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INFECTIOUS DISEASE

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Jessica K. Fairley, M.D., graduated from Georgetown University School of Medicine and completed her combined residency in Internal Medicine-Pediatrics at Brown University. She then completed subspecialty training in Infectious Diseases at Case Western Reserve School of Medicine in Cleveland, Ohio. She joined Emory in 2010 and is an assistant professor of medicine in the division of Infectious Diseases. At the Emory TravelWell Center, she prepares travelers for international travel and evaluates returning travelers with various infections. She also directs the Emory Hansen’s Disease Program, a satellite clinic of the National Hansen’s Disease Program. Her research has focused on the epidemiology and morbidity of tropical co-infections.

Ronald Trible, M.D., Ph.D., is an infectious diseases physician at Georgia Infectious Diseases, P.C., and sees consults at both Emory Saint Joseph’s Hospital and Northside Hospital. He has particular interests in HIV management and prevention (PrEP), hepatitis C and mycobacterial diseases. He completed a combined-degree training program at the University of Pittsburgh School of Medicine, including a doctoral degree in biochemistry and molecular genetics, then completed an internal medicine residency and an extended infectious diseases fellowship at Emory University.

Lance Stein, M.D., practices transplant hepatology at the Piedmont Transplant Institute. Following graduation from Temple University School of Medicine, he completed residency in Internal Medicine at Emory University, followed by a Gastroenterology fellowship at the University of California—San Diego, then an Advanced/Transplant Hepatology Fellowship at both Columbia and Cornell-New York Presbyterian Hospitals. Currently, he serves on national committees for the American Association for the Study of Liver Diseases, American College of Gastroenterology and the American Society of Transplantation.

Aneesh Mehta, M.D., is the Assistant Director of Transplant Infectious Diseases at the Emory Transplant Center. His research interests are broadly within clinical and translational viral immunology. Dr. Mehta is specifically focused on developing predictive immunologic and virologic signatures for pathogen specific protective immunity. Dr. Mehta received his BS from Emory University and his MD from the University of Oklahoma. He completed his residency in Internal Medicine in 2003 and his fellowship in Infectious Diseases in 2006, both at Emory University.

Jesse Couk, M.D., will be joining the Atlanta ID Group at Piedmont Hospital. He is currently an infectious diseases fellow at Emory University and will be graduating in June with an additional master’s degree in Clinical Research. He received his medical degree from Wake Forest University, where he also completed his internship and residency in Internal Medicine. He is board certified in internal medicine and infectious diseases.

Shalini Patel, M.D., is board certified in internal medicine and infectious diseases. She obtained her BS and MD degrees at Ohio State University and completed her internal medicine residency at Emory University. She went on to complete an infectious disease fellowship at Boston University. She currently works as Regional Medical Director of the AIDS Healthcare Foundation, a global nonprofit HIV medical and advocacy organization.

Henry Wu, M.D., is an assistant professor at the Emory University School of Medicine and serves as the Emory TravelWell Center’s Co-Director. Dr. Wu is board certified in infectious diseases and holds a diploma in tropical medicine and hygiene. Dr. Wu previously served as a medical epidemiologist at the Meningitis and Vaccine Preventable Diseases Branch of the Centers for Disease Control and Prevention (CDC).
Infectious Diseases: Old and New American Public Health Problems

By Lance Stein, M.D.

In this issue of Atlanta Medicine, we are proud to host articles from our Atlanta experts in the age-old specialty of Infectious Diseases (ID). Our ID colleagues are constantly working on the eradication of established infectious diseases that affect all parts of society. Simultaneously, they are diagnosing and managing emerging infectious threats in a whack-a-mole like scenario.

Atlanta residents have long benefited from having the top ID talent in our backyard, with the CDC attracting scientific talent, Emory University’s large infectious disease programs and drug development programs, the Yerkes National Primate Center, Grady’s pioneering HIV treatment program, and physicians now in clinical practice after working or training in those regional programs.

The history of infectious disease in Georgia dates back to colonial times. Georgia once had an endemic and problematic malaria problem, which is now long since eradicated with public health measures created in the early 20th century. Tuberculosis has long been a public health problem for our region. Georgia consistently ranks in the top 10 states of newly reported tuberculosis cases each year.

Hartsfield-Jackson Atlanta International Airport is the world’s busiest airport, so communicable infection risk in Atlanta is always a hot-button issue. Remember the traveling lawyer in 2007 with multidrug-resistant tuberculosis immigrating back to Atlanta across the Canadian border? These stories make international news and often involve our region and our ID colleagues.

Polio is long gone, but over the past year there’s been old and new infection-related stories in the news. Measles is making a comeback due to parents opting out of childhood vaccinations. We can now cure most patients with hepatitis C, albeit at a very high dollar cost. Influenza and similar viruses always seem to be on the cusp of a breakout. Ebola raised concerns locally this year due to Emory’s specialized isolation unit. What will be our next public health problem?

But what is not often seen in the media are the infectious problems that we as clinicians are treating every day that are of far more significant consequence to larger numbers of patients. This includes nosocomial infections such as catheter-associated blood-borne infections, catheter-associated urinary tract infections, clostridium difficile infection and post-operative skin infections. The numbers regarding the rates of infection are staggering. The morbidity and mortality from these are huge. The problem is of such significance that going forward, hospitals and healthcare systems are being held financially accountable for their nosocomial infection rates. It matters.

