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NIOSH cites poor fit of many current N95s, urges changes
Researchers at the National Institute of Occupational Safety and Health have determined that most N95 half-mask filtering facepiece respirators are not performing well. In data gathered for a yet-unpublished study, researchers found that only 45% of people who performed a fit test could be adequately fitted. NIOSH experts worry that the poor-fitting respirators pose a threat to health care workers. Also, NIOSH has decided to unveil the manufacturers of respirators tested in 1998. This issue includes data from that study . . . . . Cover

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In the future, infectious diseases and demographic changes will transform foreign policy, creating a new set of transnational issues that will threaten economic and political stability, says a policy analyst who studies demographic trends. Most of the population growth in developing countries will be in cities that are unprepared for the influx. One result of this will be a greater threat of infectious disease and potential political instability, he says 33

Even amid poverty, health is attainable — report
A new report by six United Nations agencies notes that the worsening epidemics of infectious disease and rising death rates are not inevitable. The report documents successful strategies for beating back TB, malaria, AIDS, childhood diseases, and maternal and perinatal conditions, even in some of the world's poorest nations. In India, for example, which accounts for 30% of the global TB burden, a massive expansion of TB treatment resulted in one-fourth of the population being covered by directly observed treatment, short course (DOTS) last year, up from just 2% in 1998. In Nepal, one of the poorest countries in the world, TB treatment success rates have more than doubled since 1994, and 75% of the population now has access to DOTS TB treatment. 33

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NIOSH cites poor fit of many current N95s, urges fit-test change

Quantitative tests needed to weed out poor products

Many respirators worn by health care workers evidently are constructed so poorly that they fit few people properly, say researchers at the Center for Disease Control and Prevention's National Institute of Occupational Safety and Health (NIOSH).

In two separate studies — one published in 1996[1], the other still awaiting publication — laboratory researchers in NIOSH's Respiratory Disease Studies Division found that many N95 half-mask filtering facepiece respirators perform poorly when tested on a panel of health care workers.

In a study published in 1998, a panel of 25 test subjects who were experienced in donning respirators tried on all 21 of the N95 respirator models available at that time. Three of the models failed to pass a subsequent fit test on any of the test subjects. In addition, 17 of the 21 respirator models tested had acceptable fit tests for fewer than half of the panel members.

"If you look at all 21 models, on average, only about 45% of the people successfully passed the fit test," says **Chris Coffee**, PhD, a senior research chemist at the laboratory research branch of NIOSH's Division of Respiratory Disease Studies and lead researcher for the 1998 study.

The data from that study were originally published without naming the manufacturers. After a period of debate, NIOSH staffers made the decision to release the names of the manufacturers, which are published here for the first time. **(See chart, p. 31.)**

A second, still-unpublished study by Coffee and others that tests the generation of N95s now on the market shows the same poor level of performance, says Coffee. "Based on what we're writing up now, the fitting characteristics [of currently available N95s] have not increased dramatically," he says. The new findings should be published sometime early this summer.

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Many experts at NIOSH say they worry that the poor-fitting respirators pose a threat to health care workers. "The worker is the one who has the potential to lose here," says **Paul Jensen**, PhD, chief of the laboratory research branch. "There are respirators out there that truly don't fit, but they're still being sold. So instead of having superior-fitting respirators, we have respirators that rely on the employer to make sure they fit properly."

"When we look at current models, and we do the standard tests, we see very high failure rates," adds **Donald Campbell**, PhD, a research scientist in the same branch as Coffee. "We have to wonder: How can they sell such things?"

Campbell, Jensen, Coffee, and others interviewed for this story all say they'd like respirator manufacturers to be held more accountable for the quality of their products — perhaps by putting a fit-testing component back into the certification process.

"NIOSH in general would like to pursue a fit-test standard" for manufacturers, says **Richard Metzler**, acting director of NIOSH's newly created National Personal Protective Technology Laboratory. "Our hope is to put [a fit-test] back into the proposed standard that we use in our respirator certification program."

That would have the effect of putting more responsibility for the fit onto the manufacturer, says Jensen. "We'd like to have it more balanced, so that workers are provided with a good respirator, and fit-testing becomes a double-check instead of the primary means of assurance," he says.

In the meantime, Metzler, Jensen, Coffee, and others at NIOSH say it's especially important for employers to make sure their employees are adequately protected — and not just by fit-testing, but by using a quantitative fit test, not a qualitative one, they add.

