NEWSLETTER

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Inhalt

Internationale Nachrichten

1. Nigeria Spends Nearly US$1.5M For Procurement Of Treatment For People With Multi-Drug Resistant TB

The Nigerian government sanctioned US$1.42 million to procure quality assured Second Line Drugs (SLDs) that will be used to provide treatment for 500 multi-drug resistant TB (MDR-TB) patients. The second line drugs ordered by the government will be delivered by Stop TB Partnership's Global Drug Facility starting June 2015.

The largest economy in Africa, and the country with the third highest TB burden in the world - Nigeria - performed a prevalence survey in 2012 to measure the burden of TB. The survey showed a doubling of the estimated overall prevalence of TB (the total number of people with TB) and a tripling of the estimated incidence (the total number of new cases), compared to previous WHO estimates.

In 2013, Nigeria diagnosed and reported 16% of the estimated TB cases. In 2010, more than 7, 000 cases were reported with MDR-TB and nearly 17 per cent of TB burden were MDR-TB patients among newly infected and re-treated TB patients. Nigeria started MDR-TB treatment in 2010 after a successful pilot in DR-TB treatment centre in University College Hospital, Ibadan, Oyo State. A year later, MDR-TB treatment was scaled up nationwide. In 2013, 2.9% of the TB cases were MDR-TB cases, according to the WHO Global TB Report 2014. There were about 426 patients who were started on MDR-TB treatment in 2013.

The introduction of new molecular diagnostics tools such as GeneXpert machines in 49 facilities in 30 states and Federal Capital Territory as on December 2013, yielded detection of more MDR-TB cases than had been envisaged for treatment under the Global Fund grant. As a result, the consolidated round nine grant from The Global Fund of US$16 million was not sufficient to support all MDR- TB patients. Therefore, the government of Nigeria had to step in to cover the gap in the number of cases being diagnosed and the number of cases being supported by The Global Fund. The government decided to buy drugs using funds from the domestic budget in order to avoid waiting lists on account of drugs for MDR-TB treatment. Since the size of the investment is large, Nigeria's Ministry of Health alone could not sanction the entire amount. It therefore required the National TB Program to work with several government arms including the Federal Executive Council, National Food and Drug Council among others. It was in December 2012 that the decision to buy SLDs was taken, and finally in February 2015, the government sanctioned the purchase of drugs. During this period, the patients were treated with drugs bought using the funds from the Global Fund and TB CARE program (USAID support).

A rising MDR-TB burden is a reality. From 665 DR-TB cases notified in 2013, the number of such cases are estimated climb to 29, 469 cases in 2020. In addition, the ambitious targets as reflected in the country's national strategic plan to address TB, means that Nigeria will likely continue to buy her own drugs. The Nigerian government and the NTP decided to use their own funding to carry out direct procurement through GDF. The decision to procure drugs through GDF, ensures that quality-assured drugs will be delivered for people living with MDR-TB in Nigeria. The NTP wanted to ensure that all

TB patients whether treated with drugs procured using government funding or Global Fund financing received medicines of the same quality. Using GDF as a procurement mechanism allows Nigeria to have access to the same kind of drug formulations, strengths and packaging, as the drugs procured through the Global Fund grant in Nigeria. Dr Gabriel Akang, NTP manager, Nigeria, said, "The Government of Nigeria is poised to support, reach and treat everyone living with TB and will continue to unite against TB." Further, as a result of dipping into domestic resources to buy SLDs, Nigeria successfully ensures country ownership and fulfills criteria of counterpart financing as required, for example, by some donors, including the Global Fund.

Professor Dr. Onyebuchi Chukwu who was holding the position of Minister of Health when this decision was made said, "We certainly need to take care of our own people. MDR-TB is one of the worst public health threats we are facing and we must ensure that we find, diagnose and treat cases as soon as possible, to avoid the spread. Having people on waiting lists for treatment was not an option for us. We hope to give an example to the entire world and to continue investing our own resources in treatment and care of our own people. We thank Stop TB Partnership, the Global Drug Facility, The Global Fund, USAID, WHO and our other partners for their support."