The contributions in the issue run the gamut, from the changing landscape of HIV epidemiology and treatment to infection control and travel medicine. All of these topics are important to understand and be aware of. But what will the future bring to our ID colleagues?.

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While globalization and increasing ease of travel have brought people and cultures closer to each other, these trends have also opened the doors to the spread of viral infections. Dengue and chikungunya viruses are classic examples of infections that have taken advantage of air travel to make their way around the world. Furthermore, vaccine-preventable diseases once under control in countries can re-emerge due to social unrest, re-introduction or disruption of local vaccination practices. The ever-changing landscape of these diseases makes it imperative for a traveler to get pre-travel advice, often in the form of a formal consultation with a travel medicine practitioner.

Historically, travel clinics have focused on preventing certain vaccine-preventable infections, including viral infections such as hepatitis A, polio, Japanese encephalitis and yellow fever. These remain as important concerns for travelers. Notably, polio has remained stubbornly difficult to eradicate and has even re-emerged in some countries in recent years. However, while often overlooked as a travel-associated infection, influenza is amongst the most common vaccine-preventable illness in travelers.

Since influenza season can vary depending on the area of the world and since the virus circulates year-round in the tropics, an influenza vaccination is an important part of pre-travel preparations, even when flu is inactive in North America. Likewise, adequate immunity against measles, mumps and rubella (MMR) can be more important than many travelers realize. Measles remains a major cause of morbidity and mortality in many African countries and has reemerged in many high-income areas, especially in Europe. Despite decreasing more than 50 percent from the prior year, from October 2013-September 2014 there were still more than 4,700 cases of measles reported in 20 European Union countries. Many adults, especially those in their 40s and 50s, may have only received one lifetime dose of MMR, which has been found to be insufficient for some individuals. Therefore, ensuring travelers born after 1957 (before which people are assumed to have natural immunity) have had two lifetime doses is important.

Dengue and chikungunya viruses are among the vector-borne infections that have emerged or re-emerged in certain geographic areas. The mosquito vectors for these viral infections (Aedes
species) are ubiquitous in rural and urban tropical areas, as well as some temperate climates; therefore, these infections can spread readily following introduction. Dengue virus (DENV) continues to cause outbreaks in Asia and the tropical Americas. Cases in Africa also occur and have likely been underestimated. 

There are four subtypes of DENV [1,2,3,4] that are now present in most endemic areas. The clinical features are notable for an abrupt onset of fever, headache and myalgias with rash in about 50 percent of cases, gaining the appropriate nickname of “breakbone” fevers. Incubation period ranges from 3-14 days, but typically occurs 4-7 days after exposure. Gastrointestinal symptoms are common as well. The most severe presentations are dengue hemorrhagic syndrome and dengue shock syndromes, which fortunately occur in the minority of cases. Since there has been documented local transmission in Florida and Texas, DENV should be considered in compatible clinical situations even in the absence of international travel.

Chikungunya virus (from the Makonde for “to walk bent-over”) was discovered in the 1950s and has been associated with many outbreaks in Africa and the Indian subcontinent in recent years. Up until 2014, illness in returning travelers to the United States was uncommon. However, in December 2013, local transmission of the chikungunya virus (CHIKV) was discovered on the island of St. Martin in the Caribbean and has since spread quickly around the Caribbean, South and Central America (see Figure 1). There has been over 780,000 confirmed and suspected cases in the Americas with 2,481 travel-associated cases from the Caribbean diagnosed in the U.S. 

Clinical features are similar to dengue virus but are notable for an often-severe episode of arthralgias that can be prolonged, lasting weeks to months. Fortunately, severe complications are rare. As with DENV, local transmission in the United States is possible due to the presence of Aedes vectors as demonstrated by 11 cases in Florida resulting from one ill traveler in 2014. Since both dengue and chikungunya viruses do not have current vaccines, mosquito avoidance, including repellants (DEET), nets and other measures, are critical for prevention.

Lastly, a review of travel-associated viral infections in 2015 would not be complete without a discussion of high-consequence infections such as Middle Eastern Respiratory-Syndrome Coronavirus (MERS-CoV) and Ebola Virus Disease. MERS-CoV has remained a public health concern in most areas of the Middle East, and travel-associated cases have been diagnosed around the world, including two in the U.S. in 2014.

The Ebola epidemic in Sierra Leone, Guinea and Liberia has changed the discussion on emerging infections and preparedness. It has also made the differential diagnosis of travelers (aid workers, immigrants, etc.) from these areas even more challenging and fraught with concerns about infection control. The Centers for Disease Control and Prevention (CDC) has up-to-date case definitions for these serious diseases, and anyone with a compatible illness and travel history needs to be triaged appropriately with immediate discussion with local and state health officials.

Despite our growing armamentarium of effective vaccines, travel medicine remains a challenging field with the constantly changing landscape of infections worldwide. Taking a travel history is critical when evaluating a sick patient. Besides simply asking what countries they have been to, it is also important to inquire about specific activities, types of accommodations (i.e. air-conditioned luxury hotel versus hostel), insect bites, animal exposure and things they ate/drank. Any of these items may put them at greater or less risk of certain illnesses during their travel and can help determine the diagnosis of an ill traveler.

