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TBeat

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
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this issue…

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CRAG, TAG Welcome Sanofi U.S. Commitment to Reduce the Price of Tuberculosis Drug Rifapentine

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SANOFI

New York, New York – The Community Research Advisors Group (CRAG) and Treatment Action Group (TAG) welcome the Sanofi U.S. decision to lower the price of the tuberculosis (TB) drug rifapentine to $32 per 32-tablet blister pack. The company indicates that the new price will become effective in January 2014 under 340(b) Public Health Service pricing.

"The previous price of rifapentine, at approximately $51 per box, made the drug prohibitively expensive for U.S. TB programs to use at desired levels. In a survey conducted by TAG and the National Tuberculosis Controllers Association, 82 percent of surveyed TB programs cited rifapentine's cost as a significant barrier to its use," said Erica Lessem, assistant director of TAG's TB/HIV program.

Rifapentine is a key drug in the prevention and treatment of TB. Innovative regimens using rifapentine to simplify and shorten TB therapy have been developed through publicly funded research conducted by the U.S. Centers for Disease Control and Prevention's Tuberculosis Trials Consortium.

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This price decrease will make TB treatment more cost-effective for U.S. TB programs and simplify treatment for patients. With this price reduction, Sanofi U.S. is taking concrete steps to bridge the gap between TB research and practice, and is setting an example that other drug companies should follow. Expansion of health care access under the Affordable Care Act could potentially increase diagnosis of TB infection, and Sanofi's price concession will make new treatment-simplification strategies easier for U.S. TB programs to implement.

"With this price decrease in hand, we now look forward to Sanofi making rifapentine more widely available outside of the United States by registering the drug in other countries, particularly in those countries where rifapentine has been studied, but is not yet available to TB patients," said Laia Ruiz Mingote, chair of the Community Research Advisors Group.

The CRAG and TAG encourage Sanofi to continue supporting TB research and increasing access to rifapentine.

About CRAG: The Community Research Advisors Group is an international, community-driven advisory body that works to ensure the meaningful representation and engagement of affected communities in research conducted by the U.S. Centers for Disease Control and Prevention's Tuberculosis Trials Consortium (TBTC). This group of research-literate activists supports a robust, comprehensive and innovative TBTC research agenda that is responsive to community needs as well as scientific priorities.

About TAG: Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

TAG Treatment Action Group

CRAG

The MISSION of the Heartland National TB Center is to build capacity with our partners. We will share expertise in the treatment and prevention of tuberculosis by: developing and implementing cutting-edge trainings, delivering expert medical consultation, providing technical assistance, and designing innovative educational and consultative products.

Open letter to Sanofi: Reduce rifapentine cost and increase research funding

Leading doctors, advocacy groups, medical organizations and U.S. TB programs call upon Sanofi to lower the price of rifapentine to ensure its accessibility and continue and expand its investments in the development of the drug for active TB.

TAG
Treatment Action Group

"The millions of people worldwide with TB (including nearly 10,000 people in the U.S. alone, and their hundreds of thousands of infected contacts) need better treatment options urgently. And care providers, TB programs and taxpayers urgently need these to be affordable, now. Sanofi, we ask you to take a stand and demonstrate your commitment to rifapentine development and access by:

1. Lowering the price of rifapentine to $35 per box of 32 tablets of 150 mg; and
2. Pledging $2 million to the TBTC for the continued development of rifapentine."

By Treatment Action Group; Published July 3, 2013, 10:34 am; Last Updated: July 3, 2013, 11:14 am

You can download the letter from here.

(http://www.tbonline.info/media/uploads/documents/letter_to_sanofi_re_rifapentine_pricing-1.pdf)

The VISION of Heartland National TB Center is to provide *excellence*, *expertise*, *innovation* in training, medical consultation, and product development to reduce the impact of tuberculosis in our region.

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Highlights

Implementation of 3HP in Houston

Program Tips and Findings for Working with a High Risk, Mobile Population

Treating tuberculosis (TB) infection remains a key component of TB prevention and elimination. Nine months of daily Isoniazid (INH) has been the standard preventive treatment for decades. Although effective, the standard regimen can be a hard sell for patients who do not feel sick. The duration and frequency of dosing are known barriers to completing treatment. Recently the Centers for Disease Control and Prevention Division of Tuberculosis Elimination (CDC-DTBE) recommended an alternative preventive treatment regimen called 3HP. Found to be as effective and safe as the standard regimen, 3HP consists of only 12 directly observed weekly doses of INH and Rifapentine within 16 weeks. The significantly shorter duration of treatment could mean higher completion rates, especially for transient populations.

DOT Workers - Michael Duong, left and Isaac Rivas, right. Houston Department of Health and Human Services

This year the Houston Bureau of Tuberculosis Control piloted the use of 3HP in the field with great success. Administrative, educational, and programmatic components had to come together prior to using the new regimen. On the administrative side, the Bureau developed standing delegation orders, created a new toxicity sheet incorporating adverse reactions specific to 3HP, and mapped out the communication flow for reporting and addressing adverse effects in the field. All field and clinic staff were trained to educate patients on the new regimen, identify adverse effects, and complete the new forms. On the programmatic level, management worked closely with facility management to establish an on-site Directly Observed Therapy (DOT) program for our first cohort of patients. Management allowed field workers to have flexible work schedules, as well. Additionally, staff members conducted weekly case management meetings used to address patient or field worker barriers to completing 3HP. Finally, managers ensured that incentives and enablers were in place to facilitate completion of treatment. These included providing snack bags with crackers, water, and juice prior to the 3HP dose to ensure patients had eaten. Five dollar food vouchers were provided after observing the 3HP dose when available.

