May 2018 | Issue 19

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AFRICAN SOCIETY FOR LABORATORY MEDICINE

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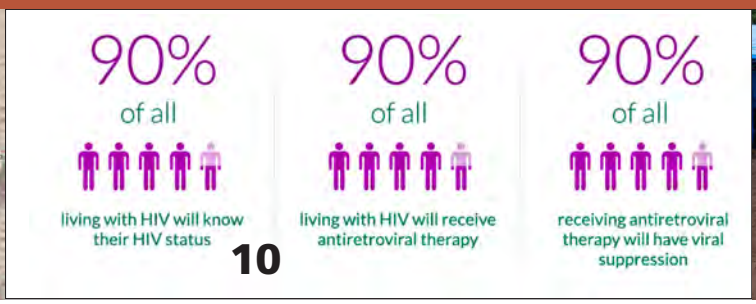
CDC prepares to join Ebola fight in Africa

In this issue:



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ONE HEALTH

DIFFERENTIATED CARE FOR STIs

EMERGING AND REMERGING DISEASES

Q & A

LEADERS FROM THE BENCH

ACCREDITATION

DEPARTMENTS

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ASLM is currently accepting article and photo submissions for upcoming issues of ***Lab Culture***. We publish timely, informative, inspirational articles relevant to the unique challenges faced by laboratories in resource-limited settings. We are interested in articles on the critical aspects of laboratory medicine, best practices, success stories, leaders in the field, industry news, etc.

To submit articles, proposals, photos, etc., please contact the Editor at newsletter@aslm.org.

Lab Culture. Established along with ASLM in 2011 as a member newsletter, ***Lab Culture*** relaunched in 2017 as ASLM's magazine for laboratory medicine in Africa. Dedicated to bringing timely, informative articles relevant to the unique challenges faced by African laboratories, ***Lab Culture*** seeks to be Africa's premiere resource for laboratory professionals and other stakeholders working on with the continent. Published six times a year as a digital edition, ***Lab Culture*** includes features on critical aspects of laboratory medicine and best practices in resource-limited settings, success stories from the continent, industry news, and more.

LAB CULTURE
ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

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Ebola outbreak in DRC: Are we better prepared this time?

The recent news of a new Ebola virus disease outbreak in the Democratic Republic of Congo (DRC) is unwelcome but not unexpected. In fact, even before the 2014 West Africa outbreak ended, health-related organisations around the world have been preparing for exactly this. It is safe to say that, at the very least, we are better prepared this time.

There are new tools available today that were not available in 2014. One of the most important for containment of outbreaks are rapid diagnostic tests, like the one recently assessed by Jean Louis et al. (Afr J Lab Med. 2017;6(1), a484). Only a few days after the DRC Ministry of Health's declaring the outbreak, rapid diagnostic tests were in use by response teams from the World Health Organization (WHO) and Médecins Sans Frontières (MSF) and diagnosing cases. Another new tool is an experimental Ebola vaccine, which was developed during the 2014 outbreak. WHO and MSF are currently vaccinating people with close contact to cases to prevent the occurrence of new cases and spread of the disease.

We have a new institution – the Africa Centre for Disease Control and Prevention (CDC) – to help coordinate the interventions that will ultimately contain and stop the outbreak. Africa CDC team was on the ground in DRC within three days of the outbreak being declared. In fact, this is the organisation's ninth intervention on the continent in its short one-year and five-month history, and it is already leveraging its influence to obtain commitments from African Union Member States to provide response personnel and other assets.

Here at ASLM we are working to mobilize the community of laboratory professionals with expertise that is needed for the containment effort on the ground. A call has been issued and laboratorians who are ready to deploy to the area can submit their resume or CV to ASLM (http://www.aslm.org/join-effort-provide-laboratory-expertise). ASLM is in contact with the agencies in the area and is ready to connect laboratory professionals with the areas they are needed most.

The ability to organise and pool resources is not a trivial point and, in fact, may be the key to effective responses for all such outbreaks in Africa. No one country has all the resources needed to contain all outbreaks. However, in the words of Africa CDC Director, Dr John Nkengasong, during a 15 May press conference, "If we can bring our resources together, we can better prepare the continent for these outbreaks." He went on to give an example of the recent Monkey pox outbreak in Nigeria and Sierra Leone. Samples from patients in these countries were transported to a laboratory in Côte d'Ivoire, which was able to provide a diagnosis within one week.

There is much more to be done. Africa CDC is also working to establish a National Public Health Institute in every African country that will function as a 'mini-CDC' and increase rapid responses and pooling of resources. Countries also need to have national policies and plans in place to address dangerous pathogens (see an example of Uganda's national biosafety and biosecurity policy in this issue) and take into account the human and environmental influences on emergence and re-emergence of such pathogens (see our feature article on One Health in this issue). By all accounts, however, the response to the DRC outbreak is not suffering the delays that contributed to the extensive spread of Ebola in 2014 and we are in a position to move beyond mere containment and towards protection of communities against the virus. That is good news indeed.

Bethanie Rammer

Infectious Disease

Common antibiotic significantly reduces child deaths across Africa. Giving the antibiotic azithromycin twice a year to young children in sub-Saharan Africa reduced childhood deaths by 13.5%, a new study has shown.

Large-scale distribution of the drug could save millions of lives in a region where one in nine children dies before age 5, according the United States Agency for International Development.

The study, published in *The New England Journal of Medicine*, looked at 1,355 randomly assigned communities in three countries spanning the continent: Malawi, Niger and Tanzania.

In about half of these communities, nearly all children aged 1 month to 5 years were given 20 milligrams of azithromycin, five times, over a two-year period. The other half of the communities received a placebo.

After the study period, mortality rates among the children given azithromycin were 5.7% lower in Malawi, 18.1% lower in Niger and 3.4% lower in Tanzania, when compared to those children given the placebo.

The findings could help accelerate progress towards meeting the United Nations' goal of ending preventable childhood deaths worldwide by 2030, according to Dr. Jeremy Keenan, director of international programs at the Francis I. Proctor Foundation at the University of California, San Francisco (UCSF) and a lead author on the study.

'The study shows we can prevent young children from dying with a simple intervention,' Keenan said in a UCSF press release. 'We could scale our newly studied intervention to reach millions of vulnerable children in resource-poor countries, in much the same way that trachoma programs, which give children and adults a single dose of azithromycin each year, have been doing for years.'

Trachoma, a bacterial infection of the eye, is the leading infectious cause of blindness worldwide. Currently, around 30 countries are distributing azithromycin to those at risk in an effort to help curb the disease, according to The Carter Center.

Although the study was not able to identify the precise causes of death in the sample population, the decreased mortality in the treatment group was likely due to drops in malaria, diarrheal diseases and pneumonia, the study states.

'Azithromycin works against lots of causes of diarrhea, lots of causes of pneumonia, and it also works against the malaria parasite. And unlike a dose of penicillin, which might work against bacteria, this is something that might work against a variety of different things,' said Dr. Jeff Griffiths, a professor of public health at Tufts University School of Medicine.

The drug's longevity is also thought to play a role in the decline.

'Azithromycin lasts in your system for a fair amount of time,' Griffiths added. 'It's not something that you immediately get rid of. It actually stays in your body for a while, so it's a reasonable drug to use for that reason.'

In the study, the youngest children -- those 1 to 5 months of age -- achieved the greatest benefit from the drug. Approximately one in four deaths in this age group were likely prevented with prophylactic use of azithromycin.

'That's hinting that the kids who really benefit are the youngest children and the ones most likely to have these infections and not to have the sort of internal resources to be able to fight them off,' said Griffiths.

The large number of subjects involved in the study suggests this could be rolled out as a large-scale preventative measure to improve child mortality rates across the continent.

'People suspected that there was going to be some kind of a benefit and this study really is a major, major contribution,' said Griffiths. 'The authors really deserve a lot of credit for conducting a study that's large enough to be able to look at this idea.'

The researchers caution that widespread use of antibiotics such as azithromycin can lead to antibiotic resistance in the future. But previous studies suggest that resistance to azithromycin and other macrolides would not likely result in resistance to other classes of antibiotics, such as penicillins, which are currently used in Africa as first-line treatments for many infections.

Azithromycin is currently used to treat a variety of infections ranging from sexually transmitted diseases such as chlamydia and gonorrhea to certain respiratory and gastrointestinal illnesses, according to the Mayo Clinic. It is still unclear how resistance to the drug would affect treatment of these conditions.

'The potential for resistance will have to be balanced against the potential to save the lives of thousands of young children,' said Dr. Thomas Lietman, director of the Proctor Foundation and a lead author on the study. 'Treating only young children may select for less resistance than treating the entire community, as we've done in trachoma programs.'

Since many countries in the region are resource-poor, the pharmaceutical company Pfizer Inc. -- which has previously donated more than 730 million doses of azithromycin, or Zithromax, for the treatment of other diseases in sub-Saharan Africa -- provided the drugs for use in the current study.

But moving forward, it is still unclear where the large influx of new medications would come from.

'Some of the large pharmaceutical companies, and in this case Pfizer, have a history of donating these kinds of agents to countries where there's a lot of need and not much in the way of resources,' Griffiths said. 'So one would hope that they would step up to the plate here.'

Cancer

IAEA helps African countries in the production and use of radiopharmaceuticals for cancer. The International Atomic Energy Agency (IAEA) started a four-year project to help 17 African countries produce and apply vital radiopharmaceuticals for treating and managing cancer and other common diseases.