Furthermore, providers should inquire about a patient’s future travel plans so they can best prevent illness while traveling abroad. Travel medicine practitioners are experts in preventing illness while traveling and are aware of the subtleties of the risks (infectious and otherwise) of international travel, especially in low- and middle-income countries. Therefore, having a low threshold for referring your patient to a travel clinic is an important step to ensure a safe and healthy trip.

Suggested Reading:

When a communicable disease is suspected physicians must decide whether additional precautions are necessary. Standard precautions are the minimum steps providers must take when performing hands-on care with a patient in any healthcare setting. The core of standard precautions is hand washing. Alcohol based hand rubs are quick, effective, and easy to use and therefore recommended by the CDC and WHO as the primary hand wash solution with only rare exceptions. Additional precautions such as contact, droplet, or airborne are always in addition to the standard precaution measures required for all patient encounters.

First Wash our Hands
A recent study of 306 healthcare facilities in the United States revealed an average hand washing adherence rate less than 50%. While physicians should be leaders in hand hygiene our adherence is generally below that of nurses. CDC guidelines recommend washing hands as follows: before touching a patient (even when gloves are worn), prior to performing aseptic tasks, after contacting the patient’s blood, wound dressings, or bodily fluids, before moving hands from a contaminated body site to a clean body site, after glove removal, and prior to exiting a patient’s care area if interacting with the patient or their environment. Performing this simple routine not only protects your immediate patient but the next patient with whom you contact.

Infectious Diarrhea
Some patients require additional precautions. These include contact (gown and gloves), droplet (surgical mask), and airborne (negative pressure room if available and an N95 mask). Patients who are suspected to have an infectious cause of diarrhea should be placed on
contact precautions if diapered and/or incontinent.\(^{1}\) The same applies to those with Hepatitis A infection due to its fecal oral mode of spread. Outbreaks of norovirus have been reported in health facilities and contact precautions should be used for all patients with diarrhea during institutional outbreaks.\(^{5}\) Soap and water is preferred over alcohol based hand rub because of the potential benefit of mechanical removal of adherent organisms. Infected healthcare workers and food handlers should be excluded from work for 48–72 hours following resolution of symptoms.

**Viral Respiratory Disease**

Respiratory viruses are typically spread via large droplets. These infectious droplets rapidly fall due to gravity so only a surgical mask is required in addition to standard precautions (droplet precautions). All influenza like illnesses should be placed in droplet isolation. The rapid flu test is not sufficient to rule out influenza due to poor sensitivity and a negative test should not be used to remove respiratory isolation precautions.\(^{6}\) Infected healthcare providers can limit spread of disease by directing their cough or sneeze into the elbow or a tissue followed by hand washing. We should also avoid working during flu season if febrile and encourage others to do the same. H5N1 and H7N9 are two strains of avian influenza that have been associated with severe respiratory disease in humans. If avian influenza is suspected the local public health authorities should be contacted and can assist with further guidance. Patients with avian influenza should be isolated in a negative pressure room and N95 masks should be worn by healthcare providers (airborne precautions). Healthcare workers also require eye protection with either goggles or a facemask.

**Parvovirus and Rubella**

Patients with Parvovirus B19 infection should also be placed on droplet precautions.\(^{1}\) Parvo B19 is associated with hydrops fetalis and fetal death, thus pregnant healthcare workers are advised to take precautions necessary to avoid infection. Rubella virus has an even higher fetal complication rate in infected mothers. Women who are not immune are advised not to care for patients with rubella. Persons exposed to rubella who are not immune should be placed on droplet precautions and exposed susceptible healthcare workers should be excluded from duty for 21 days after the last exposure. Post-exposure MMR vaccine should be offered unless contraindicated (ie pregnancy or immunocompromised state).

**Measles**

Measles virus infections have increased significantly in the past decade despite being declared eradicated in 2000. US cases in 2014 were greater than 600 and outbreaks have ultimately been linked to populations of undervaccinated individuals.\(^{7}\) Measles remains endemic worldwide with approximately 33 million cases and 122,000 deaths in 2012 \(^{8}\). Measles virus is highly contagious owing to its airborne mode of infection and prolonged survivability in aerosol. In 1981 a measles outbreak occurred at a pediatric practice in Dekalb County, GA.\(^{9}\) The source case presented to the office with a rash where he was coughing vigorously. Seven secondary cases of measles occurred due to exposure from that patient. Four of these patients had direct contact with the source, however, three children were not in the same room as the source patient and one arrived a full hour after the source patient had left. Patients suspected of having measles virus should be isolated and placed on airborne precautions.