In 2013, the National TB Programme had a total budget of US$ 139 million of which 9% was funded domestically and 38% was funded internationally according to the WHO World TB Report 2014. However, more than half was unfunded. In the face of rising co-infections and increasing co-morbidities, investment by the government, independent of donor support, is a huge step for the people living with TB in Nigeria.

Dr Lucica Ditiu, Executive Secretary, Stop TB Partnership said, "This is fantastic news! All of us must think about this carefully. It is a great example of leadership by the country's government to ensure that diagnosed cases of MDR-TB will have access to treatment. It also shows clearly that domestic investments are possible, but country stakeholders need time to create or adjust budget lines, follow in-country regulations and procedures in order to make it happen. We must keep this in mind when thinking about countries that have to step in with their domestic resources to ensure sustainability of donors investments and allow enough transition time." Joel Keravec, manager, GDF, said, "Nigeria's commitment in taking over the MDR-TB challenge by increasing its own domestic funding for SLDs procurement is an excellent example of a country working towards more sustainability and making a significant shift away from being solely dependent on a donor funded model. We are happy to promote more financial flexibility and technical support to countries like Nigeria willing to follow this leading example." GDF has recently offered financial flexibilities facilitating direct procurement procedures with countries purchasing drugs using their domestic funding.

Source: Stop TB Partnership, http://bit.ly/1IguRiq (11.04.2015)

2. Europe's Leaders Approve Riga Declaration on TB and MDR-TB

At the conclusion of the first Eastern Partnership Ministerial Conference on Tuberculosis (TB) and Its Multidrug-Resistance (MDR-TB), the Tuberculosis Europe Coalition (TBEC) applauds the approval of the Riga Declaration by Ministers of Health, Finance and Social Affairs from across European Union Member States and Eastern Partnership countries.

TBEC would particularly like to congratulate the Latvian government for taking the initiative to organise this important meeting as part of their Presidency of the EU Council and the collaborative efforts of partners across Europe, including the World Health Organisation, ECDC, the European Commission, the Global Fund to Fight AIDS, TB and Malaria, the Stop TB Partnership and civil society.

This meeting comes at a crucial time in the fight against TB and MDR-TB in Europe. The European region contends with the highest rates of multidrug-resistant TB (MDR-TB) worldwide. Fifteen of the twenty-seven high MDR-TB burden countries in the world are situated in the region and four of these (Latvia, Lithuania, Estonia and Bulgaria) are situated in the European Union. Currently, Europe is failing to tackle MDR-TB effectively. More than 50% of MDR-TB cases are not detected and less than half are cured. Without increased political and financial commitment, the number of MDR-TB cases

in Europe could skyrocket, leading towards the apocalyptic scenario of rising costs and lost lives. TB and MDR-TB is already estimated to cost European economies an astonishing €6 billion a year.

"This meeting and the subsequent signing of this declaration is a step in the right direction for TB and MDR-TB in Europe. Today many of our political leaders have signified their commitment to ending this disease once and for all. As civil society, we will now work tirelessly to ensure that these commitments are followed through and the ambition is not lost. The Slovaks agreeing to keep it as a regional health priority during their EU Presidency is a fantastic opportunity to keep political momentum" said Fanny Voitzwinkler, Head of Global Health Advocates EU Office and Coordinator of TBEC.

Despite these steps in the right direction, TBEC would like to express disappointment that not all European and Eastern Partnership countries sent high-level political representation. In particular, TBEC is concerned by the absence of Health Commissioner Vytenis Andriukaitis who had been expected at the conference but caused surprise when he pulled out just last week. The Commissioner however signalled strong support via a video message delivered to the Conference in which he recognised that underlying social factors of TB had to be addressed if we were going to the win this fight. Most importantly, the Commissioner showed his backing for the Riga Declaration when stating that it "provides a solid foundation for the eradication of TB in Europe" and that the Commission will work jointly with countries to achieve this.

"The European Commission have reiterated several times during the conference their intention to work jointly with EU members states, neighbouring countries, the WHO and civil society in order to tackle TB effectively. This is significant. It is only with joint efforts that we will be able to push the agenda forward for TB elimination in Europe. I am pleased that the Health Commissioner has sent this message of support and look forward to hearing in greater detail how they plan to work with all stakeholders in this fight," said Lucica Ditiu, Executive Director of the UN Stop TB Partnership.

