lung, says Ashkin.

The harsh anti-TB medications were unpleasant at first, Hashi recalls. "When I started treatment, I had many hard problems," he says. "I was vomiting and unable to eat. Afterward, though, when my body got into synch with the drugs, I felt better." Now he has gained weight and is responding well to therapy, which should be completed after another eight months. Once therapy ends, he will need three years of careful follow-up.

Who picks up the \$400,000 tab?

Ashkin admits he worries not only about Hashi's fate but about who should take responsibility for cases such as this one. "There's the difficult issue of who should pay for his treatment," he says, noting that total costs for curing Hashi's TB will eventually come to over \$400,000.

Hashi says he has no wish to return to Somalia and hopes he can find a job here — although with one lung missing, he says he knows he is too weak to do physical labor. He passes the time studying English, Ashkin says, and his facility with the language is rapidly improving. "He's very bright and very enthusiastic," the physician adds. "It would have been such a shame to have lost all that potential." ■

Access to AIDS drugs sparks DOTS debate

Haitian program demonstrates Small-scale success

As the debate rages over whether or not developing countries engulfed by an AIDS epidemic get generic or discounted antiretroviral therapy, public health experts are struggling to resolve what may prove a more pressing question.

Assuming that triple-therapy regimens do become widely available, how will nations that are poor in health care infrastructure cope with issues such as compliance and side effects?

An idea that's been kicking around in the AIDS community for years is to borrow directly observed therapy (DOT) from the world of TB and use it to boost compliance. Recently, in fact, a presidential committee assessing high rates of noncompliance among young AIDS patients in the United States strongly recommended using DOT on a broad

scale here at home.

When TB experts look abroad, noncompliance — with its consequent development of drug resistance — is a big concern. "We've learned from TB that making drugs available without controls is a grave mistake," says **Barry Bloom**, dean of the Harvard School of Public Health in Cambridge, MA. "If you just make antiretrovirals available, it will lead to resistance and to the growth of a black market." Growth of a black market, in turn, will give rise to a situation where only the rich and powerful have access to drugs, Bloom says.

AIDS might prove trickier than TB

The experts also worry about how low-income countries will manage the considerable array of side effects from triple-combination AIDS therapy. "There's great skepticism that with AIDS drugs, the adverse effects and the need to change drugs and so on will be so formidable that the drugs can only be given by medical personnel," Bloom says. "If that's so, it simply won't be possible to give these drugs in poor countries. We may decide that this is a much trickier disease than TB and that this won't work."

To see whether community workers with only minimal medical training will be able to manage side effects, Bloom and others at Harvard (including economist Jeffrey Sachs) are calling for the establishment of multi-country, large-scale pilot programs.

But some international TB experts say they worry that DOTS (as the international treatment approach using DOT is termed) is too cumbersome. After all, they argue, even though 200 countries have adopted DOTS, in practice only one-quarter of TB patients in those countries have access to DOTS. Perhaps, they argue, it's time to start over and try to find something that's just as effective but more streamlined.

"Let's face it: DOTS is not a perfect strategy," says **James Orbinsky**, former president of *Medecins Sans Frontieres* (MSF) and president of the Global TB Alliance's Stakeholders Association. "I think we have to be careful not to develop a 'MacMedicine' model of health care delivery."

In practice, DOTS has proven to be too expensive, others add. "For the majority of TB patients who are poor to begin with, DOTS isn't cheap," says **Ian Small**, director of MSF's Aral Sea Area Program in Uzbekistan. Small notes that DOTS works best when patients get supplements for

transportation, food, and loss of salary — but adds that that’s asking a lot of “governments with health budgets that are already stretched thin.”

That may be true, says Bloom, but isn’t that all the more reason for TB and AIDS to join forces and perhaps produce a bit of synergy? By piggy-backing AIDS treatment on top of an existing DOTS infrastructure, both AIDS patients and TB victims stand to benefit, he suggests. “Everyone’s very eager to bring in these AIDS drugs; the hope is that DOTS is something to build on,” he says.

Others agree. “The point is to avoid developing two side-by-side vertical systems and instead integrate the two,” says **Giorgio Roscigno**, MD, acting chief executive officer of the Global Alliance for TB Drug Development.

