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Monitoring safeguards considered for 2RZ guidelines

Firewall against hepatoxicity, trial suggests

Stepped-up biochemical monitoring may prove critical to preventing liver injury resulting from use of the new regimen for treating latent TB infection, TB experts say.

Revised guidelines for use of the regimen, two months of rifampin and pyrazinamide (2RZ), will probably call for laboratory monitoring at baseline and at two, four, and six weeks, says **Rick O'Brien**, MD, chief of the research and evaluation branch of the Division of TB Elimination (DTBE) at the Centers for Disease Control and Prevention in Atlanta.

The proposed revisions are in line with preliminary findings from the first randomized controlled trial using the new regimen in HIV-negative people. In that trial, subjects receiving 2RZ experienced "significantly" higher rates of both moderate and severe hepatotoxicity compared to patients taking INH, says the study's principal investigator, **Robert Jasmer**, MD, assistant professor of medicine at the University of California in San Francisco. But preliminary analysis of trial results also strongly suggests that biochemical monitoring can head off trouble, he adds.

"We did find significantly higher rates of hepatotoxicity with 2RZ," says Jasmer. "But we also showed that by using intensive laboratory monitoring, we could pick up hepatitis, rather than waiting for patients to develop symptoms and require hospitalization."

About 90% of patients with hepatotoxicity were spotted before they became symptomatic, he adds. "Had we continued therapy, I'm convinced they'd have progressed to symptoms and possibly to hospitalization," adds Jasmer.

Instead, using one blood draw at baseline and a second after one month of treatment, serious problems were averted, and not a single patient required hospitalization.

Unlike Jasmer's trial sites, public health programs trying out the new regimen haven't made consistent

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use of laboratory monitoring, because original guidelines didn't call for it. In some instances, programs have had problems with the new regimen, ranging from mild to severe, including several fatalities. Yet it's hard to determine how often problems are occurring, because no denominator exists yet for field reports.

Factors linked to trouble

Reported problems with 2RZ appear to be concentrated among specific groups, O'Brien says: patients ages 50 or older; those with underlying liver disease or a history of alcohol abuse; and those with intolerance to INH. In several instances, patients also appear to have kept taking their medication after the onset of symptoms, he adds. In addition, patients getting the higher end of the dose range for pyrazinamide — over 20 mg / kg — seem to be having trouble.

It's important for clinicians to recognize that 2RZ is neither risk-free nor less risky than INH, O'Brien adds. "This regimen is not innocuous," he said last month, addressing a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET) in Atlanta. ACET members agreed that it's crucial for TB control programs to get this message out to hospitals and private providers who may be using the new regimen.

That applies doubly to health care providers, some at the ACET meeting said. That's because health care workers often get skin-tested to meet federal or employer regulations, and not because they're at substantial risk for TB infection — a fact that increases the likelihood of false-positive reactions. Such reactors certainly shouldn't regard 2RZ as a quick and easy way to treat apparent latent TB infection, the ACET members agreed.

Revised guidelines are also expected to call for more intensive clinical monitoring, with visits at two, four, six, and eight weeks, O'Brien says. As in the first guidelines, the revised guide is expected to underscore — this time with an even heavier emphasis — the importance of teaching patients about symptoms and of making sure they know to stop taking the medicines immediately if symptoms occur, says O'Brien.

The new guidelines are also expected to recommend that the same provider see the patient throughout the course of treatment and that no more than two weeks' worth of medications be handed out at a clinic visit.

Neither the regimen's rocky start nor the expected stiffer monitoring requirements should

scare people off, say TB experts. "There may be populations where [2RZ] will prove especially useful, like captive settings where you can do intensive monitoring," says Jasmer. "That's the goal in the next few years: to find out in what settings and in what populations this will be most useful."

Faced with the prospect of four needlesticks, many patents will still probably opt for 2RZ over nine dreary months of INH, says **Lee Reichman**, MD, MPH, director of the National TB Center at the New Jersey Medical School in Newark. "Plus, INH still has such a bad reputation," Reichman notes. "Half the calls we get on our hotline are about INH."