As Marina, a former MDR-TB patient from Romania, said in her opening speech: "We must redouble our efforts towards stopping the spread of the disease, and recommit ourselves to tackling this scourge that drains the life and saps the potential of so many." TBEC believes that the approval of the Riga Declaration marks the first step in the redoubling of efforts. Those in attendance have now formalised their commitment to end TB as a public health problem in their respective countries and to strengthen and formalise regional collaboration on TB and MDR-TB at the highest political level.

Translating the approval of the Riga Declaration into concrete outcomes is now key. It will be crucial for attendees at the upcoming Eastern Partnership Summit in May 2015 to endorse the aspirations of the Riga Declaration. Moreover, we reiterate the point made by Dr Hans Kluge, Director of the Division of Health Systems and Public Health, and Special Representative of the Regional Director to prevent and combat M/XDR-TB in the WHO European Region, that we now look forward to the next EU Presidencies of Luxembourg and Slovakia to the turn the outcomes of Riga into EU Council Conclusions.

Source: TB Europe Coalition, http://bit.ly/1C2ej6h (01.04.2015)

3. TB: Taxis' deadly passenger

About a 100 members of the AIDS lobby group the Treatment Action Campaign (TAC) recently took to some of Johannesburg's busiest taxi ranks to spread awareness about tuberculosis (TB). Dodging and weaving among the queues of passengers at the Bree, Noord and Wanders street taxi ranks, activists had one simple message: Open a window and stop TB.

TB remains the leading cause of death in South Africa and accounted for almost nine percent of all deaths reported in Statistics South Africa's latest report on causes of death in the country.

TB is spread after bacteria become airborne after those living with the bacteria cough, sneeze or even speak. With minibus passengers squeezed tightly into taxis with about 19 other people, it is not hard to see why a 2013 study found that taxis carried the greatest TB risk among public transport means.

Published in the American Journal of Epidemiology, the study tracked the amount of carbon dioxide –

the gas exhaled by humans – on commutes made by minibus taxi, bus or train. Researchers then used mathematical modelling to predict commuters' TB risk by mode of transport and found that the risk was highest among taxi users. Poor ventilation in taxis meant that minibus commuters faced a five percent annual risk of contracting TB, according to the research. About 70 percent of South African households use minibus taxis, according to Statistics South Africa's 2013 National Household Travel Survey.

At TAC's recent awareness-raising drive, many taxi drivers reported that they had not previously been aware of the risks. "It is a good move that TAC, as an organisation, is actually doing this because many people do not have enough information," said taxi driver Sibongiseni Mngomezulu who works out of the Noord taxi rank in Johannesburg's inner city. "Sometimes people are ignorant to such an extent that they find themselves getting sick when that could be prevented." "As taxi drivers, we appreciate what TAC did because even we did not understand why is it so important to tell passengers to open windows," he told OurHealth.

Mngomezulu's co-worker Mfanafuthi Zwane said that the stickers were a conversation starter. He added that he planned to use the stickers to introduce the topic of TB awareness among his passengers. Fellow driver Sizwe Ngubane urged the TAC to work closely with taxi associations to promote public health messaging at high-traffic ranks. "It is a good idea to distribute these stickers so that even us passengers we will be able to see them and do what is right for us," said passenger Ntombi Moremi. "As South Africans, we are still fortunate that there are organisations like TAC that give health education through taxi ranks where there are people."

According to TAC Gauteng Secretary Godfrey Lebono, the country's largest member-based HIV organisation plans to work more closely with Gauteng taxi associations.

Construction worker Mxolisi Mtolo added that he thought government needed to do more to bring health services like TB testing into spaces like taxi ranks. "We need mobile clinics all over that will be bring health services near to people," said Mtolo, who added that visiting a formal clinic often means he loses a day's pay. "That will actually help a lot to avoid long queues." "It would be easy to take my lunch time to rush to the mobile clinic and be able to test for all sickness such as TB, HIV and others," he added.

The march comes on the heels of Deputy President Cyril Ramaphosa's 24 March launch of a national TB screening campaign. According to Ramaphosa, the campaign is expected to be the largest ever conducted in South Africa. According to Ramaphosa, at least 140,000 people have already been screened for TB as part of the campaign.