The new project builds on a previous IAEA effort to train nuclear medicine professionals, pharmacists and technicians in the safe preparation and administration of these medical drugs. It will step up education activities to create a cer-

tification process for radiopharmacists, and provide expert advice to countries in upgrading nuclear medicine facilities to handle radiopharmaceuticals.

'Many African countries offer nuclear medicine services but have limited radiopharmacy capacities,' said Shaukat Abdulrazak, Director of the Division for Africa in the IAEA's Technical Cooperation Department. 'The IAEA has previously helped the continent through equipment and more than 20 fellowships and Master of Sciences degrees in this field, but there is a need to expand these efforts with long-term educational opportunities in Africa.'

Representatives from Algeria, Burkina Faso, Cameroon, Egypt, Ethiopia, Kenya, Mauritius, Morocco, Namibia, Niger, Nigeria, Senegal, South Africa, Sudan, Tunisia, Uganda, and Zambia met with IAEA experts in Kampala, Uganda, to discuss project implementation.

Radiopharmaceuticals are medicines that contain small amounts of radioactive isotopes. They need to be produced under carefully controlled conditions and tested for quality before being given to patients. 'Their production requires the handling of radioactive substances, which increases the need for more stringent controls,' said Amirreza Jalilian, a chemist at the Division of Physical and Chemical Sciences of the IAEA's Department of Nuclear Sciences and Applications.

The drugs can be used either for diagnostic or therapeutic purposes. The vast majority (85%) are used for medical imaging, providing doctors with a better internal picture of a patient's condition.

Originally developed to diagnose and treat cancer, radiopharmaceuticals have evolved to become indispensable in the management of heart, kidney and bone diseases, as well as brain disorders such as Alzheimer's, dementia and Parkinson's.

Technetium-99m (Tc-99m) is the most widely used radioisotope for medical diagnosis. It has a short half-life, so it needs to be extracted from its parent radioisotope Molybdenum-99 (Mo-99) locally and given to a patient within hours. While large-scale production of Mo-99 can only be done in specialized facilities and is limited to a handful of countries, the extraction of Tc-99m at hospitals and nuclear medicine centres is straight forward. The radioisotope is extracted from Mo-99 using a generator the size of a coffee-machine, mixed in a vial with the appropriate molecule, given to a patient and traced using a relatively inexpensive gamma camera.

The field, however, evolves rapidly, and more advanced diagnostic techniques such as positron emission tomography (PET) are becoming commonplace. 'These radiopharmaceuticals are not only more complicated to prepare, but the quality control tests are also very different,' said Jalilian. 'There is a higher dose involved, and the nature of radiation is different and can also damage healthy parts of the body if prepared incorrectly.'

Several African countries plan to expand or upgrade their nuclear medicine and radiopharmacy facilities, including for the future production of PET radiopharmaceuticals. The project aims to prepare countries for such expansion and to develop a new generation of qualified professionals that can produce and dispense doses according to appropriate standards.

Morocco, which has developed a radiopharmaceutical post-graduate programme with IAEA support, is looking to establish a Master's Programme to train professionals from the region. 'Radiopharmaceuticals are an essential part of medical procedures,' said Naoual Bentaleb, radiopharmacist at Morocco's CNESTEN. 'We want to support and provide technical expertise to ensure their regular production and availability in Africa.'

The IAEA assists countries to improve nuclear medicine services through training and equipment, and provides advice on quality assurance systems for their safe use.

Point-of-Care Testing

EKF secures FDA clearance for POC hemoglobin analyzer. EKF Diagnostics announced Food and Drug Administration clearance and Clinical Laboratory Improvement Amendments waiver for their hand-held, reagent-free hemoglobin analyzer, the DiaSpect. The device is cleared for use in point-of-care (POC) and Certificate of Waiver settings, such as physicians' offices, clinics and other non-traditional laboratory locations.

The DiaSpect provides accurate hemoglobin measurements (precision: coefficient of variation ≤1%) within two seconds of its whole blood-filled cuvette being inserted for analysis. This ensures immediate and robust hemoglobin results for patient health checks and anemia screening at the POC.

Based on its FDA categorization, DiaSpect can be used in a variety of settings, as well as by a wide range of health care personnel. It is highly user-friendly requiring minimal training. The user simply collects a capillary or venous blood sample of 10 µL in the cuvette before inserting straight into the analyzer. DiaSpect is factory calibrated against the HiCN reference method in accordance with International Community Health Services. It is 'always on' and ready to use with no recalibration or maintenance necessary.

Lightweight and palm-sized, DiaSpect is ideal for POC testing in remote situations, not only due to its portability and unmatched measurement speed, but also through its rechargeable internal battery. This provides up to 40 days/10,000 tests continuous use, giving the flexibility of not needing a power source for weeks at a time.

DiaSpect's reagent-free cuvettes have up to 2.5 years shelf life, even after opening, and are unaffected by temperature or humidity. These disposable cuvettes can be stored from 0 to 50°C, meaning temperature-controlled storage is not necessary - short term storage is even possible at -30°C to 70°C for 24 hours. This all makes the device highly suited for hemoglobin testing in a range of locations, environments and climatic conditions.

One Health – A Method of Integrating Human, Animal, and Environmental Health

By Wubshet Mamo, DVM, PhD

Background

Since the 1800s, scientists have noted similarities in disease processes among humans and animals and that humans and animals are often susceptible to the same disease-causing pathogens. However, human and animal medicine were practiced separately until the 20th century. The history of integrative thinking about human and animal health goes back to the beginning of comparative medicine and is based on the discovery of similar disease processes in humans and animals at the end of the 19th century. In the 20th century, the concept of 'one medicine' emerged. This concept recognized that there is no difference of paradigm between human and animal medicine and that both disciplines can contribute to the development of each other[1]. Later, this was further developed to include environmental health, as scientists took a broader approach to the health and well-being of societies and began to realize that, given the interconnected interests of those working across disciplines, human health and animal health are closely intertwined and a heathy environment is fundamental to both. Following this, 'one medicine' was considered inadequate, because it did not reflect the interactions between human and animal health that reach beyond individual clinical issues[2]. Thus, the original concept of 'one medicine' was extended to 'One Health' through practical implementation and careful validation in different settings focusing on an integrative approach to these three major, but separate, disciplinary silos to maintain and also improve the health of humans, animals and the environment[2].

Human – Animal – Environment Interface

In recent years, the One Health approach has become more important because of changes in many factors affecting interactions among humans, animals and their environment. Regrettably, these changes are contributing to the emergence and re-emergence of pathogens that cause disease in humans and animals and vice-versa, i.e. zoonotic diseases, which are occurring at unpredictable rates in human and animal populations.

Rapid human population growth has resulted in higher and higher numbers of people living in close contact with animals. This increased contact, together with changes in land use, including intensified livestock and crop production and encroachment of human populations on wild animal habitats, have altered the inherent ecological balance between pathogens and their human and animal hosts. These complex, often rapidly changing patterns, and the inextricable interconnections of humans, domesticated animals including house pets and livestock, and wildlife with their social and ecological environments, contribute to the emergence of zoonotic diseases[3]. The links between human and animal populations, and the surrounding

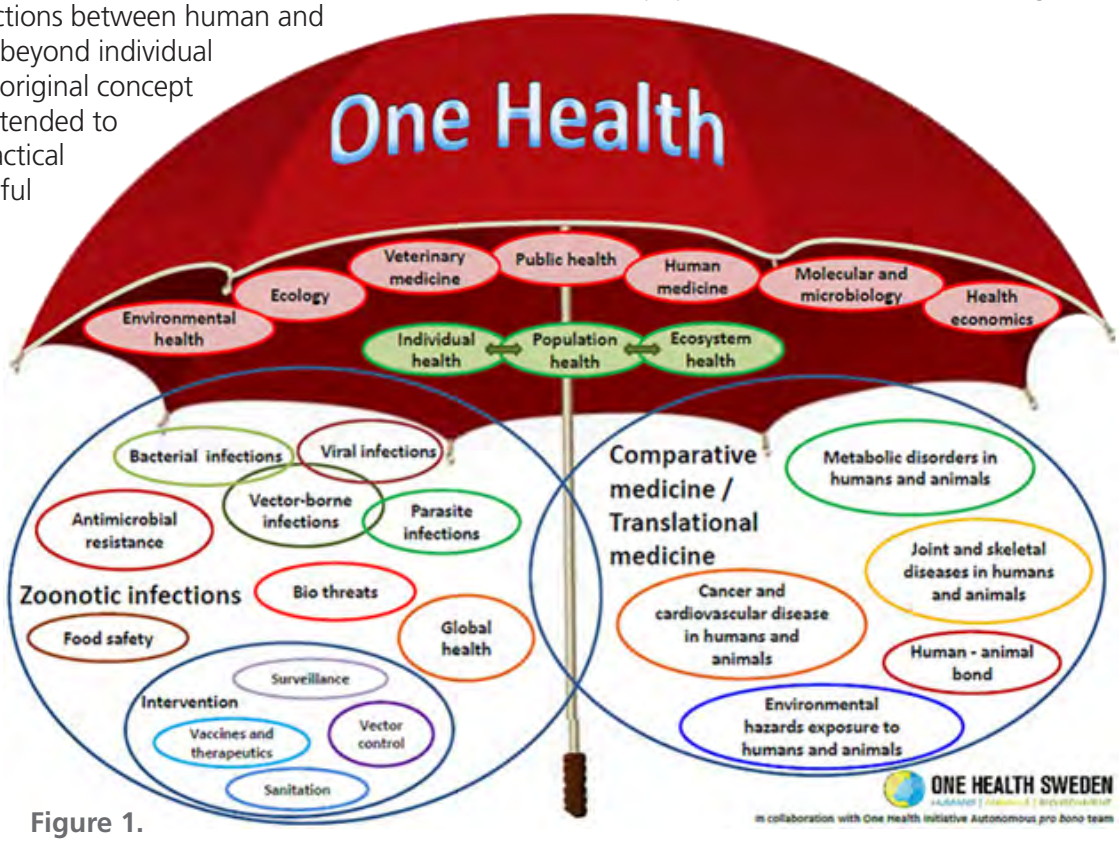


Figure 1.

environment, are particularly close in low-resource countries. For example, in many African countries, humans are in long-term, daily contact with animals that provide not only transportation, draught power and clothing, but also food (meat, eggs and milk). This close link presents a serious risk to public health and severe economic consequences.