As of mid-July, DTBE investigators were still working to finish on-site investigations of reports of liver injury apparently linked to use of 2RZ. When the DTBE conducted a "rapid survey" of public health jurisdictions across the country, they garnered 81 reports of adverse events associated with 2RZ, says **John Jereb**, MD, a medical epidemiologist at the DTBE. Those events were "uncharacterized," he adds, meaning they spanned the gamut from pruritis to insomnia to hepatitis.

In a second survey, callers to a hotline set up at the CDC in early summer had reported 54 instances of apparent liver injury linked to latent infection (with either INH or with 2RZ) by mid-July.

In 28 of the events — about 54% of the total — hepatotoxicity was severe enough that patients required hospitalization. Of those 28 severe events, 16 resulted from use of either daily or twice-weekly 2RZ. Four were linked to the use of INH only, with three of the four tied to daily INH and the fourth to thrice-weekly INH, Jereb says. The 28 events included seven deaths and one liver transplant either from use of INH or 2RZ (or, in two cases, both).

Categorization of fatalities

Here is the CDC's breakdown of the seven deaths, as of last month:

— two linked to use of 2RZ only;

— two in which patients were started on INH, developed INH intolerance, and were switched to 2RZ;

— one linked to ethambutol/pyrazinamide;

— one linked to INH alone;

— one in which a suspect case got four-drug therapy and was switched to INH once TB was ruled out.

The patient who got a liver transplant had been treated with INH only, Jereb adds. Though he survived, CDC investigators classified his case with the other deaths, because without the transplant he likely would have died.

"Clearly, more data and more research on the regimen are needed," says O'Brien. Adds Reichman: "Once we characterize these toxicities, we'll have to do a decision analysis. People will have to decide for themselves whether or not the risks and the costs are worth the benefits." ■

Search continues for case-management tool

NTCA group to vet candidates

It sounds a bit like an assignment from *Mission: Impossible*. A working group from the National TB Controllers Association (NTCA) is planning to meet in Atlanta next month, with the hopes of finding some decent case-management software for state programs to use.

Subcommittee members, along with practically everyone else in the TB world, agree there's an urgent need for such a thing — and that TB programs needed it yesterday. But several on the subcommittee also doubt that ideal solutions will be ready until some indeterminate point in the future.

Last June in Baltimore, where this year's annual NTCA conference was held, TB controllers turned down a chance to see Oriole third baseman Cal Ripken, instead turning out en masse for a night meeting on the subject. New Mexico, Florida, Alabama, and California took turns at the meeting touting the merits of case management systems they'd already developed or that were under construction.

The upshot was a resolution to take a harder look at the four states' projects, and maybe some other entries as well, to see if any existing programs fit the bill for states looking for a short-term solution.

"We're going to try to come up with some examples of best practices and then see which selection might work as an interim fix, without requiring a lot of expense in terms of training and support," says **Dennis Minnice**, a member of the subcommittee and Chicago's TB program

director. Such a fix, he says, would have to be flexible enough that other states could tweak it to meet their needs.

Plus, such a system wouldn't take too much technical support to get it up and running and then keep it going, says **Philip A. LoBue**, MD, subcommittee member and assistant clinical professor of medicine at the University of California - San Diego Medical Center.

"Support is really the main obstacle," LoBue says. "Let's say I have a program and I give it to you. You've got to install it, see if it works, and figure out what to do if it crashes. We haven't seen how we're going to deal with that."

For the long term, there's a bigger task at hand, Minnice says. "We've got to determine some uniformly agreed-upon standards; we need to bring a better focus to the subject," he says.

Agreeing on what data to collect won't be a simple task, adds LoBue. "The types of populations we deal with vary considerably," he says. "In some instances — contact investigation, for example — the science isn't well-defined, either." The result is that one program collects one set of data, while a second collects another.

That's one reason LoBue likes the idea of a system that's web-based, he points out. "That would cut down on the need to buy a lot of [hardware], since multiple users could access it with only a computer."

In the ideal world, certainly, a case management tool wouldn't make states to do tedious double-entry of data and would interface smoothly with TIMMS, the Center for Disease Control and Prevention's TB surveillance instrument, say LoBue and Minnice.

