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Infectious Disease - HIV

Spotlight: Hospice and Palliative Care

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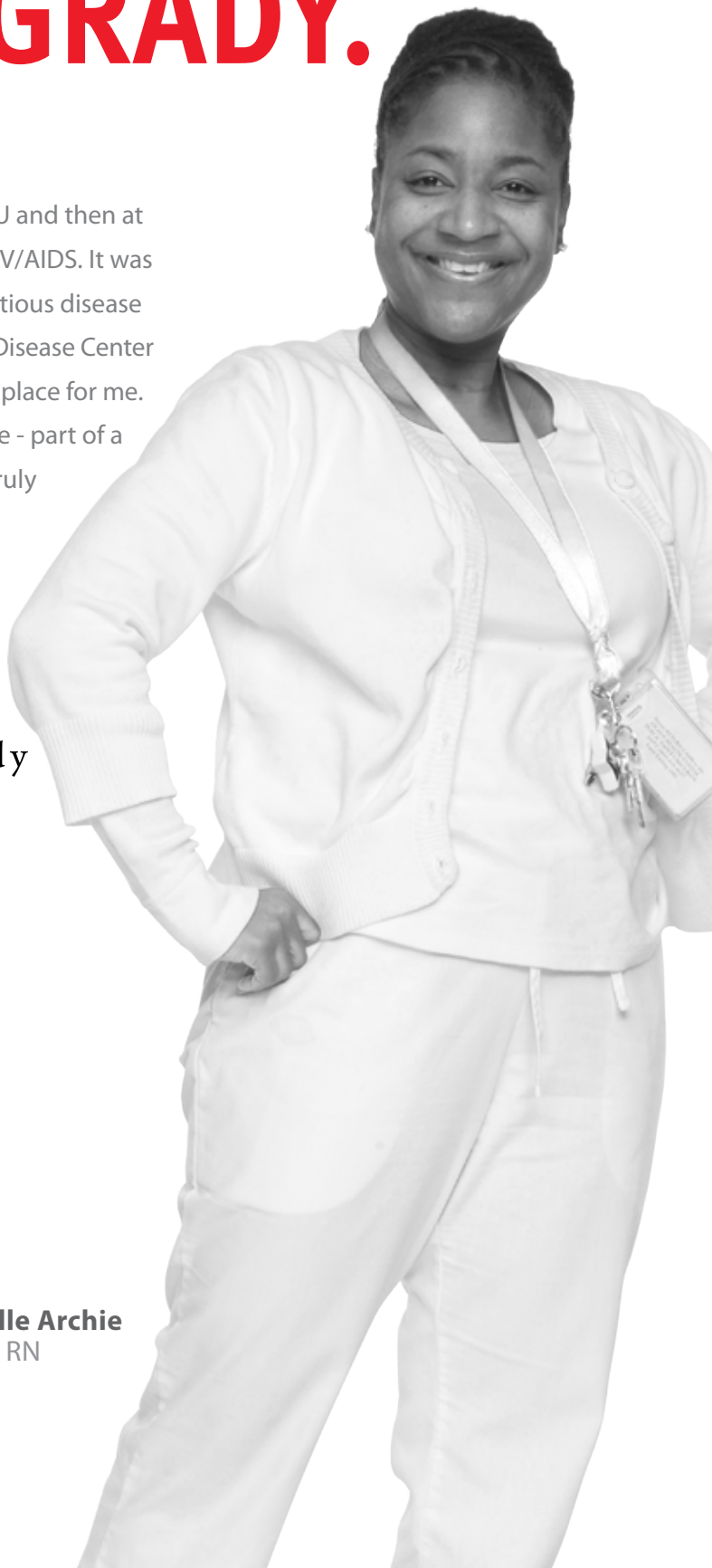

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Dr. Wendy Armstrong, Medical Director of the Infectious Disease Program at Grady Health System.

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HIV – Your Attention Needed

By Wendy Armstrong, M.D. FIDSA
Medical Director of the Infectious Disease Program at Grady Health System and Associate Professor of Medicine, Emory University School of Medicine

In 1982, a cluster of men with Pneumocystis pneumonia was reported in the *Morbidity and Mortality Weekly Report* (MMWR). This was later recognized as the first report of patients with acquired immunodeficiency syndrome (AIDS) caused by the human immunodeficiency virus (HIV).

During the ensuing three decades, we have seen the evolution of the public's response to this epidemic — from initial hysteria with calls to quarantine infected individuals to near apathy now, as HIV is no longer in the national headlines daily. Profound advances in science have transformed the course of the disease and accounted for this change. More has been learned about this virus in a short period of time than any other pathogen in the history of the world, and these advances have led to seminal discoveries that have influenced our understanding of and led to therapeutic advances for many other disease processes.

Unfortunately, despite the decrease in media attention, HIV is still very much with us and is widespread. The Southeast where we live and practice is currently the center of the U.S. epidemic.

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Dr. Wendy Armstrong, Medical Director of the Infectious Disease Program at Grady Health System, visiting with a patient.

When assessing rates of new diagnoses in the U.S. today, three of the top five states (Florida, Louisiana and Georgia) are in the Southeast. Georgia exceeds rates in California and New York, states traditionally considered to be the "hotbed" of HIV.