**Varicella Zoster Virus**

Disseminated herpes zoster infection also demonstrates airborne spread.\(^{10}\) Disseminated herpes zoster infection occurs during all primary infections (varicella or chicken pox) and rarely during reactivation. Dissemination during reactivation is more likely among those who are immunocompromised. If a patient has more than one dermatome effected by a shingles outbreak it should be assumed that they have disseminated disease and airborne precautions should be instituted.\(^{1, 11}\) Shingles isolated to a single dermatome should be placed on contact isolation if the region is not contained under clothing. Contact isolation may be discontinued once the lesion is dry and crusting has completed.
Jim Goodson, M.P.H., of the Global Immunization Division in the Center for Global Health, took this photo during his time in Manila, while participating in the response to the measles outbreak. Note the maculopapular rash on the infant’s face, which is one of the hallmark symptoms of this disease.

Middle East Respiratory Syndrome

Middle East Respiratory Syndrome (MERS) is a severe respiratory illness caused by a coronavirus with a fatality rate up to 40%. It is caused by MERS coronavirus (MERS-CoV). All reported cases are linked to countries around the Arabian Peninsula, primarily Saudi Arabia and United Arab Emirates. Two patients having MERS-CoV infection have been identified at two separate US hospitals. Patients admitted to a hospital having respiratory symptoms and known exposure to an infected individual or travel to an endemic region should be placed in airborne and contact isolation and healthcare workers should wear goggles or a face shield. Infection control should be notified so that the case can be reported to public health agencies.

Viral Hemorrhagic Fever

At this time cases of Ebola virus continue to be reported in West Africa. Guinea, Liberia, and Sierra Leone are still reported as having widespread transmission. Travelers from these countries are advised not to travel if feeling ill. If you encounter an ill patient who has either come in contact with someone with hemorrhagic fever such as Ebola or has recently traveled to endemic countries then notify public health official immediately so that they can assist with further testing and proper isolation pending results. Viral hemorrhagic fever such as Ebola and Marburg have not demonstrated airborne transmission among human populations, but due to the high fatality of these diseases every precaution is taken to prevent spread of disease. The Centers for Disease Control and Prevention (CDC) currently recommends contact and droplet precautions in addition to standard precaution measures for patients suspected of having Ebola virus. Specific guidance for healthcare settings can be found at the CDC website: http://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/infection-control.html.

Ask for Help

In addition to standard precautions, early recognition and appropriate isolation of contagions is necessary to limit the spread of infection to healthcare workers and other patients. Because of the importance of this duty clinicians should not hesitate to ask questions if they arise. Your institution’s departments of infection control and infectious diseases are excellent resources if they are available. Dedicated staff are also available at the CDC as well as local and state departments of public health. Additional information about infection control policies provided by regional departments of public health, the ID Society of America (IDSA), the CDC, and the World Health Organization (WHO) can be found online.
References

The future of cancer treatment is here. And it’s only available at WellStar. WellStar is the only health system in metro Atlanta to offer TomoTherapy® and CyberKnife® for the treatment of both cancerous and non-cancerous tumors.

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The first report of a Human Immunodeficiency Virus (HIV) associated illness appeared in the literature in 1981, and since then the medical community has dealt with an infectious disease epidemic unlike any previous disease.\(^{(1)}\) The CDC first developed criteria for diagnosis of Acquired Immunodeficiency Syndrome (AIDS) in 1982, and the epidemic has since evolved to a worldwide phenomenon.\(^{(2)}\)

Since the start of the epidemic, there have been more than 35 million deaths from HIV.\(^{(3)}\) Currently, there are 35 million persons living with HIV worldwide. The vast majority, 25 million, currently live in Sub Saharan Africa. Each year, 2.3 million new cases are diagnosed with 1.6 million HIV associated deaths per year. In the U.S., however, there are approximately 1.2 million persons living with HIV, with almost 50,000 new cases per year.\(^{(3)}\)

Prior to the advent of Highly Active Antiretroviral Therapy (HAART) in the 1990s, HIV was the leading cause of death among persons in the U.S. between the ages of 25 and 44. HIV-associated mortality decreased from 38,780 deaths in 1996 to 14,499 in 2000 due to the effectiveness of HAART.\(^{(5)}\) As HAART became available in the U.S., the death rate due to HIV dropped, and more people are now living with HIV as a chronic illness.

Unfortunately, along with effective treatment for HIV came mutations in the virus that has rendered some antiretroviral (ARV) regimens ineffective against certain strains of HIV. As people are living longer with the disease, some are transmitting the mutated virus to new patients. A recent study found that some mutation is found in 26 percent of newly infected patients.\(^{(6)}\) As a result, new ARV medications are constantly being developed to meet the needs of the changing demographics of the disease.

In the U.S., most new cases of HIV are still male, though the number of women with HIV has increased slightly as well. Although worldwide, heterosexual transmission is the most common mode of transmission of HIV, as of 2013, most males in the U.S. were infected via male-to-male sexual contact, while females were predominantly infected via heterosexual contact. The percentage of adults with diagnosed HIV infection attributed to male-to-male sexual contact was 65 percent. An estimated 17 percent of all diagnosed infections were attributed to heterosexual contact for females and 8 percent for males. All other modes of transmission, including injection drug use, accounted for less than 10 percent of new infections (Figure 1).\(^{(7)}\)