Quantitative fit tests compare two measurements: the number of particles outside the respirator and the number inside. Qualitative tests, by comparison, rely solely on subjective reports of smelling or tasting a test agent introduced into a test chamber.

Data from studies by Coffee and others have shown that quantitative fit tests are much more reliable than the qualitative tests in widespread use throughout the health care industry.[2] Manufacturing industries have moved much more

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Performance Testing Data for 21 N95 Filtering Facepiece Respirators for 25 Persons, 1996

Respirator model	Total penetration* (95th percentile)+	Respirators passing surrogate fit test: No. passing	Respirators passing surrogate fit test: Total penetration* (95th percentile)+
3M 1860	6%	14	3%
3M 8210	7%	8	2%
MSAa Affinity Pro	18%	16	1%
AirAce N95 Elastormeric	88%	4	1%
AlphaProtect MAS695	31%	0	NA
BBI RX2	11%	15	4%
Gerson 1730	10%	5	2%
Gerson 2735	6%	9	2%
MSA Affinity	18%	0	NA
Moldex 2001/2002	12%	8	2%
Moldex 2300N95	33%	3	16%
Racal Racal	41%	3	3%
Recal Delta	21%	8	4%
San Huei SH3810	26%	0	NA
Tecnol PFR95	19%	3	3%
Tecnol PFR95-110/114	13%	9	4%
Uvex Proo-Tech-N95A	50%	11	1%
Uvex Pro-Tech-N95	7%	20	2%
Willson 9510	32%	3	4%
Willson 9501	61%	1	2%
Survivair 1930	24%	6	5%
All	33%	146	4%

* Total penetration is the sum of the filter penetration and face seal leakage. For example, a total penetration of 25% corresponds to an exposure equal to 1/4 of the exposure without a respirator. Total penetration is expected to be <=10% for this class of respirators. + Ninety-five percent of wearers are expected to have total respirator penetration less than the stated value. For this class of respirators a value of <="10%" is expected. & This model failed the fit test (i.e., had a first-donning face fit leakage <="1%)" with all 25 persons; therefore, the 95th percentile total penetration could not be computed.

Source: Centers for Disease Control and Prevention. Laboratory Performance Evaluation of N95 Filtering Facepiece Respirators, 1996.*MMWR*. 47 (48):1045-1049.

swiftly than the health care industry in adopting quantitative fit-testing.

Coffee's research shows that qualitative fit-tests are prone to produce false negatives; that is, the tests often show a poor fit for respirators that actually do fit well. Using the Bitrex test, a subjective fit test, Coffee found that in 41% of the tests, wearers flunked the test, even though they were receiving adequate protection. In addition, in 9% of cases, wearers passed the test but actually received inadequate protection.

Coffee's forthcoming publication is expected to recommend that fit-testing programs in hospitals and other health care facilities switch from the qualitative to the quantitative method of fit-testing. That would have the effect of formalizing a long-standing preference at NIOSH for quantitative fit testing.

Given the widespread deficiencies of available N95 respirators, that's the right thing to do, adds Jensen. "For now, we have to make sure the employer is doing fit-testing and doing it right," he explains. "So far, [research] has shown that quantitative fit tests are much more predictive of fit than quantitative ones."

Error rate compounded with re-testing

Other recently published work from the agency reinforces the importance of testing accurately and getting a good reading the first time out. In a computer simulation, Campbell and other researchers found that subjects who flunked two fit-tests and were switched to a second and then a third respirator had diminishing chances of getting a good fit, because the rate of error is compounded with re-testing, says Campbell, lead researcher for that study.[3]

Until 1995, the NIOSH certification process for respirators included a fit-testing component. That part of the certification process was thrown out because the test substance, a vapor called isoamylacetate, did not work well with particulate respirators, which had to be modified with a different, vapor-resistant material before tests using the substance could be performed.

Plus, one NIOSH staffer adds, some inside the agency figured that "if there were crappy masks out there, people simply wouldn't buy them — or at least, they wouldn't buy a second one."

Now, the mood at NIOSH has swung back, with many experts calling for more protection for the consumer. But a change in certification standards is probably a long way off, researchers concede. One reason is simply the enormous workload facing the short-staffed agency.