Georgia leads all states in the rate of individuals living with late-stage diseases or AIDS. We have made limited progress in diagnosing patients early before opportunistic infections and other complications become prominent. As a result, despite the fact that medications can transform HIV into a chronic disease and infected persons may have a normal lifespan, we still see many deaths from late-stage AIDS.

Overall, it is estimated that approximately a quarter of those infected with HIV in the United States are on life-saving therapies with controlled viremia. The reasons for this failure of our medical system are many and include issues of poverty, a lack of regular medical care or lack of access to medical care, and comorbid issues like addiction and mental illness. But ultimately, those with the disease must be initially diagnosed.

The U.S. Preventive Services Task Force (USPSTF) has now recommended testing of ALL patients for HIV infection at least once between the ages of 15 and 65 regardless of the physician's assessment of risk, which is often very imperfect.

- Georgia leads all states in the rate of individuals living with late-stage HIV disease or AIDS.
- It is estimated that approximately a quarter of those infected with HIV in the United States are on life-saving therapies with controlled viremia.
- Grady Health System is among the largest clinics treating HIV in the United States
- More than 5,200 patients receive their care at Grady's Ponce de Leon Center

Diagnosing infected patients and initiating therapy not only benefits the individual, but also reduces the risk of transmission of HIV to nearly zero, leading to significant public health benefits.

The Infectious Disease Program (IDP, also known as the Ponce de Leon Clinic) of Grady Health System is among the largest clinics treating HIV in the United States. Currently more than 5,200 patients receive their care at the IDP; the vast majority of these have an AIDS diagnosis.

In this issue, healthcare providers and scientists affiliated with IDP/Grady Health System and Emory University offer updates on many of the central challenges in HIV today, both in clinical practice and scientifically. The articles will highlight some of the work at IDP addressing these issues.

Drs. Colasanti, Armstrong and del Rio will discuss the concept of the continuum of care in HIV and where along this continuum patients fail to achieve the goal of virologic control. Several subpopulations infected with HIV face unique challenges. Drs. Sheth, Delille, Haddad and Ofotokun have provided an update on issues specific to women; Drs. Hussen and Camacho-Gonzalez have done the same for adolescents; and Drs. Shahane, Sharma and Farber address the importance of integrated care for those with mental health and substance abuse problems.

Cancers are an important cause of death among patients with HIV/AIDS, and Drs. Nguyen and Gunthel have summarized the increased incidence of neoplastic diseases commonly encountered by people living with HIV/AIDS. Finally, Drs. Marconi and Paiardini provide a scientific update on the road to a cure.

This issue should serve to raise attention about a critically important disease that is far from gone in the United States and the Southeast. HIV infection requires the continual attention of all of us practicing medicine today. The only way we can achieve the AIDS-free generation proposed by Secretary of State Hillary Clinton in 2011 is to remain vigilant. ■

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The HIV Continuum of Care and Treatment as Prevention

A Perspective from the Grady Infectious Diseases Program

By Jonathan Colasanti, M.D., MSPH, Wendy Armstrong, M.D. and Carlos del Rio, M.D.

The treatment of Human Immunodeficiency Virus (HIV-1) infection has experienced unprecedented gains in just over three decades, transforming a once invariably fatal illness into a manageable, chronic disease.

The early years, from 1981 to 1987, saw treatment only targeted at opportunistic infections (OI). Zidovudine (AZT) entered the scene as the first FDA-approved antiretroviral (ARV) in 1987 offering a glimmer of hope to target HIV itself rather than solely the OIs. Unfortunately, this afforded no mortality benefit, and the AZT monotherapy era yielded quickly to several other monotherapy and dual-therapy options, which offered minimal increases in survival but were fraught with life-altering side effects and the emergence of HIV-1 drug resistance.

AIDS-related deaths continued to increase through 1995, when protease inhibitors (PIs) were introduced and combination antiretroviral therapy (cART), consisting of at least three drugs from two different drug classes, became a reality. A study in 1997 clearly demonstrated that patients on cART were able to maintain virologic control and achieve some level of immune reconstitution – the results of this study shifted the principles of HIV therapy forever[1]. Despite the favorable outlook, cART continued to carry with it a large pill burden, complicated dosing schedules and difficult side effect profiles, with long-term successful therapy often elusive.

Continued drug development has delivered several, once daily, highly potent and well-tolerated options for treatment, including fixed-dose combination (FDC), single tablet regimens (STR). As a result of easier-to-manage formulations and better-tolerated regimens, AIDS-related deaths have continued to decline since 1995, yet during that same time the number of persons living with HIV and AIDS has continued to increase.

Beyond the benefits to the individual HIV-infected patient taking daily cART, antiretroviral therapy and viral suppression also offers a public health benefit. The "Treatment is Prevention" initiative was clearly demonstrated in the landmark HPTN052 study, which showed a 96 percent reduction in the risk of HIV transmission among serodiscordant couples (one person is HIV positive, the other HIV negative) when the HIV-infected partner started cART at higher CD4 cell counts (earlier) compared with those who started at lower CD4 cell counts (later)[2].

However, before any individual or public health benefits of cART can be realized, a patient must navigate a number of steps as follows: undergo HIV testing, receive an HIV diagnosis, be linked to an HIV care setting, be retained in care, initiate cART, maintain excellent adherence (at least > 80 percent)[3] and finally arrive at viral suppression. It is maintenance of this viral suppression that offers optimal benefit to both patient and society.