The most common modes of transmission of HIV are different for men and women in the U.S. In 2013, an estimated 81 percent of new male infections in the U.S. were attributed to male-to-male sexual contact, 10 percent to heterosexual contact, 5 percent to injection drug use, 3 percent to...
male-to-male sexual contact and injection drug use, and less than 1 percent to other transmission categories. However, among U.S. females, 86 percent of diagnosed HIV infections were attributed to heterosexual contact, 13 percent were attributed to injection drug use and 1 percent to other transmission categories. (2) Heterosexual contact, especially among women in the U.S., remains a significant mode of transmission of HIV (Figure 2). (7)

In the U.S., the epidemic is disproportionately affecting the African American community. Though the population of the U.S. is predominantly Caucasian (63 percent), only 28 percent of those infected with HIV in the U.S. are Caucasian. While the U.S. population of African Americans is 12 percent, the percentage of HIV positive patients in the U.S. who are African American is significantly higher at 46 percent. (2) African Americans are the most affected group with HIV in the U.S. for both men and women today (Figure 3). (7)

HIV is predominantly seen in younger populations. In the U.S., persons age 25–34 years accounted for the highest rates of diagnoses of HIV infection each year, whereas, persons
55 years old and older accounted for the lowest rates of diagnoses of HIV infection each year. Though HIV in the U.S. is predominantly seen in patients under 55 years, there are an estimated 215,000 persons over the age of 55 living with HIV.\(^{(8)}\)

The rate of HIV infection (new and existing) in Georgia is one of the highest in the country. Georgia has the fourth highest rate of AIDS diagnoses in the country, with a rate of 16.5/100,000 persons. In addition, it has the six highest population of HIV patients in the U.S. However, Georgia, like the rest of the country, has seen a decline over the years in death due to HIV from 1,533 deaths in the year 1995 to 723 deaths in the year 2000 in Georgia. There were 277 deaths among persons with AIDS in Georgia in 2012 (Figure 4).\(^{(7, 9)}\)

The demographics of the HIV epidemic are similar to those seen in the rest of the country, with 78 percent (2,263) of those diagnosed with HIV infection in Georgia during 2012 were male and 22 percent (645) were female. HIV rates are increasing for younger black males and older black females in Georgia.\(^{(10)}\)

HIV continues to be a significant infectious disease in the United States. Unfortunately, 14 percent of patients with HIV are unaware of their diagnosis, which has contributed to its continued spread.\(^{(4)}\) For this reason, the United States Preventive Services Task Force (USPSTF) recommends universal routine testing for HIV for all persons between the ages of 15 to 65 regardless of risk.\(^{(11)}\) Given the high rate of new and existing HIV patients in Georgia, clinicians need to be aware of the changing demographics of the disease.

<table>
<thead>
<tr>
<th>Public Health Districts</th>
<th>HIV Infection</th>
<th>Stage 3 (AIDS)</th>
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<tbody>
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<td>No. Crude Rate</td>
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<td>115 269 60</td>
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</tr>
</tbody>
</table>

Figure 6

Figure 5: New diagnosis of HIV infection by sex and age (in years). Georgia, 2012
More information for clinicians regarding resources in the area can be found online at www.locator.aids.gov and npin.cdc.gov.

Local service providers that provide services to patients regardless of insurance include local county health departments, AID Atlanta ((404) 870-7700), AIDS Healthcare Foundation ((770) 593-6684), St. Joseph Mercy Care ((678) 843-8600) and Emory Midtown clinic ((404)778-7777). Patients can get more information at www.gacapus.com on how to access care.

For your patients who are 50 or older, or have a family history of colon cancer, a screening colonoscopy is just what the doctor ordered. In fact, when detected in its early stages, colon cancer is one of the most highly treatable and preventable cancers. And the physicians at Atlanta Gastroenterology Associates are experts at performing colonoscopies to help your patients stay healthy.

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References
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Human immunodeficiency virus (HIV) management was revolutionized a decade ago with the development of Atripla®, the first single tablet regimen (STR) approved for the treatment of HIV. Over the last few years, three new STRs have been released that each offer a fully potent triple-antiretroviral cocktail combined into one pill taken once a day.

While convenient to take and extremely effective at treating HIV, these new combination therapies can have serious adverse interactions with commonly prescribed medications. As treated HIV-infected patients live into their 60s and beyond, it becomes crucially important to be aware of how STRs may affect the management of common chronic illnesses.

**HIV Treatment Goals**

Cure of HIV is not yet a realistic option, but by using modern HIV treatment regimens to control viremia, HIV-infected patients can now be expected to live as long as their uninfected counterparts.\(^1\)\(^2\) The level of circulating virus in the bloodstream is the only parameter we can directly affect with antiretroviral agents. Though we expect the CD4 T cell count to rise with effective virologic control, ultimately CD4 cell recovery varies per individual and depends in large part on the amount of damage done to the T cell production machinery by the virus prior to treatment. Therefore, the primary indicator of success of a given HIV treatment regimen is achievement of an “undetectable” viral load as measured by the quantitative viral RNA test.

Strictly speaking, an undetectable viral load is one in which the amount of virus in the sample falls below the limit of detection of the assay being used, and this limit has gotten progressively smaller as laboratories have developed increasingly more sensitive assays. Most major antiretroviral efficacy trials define success of a given regimen as achieving a viral load less than 50 copies/mL, so, clinically speaking, this is the commonly accepted goal of therapy.