Even if a synergistic approach works well, there’s still the problem of who gets AIDS drugs, Bloom adds. “I doubt anyone is going to pay for treatment for 36 million AIDS patients from now until forever,” he says. Even if the money could be found, there probably aren’t enough drugs in the world to do such a thing, he adds. That means developing countries will have to make some hard decisions about who gets treated — the richest patients? The sickest?

‘In a country like Botswana, where 37% of pregnant women are HIV-positive, you simply can’t afford to ignore prevention.’

Bloom proposes targeting three groups that contribute most to the continued spread of HIV: Pregnant women, commercial sex workers, and truck drivers (who carry HIV from town to town as they travel). In the rush to bridge disparities of access, transmission prevention is still of utmost importance and risks getting lost in the current impassioned debate, he adds. “In a country like Botswana, where 37% of pregnant women are HIV-positive, you simply can’t afford to ignore prevention,” he says.

So far, evidence exists — slight, but encouraging — that a DOTS-style framework could work well in poor countries. In Haiti, Partners in Health (a Cambridge, MA-based health care organization with close ties to Harvard) has been using DOTS successfully for many years to treat TB patients. Recently, the group added to its treatment roster two AIDS patients. Both are

doing well, with good compliance and only negligible side effects, says Bloom.

“They’re seeing fewer adverse effects than we’d see in Brigham and Women’s Hospital here in Boston,” Bloom says. “Often in developing countries, there seems to be an inverse correlation between severity of the illness and the number of complaints about side effects you get — as if the sicker you are, the more grateful you are for anything that makes you feel better.”

Two-thirds of the Haitian DOTS supervisors are illiterate, Blooms adds. “But they can count,” he adds, “and they can fill out a form to indicate that a patient has taken his drugs.”

‘DOTS simply doesn’t work all that well’

Even though Orbinsky and others are skeptical, they still add that DOTS is a good starting point. MSF uses DOTS all the time and seeks to expand its DOTS programs, notes MSF spokesperson **Kris Torgeson**. “DOTS simply doesn’t work all that well for TB patients,” adds Torgeson. “We need to look at lots of different models, not just impose DOTS onto AIDS treatment as the de facto way to go.” In that spirit, MSF is starting its own pilot studies to see what works for delivering antiretroviral therapy to AIDS patients in poor countries and what doesn’t, says Orbinsky.

“DOTS is a starting place,” Bloom agrees. “What I’m saying is that we shouldn’t run out and make a huge investment in drugs for everyone — not until we’ve figured out how to make a positive impact on health and prevention and at the same time prevent resistance and the growth of a black market.” ■

Better TB care pledged for Atlanta inmates

Jail under court order to shape up

The fight to get better TB control procedures and other health care improvements for the 3,000 inmates at DeKalb County Jail in Atlanta has been anything but easy. To date, the struggle has been punctuated by the gangland-style slaying of a reform-minded sheriff, a drawn-out courtroom battle, investigations into charges of widespread corruption, and assorted threats to inmates.

In a blistering courtroom lecture, DeKalb County Superior Court Judge Hilton Fuller recently accused lawyers for DeKalb County of using underhanded tactics to oppose a lawsuit brought on behalf of inmates. A hemophiliac inmate at the jail scheduled to testify in the lawsuit landed in a hospital with razor cuts, the judge noted, after being assigned a razor-blade-packing roommate.

An editorial that ran in the city's newspaper the next day noted that unless health care at the jail shapes up soon, conditions there may come to resemble those in Russia, where prisons are a breeding ground for multidrug-resistant TB.

Sheriff **Thomas Brown**, elected after his predecessor Derwin Brown was murdered (under circumstances still being investigated), says better health care for prisoners tops his agenda. **Tamara Serwer**, an attorney with the Atlanta-based Southern Center for Human Rights, which has led the fight for better health care for inmates of Atlanta's jails, says changes aimed at improving TB control in the jail include the county-financed construction of six respiratory isolation rooms, the design of a TB control program to screen for TB and provide treatment, and outside monitoring.

Understaffed provider can't keep up

Although construction of the isolation rooms is already under way, the new sheriff still has his hands full, adds Serwer. Care for inmates under Correctional Healthcare Services (CHS), the jail's health care provider, "has been bad and has gotten progressively worse," says Serwer. "They've been under court order to [implement a TB control plan], but they've been so understaffed that they're just barely functioning."