The CDC's one-way patch

The CDC's TB software department has, in fact, developed a "patch" — a sort of software interface — that will enable programs to pull surveillance data out of TIMMS and put it into their case-management programs, says **Jose Becerra**, MD, MPH, chief of the computer and statistics branch at the CDC's Division of TB Elimination. But even with the patch in place, the process usually won't work the other way around, Becerra adds.

"That's because TIMMS has 350-plus rules, and the rules need to be built into the case management system before TIMMS can accept the data," he explains. Kansas' TB control program has been working with Becerra to get its data to conform with the demanding TIMMS parameters, and the program is almost there, he adds.

So why can't states just use the Kansas package? No good, explains Becerra: "Each system does case management a different way. You need a system that's flexible enough to be customized."

Both Florida and California seem headed toward integration of surveillance systems for a number of public-health disease entities. New Mexico and Florida are aiming at web-based systems, too, allowing for transmission of digitized chest X-rays or scanner-ready computerized tomography at the speed of an eyeblink.

Trying to eliminate double-entry

Florida's system is bent on eliminating double-entry, says Graydon Shepherd, the state's TB program director. "We're still doing some double entry, but we're making progress toward making the systems talk to each other," Shepherd says.

The Los Alamos National Laboratory brainiacs who've written OpenEMed, New Mexico's case management contestant, swear they can also accomplish two-way talk with TIMMS, so that "data entered into the case-management system are automatically populated into TIMMS, and vice versa," says **Gary Simpson**, MD, PhD, another subcommittee member and the state's head TB honcho.

Of course, Simpson and Shepherd both concede, the states' respective systems need more money — and more time. ■

World Bank, Russia talk about talking

Health minister writes hopeful note

The World Bank and Russia appear to be back on track and are corresponding once again on the subject of a $100 million loan to fight rising HIV and TB rates in Russia. Reports of the loan's demise notwithstanding, the situation is far from hopeless, says **Jean Jacques de St. Antoine**, the bank's program team leader for Russia.

"It's not a dead issue at all," he says. Negotiations should restart sometime within the next two to six months, he adds.

In June, the Russian minister of health went on the record as being opposed to the loan. That led many observers to conclude that the Russian government had pulled out of loan talks altogether. In truth, the minister's public bout of griping led only to a temporary impasse in which "the [Russian] government did not answer our requests to negotiate. It didn't look good at the time," concedes de St. Antoine, "but [even then] there was a chance for restarting talks." As evidence, last month an apparently chastened health ministry sent a letter to the bank announcing its willingness to revisit the subject of the loan.

Some sticks, some carrots

Throughout the spring, opposition to the loan grew among Russian drug manufacturers, who succeeded in winning the health ministry to their point of view. At the same time, though, de St. Antoine says the bank has applied a mix of sticks and carrots to continue to woo the Russians.

For example, bank officials have warned the country's finance ministry — which de St. Antoine says is the real negotiating party in the loan talks — that unless the country gets a handle on TB and HIV, Russia's gross national product could plummet by an entire percentage point over the next five years.

The health ministry, meanwhile, has received a steady stream of assurances from the bank that Russian drug manufacturers won't be locked out of the bidding wars once money for TB drug purchases becomes available.

"I know of three or four Russian companies that are candidates for WHO inspection," says de St. Antoine, referring to the World Health Organization's stiff standards for drug manufacturing practices. Companies must comply with these standards before their products can be purchased with World Bank loan funds. "Two of them would probably pass easily, either outright or with just some simple adjustments."

Plus, the bank gives an advantage to home-country manufacturers by allowing them to bid up to 15% higher than outsiders.

The issue of getting money to Russia to fight its multidrug-resistant TB epidemic remains very important to the bank, adds de St. Antoine. "I wouldn't call the TB situation in Russia a crisis, but it is certainly a serious situation," he says. "It's very important for us to maintain a dialogue with the Russian government." ■

Needed: co-sponsors for two Senate bills

Guns-for-butter move bodes well

Last month on Capitol Hill, in one of the quirks that characterize the workings of the legislative machinery, the Colombian military's loss came close to being TB's gain.