**When to Start Treatment for HIV**

All HIV-infected patients should be initiated on antiretroviral therapy as soon as they are ready and willing to initiate therapy, regardless of CD4 count or viral load. Early treatment leads to a smaller HIV reservoir and better preserved immune system,\(^3\) significantly longer lifespan,\(^4\) and, perhaps most critical to stopping the epidemic, decidedly decreased transmission.\(^5\) “Treatment as prevention” is the new mantra among many HIV providers; every day a
patient's viral load is undetectable is another day he or she cannot infect someone else.

Concerns over drug toxicity are diminishing – gone are the days of dysmorphic lipodystrophy, crippling neuropathy and daily nausea and diarrhea brought on by the limited antiretroviral agents of the 1990s. Newer agents are expected to cause no more than a few days of gastrointestinal discomfort, although a small percentage of patients may experience rash, headache, kidney disease or other rare events that could necessitate a change in regimen. Drug-drug interactions pose the greatest obstacle in choosing a modern HIV regimen, and frequently this necessitates not only the involvement of an experienced HIV provider, but often a pharmacist familiar with these potentially harmful associations.

**Classes of HIV Medications**

There are currently six classes of antiretroviral medications licensed for the treatment of HIV: nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), integrase strand transfer inhibitors (INSTIs), the fusion inhibitor enfuvirtide, and the CCR5 co-receptor antagonist maraviroc. Multiple co-formulated combination drugs now exist, greatly reducing the pill burden requirements.

The Antiretroviral Society-USA advisory panel recommends that antiretroviral therapy includes three agents from at least two different medication classes [6]. Most regimens combine two NRTIs with either a PI or NNRTI “anchor,” though newer regimens using an INSTI as the backbone are better tolerated and slightly more efficacious. (7)

**Single Tablet Regimens (STRs): The New Mainstay of HIV Therapy**

Numerous studies have since validated that patients taking Single Tablet Regimens (STRs) have better adherence, require fewer hospitalizations and demonstrate superior long-term virologic control than those patients taking a multi-pill regimen. (8-10) There are now four approved STR regimens for the treatment of HIV: Atripla® (emtricitabine/tenofovir/efavirenz), Complera® (emtricitabine/tenofovir/rilpivirine), Stribild® (emtricitabine/tenofovir/elvitegravir/cobicistat) and Triumeq® (abacavir/lamivudine/dolutegravir). All of these regimens are highly effective and proven therapies for HIV, and, in general, are very well tolerated. However, selecting the best regimen requires careful consideration, including a thorough history and physical examination, appropriate laboratory evaluation and informed discussion with the patient.

As is readily apparent, the components of these STRs are similar, thus they are all very similar regimens. With the exception of Triumeq®, all of the STRs contain two of the exact same antiviral agents, emtricitabine and tenofovir. Even the components of Triumeq® function similarly to the other STR agents and, indeed, are susceptible to the same viral resistance mutations. Thus, resistance to or intolerance of tenofovir/abacavir or emtricitabine/lamivudine can mostly or completely nullify the use of any current STR alone as a fully-efficacious regimen option.

Almost every medication contained within each STR is susceptible to a single viral mutation that induces partial or complete resistance to that drug, only dolutegravir appears to be able to withstand single resistance mutations. Consider that in an untreated individual, due to the intrinsic error rate of the HIV replicative machinery, every possible point mutation occurs hundreds of times a day. (11) Adherence is clearly critical to the success of STRs, which can be a challenge for some patients, yet better adherence to HIV regimens is achieved by using STRs versus multi-tablet regimens. This dilemma is a constant challenge for HIV providers presented with the poorly adherent patient and must be decided on a case-by-case basis.

**Over the last few years, three new STRs have been released that each offer a fully potent triple-antiretroviral cocktail combined into one pill taken once a day.**

**Currently Available STRs**

Atripla® (Bristol Myers Squibb and Gilead Sciences, released 2006)

Atripla® is the most widely prescribed and most experienced STR regimen to date. Atripla® combines Truvada® (emtricitabine/tenofovir, Gilead Sciences) with efavirenz (Sustiva®, Bristol Myers Squibb).

Adverse effects leading to discontinuation of Atripla® are mostly due to the efavirenz component, with many patients experiencing rash, morning grogginess, alterations in mood or behavior or the infamous “vivid dreams.” Most of these symptoms can actually be prevented by quickly titrating up the dose of efavirenz, though this practice is rarely used now that other more tolerable agents are available.

Patients with uncontrolled depression/anxiety disorder, or who experience worsening symptoms of depression/anxiety while on Atripla®, should not use this regimen, as efavirenz can potentiate these effects. Historically, women who could become pregnant were warned to avoid efavirenz/Atripla®. However, retrospective data demonstrate no increase in
adverse fetal effects when women became pregnant while on Atripla®, and current guidelines recommend maintaining this regimen should a woman become pregnant while on Atripla®. (12)

Importantly, ARV-naive patients who acquired HIV in the Atripla® era are at risk for having acquired the K103N mutation, which confers resistance to efavirenz and, hence, eliminates Atripla® as a stand-alone therapy. Atripla® has been used as the standard by which all subsequent STRs are compared, and each of the newer agents trend toward superior efficacy and improved tolerability.