Emerging and re-emerging diseases

There are about 1,415 microbes that are known to infect humans[4]. Approximately 60% of all human infectious diseases recognized so far, and about 75% of emerging disease threats that have affected people over the past three decades, arise from animal reservoirs[5]. Thus, the 'human-animal-ecosystem interface' is at the center of the emergence new diseases[5]. In fact, in the past 30 years, more than 30 new infectious diseases have emerged[6].

The phenomenon of emerging and re-emerging diseases is driven by various anthropogenic factors. These include genetic and biological factors, such as microbial adaptation to macro- and micro-environmental changes, along with changes in host susceptibility to infections. There are also environmental factors, such as climate change, changes in ecosystems, and changes in human and animal population densities. In addition, socioeconomic and political factors, such as increasing international travel and commerce, social inequality, poverty, conflict, famine, lack of political will, and changes in economic development and land use, also influence infectious disease emergence[5]. Over 200 zoonotic diseases have been described, and they are caused by a broad range of pathogens (**Table 1**). Zoonotic diseases clearly present significant threats to public health. However, many of them are neglected, i.e. they are not prioritized by health systems at national or international levels.

Disease emergence - outbreaks

Disease transmission between animals and humans is not new. Ever since the rise of agricultural societies, when humans began living closely with domesticated animals, we have been sharing diseases. As mentioned above, the 'human-animal-ecosystem interface' is at the center of new disease emergence[4]. Today, disease emergence is closely linked to geographic 'hot spots' where there are intensive animal-human interactions amplified by environmental changes. Changes in ecosystems resulting from human activity, such as significant changes in land use, expansion of large and intensified animal-production units, or microbial and chemical pollution of land and water sources, may result in the emergence and spread of novel pathogens. Disease emergence and outbreaks may increase, because of changing ecology, changing climate, changing ways that we interact with animals and animal habitat destruction, which all bring us into closer contact with animals that host zoonotic pathogens. For example, deforestation for agriculture contributes to the emergence of zoonotic, vector-borne diseases and populations living within or near these fragmented forests are at a much higher risk of contracting zoonotic diseases, because of increased contact with vectors at forest edges and the reduced biodiversity of the area.

Table 1: Sample of Pathogens and Related Zoonotic Diseases

Pathogen			*Zoonotic Disease*
Category	*Name*	*Type / Description*	
Bacteria	*Salmonella spp.*	Enterobacteria	Salmonellosis
	Campylobacter jejuni	Gram-negative	Campylobacteriosis, Gastroenteritis
Parasite	*Taenia solium*	Pork tapeworm	Cysticercosis/taeniasis
	Plasmodium spp.	--	Malaria
Fungus	*Trichophyton, Microsporum, Epidermophyton*	--	Dermatophytoses
	Cylindrocarpon lichenicola	Saprohytic	Keratitis
	Candida albicans	Yeast	Chlamydia, thrush
Virus	*Lyssavirus*	Rhabdovirus	Rabies
	Ebolavirus	Filovirus	Ebola virus disease
	Influenzavirus	RNA virus	Avian influenza, 'bird flu'
Others	--	Prions	Spongiform encephalopathies
	Tryponosoma brucei	Protozoa	Trypanosomiasis, sleeping sickness

Global human population growth is skyrocketing, resulting in rapid changes to the ecosystems in which we live. Animals in these ecosystems, whether wild or domesticated, share many environmental risks with humans, and we must scurry to find ways to coexist. Recent epidemics, such as the Ebola virus disease outbreak in West Africa in 2014 and the 2009 influenza A (H1N1) pandemic, also known as 'swine flu', serve as stark reminders of the unpredictable nature of pathogens and the importance of animals

in the ecology and emergence of viral strains[5]. Organisms circulating among domestic and wild animal populations can potentially pose serious threats to both animal and human health. As humans increasingly move into areas that are only sparsely populated, the risk of exposure to previously unknown agents increases.

Integrating human, animal and environmental health

Optimizing the health of humans and animals, as well as protecting the environment, has become vital for achieving an optimal health. One Health focuses on the the concept that since human, animal, and environmental health are so interrelated, it is critical to break down the traditional 'silos' between them. Therefore, in recent years, the One Health method has been gaining more recognition in public health communities and is now being endorsed by international health agencies, including the World Health Organization (WHO), the World Animal Health Organization (OIE), the United Nations Food and Agriculture Organization (FAO) and the United States (US) Centers for Disease Control and Prevention (CDC), among others. For example, FAO sees One Health as a holistic vision to address complex challenges that threaten human and animal health, food security, poverty and the environments where diseases flourish[7].

On a national level, countries as diverse as Sweden (**Figure 1**) and Kenya, as well as others, have developed national One Health strategies. In the case of Africa, the Emerging Pandemic Threat (EPT) program of the US Agency for International Development (USAID) has created a One Health Central and Eastern Africa network of public health and veterinary universities (OHCEA, www.ohcea.org). OHCEA is developing academic capacity in a number of African countries, including Rwanda, Uganda, Tanzania, Democratic Republic of Congo, and Ethiopia, to strengthen the skills and competencies needed by public health professionals to meet the challenges of emerging and re-emerging diseases.

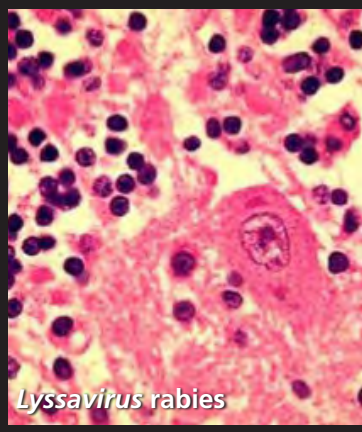
Recently, in Ethiopia, an East African Global One Heath Initiative (GOHi) was established through a partnership with the Federal Ethiopian Ministry of Health and several funding agencies (Global Health Security Agenda, US President's Emergency Plan for AIDS Relief, US CDC). The goal of GOHi is to address infectious diseases and other non-communicable diseases in Eastern Africa by using a One Health approach. In addition, GOHi will help to expand capacity for a One Health approach via applied education, training, research and outreach to more efficiently and effectively address causes and effects of diseases at the interface of humans, animals and the environment.

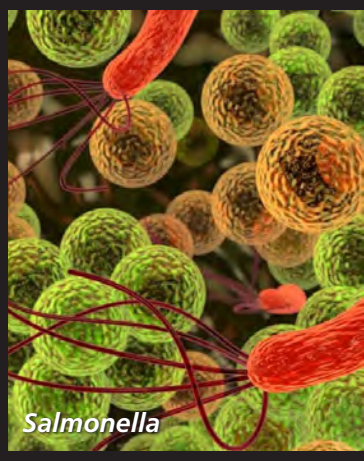
One Health, a wide-reaching strategy

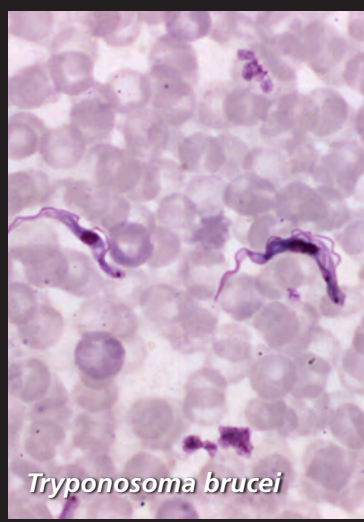
One Health provides a model for considering ways to maximize and monitor the health of human populations living in close proximity to animals in sensitive ecosystems. It provides a platform for transdisciplinary cooperation and collaboration between governments and professional organizations that may have separate missions involving one or more sectors of human, animal, or environmental health. One Health is about what we can learn from those shared risks, and it's about protecting the environment in order to optimize the health of the humans and animals, as well as the environment we all live in.