An amendment offered by Sen. Nancy Pelosi (D-CA) would have taken a $100 million chunk of foreign aid bound for the Colombian army and placed it into a USAID fund, where 70% of the dollars would have gone to fighting international TB.

Never mind that the amendment failed to pass, because lots more of the same is coming up, says **Jeff Glassroth**, MD, past president of the American Thoracic Society in New York City.

As *TB Monitor* went to press, a House version of the Pelosi bill was being planned. If that one fails, two more versions will be offered, one boosting TB funding overseas by $20 million and the other by $10 million.

"This really shows how the two TB bills before Congress both act principally as place-markers," Glassroth says. That is, they exist mostly to remind Congress that TB is a good cause in need of more money, meaning it doesn't really matter if the bills pass. "The legislative intent of the bills, we trust, will be included in larger health bills," he adds.

The House version of both the foreign and domestic TB bills has plenty of sponsors. The Senate version has a bipartisan slate of notables, but still needs co-sponsors. "Any co-sponsor is a good co-sponsor," Glassroth notes. "We need for people to get out and push this right now." ■

External reviews open doors to big changes

Warning: Not for the faint-hearted, fans warn

Wisconsin got one — and for the first time, the TB control program got itself a TB nurse, a part-time TB physician consultant, and a terrific new system for delivering medications, says **Tanya Oemig**, director of the state TB control program.

Virginia got one last year. Since then, the state TB program has been busy pushing through a series of "profound changes in the way we're structured,"enthuses **Ram Koppaka**, MD, the state TB program's public health adviser.

Mississippi got one, and presto! There was universal DOT across the land! OK, that's an exaggeration — but not by much, says state TB division director **Mike Holcombe**, MPH, MPPA.

Nearly every state TB control program that has commissioned an external program review agrees the process has potentially big rewards. But external reviews are not for wimps and weaklings, fans of the process caution. For one thing, your report card may conclude that your program has got it all wrong.

Plus, getting a review approved and carried out is just the start, says Virginia's Koppaka; the heavy lifting comes when it's time to plug in all those recommendations.

Despite the hazards and the hard work, Koppaka, Holcombe, and Oemig all agree that the reviews afford leverage required to pull off big-scale transformations.

"Many times over the past year, we've said, 'The program reviewers said to do this,'" Koppaka says. "It's helped us get a lot of stuff pushed through that otherwise we probably wouldn't have been able to do at all."

The team that carried out Virginia's review included Holcombe; Carol Pozsik, RN, MPH, director of South Carolina's Division of TB Control in Columbia; Phil Hopewell, MD, associate dean of San Francisco General Hospital and professor of medicine at the University of California, San Francisco; Brenda Ashkar, RN, MSN, PHN, former nursing director for Los Angeles County TB Control; and Sue Etkind, RN, director of the Massachusetts Division of TB Control in Boston.

Masterminding the whole process was **Russ Hansen**, the genial TB health educator and TB advocate for the Virginia chapter of the American Lung Association.

The cumulative impact of so much expertise in one place is considerable, Hansen says. "When Phil Hopewell, this internationally known TB expert, walks into the health commissioner's office, people definitely sit up and take notice," he says.

Hansen, it turns out, acts as front man for lots of the reviews, and the Virginia team members are much sought after as reviewers. Though Hansen's job description says nothing about organizing reviews, he's been doing it since he retired six years ago from the Division of TB Elimination (DTBE) at the Centers for Disease Control and Prevention in Atlanta.

Hansen says team members are drawn from an informal slate of 10 or so people who have become known as those willing to do the reviews. The ones who are available usually fill the slots, he adds.

Once upon a time, reviews were largely carried out by the DTBE, says Hansen. That changed in the early 1990s when the TB resurgence hit; suddenly, the CDC's TB experts had their hands full. Hansen made it known that he was willing to fill the gap. Because he had several decades of experience with TB program operations under his belt by the time he retired six years ago, he was a logical choice for people to call.

Drivers who know lay of the land

The review process begins with about six weeks' worth of advance preparation, Hansen says. Next, the team of reviewers flies in and begins an intensive week's worth of work on-site. Once on the ground, teams like having someone from the program provide chauffeur services — both for the opportunity to find out more about the program and to avoid getting lost.