Complera® (Gilead Sciences and Janssen Pharmaceuticals, released 2011)

Complera® (marketed as Epivlera® in Europe) combines Truvada® with rilpivirine (Edurant®, Janssen Pharmaceuticals). Like efavirenz, rilpivirine is a NNRTI, however it lacks the neuropsychiatric effects of efavirenz. Due to higher virologic failure rates when compared to efavirenz, rilpivirine is not indicated in patients whose viral load is greater than 100,000 copies/mL or whose CD4 count is less than 200 cells/mm3. Rilpivirine requires an acidic gastric environment for maximal absorption, so it is taken with a large meal and, importantly, should be avoided in patients requiring proton-pump inhibitors or other acid-suppressing medication. Otherwise, the drug-drug interactions are few and Complera® is generally extremely well tolerated.

Stribild® (Gilead Sciences, released 2012)

Stribild® combines Truvada® with elvitegravir, a novel integrase strand inhibitor only available as part of Stribild® and the new booster agent cobicistat. INSTIs have been shown to rapidly reduce viral load, enabling ARV-naive patients to achieve undetectable viral loads within 8 weeks of initiating therapy. (7, 13)

Cobicistat acts similarly to ritonavir (Norvir®, Abbvie) by blocking cytochrome P450-3A4 (CYP3A4) to augment the levels of elvitegravir. As a result, Stribild® must be used with great caution in patients taking other medications that affect the CYP3A4 pathway, including, but far from limited to: statins, antifungals, antidepressants, antiarrhythmics, calcium channel blockers, PDE5 inhibitors, steroids and anticonvulsants.

Due to the population groups studied in the approval studies, Stribild® is not approved for patients with a creatinine clearance of less than 70 ml/min. Finally, the cobicistat component typically increases the creatinine by up to 0.4 mg/dL due to its (benign) inhibition of the tubular secretion of creatinine, so a small rise in the serum creatinine should not be cause for alarm.

Triumeq® (ViiV Healthcare, released 2014)

The newest member of the STR family, Triumeq® combines Epzicom® (abacavir/lamivudine, ViiV) with dolutegravir (Tivicay®, ViiV). Abacavir-based regimens have long been used in patients with reduced creatinine clearance or who were otherwise unable to take tenofovir. Patients should undergo HLA-B*5701 genetic testing prior to taking abacavir to ensure they do not carry a genetic mutation linked to the potentially life-threatening abacavir-hypersensitivity reaction.

Dolutegravir is a novel once-daily integrase inhibitor that is highly potent and carries a minimal side effect profile. Dolutegravir has so far demonstrated robust fortitude to resistance, in part because the mutations that confer resistance to dolutegravir impart tremendous fitness costs on the virus. (14) The major drug-drug interaction is between dolutegravir and the anti-arrhythmic agent dofetilide (Tikosyn®, Pfizer), and these agents should not be used together.

Finally, unlike the other STRs, Triumeq® does not contain tenofovir, which is frequently (and conveniently) used to co-treat HIV and hepatitis B in co-infected patients. Therefore, patients with underlying hepatitis B infection who are switched from a tenofovir-based regimen to Triumeq® may require the addition of another antiviral agent to treat hepatitis B.

T.B.D. (Gilead Sciences/Janssen Pharmaceuticals, expected late 2015)

By the end of 2015, the first PI-containing STR should be available. Not yet named, this pill will combine the PI darunavir with cobicistat, emtricitabine and the new formulation tenofovir alafenamide (TAF, Gilead Sciences). TAF is a tenofovir pro-drug that has equal viral efficacy as the currently used formulation, tenofovir disoproxil fumarate, yet has greatly decreased toxicity to kidney and bone. (15) This new STR will likely be very popular due to both the better safety profile and the enhanced resistance buffering offered by the darunavir. Expect the same drug-drug interactions as seen with Stribild® due to the cobicistat boosting agent.

For many HIV-infected patients, treating their disease is now truly as easy as taking one pill once a day. Not only are STRs more convenient, they are study-proven to be better than traditional multi-pill regimens.

However, despite the seemingly simple treatment options available, HIV management remains a complex and ever-changing endeavor. In particular, as HIV-infected patients grow older, they will be susceptible to the usual age-related illnesses. The prescription medications used to treat many of these ailments can pose serious and potentially life-threatening drug interactions with antiretroviral medications. In some cases, the HIV regimen may have to be changed to
accommodate a needed drug for an illness more serious than their well-controlled HIV.

It is imperative that primary care providers and subspecialists work with their patients’ infectious diseases practitioners to minimize the potential dangers of medication interactions involving these new combination antiretroviral agents so that we can help ensure that HIV-infected patients can truly live as long and full a life as their uninfected counterparts.

References
The Physician Payments Sunshine Act (more commonly known as the Sunshine Act) passed as part of the Patient Protection and Affordable Care Act in 2010. The Sunshine Act requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals. These payments can include, but are not limited to, money for research activities, gifts, speaking fees, meals, travel, or educational items like textbooks and journal reprints.