For better or worse, CHS is going out of business and will have finished selling off its assets once its contract with DeKalb expires this April, Serwer says. At that point, it's expected that Sheriff Brown will appoint a new provider on an emergency basis for the next six months before putting out the health care contract to bidders. "We've agreed to give [the new provider] some back-up time, since they're inheriting such a mess," adds Serwer.

In adjacent Fulton County, the jail system is also under court orders to shape up efforts for screening and treatment of infectious diseases, including TB and HIV. In Fulton, more progress has been made, says Serwer. ■

TB rule goes on hold for a new review

Will new labor chief approve?

In her office at the Occupational Safety and Health Administration, Amanda Edens has been passing the time by reading the Institute of Medicine's (IOM) report on the proposed TB standard she's written.

The IOM report doesn't mention whether or not the document Edens has spent the last two years working on will become law or whether it will meet with the same fate that befell the ergonomics rule, repealed by Congress two months after it took effect in January. "The issues for TB are not going to change, but how they may interpret the solution could," is the way Edens puts it.

Along with all other pending regulations, the TB standard has been back-burnered for now. The day after President Bush took office, the White House chief of staff issued a memorandum stopping work on all pending rules so incoming staff can look them over, says **Stuart Roy**, OSHA spokesman. The past three incoming administrations have issued similar stop-work orders, Roy adds.

According to the memo, pending regulations that have already been finalized can be delayed for no more than 60 days past the day they were due to become law. At one point, "about 10" regulations including TB were pending, says Roy. Some have been finalized since that time. But since the TB standard had not yet been finalized, how long it will be on hold is anyone's guess, say Roy and Edens.

It's tough to predict how the proposed TB standard will play with newly appointed Secretary of Labor Elaine Chao. Though she is a member of the conservative Heritage Foundation and the wife of Mitch McConnell (the ranking Republican senator from Kentucky), Chao nonetheless enjoys a cordial relationship with many labor leaders. The International Association of Machinists and the Communications Workers of America both endorsed her nomination.

Also difficult to gauge is the impact of the IOM report. An IOM committee that reviewed the proposed TB standard gave it only lukewarm support, suggesting several areas where the proposed rule should be more flexible.

By comparison, a National Academy of Sciences (NAS) report released in January lent stronger

support to proponents of the new ergonomics rule. That report found that repetitive stress causes over a million injuries on the job each year and costs the nation upward of \$54 billion in compensation, lost wages, and lost productivity annually. Such costs and injuries, the NAS report said, could be averted by “well-designed intervention programs” such as the ergo rule that crashed and burned earlier this spring. ■

Gates' gift to WHO to aid diagnostics

Gates committed to TB 'for life'

A gift of \$10 million recently awarded by the Bill and Melinda Gates Foundation to the World Health Organization (WHO) should have a big impact on research aimed at finding better diagnostic TB tests for low-income settings, says a TB expert in the United States.

“WHO can do studies [in developing countries] for a lot less money than we can do here, so \$10 million is a lot for them,” says **Rick O'Brien, MD**, chief of the research and evaluation branch of the Division of TB Elimination at the Centers for Disease Control and Prevention in Atlanta.

Better TB diagnostics are badly needed in developing countries, O'Brien notes. “In most settings in poor countries, if diagnosis is done properly, it consists of smear microscopy,” he says. Cultures and rapid testing for resistance are generally unavailable in such settings. But simple smear microscopy has its drawbacks, O'Brien adds. “For one thing, it's not particularly sensitive. You miss the smear-negative cases. It also requires a lot of attention and good laboratory technique.”

TB researchers at WHO's Tropical Disease Unit have already begun assembling a specimen bank, consisting of samples of urine, blood, and sputa taken from TB patients and from others without TB. The specimens are intended for use by companies seeking to test new diagnostics.

Gates gave \$1.44 billion last year in 60 separate grants to projects aimed at improving global public health — an amount that equals more than a fourth of the \$5 billion spent worldwide annually. That's just half of the \$10 billion the world's nations ought to be spending to fight TB, says **David Nabarro**, executive director of WHO.

“The world hasn't been allocating its resources properly at all in global health,” Gates told the *Boston Globe* recently, adding that he will continue to give a billion dollars a year to global health throughout his lifetime. “I'm sure that for my lifetime, even beyond, that world health is going to be our priority,” he said. ■

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- Explain developments in the regulatory arena and how they apply to TB control measures.
- Share acquired knowledge of new clinical and technological developments and advances with staff. ■