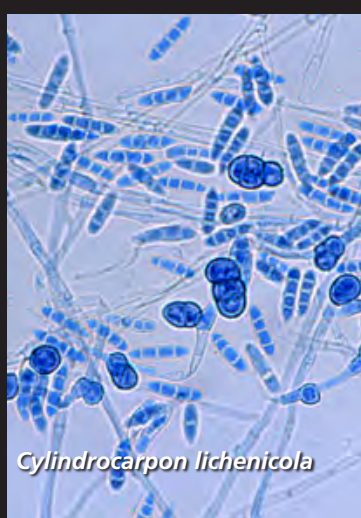
One Health benefits

There are numerous benefits to taking a One Health approach to public health. First, the higher quality or larger quantity of information and data and improved knowledge or skills of public health professionals increases the likelihood of early detection of threats and timely, effective or rapid responses. This leads to improved and/or more effective disease control and/


Lyssavirus rabies


Salmonella


Tryponosoma brucei


Cylindrocarpon lichenicola

or biosecurity measures (often related to infectious disease), which in turn have economic benefits. There are also intangible benefits, such as improvements in human and animal health and in the well-being of ecosystems[8]. Moreover, operationalizing One Health will enable collaborators to more effectively address and reduce the burden of zoonotic infectious diseases worldwide. Overall, owing to their holistic nature, One Health activities can result in a wide range of benefits, spanning aspects from the social (e.g., empowerment, poverty reduction) to the economic (e.g., cost reduction, economic growth) and environmental (e.g., ecosystem resilience, wildlife conservation) to health[7].

In conclusion

In order to develop an effective One Health implementation plan for strengthening capacity at national, regional, or global levels, there needs to be a reexamination of how existing systems are structured, resourced, and managed. Moreover, to successfully implement a global One Health method, the global community must take responsibility for strengthening local skilled workforces and infrastructure capacity, particularly in low-resource countries, in order to effectively prevent and control diseases at the interface of human, animal and environmental health and make the world a safer place. The global One Health paradigm requires working across disciplines and across administrative barriers, a crucial component for effectively tackling complex One Health issues[5].

In low-resource, developing countries, such as many countries in Africa, animal health and human health are closely intertwined, and the health of environments and ecosystems is fundamental to both human and animal health. Africa, therefore, needs to increase adoption and implementation of One Health methods to integrate and manage concerns and values about human, animal and environmental health, including zoonotic diseases. One of the most important aspects of controlling pathogens at the human, animal and environment interface is the development of adequate, science-based risk management policies that respect transboundary regulations[5], an area where capacity needs to be built in Africa.

In addition, to both advance One Health and prepare a professional workforce grounded in One Health in Africa, it is essential that the conceptual and practical underpinnings of One Health are integrated at all educational levels, especially at the high school and higher education levels, because of the complexity of the concepts and the overarching mission. The earlier in the educational experience One Health is introduced to students, the more likely it will be that they will examine population health problems through a One Health lens[9].

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Emerging pathogens and antibiotic resistance make STIs an urgent challenge

By Anjana Bhattacharya, PhD

The landscape of sexually transmitted infections (STIs) has been shifting rapidly in recent years, with prevalence rates of certain STIs climbing and new diseases taking a toll. There is a disproportionate disease burden among high-risk populations such as pregnant women, sexually active adolescents, men who have sex with men (MSM), and HIV-infected individuals. In some of these populations, STI co-infections are much more frequent than they are in the general population[1].

Testing for STIs has always been complex due to the asymptomatic occurrence of some of the most common infections, such as herpes simplex virus (HSV) 1 and 2. There are at least 50 million individuals infected with HSV2 in the United States (US), of which only 10% to 25% have been diagnosed[2]. Diagnostic difficulties are compounded further due to the rapid emergence of antibiotic resistance, with STIs like *N. gonorrhoeae* and *M. genitalium* evolving into STI 'superbugs'. Prevention of these superbugs warrants the need for widespread antimicrobial resistance surveillance.

Some STIs that were thought to be well contained, such as syphilis, are reemerging. With nearly 28,000 known cases in the US in 2016, a 17.6% increase compared to 2015, syphilis prevalence is on the rise[3].

For clinical laboratories working to diagnose STIs, these emerging trends and newer diseases can be extremely confounding.

Molecular detection of STIs

Molecular testing offers sensitive and faster STI diagnosis compared to culture-based and other conventional assays, thereby improving patient outcomes. Higher-sensitivity detection of trichomoniasis, which is commonly underdiagnosed because of the low sensitivity of wet mount microscopy methods, is now possible due to the adoption of molecular platforms. Even for diseases such as genital herpes where the infection cannot be cured, higher sensitivity improves patient and partner management.

In some cases, however, FDA-cleared molecular tests are not available. There is a pressing need for a molecular test for *M. genitalium*, a fastidious organism for which culture takes far too long to yield medically actionable results. In select laboratories, *M. genitalium* is diagnosed by molecular testing of urine or urethral, vaginal, or cervical swabs, typically using in-house PCR assays that can be validated as laboratory-developed tests (LDTs)[4]. Data generated using these LDTs indicates a 1.1% to 3.3% prevalence rate for *M. genitalium* in the general population[5,6]. However, the true prevalence may be severely underestimated.

Antibiotic resistance

For many STIs, it is as critical to detect markers of drug resistance as it is to perform pathogen identification. *N. gonorrhoeae* and *M. genitalium*, in particular, have very high rates of antibiotic resistance. The Centers for Disease Control and Prevention (CDC) made it a priority to fund projects designed to tackle gonorrhea resistance as an urgent threat. The CDC also recently updated its treatment guidelines to slow the emergence of cephalosporin resistance, which will greatly limit treatment options and could cripple gonorrhea control efforts[4].

The substantial decline in the capability of laboratories to perform essential gonorrhea culture techniques required for antibiotic resistance/susceptibility testing is a major challenge to monitoring emerging antimicrobial resistance in *N. gonorrhoeae*[7]. Molecular testing has been piloted as a means of identifying antibiotic resistance markers, with those results guiding treatment paths for patients. A recent study at the University of California, Los Angeles, demonstrated the use of a rapid genotyping assay to predict whether *N. gonorrhoeae* strains were susceptible or resistant to ciprofloxacin[8]. The study led to reduced reliance on broad-spectrum antibiotics and increased use of more targeted therapies that led to improved patient outcomes.

The need for genotypic resistance marker typing is even more pronounced for *M. genitalium,* as its slow growth rate obviates a phenotypic antibiotic susceptibility testing approach. *M. genitalium* exhibits a remarkable capacity to develop antimicrobial resistance—specifically to the macrolide azithromycin—very rapidly after introduction of treatment[9,10]. In fact, there are high rates of macrolide resistance reported in the US already for *M. genitalium,* with some areas recording resistance rates as high as

50%[11].

One school of thought is that syndromic management of non-gonococcal urethritis using macrolide antibiotic treatments causes strains containing macrolide mutations to predominate, resulting in drug resistance[12].This has already led to European STI treatment guidelines advocating for the detection of macrolide resistance-mediating mutations in all *M. Genitalium* positive cases[13].

Looking ahead

Emerging STIs and high rates of associated antibiotic resistance are poised to become major public health threats, caused in part by the syndromic management activities that lead to overuse of broad-spectrum antibiotics. There is a critical need for resistance typing for gonorrhea that might become untreatable, if resistance emerges to the current dual therapy regimen.

Additionally, *M. genitalium* has already become a difficult bacterium to treat on a syndromic basis. In the ideal clinical setting, specific diagnostic tests for *M. genitalium* would be as readily available as tests for *C. trachomatis* and *N. gonorrhoeae,* and detection of both *N. gonorrhoeae* and *M. genitalium* would be accompanied or followed by molecular detection of drug resistance-mediating mutations. Due to the unique aspects of these two STIs, a precision-based treatment approach guided by their resistance profile post-diagnosis might be more useful than the current syndromic approach.

Even when they are not antibiotic-resistant, STIs represent an urgent area of clinical and diagnostic need. The emergence of new STIs, combined with the re-emergence of infections long thought to have been overcome, make this a dynamic and important field. Molecular testing must continue to improve for this segment of public health, in order to provide reliable results for an increasing number of sexually transmitted pathogens with faster turn-around times and more robust workflows.

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The case for universal chlamydia screening

By Michael D. Randell, MD, FACOG

The current risk-based chlamydia screening strategy has provided evidence for a growing infection crisis, and yet at the same time contributes to the alarming infection problem by not adequately screening infected women. Most chlamydia infections are asymptomatic and, therefore, many unknowingly infected patients are not motivated to visit a physician, receive a diagnosis, and have their case reported. This causes infection prevalence to be underestimated.

Screening practices themselves can also influence prevalence statistics. The US Preventive Services Task Force (USPSTF) and the Centers for Disease Control and Prevention (CDC) recommend annual screening of all sexually active women aged <25 years and screening of older women at increased risk (for example, women who have new or multiple sex partners). In the absence of more rigorous screening for infections, reported prevalence will be artificially low. The CDC estimates that 1.6 million people in the US are currently infected with *chlamydia trachomatis* (chlamydia), making this bacterial infection the most common

notifiable sexually transmitted infection (STI) in the US[1].

Barriers to chlamydia screening

Screening rates in the US are especially low for young adults[2]. Only 40% of sexually active women aged 15 to 21 reported having had a chlamydia test in the past 12 months[3]. Screening rates were lowest among patients aged 15 to 19—the cohort with the highest chlamydia prevalence[3]. The CDC has estimated the chlamydia prevalence of sexually active persons aged 14 to 19 to be 6.8%[3].

Too many women, especially young women, are not screened for chlamydia, leaving them vulnerable to the health problems that arise from untreated infection and increasing the likelihood that they will infect others. There are multiple interrelated barriers to adequate screening that compromise risk-based screening efficacy. Some physicians are not aware of the USPSTF and CDC recommendations and, in turn, do not incorporate regular screening into their practice. Others lack information about the sexual activity of their patients and therefore cannot act based on patient infection risk. The underlying reasons for this information gap relate to the fact that patients do not always fully disclose their sexual activity. The upshot of this situation is that physicians, who are aware of the unreliability of sexual history information provided by patients, simply stop asking about patient sexual activity and are in no position to accurately assess risk.