This process has been termed the HIV Care Continuum, and two studies in 2011 illustrated national estimates of what this Care Continuum looks like for HIV-infected persons living in the United States (Figure 1).[4,5] The data show that nationwide, about two-thirds of HIV-infected patients are linked to care, less than half are retained in care and only between 19 percent and 28 percent achieve viral suppression. This provides an excellent visual representation of HIV/AIDS care in the United States and highlights the challenges that exist if we are to garner the full individual and public health benefits of antiretroviral therapy.

The development of this Care Continuum was well situated on the heels our first National HIV/AIDS Strategy, which was developed in July 2010.[6] The second goal of this national strategy is to "increase access to care and improve health outcomes for patients with HIV,"[6] Achieving this goal will come from improvement in the process of HIV care along each step of the continuum. Following the development of the HIV Care Continuum, President Barack Obama signed

an executive order in July 2013 for an HIV Care Continuum initiative, promising mobilization and coordination of federal efforts to direct resources into improving outcomes along the Care Continuum and ultimately improve health outcomes for patients living with HIV/AIDS (PLWHA).[7]

At the Infectious Diseases Program (IDP) of Grady Health System (GHS), HIV-infected patients are living this Care Continuum daily and fall within various stages of the continuum. The IDP is a Ryan White funded clinic with more than 5,000 HIV-infected patients, the vast majority of whom carry an AIDS diagnosis.

Previous studies have shown that risk factors for poor retention in care and virologic failure include being African American, a woman, youth, a substance abuser, living in poverty, lacking transportation or having food insecurity[8-17]. Many of the patients who are cared for at the IDP fit into one or more of these categories, bringing a host of challenges to the efforts at IDP aimed at successfully guiding patients through the continuum.

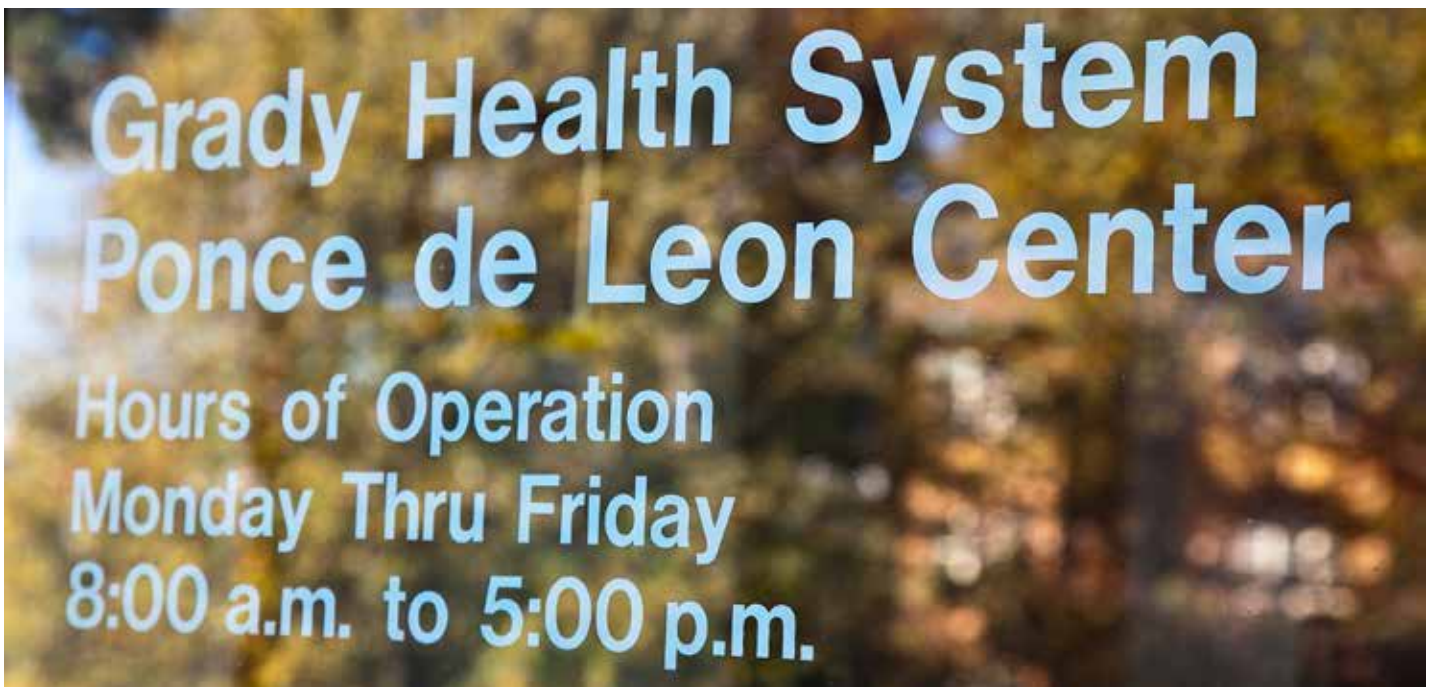
The majority of the patient population at IDP is African American, while 28 percent of the cohort are women and 20 percent are younger than 20 years of age. Nearly all are below twice the Federal Poverty Level. Given the population who receives treatment at the IDP, this clinic is in a unique and privileged position to not only study the multitude of factors affecting the Care Continuum but also to test interventions that will ultimately improve outcomes of care.