Reviewers use "Essential Components of a TB Control Program," the venerable and thoroughly objective 1994 CDC document, as their measuring stick.

After the site visit, two more weeks are devoted to writing up findings and recommendations. The cost for the entire process runs from $10,000 to $20,000, which covers travel expenses, meals, and modest honoraria for team members. "No one's going to pay for their retirement with these kinds of fees," stresses Hansen.

Reasons for requesting a review are varied. In both Wisconsin and Virginia, TB programs were poised at transitional moments, with both Oemig and Koppaka wanting to start their jobs with a fresh slate of ideas. "Sometimes we get so busy shuffling paper, we can't see the forest for the trees," says Holcombe.

In other instances, TB program leaders have a specific agenda they're trying to push, or an issue they want examined more closely, says Hansen. "They could have some issue related to nursing, or clinics, or outreach; or maybe a program is considering going more to private providers." At such times, it helps to have someone from outside make the recommendations, he adds.

Holcombe agrees. "Having an outside expert come in and say the same thing you've been saying

for years carries a lot of weight," he says. "And you have this document you can hold up in a budget or a legislative conference. It's not just you, a lowly employee; it's some high-powered expert. People definitely respond to that." ■

Former Monsanto exec is Bush's OSHA choice

Foe of ergo rule calls him 'good friend'

President Bush has announced his intent to name John L. Henshaw, MPH, as his pick for the assistant secretary who will head the Department of Labor's Occupational Safety and Health Administration (OSHA).

Henshaw, 51, is currently serving as director of environment, safety, and health for Astaris LLC, a joint venture of a Monsanto spin-off called Solutia Inc. and a second company called PMC. Henshaw served for 16 years in the Air National Guard as a bio-environmental engineer, and he came to St. Louis-based Monsanto as an industrial hygienist in 1975.

According to press accounts, Henshaw's nomination has been sought by Sen. Kit Bond (R-MO), a harsh critic of the ergonomics rule. That rule was an early casualty of the Bush administration. Bond has called Henshaw "a good friend" who would be "a credit to the administration."

Because Henshaw "knows the subject" of industrial hygiene, "it won't take him long to be brought up to speed" on the proposed TB rule, says **Mandy Edens**, MPH, the industrial hygienist at OSHA who has served as chief architect of the rule. That could mean relatively swift action on the rule, assuming that Henshaw is confirmed as the new chief.

Confirmation hearings on new appointees might be bogged down in partisan disputes, now that the Senate has slipped from Republican control, thanks to the recent defection from the party by Sen. Jim Jeffords of Vermont. Plus, OSHA — a relatively small federal agency with just 2,300 employees nationwide — is more or less at the end of the Labor Department line when it comes to appointments, notes Edens.

"Three or four other senior appointments have to be made first," she notes.

All this suggests the TB rule will continue gathering dust for the foreseeable future. ■

Rocky Mountain states ponder forming group

When crisis hits, networking proves critical

Representatives from state TB programs from the far-flung northern Rocky Mountain states were set to meet as a group for the first time late last month in Jackson Hole, WY.

The meeting, intended as an exploratory look at forming a new regional group, was called by **Alex Bowler**, MPH, TB control officer for Wyoming. On the invitation list were Montana, Colorado, Utah, Idaho, Nebraska, North and South Dakota, and Wyoming.

The invitees all have plenty in common, which makes a regional group a good idea for them, Bowler maintains. "We all have widely scattered populations, except for metropolitan Denver, and we're all low-incidence states," he says. When Bowler says "low-incidence," he's not kidding, either: Wyoming's rate last year was a mere fly-speck of 0.8 / 100,000. "That can make it hard to keep an edge," he adds. All the states also have Indian reservations, where TB can pose a problem, Bowler notes.

Regionalization is one issue Bowler was definitely planning to kick around at the first meeting. The recommendation that states like Bowler's regionalize some of their services (one of the suggestions contained in last year's Institute of Medicine report on TB elimination) is hardly a popular subject in Wyoming.