Source: Health-e, http://bit.ly/1FErdfK (12.04.2015)

Forschung & Entwicklung

1. Study finds increasing size of elderly population as major contributor to TB infection in China

A major contributor to the number of tuberculosis infections and cases in China will likely be the elderly over the next few decades, requiring a refocus in efforts to control a disease affecting millions of people in the country, according to preliminary new research presented today at the Fourth Global Forum on TB Vaccines in Shanghai. The researchers from the London School of Hygiene & Tropical Medicine found that developing a "post-infection" vaccine could reduce overall TB rates in China by almost a third by 2050.

Globally, 2050 is the target year for eliminating TB as a public health problem. China is acknowledged to have made a great deal of progress in controlling the disease over the last 20 years, but it is still hard hit by the TB epidemic. According to the World Health Organization, China has an estimated 980,000 new cases of TB every year, second only to India, and 41,000 deaths each year result from the infectious, airborne disease. More troublingly, a third of the world's drug-resistant TB cases are found in China.

"We chose to study TB trends in China given the magnitude of the disease burden present and the

anticipated increase in the number and proportion of elderly people within the population. We wanted to understand how these factors would affect the attempt to eliminate TB in the country," said Rebecca Claire Harris, an epidemiologist with the London School of Hygiene & Tropical Medicine in the UK, who presented the results.

"This is the first time the possible impact of giving new TB vaccines to older adults has been considered in any setting, and could inform how future clinical trials and vaccine deployment plans are developed," said Harris.

Preliminary study results predict that the elderly (those aged 65 years and above) contribution to TB infection transmission in China may increase from 18 percent to 53 percent, and their burden of TB disease may increase from 13 percent to 71 percent of all new TB cases.

"Our preliminary findings suggest that in China it may be useful to increase TB control efforts for preventing disease in older adults and the elderly, and that development of new TB vaccines aiming to protect this population could have substantial impact," Harris said. "Targeting older adults is a departure from the current thinking in the field, which mostly focuses on developing vaccines for children and adolescents. This also may be different from other parts of the world, such as sub-Saharan Africa, where there is much more disease in young adults."

According to the researchers, a combination of the success in China in bringing down TB transmission and the increasing size of the elderly population are contributors to this expected trend. The population that will be elderly during 2025 to 2050 may have been infected back in the pre-1990 era when transmission was still very high. As they get older, their risk of reactivation of infection increases, so they are more likely to develop disease and contribute to disease figures. Whereas because disease transmission has declined so much in recent years, younger people are now infected in relatively lower numbers, so the number of younger people developing disease will also become lower since most disease in this group is due to recent infection.

The researchers used mathematical models to explore the potential impact of new TB vaccines and found that some types could reduce the rate of TB in China by up to nearly a third by 2050. An effective vaccine option of those explored for China was found to be one that could be given to older adults, including those who have already been infected by the bacteria that cause TB but who haven't yet developed TB disease. Such a vaccine, if it had 80 percent efficacy, 20 years duration of protection, and covered 70 percent of people aged 55-64 in 2025-27 and then 55 year olds as part of a routine program, could reduce the rate of new TB cases in China by 31 percent by 2050, avoiding up to 3.7 million cases between 2025-50, the results suggest. Even at lower efficacy and coverage, such a vaccine given to older adults could prevent hundreds of thousands of TB cases.

"If our research continues to validate results to date, it would highlight the importance of ensuring TB vaccine trials include these older age groups and that China begins to plan how a vaccine or other interventions to prevent infected people developing TB could be delivered to people of this age group," said Harris. "However, these early results suggest that even the most effective older adult vaccine will need to be part of a wider control package to reach the WHO 2050 TB elimination goal in China."

BCG, the nearly 100-year-old existing TB vaccine, works most consistently in infants and is largely ineffective against the most common and contagious form of the disease, that is, TB in the lungs. Decades of widespread use of this vaccine has failed to control the global TB epidemic, leading researchers globally to work on development of new, more effective TB vaccines.

The two nonprofit organizations at the forefront of this vaccine development work, the U.S.-based Aeras and the Netherlands-based TuBerculosis Vaccine Initiative (TBVI), helped organize the international gathering of TB and TB vaccine experts in Shanghai this week.