In addition, a logistical hump looms in the road: the question of whether the test panel used to assess fit is still relevant. Respirator manufacturers and NIOSH experts both agree that the panel may need to be updated, because subjects are chosen on the basis of facial types prevalent in 1972, the year scientists at Los Alamos National Laboratory in New Mexico took anthropometric measurements of face types considered typical of the U.S. health care worker population at that time. Since then, the composition of the health care work force has changed. Now, for example, there are more women and more foreign-born people working in health care.

In addition, some in the respirator manufacturing industry dispute whether the six exercises used during the fit test are relevant to tasks performed by health care workers on the job.

NIOSH researchers are preparing to undertake new anthropometric measurements, but that will take time, they say. Regarding the industry's complaints about the relevance of the exercises, Coffee says he's not convinced there's a problem. "The idea is to stress the face seal," he notes. "I don't know if the movements [in real life] are any more or less stressful, since there are no data one way or the other. We need to do a simulated workplace test, and then a fit test, and compare."

While workers wait on NIOSH for more information, it probably makes sense for the health care industry to develop its own system of certification for respirators, much as the fire-fighting industry has already done, says Coffee. "You set up your own program, basically, and leave NIOSH out of it," he says. "That way, you make sure that only good-fitting respirators get that seal of approval."

The bottom line, he adds, "is to start with a respirator that fits the majority of people — say, between 85 and 90% — and then use a [quantitative] fit test to find those without a good fit."

References

1. Laboratory performance evaluation of N95 filtering Facepiece respirators. *MMWR* 1998; 48:1045-1049.

2. CC Coffee, Z Zhuang, DL Campbell. Evaluation of the Bitrex qualitative fit test method using N95 filtering facepiece respirators. *J Int Soc for Resp Protection* 1998; Spring-Winter:48-55.

3. DL Campbell, CC Coffee, SW Lenhart. Respiratory protection as a function of respirator fitting characteristics and fit-test accuracy. *AIHA J* 2001; 62:36-44. ■

TB and global security: A look into the future

Population shifts to compound problem

In coming years, infectious diseases will join forces with demographic changes and begin transforming the concept of foreign policy, creating a new set of transnational issues that will threaten economic and political stability, says a policy analyst who studies demographic trends.

According to **Steve Durand**, senior policy expert at the Population Resource Center, the players on the new global stage won't be just national governments, but will include the pharmaceutical industry and major philanthropists. The Population Resource Center is a 20-year-old Washington, DC-based nonprofit organization that works to disseminate findings from the scientific and research communities to policy-makers.

In Durand's scenario, population growth is one of the engines driving the change. "Within the next 12 to 13 years, the world will add another billion to the population," Durand says. "Ninety-five percent of the growth will take place in the developing world, and there will be huge migrations into urban areas." The result is that half the population will be located in cities in the developing world — cities in which infrastructures will be overwhelmed, where there will inadequate sewer systems or safe water, and where infectious disease will abound. Factor in trends in antibiotic resistance, and you begin to see the scope of the problem, Durand adds.

Gates Foundation commissions talks

A report issued last June by the Office of Global Affairs at the Central Intelligence Agency reaches many of the same conclusions, he says. "They talk about [these trends] in terms of their impact on national security," he says. "You can see why, looking at the impact of AIDS on Africa, where the epidemic is creating enormous economic instability."

Transnational issues such as infectious disease were the topic at a conference last month in Maine, held in conjunction with that state's chapter of the United Nations Association.

In attendance were about 150 health care providers. That's not business as usual for the Population Resource Center, Durand adds, because his audience usually consists of members of Congress and other policy-makers. The recent conference is one in a series commissioned by the Gates Foundation, which asked the center to stage a series of talks in a civic, not political, setting, on the subject of health, the environment, and demographics.

The center specializes in a variety of issues related to demographics, Durand says, including family planning, infectious diseases, aging, and environmental concerns such as urban sprawl.

"What we often do is take a 50-page paper and turn it into something digestible," says Durand. "There's a ton of information out there, but in truth, no politician or staff member has the time to read it all." ■

Even amid poverty, health is attainable — report

But 'massive effort,' political will are requisites

Two out of three deaths among children and adults (ages 0-44) in Africa and Southeast Asia are due to just a few diseases: TB, AIDS, malaria, childhood diseases, and reproductive conditions.

A new report issued jointly by six United Nations agencies on Dec. 19 shows that worsening epidemics of infectious disease and rising death rates are not inevitable. The report, titled "Health, A Key to Prosperity: Success Stories in Developing Countries," documents successful strategies for beating back TB, malaria, AIDS, childhood diseases, and maternal and perinatal conditions, even in some of the world's poorest nations.