Health risks of untreated chlamydia

Untreated, chlamydia infection in women can persist and lead to complications that can have a lifelong impact[4]. Chlamydia can spread to the uterus, ovaries, or fallopian tubes, causing pelvic inflammatory disease (PID). PID can lead to infertility, persistent (chronic) pelvic pain, and an increased risk of ectopic pregnancy. Additionally, if a chlamydia infection is present during pregnancy, there is a potential risk that the infection could be transferred to the fetus and cause conjunctivitis and pneumonia. Chlamydia left untreated during pregnancy may also increase the risk of premature birth, miscarriage, or stillbirth.

Proposal for universal screening

A cost-effectiveness study evaluated a universal screening method designed to overcome some of the barriers inherent in the risk-based strategy. A universal screening approach means that all women between 15 and 24, regardless of what the physician knows about patient sexual activity, would be informed that screening is routine, and unless they elect to 'opt-out', they will be screened annually. This screening as a default practice avoids the opportunity for infection risk misrepresentation/misunderstanding, and it also opens a dialogue about chlamydia infection between patients and physicians.

Cost-effectiveness of universal screening

Universal screening for chlamydia, by design, would screen more women than risk-based screening and for that reason could be mistakenly presumed to cost more. To evaluate whether the benefits accrued from identifying and treating more infected women might offset the operational costs of testing kits, a recent study evaluated the cost-effectiveness of universal screening for high-risk young women aged 15 to 24 in the US[2]. The study used a basic compartmental heterosexual transmission model that assumed 80% insurance coverage, 83% healthcare utilization, and 75% test acceptance. The model expected an annual testing coverage rate of 50% compared with risk-based screening (30%).

Results of this modeling study predicted that the universal testing strategy would decrease overall chlamydia prevalence by >55% (2.7% to 1.2%) compared with risk-based screening. In addition, this strategy would reduce costs by improving health outcomes more than current testing. Costs in this study include costs of testing, costs of treatment, and costs related to subsequent patient outcomes. According to the modeling, predicted cost outcomes for a hypothetical population of 100,000 individuals aged 15 to 24 years would be $105 million for no screening, $89 million for risk-based screening, and $71 million for universal screening. The study concluded that decreasing infection prevalence, spread of infection, and adverse consequences of disease has cost benefits that offset the cost of testing more women.

Current risk-based screening for chlamydia is leaving too many women, particularly young adults, out at a time when infection rates are soaring. Not identifying and not treating women with infections promotes the likelihood of long-term negative health consequences that could have been prevented and enables the continuation of the infection cycle through partners of infected women. Laboratory professionals serve as integral partners to physicians in the chlamydia screening process. By advocating for a universal screening strategy with physician and healthcare partners, laboratorians can accelerate the transition to a viable, cost-effective

method to lower chlamydia prevalence and raise the standard of care.

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STI prevalence in Africa: A snapshot

By *MLO* staff

Sexually transmitted infections (STIs) are a major global cause of acute illness, infertility, long-term disability and death with serious medical and psychological consequences of millions of men, women and infants. In addition, STI prevalence is difficult to collect, particularly in sub-Saharan Africa, where inexpensive, feasible diagnostic tests are not available in most clinical settings.

In Africa, prevalence of curable sexually transmitted infections (STIs) — chlamydia, gonorrhea, syphilis and trichomoniasis—among women aged 15 to 24 exceeds that of older women and similar-aged men in sub-Saharan Africa, according to research published in *PLOS Medicine*[1].

In fact, recent studies suggest a higher STI prevalence (particularly in women) in clinic or community-based populations in South Africa than among, similar populations elsewhere in southern or eastern Africa. Studies also suggest greater prevalence among higher-risk populations for certain STIs (example, gonorrhoea and syphilis), but not for others (example, herpes simplex virus 2 (HSV-2) and bacterial vaginosis (BV), which have high prevalence across all population types).

For chlamydia, prevalence is similar to or even greater than among women in eastern Africa recruited from higher-risk settings such as where transactional sex frequently occurs. However, in clinic or community-based populations elsewhere in southern or eastern Africa, the estimated chlamydia prevalence is lower and similar to that of high-income countries in Europe and in the United States with well-established chlamydia control programmes[2].

Meanwhile, a drug-resistant form of gonorrhea is spreading around the globe and incidences of gonorrhea are amongst the highest in the world in sub-Saharan Africa.

With the exception of the Solomon Islands and Papua New Guinea, there are 12 countries where 5% or more of pregnant women still have syphilis, are all sub-Saharan African countries: Liberia (11.8%); Malawi (10.1%) and Somalia (8.7%)[4]. Syphilis in pregnancy causes stillbirth, prematurity, low birthweight, neonatal death, and infections in newborns. These adverse outcomes can be prevented with a simple and inexpensive test and treatment with penicillin. Bedside tests for syphilis have been tested in sub-Saharan Africa. The Dual Path Platform (DPP-point-of-care testing) Syphilis Screens tests is perfect for rural areas without development of infrastructure[3].

HSV-2 and BV prevalence is relatively high across all regions and population types[2]. However, there is an even higher prevalence of HSV-2 (39%) among women aged 15-24 in South African clinic and community-based populations[1].

M. genitalium, a lesser known STI that causes urethritis in both men and women, as well as cervicitis and pelvic inflammation in women, was described for the first time in sub-Saharan Africa in 2015[5]. Overall, 10.8% of women were infected with *M. genitalium*.

South Africa's National Strategic Plan for HIV, tuberculosis and STIs (2017-2022) has placed prevention as the first goal with the bold target of reducing new HIV infections by more than 60% and cutting tuberculosis incidence by at least 30%. South Africa, which has the highest HIV/AIDS prevalence in the world, intends to test and treat at least 6.2 million people with HIV by 2020[6].

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Laboratory preparedness: Ebola and other emerging infectious diseases

By Triona Henderson, MD, MPH, and Sheldon Campbell, MD, PhD

The 2014-2015 Ebola virus disease outbreak in West Africa spread across international borders and affected thousands within the countries of Liberia, Sierra Leone, and Guinea, as well as small numbers of patients in several other countries around the world.

Ebola virus belongs to the Filoviridae family of linear, negative-sense, single-stranded RNA viruses. Within this family, the current outbreak species, Zaire ebolavirus (commonly named Ebola virus) is one of the five distinct species within the Ebolavirus genus[1]. Most Ebola viruses can cause severe and often fatal hemorrhagic disease in humans.

People infected with EVD commonly present with non-specific symptoms such as fever, severe headache, muscle pain, weakness, fatigue and, importantly, vomiting and other gastrointestinal symptoms such as severe diarrhea. Less than half of cases demonstrate hemorrhage[3]. The reservoir for the virus is probably in fruit bats and is transmitted either directly to humans or indirectly via interactions with apes.

Human-to-human spread occurs by direct contact with bodily fluids. The most probable sources of infectious virus responsible for person-to-person transmission are blood, urine, vomitus, and diarrheal fluids, but the virus has been detected in most body fluids. While respiratory spread via aerosolization of infective viral particles has been postulated, both the basic biology of the virus and the epidemiology of it suggest this is extremely unlikely. Secondary cases among individuals who did not have direct contact with virus-laden material are rare and poorly documented, and the virus does not survive in droplet nuclei. Nevertheless, many of the victims of past outbreaks have been healthcare workers.

Assessing the risks

Hospitals and laboratories planning the management of any emerging infectious diseases should begin by characterizing the risk of infection by the offending agent. Factors that affect the risk from an emerging pathogen include:

- The route of transmission
- The location of the virus in the body during infection
- How much infectious virus is present
- How common the infection is
- How pathogenic the agent is
- What clinical activities are performed on infected or potentially infected patients.

Performing a risk assessment allows the facility both to gauge the degree of risks to employees and to mitigate known and expected risks.

As the West Africa Ebola epidemic evolved and threat to other countries around the world increased, numerous governmental and nongovernmental bodies, including the Centers for Disease and Control (CDC) and the American Society of Microbiology (ASM), issued guidance on preventing transmission of the Ebola virus in the clinical laboratory setting[4,5].

The guidelines from each organisation outlined actions that healthcare facilities and their laboratories may take in categories including test ordering, sample collection, and the use of processing, personal protective equipment to minimize the risk of transmission of Ebola virus to healthcare workers. They highlight the need to follow standard precautions for specimen procession and handling, and they suggest additional steps to follow with regard to contact, droplet, and airborne precautions as they pertain to healthcare workers.

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However, guidelines from different sources contain significantly different recommendations for important tasks including sample collection and labeling, transport, processing, and performance of routine testing. Individual laboratories are faced with the unenviable task of performing risk assessments and sorting through contradictory guidelines to create local policies.

It is critical to assess risks in the context of clinical settings and patient populations and to recognize that zero risk is unattainable. Also, as the outbreak progresses, the epidemiology and quantitative risks evolve and vital lessons may be learned along the way.

Thus it is necessary for laboratories not only to create policies and procedures, but also to review and revise them as the outbreak continues.

What tests should be performed?
Who collects the specimens?
How is the specimen transported?
How are patients at-risk or infected with Ebola virus identified?
How is the laboratory notified of patients and of specimens from those patients?
How are lab personnel who handle specimens tracked and assessed for potential exposure?
What PPE will be used for each procedure?
How will PPE competency be established and maintained?
How will the sample be handled once in the laboratory?
How will spills be managed?