"When you say 'regionalize,' if you're talking about education or highly specific laboratory services like DNA fingerprinting, then I'd say that's all right, " says Bowler. "If you mean forced regionalization of essential services, I'd have to say no." When it comes to laboratory services, "regionalization" suggests slow turnaround time and losing control of isolates, he explains. "You can't enforce your states' reporting requirements in another state," he points out. Wyoming already contracts with one TB lab on the East Coast, and Bowler is less than satisfied with that arrangement.

On the positive side, states so far from everywhere else on earth relish the prospect of having someone with whom to network. In Colorado, where rural TB controllers are just now emerging from a trial-by-fire ordeal involving two multidrug-resistant TB cases, one of Bowler's

colleagues says she likes the idea a lot.

"These MDR-TB cases are always going to be a crisis in a low-incidence state like ours," says **Gayle Schack**, RN, public-health nursing consultant for the state's TB program. "The most important thing when something like this happens is to work together and not fly off the handle when the tension gets high."

Good cross-state teamwork helped save the day in both MDR-TB cases, Schack believes. First, TB experts called in to consult by teleconference concluded that some of the cases' 80-plus contacts had probably been previously infected; others seemed likely to have been infected by the source case.

Two separate regimens for treating contacts were duly devised, and Schack got the word out to neighboring states where contacts were located. Things were just settling down, she sighs, when a nearby state sent Colorado yet another MDR-TB case.

Rock-bottom case rates like Wyoming's notwithstanding, Schack adds that she's seeing other low-incidence states get hit with occasional four-alarm fires like hers and is watching her own state's case totals climb, thanks to a spurt in population and an influx of foreign-born residents.

"We've got to work together so we can have a voice," she says. "That way, maybe we can keep from being forgotten." ■

Pfizer offers fluconazole to poor countries

Prevention getting top priority

Pfizer of New York City has offered to provide fluconazole free of charge in least-developed countries for treatment of fungal infections in AIDS patients.

Gro Harlem Brundtlandt, director-general of the World Health Organization in Geneva, Switzerland, called the step "very good news. I welcome [Pfizer's] offer to expand access to fluconazole. This is an important drug to treat fungal brain infections and esophageal candidiasis, which are common among AIDS patients."

She added, "The private sector is showing it is willing to do its part to fight the HIV / AIDS epidemic. I am confident that they will work with governments and international organizations in their efforts to strengthen health systems so that they are able to provide the care needed. This is a great challenge for all of us."

A proposed new multibillion-dollar global fund for health will, however, concentrate on AIDS prevention rather than on the mass purchase of expensive antiretroviral drugs, according to **David Nabarro**, executive director at WHO. He said there had been "an extraordinary degree of convergence" of opinion on the subject at a recent United Nations conference in Geneva.

The fund is likely to be launched this month at a United Nations conference on AIDS in New York. Kofi Annan, the UN secretary-general, has said the fund needs $7 billion to $10 billion, but it looks likely to raise only $1 billion this year, with the United States pledging $200 million.

Nabarro estimated that 70% to 80% of the fund would be used to combat AIDS, with the remainder used for prevention and treatment of TB and malaria.

Developing countries have expressed concern over the imposition of technocratic solutions that will prove impossible to implement. Even with offers of cheaper drugs from pharmaceutical companies, many experts believe that a mass AIDS treatment program with antiretrovirals still will be too expensive and difficult to administer.

South Africa already has indicated it will not embark on a large program of AIDS treatment. "Antiretrovirals are still expensive," said **Jo-Anne Collinge**, spokeswoman for the South African department of health. "They are beyond the budget of the health department." ■

Correction

An article in the July issue on latent treatment for TB infection using two months of rifampin and pyrazinamide should have stated that **Edward Nardell**, MD, was speaking of his experience at The Cambridge Hospital, and at his own TB clinic, where two patients of hepatitis were hospitalized. The patient in a third case, in Framingham, MA, was not hospitalized. In addition, Nardell is state TB control officer; and associate professor at Harvard Medical School. The halt on treatment with the two drugs applies only to Nardell's clinic. ■

Stalled TB rule leaves fit-testing confusion

Hospitals perplexed about respirator compliance

With a pending tuberculosis standard still stalled, hospitals face confusion as they try to comply with existing requirements for their respiratory protection programs. Annual fit testing, a controversial aspect of the tuberculosis standard proposed by the Occupational Safety and Health Administration (OSHA), is currently required for all respirator use except in TB prevention. Current OSHA regulations do, however, require hospitals to provide at least initial fit testing for employees who may provide direct care to tuberculosis patients.