In India, for example, which accounts for 30% of the global TB burden and nearly half a million TB deaths each year, a massive expansion of TB treatment meant that by the end of last year, one-fourth of the population was covered by the five-pronged strategy known as directly observed treatment, short-course (DOTS), up from just 2% in 1998.

In Nepal, one of the poorest countries in the world, TB treatment success rates have more than doubled since 1994, and 75% of the population now has access to DOTS TB treatment.

Vietnam has reduced the death toll due to malaria by 97% in five years, through the use of locally produced high-quality drugs and the provision of insecticide-treated bednets.

Malawi, one of the world's most impoverished nations, has boosted its measles immunization rate from 50% in 1980 to almost 90% today. A 1998 immunization campaign reached over 4 million children with measles vaccines and provided Vitamin A supplements for younger children at a cost of $.78 per child. Vitamin A given a few times a year can prevent 1 in 4 child deaths due to infectious disease. Globally, measles remains the greatest preventable killer of children, taking 900,000 young lives every year.

In the introduction to the report, the World Health Organization's Director General **Gro Brundtland** says, "We know what works. A number of health interventions and tools can dramatically reduce deaths from the main killer diseases." The report is a call for taking these interventions to scale, making them available worldwide as a concrete, results-oriented, and measurable response to poverty and the global threat of infectious disease.

Combating infectious disease and protecting the lives and health of people in the world's poor nations is not only the right thing to do; it is central to securing lives, the report argues. Diseases such as TB cannot be stopped at national borders, and they grow more dangerous and difficult to treat the longer the global community waits to put in place effective basic treatment programs, it says.

The report cites the fact that TB treatment using DOTS is one of the most cost-effective health interventions available (based on World Bank data), yet DOTS reaches fewer than 1 in 4 of those sick with TB.

If TB is improperly treated, it mutates into drug-resistant strains that are more costly to treat (and sometimes fatal). In the United States, a standard case of TB costs roughly $2,000 to treat, while multidrug-resistant TB can cost as much as $250,000, without a guarantee of success. In the world's poorest nations, a full six months of drugs to cure a drug-sensitive case of TB costs as little as $10.

Infectious diseases are not only a threat to public health but also may predict or even contribute to the undermining of global stability, the report says. A 1995 CIA report commissioned by Vice President Al Gore looked at the reasons governments fall. In considering 600 factors associated with 113 cases of state failure, the CIA found the best predictor of state failure was a high infant death rate. Worldwide in 1999, almost 11 million children under age five died from mostly preventable diseases and malnutrition. ■

Strain-typing project gets its report card

Technology's an overachiever, experts say

Since 1996, seven sites across the country have been doing DNA fingerprinting on all their TB isolates. Now, it's time to evaluate the results, says a TB laboratory expert at the Centers for Disease Control and Prevention.

"We wanted to see whether doing this would benefit TB control programs, to see whether it was practical and cost-effective, and to look at how much work it is," says **Jack Crawford**, PhD, chief of the immunology and molecular pathogenesis section of the Division of AIDS, STDs, and TB Laboratory Research Division at the CDC in Atlanta.

What Crawford's found seems to be a combination of good and not-so-good news.

On one hand, it's clear that TB control programs see tangible benefits from strain typing, because it lets them zero in on ongoing transmission that otherwise might have been missed. Programs "like [using the technology] a lot," he adds.

At the same time, the technology is costly and entails a lot of work. Arguably, it provides more information than programs actually need, he adds. That's why he and other researchers are looking at whether there may be cheaper, simpler ways to accomplish the same thing — maybe by using less costly, simpler methods to pre-screen isolates before deciding whether to go ahead with strain typing.

A little too much detail?

"The trouble with DNA fingerprinting is that it's very specific, as well as fairly specialized," Crawford notes. After strain-typing about 16% of all TB isolates in the country, the seven-site project has turned up a whopping 6,000 fingerprints out of 12,000 isolates. "That's a little more specific than you really need," he adds. Plus,

the technique is not one that every lab can implement.

What Crawford would like to try out is a handful of simpler, cheaper screening tools, including two methods using polymerase chain reaction (PCR). One PCR-based method involves using a hybridization assay; the other searches for the same sequence of alleles repeated end-to-end a variable number of times.

Another possible screening tool is spogliotyping. This is another kind of hybridization assay in which the aim is to determine the presence or absence of a particular sequence expressed in a digital form.