The IDP has been organized with structural and programmatic features that make the journey through the HIV Care Continuum as seamless and easy as possible for the patient. For example, dedicated pediatric, adolescent and women's clinics allow patients to receive care from experts in these populations. Mental health, substance abuse treatment, oncology, dermatology, pharmacy, basic radiologic, dental and ophthalmologic services are available in the same clinic site to provide integrated care and minimize referrals and transportation costs. Community-based organizations such as AID Atlanta, Project Open Hand and Living Room are available on site and help to provide case management and access to food and housing for those in need.

Additionally, a small urgent care facility is equipped to deal with acutely ill patients, so that patients can receive continuity of care even during these acute events. Finally, IDP has a special clinic, the transition clinic, which is specifically targeted toward patients who miss scheduled appointments where they can always be seen as a walk-in, are able to get meals, receive same-day mental health and substance abuse services, and receive medication adherence assistance.

Numerous, ongoing programs and/or research studies at the IDP address barriers at each step along the continuum in order to improve patients' quality of life and clinical outcomes. Figure 2 illustrates the various programs overlaid on a continuum of care graphic, to highlight which stage of the Care Continuum the program was designed to improve.

As a clinic designed to provide comprehensive care to patients already diagnosed with HIV/AIDS, IDP does not provide HIV testing. However, a local community-based organization, AID Atlanta, conducts HIV testing on a weekly basis at the IDP. In addition, the clinic has built relationships and collaborations with a host of community-based and healthcare organizations throughout the Atlanta metro area that provide these services to facilitate linkage to care after an HIV diagnosis. At Grady Memorial Hospital, the HIV Continuum of Care Team has been established to



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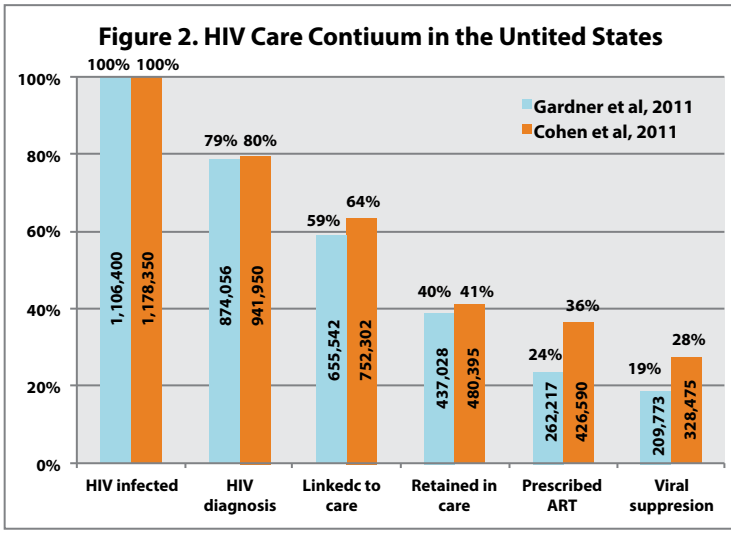

Figure 1. Source: Data from Gardner et al, 2011 and Cohen et al, 2011

seamlessly transition patients newly diagnosed during a hospitalization into care, and collaboration exists so that HIV testing programs, such as the one taking place at the Grady Emergency Department, can easily link patients who test HIV positive to care.[18]

Ongoing research studies are attempting to improve linkage and re-engagement in care at the IDP. NIH/NIDA-funded Clinical Trials Network study 049 (CTN049 or Project HOPE) is a multisite randomized controlled trial to evaluate the use of patient navigators, contingency management (rewarding adherence to a treatment plan, in this particular case, with a monetary reward) or a combination of the two in improving the linkage of hospitalized substance abusers to HIV outpatient care.

Living Well is a randomized controlled trial funded by the NIH/NINR directed to hospitalized patients with a new AIDS diagnosis or who have never been in care to evaluate the use of a palliative care approach at improving linkage and engagement in care. Project RETAIN is another NIH/NIDA-funded study that is evaluating in a randomized controlled trial virologic suppression among HIV-infected cocaine and crack users comparing standard of care with the use of the transition clinic. The Antiretroviral Treatment and Access to Services (ARTAS) program is an evidence-based program for improving linkage to care that employs a linkage coordinator, who is responsible for assisting patients with a new diagnosis of HIV to enroll in HIV care at IDP. The Compassion Based Contemplative Meditation and Training Project is designed to enhance patient well-being through use of Tibetan Buddhist meditative practices. Investigators will be evaluating if this in turn improves retention rates for patients already receiving care at IDP.

Finally, two projects are focused primarily on medication adherence and, in turn, virologic suppression. An incentive study evaluated the effects of traditional contingency management versus a more patient-centered approach, where patients choose their goals and how they will be rewarded. The Music study is aimed at improving adherence through culturally appropriate music developed by hip-hop and other contemporary musicians to improve ART knowledge and adherence. These studies and programs have taught us that substantial efforts are necessary to keep many of our patients engaged in care, returning to clinic visits and adhering to medication regimens.

In an overarching project, in collaboration with the Georgia Department of Public Health, investigators are building the HIV Care Continuum model for the IDP (such as those depicted in Figure 2 to gain a deeper understanding of where failures along the continuum happen. Subsequently, resources and future programs can be targeted at overcoming the barriers, which result in failure at that particular step along the continuum.