"Tuberculosis is a major public health threat, tied with HIV as the leading cause of death globally among infectious diseases, with antibiotic resistance a major treatment challenge, yet we are years behind where we should be in vaccine development due to lack of acknowledgement of the TB health threat and the resultant lack of investment in new tools," said Tom Evans, CEO of Aeras. "One of the reasons the global TB vaccine community is excited to meet in China is the level of

commitment we've seen from the authorities here to innovative research, including developing the world's only TB vaccine candidate currently in a Phase 3 trial."
The Phase 3 trial of the Chinese vaccine, called VaccaeTM, is sponsored by Anhui Zhifei Longcom Biologic Pharmacy Co., Ltd. Scientists running the trial of this vaccine, are providing an update on progress at the TB vaccine Forum. According to Aeras, aside from VaccaeTM, there currently are 14 vaccine candidates in various stages of clinical testing, including GSK's M72+AS01E candidate, which is currently in Phase 2b testing at sites in Africa.
"The global clinical trial pipeline for TB vaccines is more robust than ever before, yet at the same time there is still much we need to learn about how TB exactly attacks the body and manages to evade the natural immune response," said Tom Ottenhoff, member of the scientific team of TBVI. "Fortunately, the TB vaccine community has managed to come together at these forums in order to coordinate joint research efforts so that the relatively little funding available for our efforts is used in the most effective manner possible."
TB can affect anyone but often strikes those who live in poverty, have poor nutrition, limited access to healthcare, and live in overcrowded conditions. In China, out-of-pocket TB treatment costs account for more than half of the average annual household income for the rural poor, according to Aeras. And because each individual with active TB typically infects between 10 and 15 others, entire families and communities are at risk.
Source: News-Medical.net, http://bit.ly/1A7ponm (25.04.2015)

2. Blood-based Biomarkers Could Enable Simple, Accurate TB Tests for Diagnosis and Monitoring
Researchers have identified blood-based biomarkers in patients with active tuberculosis (ATB) that could lead to new blood-based diagnostics and tools for monitoring treatment response and cure.
The study was published online March 30 in the *Journal of Clinical Investigation*. It was led *by* TB immunologist Jyothi Rengarajan, PhD, assistant professor of medicine (infectious diseases), Emory University School of Medicine and Emory Vaccine Center and Yerkes researcher, and Susan Ray, MD, Emory professor of medicine (infectious diseases) and Hospital Epidemiologist at Atlanta's Grady Memorial Hospital.
Tuberculosis (TB) is a major global public health problem. In 2013 alone, there were an estimated nine million cases of ATB disease, and 1.5 million people died from TB. In addition, the World Health Organization estimates that two billion individuals are asymptomatically infected with *Mycobacterium tuberculosis* (Mtb), the bacterium that causes TB, and are considered to have latent Mtb infection (LTBI). Individuals with LTBI can activate to full blown ATB when their immune systems are weakened. Indeed, the risk of developing TB is up to 20 times greater in people living with HIV, and one in four AIDS-related deaths each year is due to TB.
First author of the research article is Toidi Adekambi, PhD, research associate in the Rengarajan lab and at Emory Vaccine Center.
The research team sought to identify blood-based biomarkers in patients with ATB. They hypothesized that expression of immune activation markers on Mtb-specific T cells would be associated with the amount of bacteria present within an infected individual and could thus provide a gauge of Mtb infection. They reasoned that individuals with ATB disease would harbor higher frequencies of immune markers CD38+/HLA-DR+/Ki-67+ in their blood than those with LTBI or those who had cleared their infection after successful treatment.
For this study, the researchers enrolled three groups of individuals in the metro Atlanta area: those with asymptomatic LTBI; patients with un-treated ATB; and patients undergoing treatment for ATB.
They found that the frequencies of Mtb-specific CD4 T cells that expressed immune markers CD38, HLA-DR and Ki-67 accurately identified ATB patients with 100 percent specificity and greater than 96 percent sensitivity. They also were able to validate the ability of these biomarkers to accurately classify ATB and LTBI in an independent cohort from South Africa. These markers also distinguished individuals with untreated ATB from those who had successfully completed anti-TB treatment and correlated with decreasing bacterial loads during treatment.