It has yet to be determined when and where the new technologies will get a workout, Crawford notes. "We haven't made up our minds yet about how we'll implement this — probably not this year, but maybe next year."

DNA fingerprinting has been used since the early 1990s in outbreak investigations. Landmark studies of the technique by San Francisco TB researchers encouraged other programs to begin using it on an ongoing basis as a way to ferret out ongoing transmission. Sites for the CDC project include Massachusetts, New Jersey, Michigan, Maryland, parts of Texas, and California. ■

IOM report lauded by OSHA's foes

'Low risk' criteria called too stiff

Opponents of the TB standard proposed by the Occupational Safety and Health Administration (OSHA) say they are pleased with a recently released report from the Institute of Medicine (IOM) that eyes the impact of implementing the new OSHA rule.

"The findings of the IOM are consistent with what we've been presenting to OSHA and to the IOM," says **Rachel Stricof**, MPH, an epidemiologist at the New York State Department of Health in Albany and a member of a task force for the Washington, DC-based Association for Professionals in Infection Control and Epidemiology (APIC). APIC has lobbied hard to convince Congress that plugging in the proposed standard would drive up costs without substantially benefiting employees in health care facilities — a complaint echoed in the IOM report.

"To the extent that an OSHA standard inflexibly extends requirements to institutions that are at negligible risk for occupational transmission of TB, the standard is unlikely to benefit workers. At the same time it would impose significant costs and administrative burdens on covered organizations, and absorb institutional resources that could be applied to other, potentially more beneficial uses," the report says.

Specifically, the report takes the proposed standard to task on three counts:

- It raises questions about data the federal agency used in its projections of cases that implementing the standard would avert.
- It questions the usefulness of OSHA's narrowly defined standard of what constitutes a "low risk" facility.
- It tackles issues related to use of respirators and fit testing, arguing that not enough data exist to make a call for or against their use.

Low-risk definition said too strict

The report questions OSHA's claim that between 1,477 and 1,744 cases of TB could be prevented among health care workers each year by plugging in the TB rule. "In its surveillance report, CDC lists a total of 551 cases of [TB] among health care workers, and 16 cases among correctional facility workers," the IOM panel writes. "This figure is less than two-thirds the number of cases that OSHA predicted would be prevented. Moreover, of the reported cases of active disease, some proportion will have been the result of community rather than workplace exposure."

The OSHA definition for a "low risk" facility is also overly stringent, the report suggests. Under the proposed criteria, to qualify as low-risk, a facility must have had no confirmed cases of infectious TB during the previous 12 months and must be located within a county that has had no confirmed cases of infectious TB during one of the previous two years and less than six cases during the other year.

"Even if a facility had admitted no tuberculosis patients in the preceding 12 months, had no cases in its service area, and had a policy of referring those with diagnosed or suspected TB, this facility could not qualify for this 'lower risk' category if the surrounding county had reported one case of TB in each of the two preceding years," the report notes.

A better way to assess risk might be to take into account a hospital's service area, says **Marilyn Field**, MD, the IOM report's project officer.

Finally, a paucity of data makes it difficult to lay down standards governing the use of respirators and fit-testing, the report cautions. The committee said it found no epidemiologic studies, either initially or annually, that have evaluated either qualitative or quantitative studies of N95 fit-testing.

"Administrative and environmental controls have clearly been shown to be effective," adds Stricof. "What has not been shown to be effective are respirators and fit-testing programs." ■

Will new administration mean changes for TB?

New HHS head one to watch

When a new, more conservative presidential administration took over in January, TB experts were quick to spot at least one silver lining. Widespread conventional wisdom in the TB community has it that chances for passage of the new TB standard proposed by the Occupational Safety and Health Administration are considerably dimmer than before.

But those who get paid to fret about such things say they're looking anxiously at new administration appointments - in particular, the new Secretary of Health and Human Services, former Wisconsin Gov. Tommy Thompson.

"We're watching his strong interest in state experimentation, which could be read to mean block grants," says **Gary Billings**, a spokesman for the New York City-based American Lung Association (ALA). Thompson himself hasn't mentioned the dreaded "B" word, Billings hastens to point out. It's just that the former governor is known for having retooled his own state's welfare system and for having a less-than-reverent attitude toward federal control of programs (Thompson has referred to the nation's capital as "Disneyland East").