Faculty, staff and trainees at IDP are committed to using evidence-based practices to improve patients' progress through the Care Continuum, sustaining patients in care and maintaining virologic suppression for the benefit of the patients and the Atlanta community at large. In addition to using current evidence-based practice, Figure 2 illustrates how the IDP is focused on furthering the science behind the delivery of HIV care to give patients their greatest chance at success.

Treatment options for HIV have improved immensely since the early 1990s, now with excellent pharmacological options to control the virus in infected individuals as well as ARVs becoming a part of the HIV prevention armamentarium. As a result of these advances, the rate of virologic suppression has

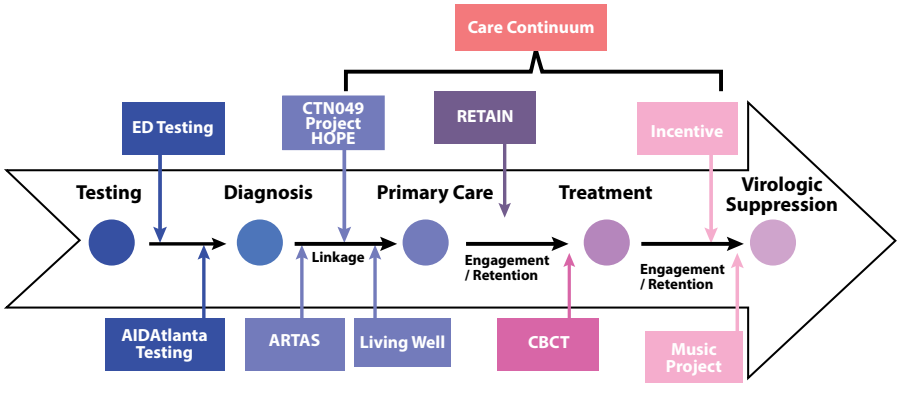

Figure 2. Programs at Grady's Infectious Diseases Program (IDP) overlaid on an adaptation of a Care Continuum illustration from the Institute of Medicine's *Monitoring HIV Care in the United States: Indicators and Data Systems.* Vincent Marconi, M.D., initially developed the concept for this figure.

The HIV Care Continuum in the U.S.
Source: Data from Gardner et al, 2011 and Cohen et al, 2011.

improved even among hard-to-reach populations such as the one seen at the IDP[19], yet many patients are still not benefiting from antiretroviral therapy because they are never diagnosed, they are diagnosed and start treatment late in their disease process, they are not linked to care or they fall out of care.

The HIV Care Continuum serves as call to action for HIV providers and policy makers to improve HIV care outcomes throughout the United States. Monitoring the HIV Care Continuum will serve as tool and a benchmark in the improvement of the HIV care process, nationwide and locally at the IDP[20]. ■

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Carlos del Rio, M.D.

Dr. del Rio is the Chair of the Department of Global Health at the Rollins School of Public Health and Professor of Medicine in the Division of Infectious Diseases at Emory University School of Medicine. He is also Program Director of the Emory AIDS International Training and Research Program and co-Director of the Emory Center for AIDS Research. Dr. del Rio attended medical school at Universidad La Salle and did his Internal Medicine and Infectious Diseases residencies at Emory University.

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Rising up to the Challenges of Adolescent HIV-Infection in Atlanta

By Andres F. Camacho-Gonzalez M.D. and Sophia A. Hussen M.D.

At a time when HIV rates are stabilizing in most population sub-groups, the prevalence of HIV in youth is steadily increasing in the United States.

This trend is explained in part by increased survival of perinatally infected youth, but it is primarily attributable to increases in incident infections during adolescence. In fact, adolescents and young adults between the ages of 13 and 24 now make up the fastest-growing group of HIV-positive individuals in the country. Georgia is also ranked 4th in the nation for new HIV cases, and, despite extensive local prevention efforts, rates of new HIV cases are essentially unchanged since 2005.

Youth living with HIV (YLHIV) face a host of complex medical and psychosocial challenges that require intense and holistic support in order to optimize care. Understandably, there is concern that the combination of socioeconomic disadvantage and multiple types of stigma, superimposed on the developmental and physical turbulence of normal adolescencent development, may leave YLHIV at high risk for loss to medical follow-up, poor antiretroviral (ARV) adherence and generally suboptimal health outcomes.

Adolescents in general are known to have poor utilization of healthcare and prevention services. Despite national recommendations, it has been estimated that only 38 percent of adolescents receive preventive visits, and of those, only 40 percent spend time alone with their physicians receiving counseling on topics such as sexuality, mental health and substance use. Many adolescents rely on emergency departments for primary care, and they are more likely to be uninsured than any other age group.

In addition to the importance of medical care for the health of individual YLHIV, the ability of YLHIV to cope successfully and adhere to their medicines has additional public health implications for prevention of secondary transmission. As increasing numbers of YLHIV enter the healthcare system, it is imperative that HIV care is situated within relevant developmental and cultural contexts to optimize clinical, personal and public health outcomes.

The Ponce Family and Youth Clinic (PFYC) is the pediatric and adolescent-focused clinic within the larger Grady Infectious Disease Program (IDP). At the PFYC, we deal with these epidemiological realities and public health imperatives on a day-to-day basis. Currently the PFYC serves a total of 588 children and adolescent ages 0-24, 47 percent (279) of whom are between 16-24 years of age. In recent years, we have seen a rapid influx of newly infected adolescents into our clinic—the majority of whom are young men who have acquired HIV through sexual contact.