Table 1. Assessing and planning patient sample workflow.

The laboratory context

Laboratory issues exist that all institutions performing testing on or taking care of patients with the virus must address **(Table 1)**. Assessing and planning the workflow of patient samples is exceedingly important.

For example, when a patient infected with Ebola virus arrives at a hospital for treatment, the institution must determine how patient specimens will be handled to most effectively reduce risk to those handling them. They must assess the types of testing that must be done to ensure that appropriate levels of care are maintained as well as the way in which the laboratory does the specified testing.

Is the risk of testing a patient sample in the laboratory low enough to utilize enhanced PPE

with standard sample processing, or would it be better to keep patient testing at the bedside? If a spill occurs in the laboratory, will the response affect the availability of testing for other patients?

The American Association of Blood Banks (AABB) has assessed the transmission risk of Ebola virus via blood transfusion. The organisation's risk characterization of Ebola virus transmission through the blood supply and public health risk estimates conclude that there is insufficient data to make recommendations regarding donor deferral periods of patients previously infected with Ebola virus or those individuals who had high risk contact[6].

However, when an Ebola infected patient requires transfusion therapy, the AABB recommends exposing laboratory personnel to patient blood as little as possible during pre-transfusion testing, by transfusing type O Kell-negative blood[7].

Policies and procedures

In addition to the promulgation of policies and procedures for handling samples associated with potential EVD, practice and drills of those procedures, particularly the donning and doffing of personal protection equipment (PPE), are essential.

Ultimately, all staff caring for patients and processing specimens need to be well-versed in the plan, with drills being performed so that staff is aware of how to communicate with management.

Further, specimen collection, labeling, and transport must be a priority in overall planning. While stringent precautions for handling samples from patients with potential or proven EVD are essential, and hospital policies and procedures should include early identification of patients at risk and notification of laboratories, laboratories should recognize that patients with EVD may present with confusing or inadequate histories, and specimens may be sent to the laboratory before the possibility of EVD infection is raised.

Reinforcing careful adherence to current standard precautions against blood-borne pathogens is an essential precaution against EVD, other emerging pathogens, and the known hazardous pathogens found in routine laboratory practice.

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Photos courtesy of the CDC.

CDC prepares to join Ebola fight in Africa

The United States Centers for Disease Control and Prevention (CDC) is preparing to deploy staffers to several cities and towns deep in the Congolese jungle amid a new Ebola outbreak that has claimed at least two dozen lives.

The CDC maintains an office in Kinshasa, the capital of Congo, about 350 miles from the epicenter of the outbreak. The dozen or so staffers who work in that office are likely to deploy to the hot zone once they receive a formal invite from Congo's health ministry.

In an interview, Pierre Rollin, one of CDC's top Ebola experts, said the World Health Organization (WHO) is leading the response and coordinating among both governmental and nongovernmental organizations responding to the ongoing outbreak.

'We're offering them a roster of 12 or 15 people that will be able to go there,' Rollin said. 'They're ready to go as soon as they've got an invitation. The invitation is from the Ministry of Health through the WHO.'

The news comes one day after health officials reported the first Ebola case in a major Congolese city, a troubling shift for the outbreak.

Four years after an Ebola outbreak in West Africa killed more than 11 300 people, the groups that respond to a new outbreak practice familiar roles. WHO coordinates national and international efforts. UNICEF manages communications between the groups. Doctors Without Borders has taken the lead on patient care, opening Ebola treatment centers and isolation wards in the city of Mbandaka and the town of Bikoro.

The Red Cross is handling safe burials of those who succumb to the disease. Virus transmission through traditional burials accounted for the vast majority of Ebola's spread through Guinea, Liberia and Sierra Leone, the West African countries hit hardest by the 2014-2015 outbreak.

In total, WHO is working with 22 governmental and nongovernmental organizations responding to various aspects of the outbreak, ranging from CDC to the Red Cross/ Red Crescent, the International Organization for Animal Health and Gavi, a group that will help vaccinate thousands of residents.

The relative isolation of the communities where the virus began to spread last month is both a blessing and a curse for the efforts to stop Ebola's progress. On one hand, remote villages mean the virus's spread is contained naturally. On the other, it means that once a virus does spread, responders are slower to arrive.

'We know that the roads are very bad. We know that the rainy season has started. We know that there are a lot of villages that have to be visited,' Rollin said. Travel between Bikoro and Mbandaka 'can take from half a day to four days. And we're not talking about thousands of kilometers, we're talking about 200 kilometers, or 150 miles. But the roads are so bad that it takes all that time.'

'We don't know exactly what is happening in some villages,' Rollin added.

The United Nations has opened an air bridge between Kinshasa and the two impacted cities, ferrying supplies and responders on regular flights. The UN is also providing helicopters to speed responders to more remote villages where the virus may be present.

At least 44 people in the region have shown symptoms of a viral hemorrhagic fever. Ebola has been confirmed in three of the cases. At least 23 people have died.

Rollin said the new Ebola vaccine, first shown to be effective during the tail end of the West Africa outbreak in Guinea, will be a critical new tool to fight this outbreak. Healthcare workers will be the first to receive the vaccine. Then workers will vaccinate those who have come into contact with the infected, as well as those who have come into contact with the first set of contacts, a practice known as ring vaccination.

Rollin, who has deployed to fight Ebola outbreaks for decades across Africa, said he expects to travel to Congo this weekend.

Once an organization that prided itself on sending small teams of responders to combat outbreaks, CDC became a much more agile and active responder during the 2014-2015 outbreak. The agency deployed more than 1400 epidemiologists, virus hunters and contact tracers to Liberia, Sierra Leone and Guinea over the course of more than a year.

What is the comparative advantage of plasma vs. dried blot spots for HIV viral load testing?

by Robert Luo, Debrah I. Boeras, and Rosanna W. Peeling
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The World Health Organization (WHO) recommends HIV viral load testing for monitoring people living with HIV/AIDS in order to diagnose and confirm treatment failure[1]. The UNAIDS 90-90-90 goals also rely on viral load monitoring to achieve the third "90," where 90% of individuals on treatment should have suppressed virus. Over 20 million people are currently on antiretroviral treatment worldwide but less than 30% of those on treatment have access to viral load testing (WHO/UNAIDS data). Scaling up access to viral load testing is critical for both fighting the HIV/AIDS epidemic and ensuring that all patients receive appropriate care[2].

Plasma has always been the standard of care sample type for HIV viral load testing. Clinicians and labooratory staff have the most experience with plasma as a sample type, and virtually all the major clinical, pharmaceutical, and laboratory studies of HIV have used plasma-based viral load testing to monitor patients, assess the efficacy of drugs, and evaluate patient outcomes. However, the use of plasma is typically more demanding, requiring trained staff to perform phlebotomy, cold chain transport, and centrifugation to prepare plasma samples from whole blood.

To expand access to viral load testing, dried blood spots (DBS) have recently been used as an alternative. Traditionally used for HIV early infant diagnosis in resource-limited settings, DBS viral load testing is now recommended by WHO "in settings where logistical, infrastructural or operational barriers prevent routine viral load monitoring using plasma specimens[3]. "While initially DBS were only considered for use at a virological failure threshold of 3000 to 5000 copies/mL, in 2014, WHO aligned the threshold for DBS at the same 1000 copies/mL threshold as plasma[4]. Dried blood spot (DBS) testing differs from plasma-based testing in many ways [5,6]: **(Table 1)**

- Much smaller sample volume requirements
- Can be collected using finger or heel prick and does not require a trained phlebotomist
- Does not require cold chain transport or storage
- Performance characteristics (e.g. limit of detection) may be reported in relation to whole blood which can contain cell-associated DNA in addition to cell-free RNA found in plasma
- Can have lower sensitivity and specificity for treatment failure compared to plasma

Table 1: Comparison of Plasma and Dried Blood Spots for HIV Viral Load Testing

	Plasma	Dried Blood Spots
Technical requirements	Trained staff to perform phlebotomy to collect venous blood	Finger prick using a lancet
	Cold chain transport required to conserve sample stability	No cold chain required
	Centrifugation capabilities to prepare liquid plasma from whole blood	Extraction requiring several manual steps
Performance	Reference standard for viral load with a lower limit of detection of 20-100 copies/mL of plasma; WHO recommends a threshold of 1000 copies/mL of plasma	Sensitivity lower than that for plasma as a smaller volume of whole blood is collected for testing; lower limit of detection is 100% reliable at viral load ranges of 3000-5000 copies/mL blood and 85-90% sensitive at 1000 copies/mL [4,5,6]
Quality assurance	Standard laboratory quality controls (QC) and proficiency testing in place	Quality assurance for DBS in development but needs standardization
Implementation challenges	Access to viral load testing through laboratories and point-of-care devices remain a challenge in terms of affordability and availability of technical expertise to operate the equipment	Limited data available on how well DBS samples have been used for viral load

UNAIDS 90-90-90 strategy for reducing HIV by 2020.

- Typically require more manual sample preparation steps than plasma prior to testing
- Fewer data exist on the use of DBS for viral load monitoring, including with respect to implementation research, longitudinal monitoring, patient and programmatic preferences, cost effectiveness, result reporting (e.g. if results returned to patients and clinicians), and impact on patient outcomes
- Quality control and proficiency testing programs are still under development

While DBS-based viral load testing has obvious advantages, its use requires strict quality assurance in terms of the type of filter paper used, lot-to-lot consistency of filter paper, correlation of size of the blood spot (punch size and saturation) to sample volume, storage conditions, method of extraction and the appropriateness of the extraction buffer with the viral load detection system[7]. To address the last point, some companies have already obtained regulatory approval for the use of DBS for viral load testing.