"He's also made a series of comments in which he says states should be innovators in health care policy and that he'd like to give them more power and authority," adds Billings.

On the brighter side, the ALA has approached U.S. Sen. Henry Waxman about the possibility of the legislator introducing an omnibus TB bill, Billings reports. ALA chief Fran DuMelle has been hard at work on the omnibus bill, along with representatives from the National Coalition to Eliminate Tuberculosis. The bill will seek authority (and, of course, funding) to carry out projects outlined in a recent Institute of Medicine report, says Billings. Chief among the projects will be in-country TB screening of immigrants from high-burden countries. ■

Fixed-dose combinations get a boost from WHO

Move should cut down on dosing errors

The concept of fixed-dose combination therapy (FDCT), a sometime ugly duckling in the world of directly observed therapy (DOT), got a makeover recently when the World Health Organization gave it a thumbs-up, commending it especially to health ministries in developing countries. TB experts in the United States are divided in their reaction to the change.

The policy change was announced recently by **Sergio Spinaci**, MD, a TB expert at WHO who currently serves as executive secretary of macroeconomics and health at the organization. Combination regimens are now both cheaper and more readily available, Spinaci pointed out, and their use should help cut down on dosing errors as well as supply problems, he said.

Historically, support for FDCT both here and abroad has been tepid, partly because of fears that fixed-dose regimens might undercut the motivation for implementing DOT because one of the main goals of direct observation is to make sure patients take all their pills, not just some of them.

The most positive effect of the new policy is that it will prevent patients "from picking and choosing" from among their medications, says **Jim Yong Kim**, MD, PhD, executive director of the Boston-based nonprofit organization Partners in Health. "This way, you can't take out the rifampin and sell it on the black market for [treatment of] STDs," he says, citing one not-uncommon scenario.

Kim dismisses concerns that FDCT will crowd out DOT. "No one wants to see it replace DOT," he says. "The idea is to make DOT easier."

Even though common sense suggests that packaging separate components of a regimen into the same pill should decrease the likelihood of resistance, that's technically an untested assumption, Kim and others note. No trial has ever directly compared FDCT to other dosing methods, says **Rick O'Brien**, MD, chief of the Research and Evaluation Branch of the Division for TB Elimination at the Centers for Disease Control and Prevention. Still, there is evidence to suggest the optimists are right about FDCT, he adds. The nation of Brazil, for one, has steadfastly resisted implementing DOT, uses FDCT, and boasts of notably low rates of drug resistance.

On the other hand, if FDCT is used in a setting where resistance already has a foothold, there could be trouble, says **Tom Moulding**, MD, professor of clinical medicine at Harper/UCLA Medical Center in Torrance, CA. That's because ethambutol and pyrazinamide don't work as well as rifampin and isoniazid, he explains. If one of those so-called "twin pillars" already isn't working and a patient with mono-resistance who self-administers medications begins to skip doses, the result could be treatment failure and more drug resistance, Moulding warns.

FDCT reduces drug distribution costs

On the plus side, in developing countries where distribution systems are unreliable, implementing FDCT will assure that clinics get all the TB drugs they need, not just some of them, points out Moulding. It should keep costs down, too, he adds: "If you've got three drugs coming from three different companies, the amount of work you've got to do to make sure they all get there will be cut by using FDCT. Distribution systems are where you incur a lot of the cost."

The cost of the pills themselves has begun to come down, adds Kim. "Manufacturers in India are beginning to work on [FDCT], and soon we should see begin to get very low," he says.

Kim claims that the use of FDCT won't result in TB patients taking fewer pills, because doses need to be adjusted according to a range of body weights, Kim adds. "So the number of pills people take will probably be about the same," he says. It's also unlikely that FDCT will ever be used for treating multidrug-resistant TB, he says. "People have actually raised such a possibility, but I doubt it will happen," he says. "With treatment for MDR-TB, you have so many side effects that you want to retain flexibility." ■

HIV/TB partnerships paying off for Florida

Projects in urban counties, among Haitians

In Florida, partnerships between TB and HIV health care providers are starting to pay off with a decrease in TB cases, says **David Ashkin**, MD, medical advisor to the state's TB control program. "Instead of the old way of doing business, where we had separate programs, we decided we wanted to start putting TB into programs that dealt with vulnerable populations," says Ashkin.

Two years ago, TB cases in the state appeared to have leveled off, adds Ashkin. Now, however, TB controllers think they'll see a drop in cases of about 10%, once last year's case count is completed.