Adolescents and young adults between the ages of 13 and 24 now make up the fastest-growing group of HIV-positive individuals in the country.

Meeting these young men and hearing their stories is often heartbreaking, as they frequently relate tales of poverty, victimization and bullying, and other childhood traumas. In spite of these obstacles, however, and notwithstanding the toll that their new diagnosis takes on them, many of these patients also display remarkable resilience and, with the support of our multidisciplinary staff, achieve optimal clinical outcomes as well as their own developmental goals of transitioning to adulthood.

One example of such a story is that of "Andre," a 22 year old who came from a troubled childhood and an abusive household. At school, he was bullied and socially isolated, mainly for being overweight. Andre's family rejected him when they found out about his sexuality, forcing him into transient and often unstable housing situations. He was finally able to break the cycle of abuse and housing insecurity when he moved to Atlanta to live with a friend.

Soon after his move, however, he started to feel ill and was ultimately diagnosed with HIV at the age of 20. He was devastated by this news and fell into what he described as a state of deep depression, until he came to the PFYC for his first medical appointment.

When he met with his medical provider for the first time, she taught him about HIV and helped him to understand immediately that HIV was a manageable, chronic condition. In addition to following up with her on a regular basis, he also immersed himself in other parts of the clinic support system—attending the weekly youth support groups on Tuesdays and forming close personal bonds with his psychologist and social worker. Referring to specific members of his medical care team and also to the clinic personnel in general, Andre, like many of our patients, describes the PFYC as a "family," where he feels comfortable, supported and accepted.

Due in part to the support and self-esteem he gets from these interactions, Andre always comes to his appointments reliably. He takes great pride in his improving health and perfect adherence—stating that he has never once missed a dose of his prescribed HIV medicines. He has disclosed his status to some friends with mostly positive responses. He is also working full-time and hoping to complete his GED within the year.

Andre's story is representative of many in our clinic and shows that in spite of seemingly tough odds, many of our patients are quite resilient and are able to achieve excellent medical outcomes in the setting of the multidisciplinary support provided at the PFYC.

Our services are diverse and designed to help these vulnerable youth cope with a range of challenges that they might encounter. Our medical staff includes five physicians and two physicians' assistants, all of whom are highly experienced in, and passionate about, providing quality care for YLHIV. Additionally, the PFYC has three social workers dedicated exclusively to the pediatric/adolescent population, and each new patient is assigned to a social worker when they enroll in the clinic—providing a valuable system for keeping track of patients and getting them back into care if they miss an appointment, as well as helping them to navigate logistical challenges in their lives more generally.

We also have a pediatric psychologist who conducts individual therapy as well as group sessions for our HIV-positive adolescents. Other specialized services include a pediatric nutrition expert, as well as the range of other services available to patients in the IDP clinic more generally. With so many different professionals within the PFYC being involved in each young person's care, it becomes relatively difficult for a patient to fall through the cracks and become lost to care.

Although many of our patients do well, there is also a lot that remains to be done—YLHIV still face considerable challenges from both a medical and a psychological standpoint, and there is a lot that is unknown about this population, as most HIV research has been conducted exclusively in older adult populations. To address these gaps in our collective knowledge, the medical providers at the PFYC are also involved in a variety of research endeavors designed to improve clinical care, outcomes and basic scientific understanding of pediatric and adolescent HIV.

The range of interests of our physician-researchers is broad and includes basic research focused on natural placental mechanisms of protection for prevention of mother-to-child transmission, immunology research with primates, clinical and translational research on vitamin D levels in HIV infection, neurobehavioral outcomes of HIV-infected children and adolescents and socio-behavioral research focused on engagement in care.

The need to improve engagement in HIV care for youth is one of the most pressing issues in this population. Epidemiologic and anecdotal evidence suggest that although adolescents and young adults are coming to the PFYC in record numbers, there remain many undiagnosed cases in the community who could benefit from our care. As a result, one of our major initiatives right now is to create community and academic partnerships to improve linkage to HIV care at the PFYC for youth who are newly diagnosed with HIV and to create programs within our clinic to keep youth engaged in care once they are enrolled.

The Metropolitan Atlanta Community Adolescent Rapid Testing Initiative (MACARTI) is a multidisciplinary outreach project at the PFYC aiming to decrease the time to first medical visit, improve HIV care parameters and increase the retention rate among those patients who test positive. This project, created with the participation of our current patients, uses a combination of venue testing (at bars and nightclubs, public parks, libraries, malls, community centers, health care centers and sports venues), motivational interviewing techniques and intensive case management support at the time of testing and throughout their HIV care, helping us decrease the average time to first medical visit to two weeks after diagnosis and increase our retention rates to at least 80 percent.

Other retention initiatives specifically tailored to serve our youth include the development of a mobile phone application to remind patients to take their medications and come to medical visits, to provide another platform for learning about HIV and to allow patients to interact with members of the medical care team. We hope that by taking advantage of mobile technologies, we will expand our services beyond the clinic borders—an essential component of providing care in adolescent HIV infection.

Providing care for the unique youth population at the PFYC is both challenging and rewarding. Unfortunately, epidemiologic trends suggest that our clinic population will continue to grow in the years to come. It is our hope that by continuing to provide high quality, multi-disciplinary youth-focused care, and by developing novel ways of approaching and decreasing health disparities among youth, we can continue to improve the lives of YLHIV in Atlanta. ■

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HIV Infection in Women

By, Cecile Delille M.D., Lisa Haddad M.D., Igho Ofotokun M.D. and Anandi Sheth M.D.