"In order to reduce the burden of TB globally, identifying and treating all TB cases is a critical priority," notes Rengarajan. "However, accurate diagnosis of active TB disease remains challenging, and methods for monitoring how well a patient responds to the six-to nine-month long, four-drug regimen of anti-TB treatment, are highly inadequate.

"In this study, we have identified T cell biomarkers that accurately identify ATB patients. These biomarkers have the potential to lead to new blood-based diagnostics for TB as well as provide a set of tools for monitoring treatment response and cure."

Currently, diagnosis of pulmonary ATB relies on extensive evaluations of clinical symptoms, X-ray assessments and direct detection of Mtb bacteria in a patient's sputum, which is essentially mucus that is coughed up from the lower airways. The most widely used sputum-based test involves microscopic detection of Mtb in sputum smears, but the test is poorly sensitive and a high proportion of TB cases are smear-negative.

Nucleic acid amplification-based tests are more sensitive for diagnosing ATB but do not differentiate between live and dead Mtb bacteria and are therefore not useful for monitoring clearance of Mtb during and after treatment. Culturing Mtb from sputum is currently the gold standard for TB diagnosis and for monitoring treatment response, but takes three to six weeks for results due to the slow growth of Mtb. Sputum samples are also difficult to obtain, particularly in children, elderly and weakened/bed-ridden patients and therefore, blood-based tests are attractive alternatives to sputum-based tests. However, no blood-based tests for ATB are currently available.

"Our findings show that blood-based biomarkers have the potential to accurately diagnose ATB and discriminate between ATB and LTBI," says Rengarajan. "We are now interested in evaluating these biomarkers in larger studies in TB-endemic areas and across a roader spectrum of Mtb infection, including extra-pulmonary TB and in HIV-infected populations.

"Blood-based biomarkers will be particularly useful in situations where sputum-based diagnosis of TB is more difficult. Because these biomarkers provide a gauge of Mtb load within individuals, they could also have utility as surrogate markers of treatment response and as predictors of treatment efficacy, cure and relapse in patients undergoing treatment for drug-susceptible as well as drug-resistant TB."

Source: Emory University, http://bit.ly/1bdX0tk (03.04.2015)

3. Why researchers say fake and low-quality drugs are a 'global pandemic'

Counterfeit drugs are now an estimated $75 billion industry, and experts say the problem presents a "real and urgent" threat to public health around the world. (iStock)

Fake and substandard drugs are responsible for tens of thousands of deaths around the globe each year, and the persistent lack of reliable medicines in poor countries threatens to roll back decades of efforts to combat malaria, tuberculosis, HIV/AIDS and other conditions, researchers said Monday.

"The pandemic of falsified and substandard medicines is pervasive and underestimated, particularly in low- and middle-income countries where drug and regulatory systems are weak or non-existent," Jim Herrington, a University of North Carolina public health professor who co-edited a collection of articles on the topic published in the American Journal of Tropical Medicine and Hygiene, said in a statement.

The articles, funded in part by the Bill and Melinda Gates Foundation, detail various aspects of the long-standing problem of substandard drugs, as well as looking at potential solutions to reducing the harm they cause each year.

One piece describes the discovery of falsified and poor quality malaria drugs that contributed to the deaths of an estimated 122,000 African children in 2013. In another study, scientists examined nearly 17,000 samples of antibiotics, antimalarial and anti-tuberculosis drugs and found that as many as 41 percent failed to meet quality specifications. While such investigations offer clues to the scope of the problem, researchers say it remains unknown exactly how pervasive counterfeit and low-quality drugs are. Falsified medicines account for an estimated $75 billion market annually, but even that is simply an educated guess. While the problem is most pervasive in poor countries dealing with