HIV providers routinely screen for TB

Two programs under way are helping make the difference, Ashkin says. First, TB controllers have mounted a long-term effort to get short-course prophylaxis into HIV-infected populations in Broward and Dade Counties. "Two and half years ago, we went to HIV-care providers in those two counties," Ashkin says. "We integrated routine TB screening into the clinics, using TB program personnel and expertise."

Co-infected patients have tolerated the short-course prophylaxis (consisting of rifabutin and pyrazinamide) remarkably well, he adds. "Compliance rates have been about 90%," he says. "Tolerance has been very good. We're reading about side effects from this regimen, but that's not what we're seeing here," he adds.

One reason for that may be that HIV-infected patients are used to coping with side effects, Ashkin says. "Unfortunately, these individuals are taking so many medications with side effects that side effects become a way of life," he says. By comparison, motivation isn't nearly as high for someone "who's a healthy individual, who's not experiencing any symptoms, and who has a small chance of actually developing active disease," he adds.

Another plus for the short-course regimen is that it's finite, he points out. "A lot of [HIV-infected people] have the mindset that they're going to be taking medications for the rest of

their lives," he says. "Here's a situation where you take medication for two months — and that's it!" Once the threat of developing TB is explained to them, HIV-infected patients tend to appreciate the risk of disease as well as the benefit prophylaxis can bestow, he adds.

Like sparks in a gas-filled room

Screening for TB at HIV clinics has turned up more than just candidates for prophylaxis. "We've actually turned up several active cases," he says. "That's very scary. If they'd gone undetected, they'd be sitting in these clinics surrounded by other people with HIV, spreading disease to this extremely vulnerable population."

Instead, TB cases in Broward and Dade have been dropping — although Ashkin adds that part of what's happening could also be attributable to the wider availability of triple-therapy regimens for AIDS, he adds.

The state's Haitian community, another population with high rates of co-infection with HIV and TB, is the target of another effort to integrate HIV and TB programs, Ashkin says. "Haitians only make up 4% of our population in the state, but they account for 26% of our foreign-born TB cases," he points out. As in Dade and Broward, TB controllers have begun to partner with agencies serving the HIV-infected portion of the Haitian population; but in this case, getting a handle on the scope of the problem is proving trickier.

"You can't say all Haitians are infected with HIV," he says. "What's clear is that among those with TB, the real problem is HIV." What complicates surveillance work for both HIV and TB infection is that the Haitian community is very close-knit, with its own deeply held traditions. The result, Ashkin adds, is that many Haitians are resistant to incursions by outsiders and suspicious of Western-style medicine.

Studies from an immigrant processing center in Guantanamo Bay, Cuba, suggest that TB infection rates may be as high as 50%. An added complication is that many Haitians travel back and forth to their homeland, where they may be exposed to TB again and again.

To see whether there is ongoing transmission of TB among Haitians, TB controllers are doing DNA fingerprinting, says Ashkin. To try to figure out whether Haitians are bringing TB back from visits home, TB controllers are collaborating with researchers in Haiti to get isolates for comparison.

If studies point to recurring reinfection, then prophylaxis for this population may not be short-course at all, but may have to be prolonged, Ashkin notes.

"This is an instance where it's so important that we in TB don't work in isolation from other parts of public health," Ashkin says. "In this case, TB travels on the coattails of HIV. I compare it to sparks in a roomful of gas: Sooner or later, something is going to ignite." ■

One-third of HIV patients were not aware of their risk

Should physicians screen all patients for HIV?

HIV testing remains controversial, despite clear evidence that routine testing and early diagnosis can help HIV-infected patients receive the medical care they need earlier in their disease progression, which could have a positive impact on their long-term prognoses.

New research shows that more than one-third of HIV-infected patients at two urban hospitals were not aware of their HIV risk before they were tested for the virus, especially if their source of infection was through heterosexual sex rather than homosexual sex or injection drug use.

"Acknowledging that awareness of your risk is the first step to getting tested," says **Jeffrey H. Samet**, MD, MA, MPH, associate professor of medicine and public health at Boston University School of Medicine and Public Health.

Risk extends beyond obvious groups

"We've done a reasonable job in the last 20 years of making it clear that people who inject drugs and have unprotected sex with men are at higher risk of infection," Samet says. "But what's happening is that more than those risk groups are at risk. Anyone having sex without condoms with a partner who is not known to be HIV-negative is also at risk."