Photo credit: Jack Kearse, Emory University

Marcia Holstad, a nurse at Grady Health Systems' Ponce de Leon Center, supports a patient.

Globally, women represent more than half of the 30 million people living with HIV/AIDS[1]. Despite advances in treatment, HIV infection is a leading cause of death among women of childbearing age worldwide[2,3]. In the United States, nearly one-quarter of HIV infected persons are women, a striking shift from the 1980s, when women represented less than 8 percent of all cases. Racial disparities in the burden of HIV are magnified in women; black and Hispanic women have been disproportionately affected in the United States, with 80 percent of new cases occurring in these groups. Additionally, geographic inequalities exist, with increasing burden among women in the Southern United States.

Why are Women at Risk?

Women are particularly vulnerable to HIV infection due to a complex array of factors. Women may not be aware of their partner's risk factors for HIV and may not be able to successfully negotiate consistent condom use or mutual monogamy with their partners. Furthermore, women often lack control over available HIV prevention options, such as condom use and male circumcision.

Challenges that many women face, such as domestic violence, discrimination, stigma, substance abuse, mental health disorders and poverty increase their HIV susceptibility. Finally, women are more susceptible to HIV during unprotected vaginal sex then men, with even higher risk during unprotected anal sex.

HIV prevention efforts aimed at women are particularly needed to improve the health of women and their partners and also to protect

their infants from acquiring infection during pregnancy. Although behavioral interventions are effective in reducing the risk of HIV infection, HIV transmission risk is not eliminated, as these interventions are not always consistently implemented nor are they universally effective.

Approaches that utilize prevention tools that women can control would have tremendous public health impact. To this end, HIV pre-exposure prophylaxis, a strategy in which antiretroviral drugs are used orally or topically by HIV-uninfected persons before potential HIV exposure, has recently shown promise in HIV prevention. The daily oral fixed-dose combination tablet containing tenofovir disoproxil fumarate and emtricitabine is approved by the Food and Drug Administration for use among sexually active adults at risk for HIV infection. Additionally, a tenofovir-containing vaginal microbicide has shown promise for HIV prevention in at-risk women and is being explored further[4].

Fifteen percent of women who are HIV infected are unaware of their status, demonstrating that routine HIV testing in women per Centers for Disease Control and Prevention (CDC) guidelines is paramount to improving women's health and preventing HIV transmission. Additionally, linking HIV-infected women into appropriate medical care, retaining them in care and optimizing HIV therapy for affected women are crucial to maintaining health, improving in survival and reducing HIV transmission in the community[5,6].

Relative to men, women living with HIV infection have been shown to be more vulnerable with regard to healthcare resource utilization[7-9], potentially due to challenges such as transportation, child care, insurance, substance abuseand stigma. The key HIV health indicators, such as rates of clinic visits, antiretroviral treatment adherence, virologic suppression and mean CD4 T-cell counts, are lower for the HIV-infected women of racial/ethnic minority backgrounds[10,11].

Since many of these women are the sole providers of care for their children, illness and death ultimately threatens the stability and welfare of families in their communities. These statistics underscore the urgent need for interventions aimed at women for the prevention and effective treatment of HIV infection.

Is HIV Treatment Different for Women?

Research indicates that women and men with HIV infection can achieve nearly normal lifespans if treated with effective antiretroviral agents. HIV therapies have evolved from complicated, sub-optimal and toxic regimens to simple, effective regimens with fewer side effects. Patients treated successfully in the current era have low or undetectable viral loads and thus have the potential to normalize many of the effects of HIV and the pathology related to the immune response.

Furthermore, patients treated earlier in the course of their HIV disease may have different late-stage disease manifestations than those in whom the virus remains unchecked for a longer period. However, some studies suggest that women living with HIV often delay entry into care and starting antiretroviral therapy, particularly if they have competing work or family responsibilities, economic or insurance barriers, poor education, substance abuse or mental health disorders[12].

In general, medical treatment of HIV-infected men and women are the same, although genital infection and cervical cancer screening, pregnancy and family planning add additional complexities to management of HIV infection in women.

Although studies are mixed, most suggest that adherence and response to HIV therapy are similar for men and women. However, women may be at increased risk for complications such as lactic acidosis, rash, hepatitis, nausea and vomiting, bone loss and fat accumulation with certain antiretroviral medications[13]. Compared to women without HIV infection, HIV-infected women are at risk for recurrent candida vulvovaginitis, recurrent pelvic inflammatory disease, persistent or recurrent bacterial vaginosis, severe and prolonged genital herpes infections, cervical dysplasia and cancer, and abnormal uterine bleeding. The presence of any of these conditions should trigger HIV testing in a woman who does not have a diagnosis of HIV, and women with HIV should be screened regularly and managed aggressively for these conditions as several of them can increase their risk of transmitting HIV to their partner.

What Happens When HIV-infected Women Become Pregnant?

HIV can be transmitted from mother to child during pregnancy, labor, delivery or breastfeeding, but it most commonly occurs between the last few weeks of pregnancy through delivery if breastfeeding is avoided. However, if HIV is diagnosed before or during pregnancy, transmission to the child can be reduced to <1 percent if women receive appropriate medical treatment, antiretroviral therapy is effective at reducing the virus to undetectable levels in the

mother and breastfeeding is avoided. To achieve this goal, specific guidelines for the management of pregnant women with HIV infection exist and should be used to guide clinical practice[13].