Moving forward

New research into areas such as plasma separation cards and devices, along with point-of-care viral load testing using finger prick or plasma, may provide similar or better alternatives to DBS. However, each solution comes with its own unique set of advantages and disadvantages.

As programs expand their viral load testing capabilities, combinations of plasma and alternative testing modalities such as DBS should be carefully considered to ensure increased access to viral load testing and optimal clinical care of patients. One of the major challenges will be finding the best balance for a program and building the infrastructure and support for all sample types needed to make a program successful.

Summary

Although the WHO guidelines recommend the use of plasma over DBS for HIV viral load testing, DBS and other solutions are still needed to reach patients who do not have access to plasma-based testing. In many resource-limited settings with significant rural populations, this can account for 50% or more of HIV-infected individuals on treatment living in a country. Without an alternative to plasma, the UNAIDS 90-90-90 goals will not be met, as there are not enough laboratories and sample transportation networks that would enable plasma to reach all people in need of a viral load test. DBS have been studied on all major HIV viral load platforms, and some tests already have regulatory approval.

Sample types alone will not solve problems related to access to testing and care. Strengthening programs, laboratories, and country resources, along with empowering and educating patients, clinicians, and laboratory staff, will all be needed in the context of strong political and funding commitments to ending the HIV/AIDS epidemic.

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Meet Professor Alash'le Abimiku, MSc, PhD

Executive Director, International Research Centre of Excellence, Institute of Human Virology Nigeria
Professor, University of Maryland

Professor Alash'le Abimiku co-founded the Institute of Human Virology Nigeria (IHVN) in 2004, is the founding Executive Director of the International Research Centre of Excellence (IRCE) at IHVN, and is a Professor of Medicine, Epidemiology and Public Health at the University of Maryland in the United States (US). Prof Abimiku first demonstrated the unique nature of the HIV strain prevalent in Nigeria in 1993 as subtype G during her postdoctoral training at the US National Institutes of Health (NIH). Since then, she has trained a cadre of pre and post-doctoral Nigerians who are engaged in advanced laboratory science and research through the University of Maryland-IHVN NIH Fogarty AIDS International Training and Research Program Grant. She is internationally recognized in her role on the board of the African Society for Laboratory Medicine (ASLM) and the World Health Organization's HIV Vaccine Advisory Committee. She is the Principal Investigator on a number of US Centers for Disease Control and Prevention (CDC) and NIH-funded grants, and has published over 80 peer-reviewed journal articles, 70 abstracts and/or proceedings, and 4 book chapters. She is affiliated with over 15 scientific organisations as Co-chair, Associate Editor and member, has been invited to give over 15 major speeches and has received a number of awards for excellence, including a Member of the Order of Niger (MON) award in 2014 from Nigerian President, His Excellency Goodluck Ebele Jonathan.

Who is Prof Alash'le Abimiku? Please tell us about your education and professional journey.

I was trained as a Medical Microbiologist with a specialization in retrovirology after going to one of the best universities in Nigeria, Ahmadu Bello University, Zaria and to the London School of Hygiene and Tropical Medicine in the United Kingdom for my MSc and PhD degrees. I was able to do this all on scholarships thanks to my father, a very wise policeman, who insisted that all eight of his daughters not only go to school, which was unheard of at the time, but that we perform at the top of our class.

I went on to do my postdoctoral training and obtain a faculty position in the United States (US). This opportunity and the influence of my father enabled me to help establish the first reliable HIV research laboratory in central Nigeria. I was able to maintain my roots in Nigeria, while learning from some of the world's best scientists who involved me in international collaborations at the highest level of excellence.

What is the idea behind IHVN and IRCE? How did you come to be the Executive Director of at IRCE at IHVN and a Professor at the Institute of Human Virology at the University of Maryland School of Medicine in Baltimore?

IHVN was first established in 2004 through funding from the US President's Emergency Fund for AIDS Relief (PEPFAR) as an affiliate of the Institute of Human Virology at the University of Maryland School of Medicine. In 2010, IHVN became an indigenous, non-governmental organisation with its own board, while maintaining a strong collaboration with the University of Maryland. IHVN's vision is to become a centre of excellence that serves the health, research and training needs of Nigeria, and beyond, in the West African region and other parts of sub-Saharan Africa. IHVN has grown into an organisation of over 500 staff members, 95% of whom are Nigerian. We work in collaboration with Nigerian University Teaching Hospitals and local and international donor organisations for our large public health programme implementation through PEPFAR and the Global Fund. To stay on its mission of providing health service implementation, capacity building, and research, and ensuring equitable access to individuals and communities through innovative and evidence-based strategies and address the new challenges of a large organization, IHVN created two centres in 2016: the Center for Public Health Implementation (CPHI) and IRCE. While CPHI continues to implement IHVN's PEPFAR and Global Fund grants, IRCE is now focused on providing an enabling environment for scientists at IHVN. We can utilize the extensive programmatic infrastructure of CPHI to support research activities and in turn, the research conducted can provide innovative and evidence-based implementation strategies to enhance IHVN's public health implementation programmes. The ultimate goal of IRCE is to expand the culture of research and increase the number of young Nigerian researchers learning the ropes of how to conduct research at international standards and to compete successfully for research grants.

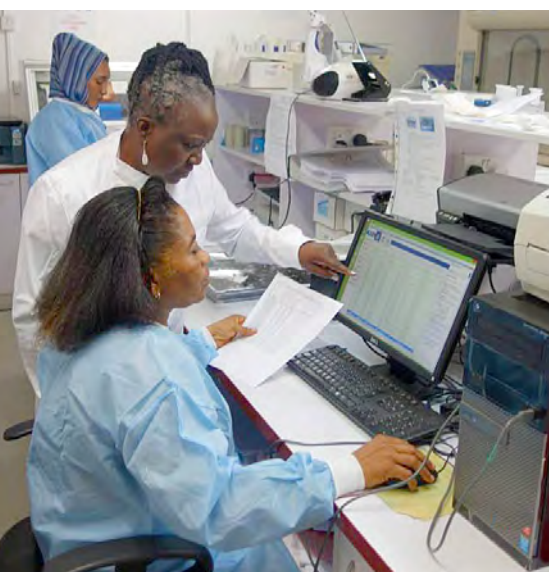
What is the relationship of IRCE to ASLM?

IRCE is very much about translational research, which is relevant to local health issues and informs large treatment programmes like PEPFAR and the Global Fund that are being implemented by IHVN through CPHI. A number of diagnostic tools and new technologies require research investigations to identify the best algorithm for their use and how best to use them in the local settings without compromising specificity and sensitivity. We recently received a grant from the US NIH to develop a Human Heredity and Health in Africa (H3 Africa) biorepository at IRCE to facilitate genomic studies in African populations and support research into other diseases as well. Thus, IRCE contributes to the larger mission of ASLM to evaluate diagnostic tools and algorithms for the continent, as well as helping in their development to some extent by contributing valuable biological samples from Africa. The art of developing and operating a biorepository that is compliant with the standards of the International Society for Biological and Environmental Repositories is experience that can be shared with the network of ASLM laboratories that support the Global Health Security Agenda. In addition, although IHVN now has well-trained laboratory staff to continue supporting sites that provide HIV treatment, care and prevention, there is a need to continue to build capacity over several years and to form networks and partnerships to strengthen these programmes. ASLM is taking a clear leadership role in building laboratory capacity and maintaining partnerships within the continent, which is very important.

The conferment of National Honours Award by His Excellency, Goodluck Ebele Jonathan, (GCFR) to Prof. Alash'le Abimiku, (MON)

What will be the most important emerging challenges for public health in Africa over the next 5 years, and how can ASLM work with IRCE to meet those challenges?

Although Africa has a lot of the resources required for a robust and efficient healthcare system and the intellectual capacity necessary, we face challenges that bar the continent from achieving sustainable improvements in health system performance and in research. By providing the framework to support talents from Africa and encourage collaborations and networking with one another and with researchers around the world using the same rigorous scientific standards, ASLM and IRCE together can help to bring solutions for the health challenges of Africa by Africans to the fore. I am confident that as Africans, our strengths outweigh our challenges. To effectively solve the challenges we face on the continent, we need to draw from past lessons learned, current available resources, the size of our population and the tenacity of our people.



Prof. Abimiku going through laboratory data with her staff.

What advice would you give the next generation of African laboratory scientists?

Based on my experience, I know that we can reverse 'brain drain' to a 'brain gain' in Africa. I would encourage the next generation to be passionate about what they do and remember that their uniqueness lies in the fact that they are Africans, which they should use to contribute to the 'brain gain' drive for Africa. They also must learn to put 'Africa first', to follow in the footsteps of other successful Africans, including those in the diaspora who actively advocate for programs that benefit Africa. That comes with capacity development of African scientists and infrastructure with full engagement and collaboration of highly esteemed investigators and institutions in the north leading to 'brain gain' for Africa. Lastly, be proud of who you are and have a curious and an open mind that allows you to bring your own uniqueness to the table. It always pays to be a team player but don't forget your uniqueness and dreams in the process. Scientists from the developing world have a lot to contribute to research, so make sure that you take your place in the global effort as an equal partner who is honest, dependable, accountable and respected.