"We are now under seven different guidelines [including a respiratory protection standard and compliance directives] in order to figure out what we're supposed to do in hospitals," says **Larry Lindesmith**, MD, FACOEM, FCCP, medical director of employee health and safety at Gundersen Lutheran Medical Center in La Crosse, WI. "Depending on how you read as many as seven different guidelines, it's no surprise we end up with different approaches in different places."

This confusion is a major justification for a new TB standard, he says. "They were making good progress towards it being a reasonable standard in their final drafting," says Lindesmith, who saw a draft version. However, under the Bush administration, Lindesmith and others expect the TB standard to be stalled, at best.

IOM: TB standard based on flawed estimates

The TB standard's future has been further clouded by an Institute of Medicine (IOM) report as well as a Centers for Disease Control and Prevention announcement that TB guidelines are being revised once more. The IOM panel said the proposed OSHA standard didn't allow enough flexibility and was based on flawed estimates of the TB risk.[1] Qualitative fit-testing involves releasing saccharin or Bitrex (a bitter substance) into the air and asking the respirator-wearer whether he or she detects it.

According to **Gregory Wagner**, MD, director of the division of respiratory disease studies at the National Institute for Occupational Safety and Health (NIOSH), that is a minimal test necessary to make sure the respirator conforms to CDC guidelines. "Anybody who is required to wear a respirator should be fit-tested on a regular basis," he says. "If someone's wearing a respirator, they ought to have some reasonable assurance it's going to be effective." **(For a copy of a fit-testing personnel form recommended by NIOSH, see p. 98.)**

To make this procedure more feasible, Lindesmith recommends that hospitals streamline the number of employees that might need to wear respirators to care for TB patients.[2] That is what Lindesmith does at Gundersen Lutheran, which treats two or fewer TB patients a year. Out of 6,000 employees at the medical center, "our initial list had 1,000 people who might be exposed. We've cut that down to 300," he says. "That's still way too many."

Yet hospitals around the country struggle with the initial fit test. "It's very cumbersome to do the test," says **Jill McElvey**, RN, MSN, employee health coordinator at South Georgia Medical Center in Valdosta. "It's real subjective whether the employee tells you they smell the saccharin."

Fit checking vs. fit testing

Is fit testing really necessary? Does it improve worker protection against TB? The answer is no, according to critics of the proposed TB standard, such as the Association for Professionals in Infection Control (APIC) in Washington, DC.

"Certified respirators and fit testing have not been established to be necessary in controlling TB transmission in health care facilities," asserts **Rachel Stricof**, MPH, a member of the APIC TB task force and an epidemiologist in the New York state Department of Health in Albany. "That is not to say that respiratory protection may not be necessary," says Stricof. "The air in the room of an infectious TB patient may pose a significant risk to persons entering, and therefore, some level of respiratory protection should be used. The question is, how much is enough? And what can be done to increase the likelihood that workers use the respiratory protective device properly?"

Stricof argues that simple fit checking, in which workers check the seal, and efforts to improve comfort and use of respiratory protection are more important than fit tests. In a survey of 41 nurses at a hospital that had experienced a TB outbreak, Stricof and her colleagues found that 42% of respondents were not consistently wearing

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TB Respiratory Protection Program in Health Care Facilities Administrator's Guide

Fit-Testing Record for Respirator Users

Employee: _____

Job Title: _____

SS#: _____

Date of Birth: _____

Employer: _____

Employer Phone Number: _____

Age: _____ Height: _____ Weight: _____

Description of condition requiring RPE use: _____

_____

Fit-Testing Record

PE Manufacturer _____

Model Number _____

Facepiece Type and Size _____

NIOSH Approval Number _____

Cartridge Type _____

NIOSH Approval Number _____

Medical Restriction Noted by Physician? ☐ Yes ☐ No

Odor Detection Adequate? ☐ Yes ☐ No

Date Fit-Tested _____

Test Atmosphere _____

Pass/Fail _____

Comments _____

_____

_____

_____
Signature of Fit-Tester

_____
Date

Source: National Institute for Occupational Safety and Health, Washington, DC. Web: http://www.cdc.gov/niosh/99-143.html.