The Centers for Medicare & Medicaid Services (CMS) has been charged with implementing the Sunshine Act. Through CMS’ Open Payments program, manufacturers now are required to submit annual data on payment and other transfers of value that they make to covered recipients. These reports are made once a year and are available for public view on CMS’ website, http://www.cms.gov/openpayments/.

Who is most affected by the Act?

The goal of the Sunshine Act is to increase the transparency of financial relationships between healthcare providers and healthcare manufacturers, thereby exposing potential conflicts of interest. Although the law certainly affects both entities, most of the burden falls on companies identified by the government as “applicable manufacturers,” says Tynan Olechny, principal with Pershing Yoakley & Associates, PC (PYA), a firm that provides audit, tax and consulting services to the healthcare industry, among others.

“From our perspective, it’s the life sciences companies that are most affected by the law,” said Olechny. “These organizations need an internal infrastructure to report the payments accurately and to ensure that services for which they are making payments to physicians are fair market value and commercially reasonable.”

So, how is fair market value of a healthcare service determined? While valuing each transaction is “facts and circumstances specific,” of the three formal valuation approaches — income, market and cost — utilized in determining the fair market value, the market approach is often used in valuing some common life science services such as clinical research activities and speaking fees, according to Lyle Oelrich, also a principal with PYA.

“As the appraiser, it’s our responsibility to investigate various data sources in an effort to find comparable data to the transaction we’re valuing,” explained Oelrich. “When we find similar transactions, we can rely on those as a baseline and then make any appropriate adjustments based on the specifics of the situation to determine the fair market value when relying upon the market approach.”

Because payment data is now public and, therefore, subject to more scrutiny under the Open Payments program, many healthcare manufacturers have implemented or revamped existing payment processes to ensure they offer fair market value for physician services.
How does the Sunshine Act affect physicians?

While the Sunshine Act technically doesn’t require any action on the part of physicians regarding the actual reporting of data to CMS, it’s important that they be aware of the data being submitted by healthcare manufacturing companies in connection with their names, says Olechny.

“Physicians — even though they may not be responsible for obtaining a fair market value opinion for their services — carry some amount of risk for their professional reputations,” said Olechny. “Since the data is publicly available on the CMS website, we recommend that physicians incorporate a review of that data into their compliance activities to ensure that it is accurate. It’s relatively easy to go online and see if what the government says you’ve received as payment for your services is what you know you’ve actually received as payment.”

Currently, manufacturers should have already submitted their 2014 calendar year data to CMS. This data is scheduled to be publicly posted on the Open Payments site in June 2015. However, beginning April 6, 2015, the data is available to physicians for a 45-day review period.

“Physicians can register on the site and dispute any transactions with which they disagree during this 45-day period, and then there is a 15-day resolution period following that,” noted Oelrich. “We can assume that if the government is capturing the data, they are reviewing it. So, this is an important window of opportunity for physicians to correct any data they believe is inaccurate.”

Oelrich adds that physicians need to be prepared to talk with patients who may be knowledgeable and have done their research on the Open Payments website.

“Physicians should be able to discuss what these payments mean and how they impact or do not impact a patient’s care,” he said. “That’s really what this regulation is all about — it all comes back to ensuring the best care for the patient.”

Sunshine Act Facts

Analytics performed by PYA on the publicly available database of reported Sunshine Act payments for the initial reporting period of August-December 2013 revealed the following:

- Georgia ranked 12th in the nation in total general payments reported by life sciences manufacturers.

- Georgia was the 8th highest state with respect to reported research payments.

- In Georgia, neurosurgery was the specialty that received the most payments from life sciences companies, followed by orthopedic surgery and internal medicine.

- Approximately 5% of physicians for which payments were published registered on the Open Payments site to review and dispute reported information before it was made publicly available.

- Approximately 10% of the value of total payments reported during the initial reporting period has yet to be published due to unresolved disputes.

Source: Pershing, Yoakley & Associates, P.C.
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We are excited to announce the expansion of our social media activities using our current Facebook, LinkedIn, and Twitter accounts to advocate excellent medical care within our community, promote camaraderie among ourselves and inform other area physicians about our important role. We feel that by enhancing our social media presence, we will help uphold our mission statement: “To champion our community’s well-being and safety while advocating a healthy environment in which physicians practice and serve.”

Our member Faria Khan, M.D., has volunteered to lead this initiative as the new communications chairman and is very excited to get started.

The Medical Association of Atlanta has:

- Started a MEMBER SPOTLIGHT feature on both our Facebook and LinkedIn pages. The member spotlight displays a picture of one of our members as well as provide a short bio. We might be featuring you, so be ready if Dr. Khan happens to send you an email requesting a little bit of time for a short interview.

- We are TWEETING daily on certain medical topics or anything else that might be interesting in the local, regional or national medical world.

- Additionally, are discussing various “HOT TOPICS” within the medical world that are posted on our social media outlets. For this particular discussion, Dr. Khan will contact one or two of you for your opinion.

- Also, please let Dr. Khan know of any professional announcements you might have that she can post on our sites as well.

- Finally, if you have any more ideas about how we can further improve our social media presence, please contact Dr. Khan with your ideas at fkhan@maa-assn.org.

So, get noticed!
Thank you!

Faria Khan, M.D

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