LINKS:

Institute of Human Virology Nigeria (IHVN)

International Research Centre of Excellence (IRCE)

Human Heredity and Health in Africa (H3 Africa)

International Society for Biological and Environmental Repositories

Uganda's Biosafety and Biosecurity Milestones: Effective coordination makes a difference

Atek Kagirita, MPH, Msc, UNHLS/MoH, National Biorisk Management Coordinator.
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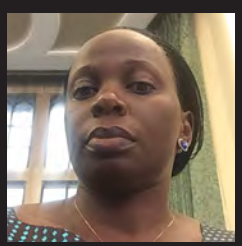


Dr. Susan Nabadda Ndidde, M Med, UNHLS/MoH, Executive Director.
Uganda National Health Laboratory Services, Ministry of Health, Kampala, Uganda

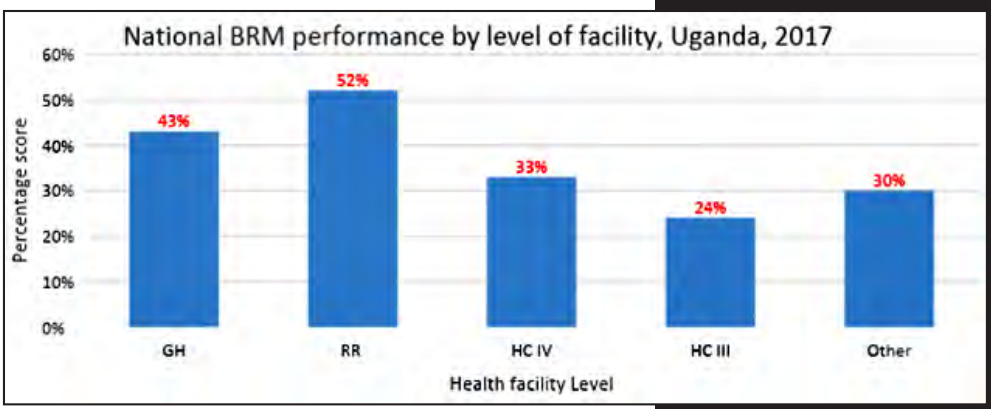
The recent emergence and re-emergence of infectious disease outbreaks, including Ebola and Marburg diseases, has dramatically emphasised the crucial role of laboratory biosafety and biosecurity management. Uganda's laboratory sector opened its doors to biosafety and biosecurity in 2010 after strategic trainings offered by Sandia National Laboratories (New Mexico, United States [US]). A number of efforts then commenced with dedicated support from the governments of Uganda and the US. In addition, various sectors, research institutes and Uganda's National Council of Science and Technology pushed biosafety and biosecurity efforts to fulfil international protocols. Starting in 2012, coordination of biosafety and biosecurity in the health sector was consolidated under the National Biosafety Biosecurity coordination office based at the Central Public Health Laboratories/Uganda National Health Laboratory Services (CPHL/UNHLS), which has since implemented a strategic roadmap to improve the safety and security of populations from biological hazards and threats.

Achievements

Policy level. Uganda's National Laboratory Policy 2009[1] expresses support for biosafety and biosecurity. There is also a specific draft laboratory biosafety and biosecurity policy and a strategic plan for 2016-2021. These are implemented by a National Multisectoral Biosecurity Engagement committee, which draws membership from the security, defence, agriculture, civil aviation, health and environment sectors, as well as from research institutes and others.

Capacity building. CPHL/UNHLS created a programme that has trained over 1000 laboratory staff using a national harmonised curriculum and standardised training materials. Trainings are conducted by an accredited local pool of trainers (n=40) and cover three tracks: basic, laboratory, and leadership and management. These trainings have greatly improved the biosafety management practices of laboratories that underwent Strengthening Laboratory Management Toward Accreditation training, with 100% of laboratories achieving the 43 points available for Facilities and Safety on Stepwise Laboratory Improvement Process Towards Accreditation audits. Specific improvements have been observed in use of personal protective equipment, increased hazard and risk communication and field biosecurity practices through improved management of infectious substances.

Documentation. CPHL/UNHLS developed and distributed a revised National Laboratory Biosafety Biosecurity Manual 2015, laboratory infrastructure guidelines, assorted standard operating procedures and a national standardised Biorisk Management Audit Checklist. The score-based checklist is a locally developed



Overall biosafety biosecurity performance across levels of laboratory service delivery (GH, general hospital; RR, regional referral hospital; HCIV, Level IV health centre; HCIII, Level III health centre)

tool for biosafety and biosecurity performance measurement and continuous improvement. The tool was designed to conform with the requirements of CWA 15793 and ISO 17189 (Box 1). In 2017, the tool was used for a multisectoral laboratory audit to create a nation-wide baseline. The 210 laboratories assessed achieved 33% performance, which was below previous results (49%) from a Global Health Security Agenda (GHSA) pilot assessment.[2] The difference was due to the restrictive nature and scoring basis of the new tool. The tool will be further refined with the hope that other African countries will use it to improve measurement of biosafety and biosecurity performance.

Before: Washing of tubes for reuse in laboratory. After trainings, this practice was abolished.

Multisectoral engagements and partnerships. A number of Biosafety Officers in Uganda have attained international certification by the International Federation of Biosafety Associations, and the first high-level, regional Multisectoral Biosafety and Biosecurity conference was held in November 2016, both of which symbolise the consolidation of the efforts of different sectors. The implementation of biosafety and biosecurity in a multisectoral approach is a formidable and exciting undertaking that improves collective national capacities for safety and security. Through this approach, Uganda achieved a score of 3 (developed capacity) during the concluding Joint External Evaluation by the World Health Organization.[3]

The Uganda Ministry of Health, with support from the US Centers for Disease Control and Prevention and the American International Health Alliance, has trained and certified six Biomedical Engineers who provide necessary but ever-expensive biosafety cabinet servicing and certification. Another local non-governmental organisation, the Infectious Diseases Institute, procured tool kits and spare parts. This team has done a wonderful job of cutting expenses for foreign experts, reducing waiting times, and improving local capacity for equipment servicing and infection control.

Importantly, Uganda's biosafety and biosecurity programme enjoys a supportive political environment, which includes the President of Uganda, His Excellency Yoweri Meseveni, who declared his support of the initiative to sectors' top management during the fourth GHSA high-level ministerial meeting. In 2017, the Permanent Secretary of the Ministry of Health released a circular directing all laboratories to have a designated 'Biosafety Officer'. In addition, during leadership and management track trainings, participants are encouraged to develop and implement safety policies in their facilities. In addition, a biosafety and biosecurity bill is being prepared to foster an even better environment.

The programme is now sourcing partnerships and support to expand into the private sector and increase support to lower tier facilities. The goal is to improve biosafety and biosecurity performance to 65% by the end of 2018. Despite limited resources, an effective coordination mechanism can deliver an effective biosafety and biosecurity program in Africa. Empowering central coordination mechanisms and focusing on standardised approaches with a locally enabling environment makes the necessary difference.

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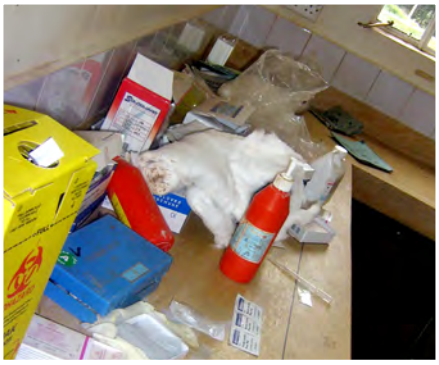
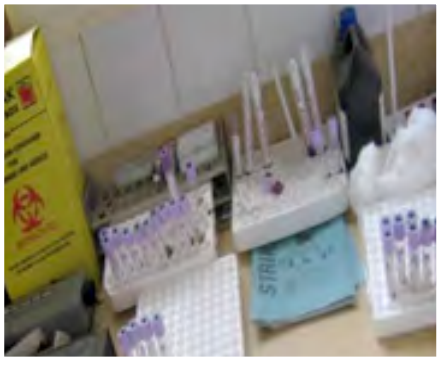
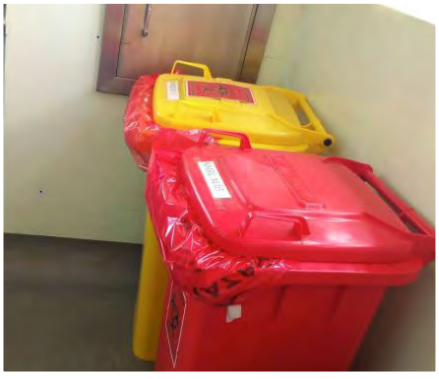
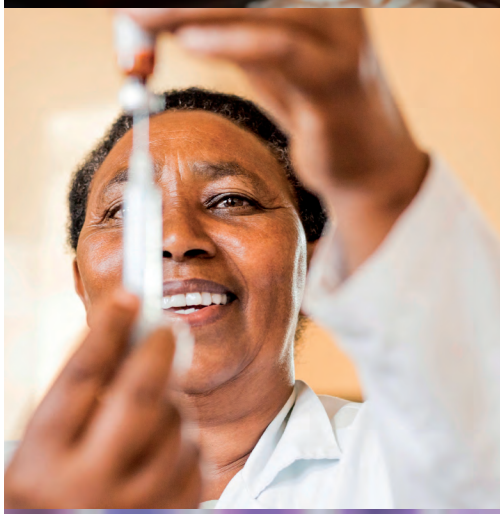




Before: Poor waste management practices (above).

After: Improved waste management practices (below).





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