On the back burner: TB rule faces indefinite delay

No date offered for final version

The Occupational Safety and Health Administration's (OSHA) tuberculosis regulation remains alive — barely — as the agency included it on its most recent regulatory agenda, but without a target date for a final rule.

Previously, OSHA had indicated that publication of a final TB rule was imminent. The rulemaking was delayed as the agency focused on completing the ergonomics standard by the end of 2000. In the regulatory agenda that was published in the *Federal Register* on May 14, OSHA listed occupational exposure to tuberculosis as one of its "long-term actions." OSHA officials declined to comment on the change.

The proposed standard faced stiff opposition, including arguments from the Association for Professionals in Infection Control in Washington, DC, that the standard presented an unnecessary burden and a misdirection of resources.

In January, an Institute of Medicine panel issued a report that supported the need for a regulation but criticized key provisions of OSHA's proposed rule. The proposed standard on tuberculosis fails to provide enough flexibility to hospitals at low risk and relies on outdated and flawed estimates of the tuberculosis threat, the panel concluded.

OSHA officials already had acknowledged that the final TB standard would differ from the version proposed in 1997 on issues such as the frequency of respiratory fit testing and skin testing. The indefinite time line for a final rule may indicate more extensive changes.

When OSHA began working on a TB rule in 1994, tuberculosis cases were rising across the nation. Outbreaks occurred in several U.S. hospitals, including cases of the deadly multidrug-resistant strain. TB cases have declined by 35% since 1992.

The Centers for Disease Control and Prevention in Atlanta issued guidelines for preventing the spread of TB in health care facilities in 1990 and updated them in 1994. The CDC is now reviewing those guidelines, with another update expected in 2002. ■

the respirators "in an appropriate manner."[3]

APIC's criticisms of fit-testing dovetailed with the IOM report, *Tuberculosis in the Workplace*, which recommended that fit-testing requirements be linked to the level of TB risk. The report noted studies that showed weaknesses of quantitative fit tests. One study cited by the panel indicated that education and fit checks were more effective than fit tests.

"There was concern about overreliance on fit testing," explains IOM panel member **Scott Barnhardt**, MD, MPH, medical director of Harborview Medical Center in Seattle. "But there was equal concern that for respirator programs to be effective and not provide workers with false reassurance of protection, you needed to have reasonable respirator programs that include components of education and training of the workers and fit testing. It really was a matter of balance."

Wagner notes that NIOSH researchers are continuing to investigate the effectiveness of fit tests. He agrees with the IOM panel that more work needs to be done with manufacturers to create better-fitting respirators in general. "I welcomed their finding and suggestion that attention should be paid to the inherent fitting characteristics of respirators," he says. "Overall, I thought the report was supportive of the need for worker health protection, and supportive of the potential of an OSHA rule to be able to contribute to that."

Meanwhile, beyond the controversies surrounding fit testing, one consensus emerges: Despite declining TB rates nationwide, hospitals need to maintain vigilance in identifying and isolating TB patients. "The major failure in the 1980s

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. ■

[when TB outbreaks occurred] was relaxing the vigilance with which we tried to identify and isolate patients, both on an outpatient basis and an inpatient basis," says Barnhardt.

[Editor's note: Detailed information on establishing a respiratory protection program is available in the NIOSH Administrator's Guide (Publication 99-134). NIOSH also has created an instructional video, "Respirators: Your TB Defense" (video library #214), available from the NIOSH Publications Office via e-mail (pubstaft@cdc.gov). Web site: www.cdc.gov/niosh/nioshmail.html. Telephone: (800) 35-NIOSH or (800) 356-4674.]

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