malaria and other infectious diseases, it also affects medicines for cancer, cardiovascular disease and other serious illnesses around the globe, experts said.
"We know this epidemic is occurring over a very wide area, crossing international boundaries and affecting a large number of people," Gaurvika Nayyar, a program manager for the U.S. Pharmacopeial Convention, a scientific nonprofit that sets standards for drugs, said at an event on the topic Monday in North Carolina. "This is just the tip of the iceberg."
The World Health Organization has repeatedly warned about counterfeit drugs, particularly in developing countries, and in the past has worked with international investigators in an effort "to dislodge the criminal networks raking in billions of dollars from this cynical trade."
According to the Centers for Disease Control and Prevention, drug counterfeiting is most common in countries without strong regulations governing the manufacture of medicines, and few ways to enforce existing laws. The CDC has estimated that 10 to 30 percent of medicines sold in developing countries are counterfeit, far less than than the estimated 1 percent or less in the United States, Australia and other industrialized countries.
In January, the Food and Drug Administration created a new unit, the Office of Pharmaceutical Quality, aimed at ensuring the consistency, safety and quality of drugs that reach the American public. That's a complex undertaking, given the large number of drugs that come from India, China and many other countries.
"Globalization ... has redefined the field of medical product regulation by adding layers of complexity to the supply chain and creating opportunities for the potential contamination and/or intentional adulteration," former FDA commissioner Margaret Hamburg wrote in an essay accompanying Monday's collection of articles. "Today's medical-product landscape blurs the line between domestic and foreign production, drawing attention to the need for global quality and safety oversight to prevent patient exposure to falsified products."
Researchers said Monday that innovative ways of testing drug quality are emerging, such as simple paper-based test cards that are easily portable and can identify low-quality malaria medications. But they argue that new technologies alone will not be enough to tackle the far-reaching pandemic of fake and poor-quality drugs. That, they argue, will require more public awareness, more international coordination and leadership focused on the problem and tougher laws to prosecute criminals who profit from selling counterfeit medicines.
Source: Washington Post, http://wapo.st/1Gbnwi6 (24.04.2015)

Reportage

1. Fighting TB with a Drive-in Film and Test
Some lives hang on the distance of dusty roads, with a cure out of reach. Take tuberculosis, an ancient disease that still kills about 4,100 people each day around the world because the tests to diagnose it and the drugs to treat it are inaccessible to many in need.
If caught early enough, tuberculosis is usually curable. But the most common and accurate test involves, culturing a person's saliva for about a month. "While you wait, you infect others and maybe you die," said Mario Raviglione, director of the global tuberculosis program at the World Health Organization. In 2010, however, a device capable of isolating bacterial DNA and diagnosing TB within hours became available. Named GeneXpert, the device enabled more timely and effective treatment. It was accepted for use by the World Health Organization, and the United States Centers for Disease Control and Prevention said it was "revolutionizing tuberculosis control."
Still, there are scant signs of a revolution on the ground. The situation illustrates our impetuous worship of technology: Innovations make a splash, but little consideration is given to the mundane systems required for their success. Throughout the developing world, potentially lifesaving devices like GeneXpert gather dust for lack of affordable transportation that might connect patients to the

technology, and for lack of trained staff, electricity and relatively expensive materials necessary for their operation.

GeneXpert could indeed be revolutionary if these pieces were put in place — and it's feasible to do so. One effective approach I observed in southern Tanzania was a mobile diagnostic lab housed in a van that offers movies by night to lure potential patients, and runs GeneXpert's TB test, as well as H.I.V. and cervical cancer tests, by day. A small team made up primarily of Tanzanian doctors and technicians operates both the movie projector and the diagnostic equipment; they pick up supplies as needed and travel to remote areas to serve villagers who otherwise would have limited access to these health tests.

This simple strategy allows them to deploy technology far more rapidly than through traditional channels, says Petra Clowes, a German doctor in the mobile lab who works jointly with the University of Munich and the Medical Research Center in Mbeya, Tanzania. Consider the difference: in 2011, the main hospital in Mbeya conducted 58 GeneXpert tests; the mobile lab ran 816. In 2012, the hospital conducted 39 tests; the mobile lab ran 1,265.

These tests are essential to the goal of halting tuberculosis, which depends on health workers catching and treating the disease before bacteria become airborne via coughs. The W.H.O. estimates that three million people infected with TB don't know it. Many die needlessly, and their loved ones never learn why — and often become infected themselves. If at-risk people were screened for the disease preemptively, TB incidence might drop by 40 percent over a year, according to estimates drawn from an intervention in Pakistan.

"One of the biggest challenges in TB control is the many people missing," says Raviglione, who praises the proactive approach taken by the Mobile Diagnostic Lab as a promising pairing of advanced technology, accessibility and appeal. "Now if it can be sustained financially," he adds, "that is the question mark."