Highlights

Once these components were in place, the staff was ready to observe 3HP in the field. Our first cohort of patients included thirteen homeless men identified during a routine congregate site contact investigation. Previous efforts to provide follow-up and preventive treatment at this homeless shelter had not been successful. Shelter management was willing to work with the health department to provide on-site DOT. We were eager to see if the on-site DOT and shorter regimen would make preventive treatment a more feasible option for this hard-to-reach population.

Of the thirteen patients who began treatment, 12 (92%) completed the regimen. One patient (8%) discontinued treatment due to a reported adverse reaction. Of the twelve patients who completed, three reported adverse effects. The first patient reported itching, bloating, and vomiting; this was treated effectively with Benadryl and Gaviscon. The second patient experienced some numbness, dizziness, and tingling to the arms for five minutes after receiving a dose; he was advised to drink more water which alleviated this effect. The last patient went to the emergency room for dehydration, which was effectively treated with an IV bolus. Upon further investigation, the dehydration was found to be work-related.

Overall, the Houston Bureau of TB Control has had a positive experience with this new regimen. The reported adverse effects have been consistent with previous studies. With proper training and support from the nursing staff, field workers can provide 3HP without difficulty. Our staff and our patients prefer the regimen because it takes less time and effort to finish. A shorter regimen does not eliminate the competing social priorities experienced by the homeless but it gives them a better shot at completing their treatment.

Reported by: Richard Stancil, Bureau Chief, Houston Department of Health and Human Services (HDHHS) Bureau of TB Control; Barbarah Brissette, BSN, RN, Chief Nurse, HDHHS Bureau of TB Control; Quang Hoang, Field Manager, HDHHS Bureau of TB Control; Steven Dang, Senior Staff Analyst, HDHHS Bureau of TB Control; Patrick Ndibe, Public Health Advisor, CDC; Nydia Palacios, Public Health Advisor, CDC.

Staff involved in the 3HP pilot left to right:
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CDC

Heartland would like to announce that ***Delfina Sanchez*** has been transferred from Project Coordinator to Education Specialist. If you are involved in the Training and Education aspect of Heartland, please keep an eye out for any communication from her. Congratulations Delfina!

Contact Investigation Mini-Fellowship

The Contact Investigation Mini-Fellowship Pilot was held August 6-8, 2013 at the Texas Center for Infectious Disease with a visit to San Antonio Metropolitan Health District City Chest Clinic.
This mini-fellowship included stand up presentations, group exercises, group discussion, and patient interactions.
The course was piloted to a group of four participants; the overall feedback was very positive. Participants noted that three days should be the minimum but that four days would work best. This mini-fellowship will be made available in 2014. If you are interested in attending or have additional questions contact Jessica Quintero at jessica.quintero@uthct.edu or 210-531-4568.

Resources

TB LINKS

TB Education and Training Network
http://www.cdc.gov/tb/education/Tbetn/default.htm

Find TB Resources
www.findtbresources.org

Tuberculosis Epidemiologic Studies Consortium (TBESC)
http://www.cdc.gov/tb/topic/research/TBESC/default.htm

Regional Training and Medical Consultation Centers' TB Training and Education Products – (Joint RTMCC Products Page)
https://sntc.medicine.ufl.edu/rtmccproducts.aspx

Program Collaboration and Service Integration (PCSI)
http://www.cdc.gov/nchhstp/programintegration/Default.htm

****If your organization has any additional links for TB resources you would like published, please send them to Alysia.Wayne@uthct.edu****

TRAININGS

2014 HNTC Training Calendar

Date	Course	Location
January 28	TST Practicum	Harlingen, Texas
February 5, 12, 19, 26	Introduction to TB Nurse Case Management	ONLINE COURSE
April 1, 8, 15, 22, 29	TB Corrections Liaison	ONLINE COURSE
April 1 - 3	TB Nurse Case Management	San Antonio, Texas
April 3	TST Practicum	San Antonio, Texas
May 6 - 9	TB Intensive	San Antonio, Texas

The calendar will be updated in every newsletter as well as on the website to show trainings that have been confirmed; Proposed topics are subject to change

Please visit our website: **http://www.heartlandntbc.org/training.asp** to find detailed information concerning registration and participation.

Products from the Heartland National TB Center are available for download at **http://www.heartlandntbc.org/products.asp**

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RECENTLY PUBLISHED: Provisional CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Fumarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis

MMWR: Recommendations and Reports
October 25, 2013 / 62 (rr09); 1-12

This report provides provisional CDC guidelines for FDA-approved and unapproved, or off-label, uses of bedaquiline in certain populations, such as children, pregnant women, or persons with extrapulmonary MDR TB who were not included in the clinical trials for the drug. CDC's Division of TB Elimination developed these guidelines on the basis of expert opinion informed by data from systematic reviews and literature searches. This approach is different from the statutory standards that FDA uses when approving drugs and drug labeling. These guidelines are intended for health-care professionals who might use bedaquiline for the treatment of MDR TB for indicated and off-label uses. Aspects of these guidelines are not identical to current FDA-approved labeling for bedaquiline.

For the complete Recommendations Report, please visit: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6209a1.htm?s_cid=rr6209a1_w