Samet argues that because the down side of HIV testing is so negligible and the up side of knowing one's HIV status is so significant, the medical community should have a very low threshold for HIV testing.

Already, nearly one-third of adults in the United States have been tested for HIV. Some of those adults have voluntarily sought their HIV status, but for many others the testing is done routinely as part of blood donor screening, life insurance screening, and military service.[1]

"Those generally are people who are not in risk groups," Samet adds.

In the Boston study, investigators found that 80% of HIV-infected patients initially presented to medical care with CD4 cell counts of less than 500/µml, and 37% had counts of 200/µml or less.[2]

The study population included 203 outpatients at the Boston Medical Center (previously called the Boston City Hospital) and Rhode Island Hospital in Providence between February 1994 and April 1996.

Although this time period encompassed the pre-protease inhibitor era, the findings would likely be the same today, Samet notes.

"This was all post-Magic Johnson's HIV disclosure," Samet says.

When pro basketball star Magic Johnson announced that he was infected with the virus, public health officials hoped that the public would finally realize that many more people were at risk than they had believed, he adds.

The study shows that people continue to remain ignorant about their risk-taking behaviors. And although the investigators have not formally studied more recent data, it would appear that the problem still exists, Samet says.

"We've made a little progress, but without a doubt there are many, many people coming in with opportunistic infections and still coming in quite late," he says.

The study found that HIV-infected patients who first presented with lower CD4 cell counts were more likely to have these characteristics:

- no or only one close friend;
- had not been in jail in the past 10 years;
- had been voluntarily tested;
- had lower hope and a poor quality of life;
- had more symptoms of HIV infection;
- were older.[2]

Another interesting finding was that among the patients who knew they were at risk for HIV, they still would wait months to years before being tested. The median time lapse between when a person first felt at risk and when he or she was tested was one year. The mean time lapse was 2.5 years.

Based on an analysis of the subjects' CD4 cell counts, investigators speculated that many HIV-infected patients have had the disease for 6.0 to 11.6 years before being tested. This is their approximation of a mid-range period of delay.

This brings the issue back to medical treatment and policy, Samet suggests.

"It was the heterosexual group that was least aware of HIV risk at time of testing, and that finding to me is totally compatible with what we're seeing clinically," Samet says.

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The solution is for clinicians to lower their threshold for recommending HIV testing, he adds.

Rather than providing testing as a diagnostic tool in the cases of patients who have symptoms that could signify HIV disease, primary care physicians could use HIV testing as a screening tool. As such, it would be similar to Papanicolaou smears for cervical cancer or mammography of older women for breast cancer.

A Pap smear is given routinely in the case of a disease that has a prevalence rate of 0.1%. By contrast, the national prevalence rate of HIV infection is 0.3%.[1]

Samet admits that routine universal testing, while ideal from an epidemiological perspective, will not be feasible. However, physicians could lower their threshold for when to suggest testing.

Here are some possible scenarios in which routine HIV testing could be applied:

• A hospital has one or more patients with newly diagnosed AIDS per 1,000 patient population. Hospitals with an incidence rate this high could routinely test all inpatients for the disease.

• Patients presenting with varicella zoster virus, community-acquired pneumonia, tuberculosis, or hepatitis C, or who have a history of any sexually transmitted disease or recurrent vaginal candidiasis should be tested.

• Patients who have experienced sudden weight loss, unexplained lymphadenopathy, or dermatological diseases should be tested.

• Physicians should offer testing to patients who have reported on their physical report a history of alcohol dependence, cocaine abuse, homelessness, or psychiatric hospitalization.

• Clinicians could routinely approach the subject by asking new patients to consider having an HIV test if they have had any unprotected sexual contact with a person who is either HIV-positive or who has an unknown HIV status.

Clinics and clinicians who promote testing under these circumstances will undoubtedly find additional cases of HIV that otherwise would have fallen through the cracks. At least that was the experience Samet had when his hospital made a major push for HIV testing of all untested patients. Unfortunately, the time and energy needed to maintain such an effort proved too difficult to maintain, Samet says.

"It's hard to implement because people are in and out of the hospital or clinic," he explains. "But it was clearly a useful policy in our setting."

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CE objectives

After reading each issue of *TB Monitor,* health care professionals will be able to:

• Identify clinical, ethical, legal, and social issues related to the care of TB patients.

• Summarize new information about TB prevention, control, and treatment.

• 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. ■