When the van arrives, word spreads fast about the nighttime movies on a screen atop the van. Before showtime, the team airs educational health announcements, including the message that tuberculosis can be cured if caught early. A team technician acknowledges that the educational messages are rather dull, but says there aren't many Swahili public service announcements to choose from. A subtler, more effective service may be provided by the van's African dramas and comedies, which don't just attract crowds, but brighten the dreary experience of being tested for deadly diseases.

Another key to the van's success is the anonymity it offers by providing an alternative to visiting a local nurse and having word of a patient's sickness reach neighbors. Tests are free in the mobile lab, with the GeneXpert test provided to anyone with a chronic cough or H.I.V. (which lowers the body's natural defenses to TB bacteria). Last March, the team also started screening women for cervical cancer, a treatable disease that, for lack of testing, remains the leading cause of cancer deaths among women in developing countries.

Anyone who tests positive for a disease is referred to a clinic for treatment. Of course, some may skip follow-up visits, but the Tanzanians who go appear to have a relatively high rate of adherence to the six-month, free course of medicine for tuberculosis, with an 88 percent cure rate among those treated.

In 2009, the van project's founder, Michael Hoelscher, an infectious disease specialist at the University of Munich and at Tanzania's Mbeya Medical Research Center, received funding for the lab from the European Union and the German government. Over the years, money for tests, fuel and upkeep has been provided by the Maryland-based Henry M. Jackson Foundation for military medicine research and other Western donors, while the Tanzanian government pays salaries for some of the staff on board. The local health system's close tie to the van distinguishes this approach from many other programs funded by aid organizations: Those are often directed by outsiders who return to their homeland when funding for the project dries up.

To expand, the team will likely have to demonstrate more than the ability to conduct reliable tests in remote areas; they'll have to show donors or African governments that the approach also saves

money in the long run. A large chunk of their budget goes to the GeneXpert tests, which cost $9.98 apiece. About 96 percent of the tests come back negative. But the 4 percent that reveal infection — especially when a seemingly healthy person tests positive for tuberculosis — could bring big health care savings, by allowing early treatment that prevents hospital stays and reduces the risk of transmission.

Studies in the developed world confirm that even a small percentage of cases caught early can translate to significant savings, if the cost of testing is low. Alistair Story is a nurse specializing in tuberculosis who screens at-risk people for the disease with a mobile X-ray unit in the United Kingdom. A 2011 study about the mobile service, published in the British Medical Journal, estimated that for every $9,500 to $15,000 spent by the " screening unit, at least one year of "quality" life was gained for the program's targets. ("Quality" years is a measure commonly used to assess the value of a medical intervention; the British government considers a year worth at least $31,500.)

"As purse strings become tighter, this group needs evidence of cost-effectiveness," says Story. He recommends that the Tanzanian mobile lab team sequence genes from TB strains it identifies to determine whether the operation is stopping those strains from spreading. If many people have the same strain in a region, it means the disease is being diagnosed too late to prevent transmission. By contrast, the appearance of different strains would indicate that the van is in fact interrupting transmission.

This analysis would also help the team target villages where they could have the biggest impact – a strategy Story uses in his work in Britain. "From a technical perspective, I would be delighted to collaborate with this group to understand how often they should return to a place and screen," Story says. Hoelscher welcomes the offer. Still, budgets are so tight in Tanzania that cost-effectiveness may not be enough to keep the program running. The government estimates that it would take $61 million annually to test and treat tuberculosis across the country. In 2014, the government and international donors together spent only $18.3 million.

In addition to more vans, Joshua Mwakyelu, a Tanzanian doctor on the mobile lab team, says he would love to be able to expand the range of tests the van offers. "People have many problems and not a lot of access to health services," he says, "so they're annoyed when we can't do it all." By the end of 2016, his team plans to incorporate a new device — a viral load analyzer — that detects the level of H.I.V. circulating within a person's body, in order to monitor how well the antiretroviral drugs the patient takes suppress the disease.

With such remarkable lifesaving technology available, the big challenge for donors, governments and other social innovators today is to come up with newer and better ways to take them on the road.

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