The first step to reduce HIV transmission from mother to child is to conduct HIV screening for all women in the first trimester of pregnancy and repeat screening during the third trimester, per CDC guidelines[14]. Repeat testing in the third trimester is particularly crucial for women at risk of HIV, because pregnancy increases risk of HIV acquisition, and the possibility of HIV transmission in utero is increased during the late third trimester.

All pregnant women with HIV infection should be started on effective antiretroviral therapy, monitored closely to ensure an appropriate response and screened for genital infections that could increase transmission risk. For all women presenting in labor without prenatal care, a rapid HIV test is recommended as an important strategy to reduce the likelihood of HIV transmission from mother to child. Intravenous antiretroviral medications during delivery, delivery by Cesarean section and avoidance of invasive procedures during pregnancy and delivery may further reduce risk in certain women.

Research is ongoing to improve strategies to help HIV-infected men and women who wish to conceive do so in a way that minimizes risk to an HIV-uninfected partner and unborn child. These strategies involve initiating antiretroviral therapy for the HIV-infected partner, considering periconception pre-exposure prophylaxis for the HIV-uninfected partner and using home insemination or assisted reproductive technologies.

Finally, preventing unintended pregnancies among women with or at risk for HIV is a crucial part of prevention of HIV transmission from mother to child. First of all, family planning clinics provide an important venue for women of reproductive age who are living with or at risk for HIV to access the health care system7. The most recent World Health Organization (WHO) and CDC guidance recommends no restriction on the use of any hormonal contraceptive method for women at high risk of HIV or for women living with HIV[15].

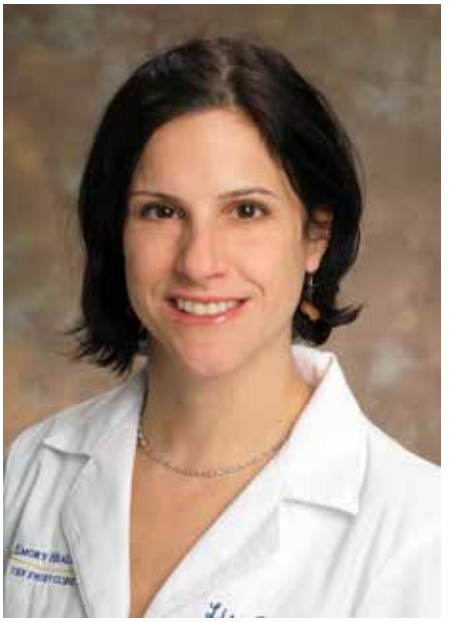
Furthermore, long-activing contraceptives, such as intrauterine devices (IUDs) and contraceptive implants, the most effective reversible contraceptive methods, are safe for most HIV infected women. To simultaneously prevent unintended pregnancy and HIV transmission or acquisition in women, consistent and correct condom use plus highly effective contraception are necessary. Finally, clinicians who care for women living with HIV should be aware of possible drug interactions between some hormonal contraceptives and some antiretroviral medications that could render certain contraceptive methods less effective.

Work at the Grady Infections Diseases Program

The Grady Infectious Diseases Program Women and Family Clinic provides comprehensive medical care for women and their families, including care of women during pregnancy, infants of all HIV-infected women after delivery until HIV infections is excluded, and all HIV infected children. This comprehensive care includes HIV treatment, case management, adherence counseling, peer counseling, nutrition and on-site pharmacy, radiology, and laboratory services. In addition, the clinic provides subspecialty care in the areas of mental health and substance abuse treatment, hepatitis C, dermatology, ophthalmology and oral health.

For women in particular, integrated pediatric and women's services in the same clinic and on-site child care provide avenues for improved access to care. Furthermore, on-site and referral care for cervical dysplasia and family planning services are available to address the complete needs of women living with HIV.

Researchers at the Grady Infectious Diseases Program are working in several different areas to improve women's health in the setting of HIV infection. Investigators at the clinic are working to maintain a cohort of women who are HIV-infected or at risk for HIV acquisition as part of the multi-center, NIH-funded Women's Interagency HIV Study (WIHS). This prospective study was established in 1993 to understand the epidemiology, disease progression, treatment outcomes and co-morbidities of women living with HIV in the United States.



Lisa B. Haddad, MD, MS, MPH

To date, the WIHS has conducted research on the impact of viral resistance, the effect of co-infections (such as hepatitis and human papillomavirus), antiretroviral treatment effects, metabolic abnormalities and toxicities of therapy, the impact of hormonal factors on HIV disease throughout all stages of a woman's life, the effects of aging on HIV disease and behavioral research including substance use, neurocognitive functioning, mental health and physical impairment.

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The Atlanta WIHS site was funded in January 2013 in an effort to expand the WIHS cohort to include the southern United States, a region where the AIDS epidemic is expanding among women, particularly those of racial/ethnic minority backgrounds.

In addition, investigators at the Grady Infections Diseases Program are conducting ongoing research toward understanding the impact of metabolic complications of HIV infection in women, such as bone and cardiovascular disease, providing safe and effective family planning options for HIV-infected and HIV at-risk women, learning more about HIV transmission in women to develop future prevention tools that women can control and studying the relatioship between domestic violence and HIV infection in women. ■

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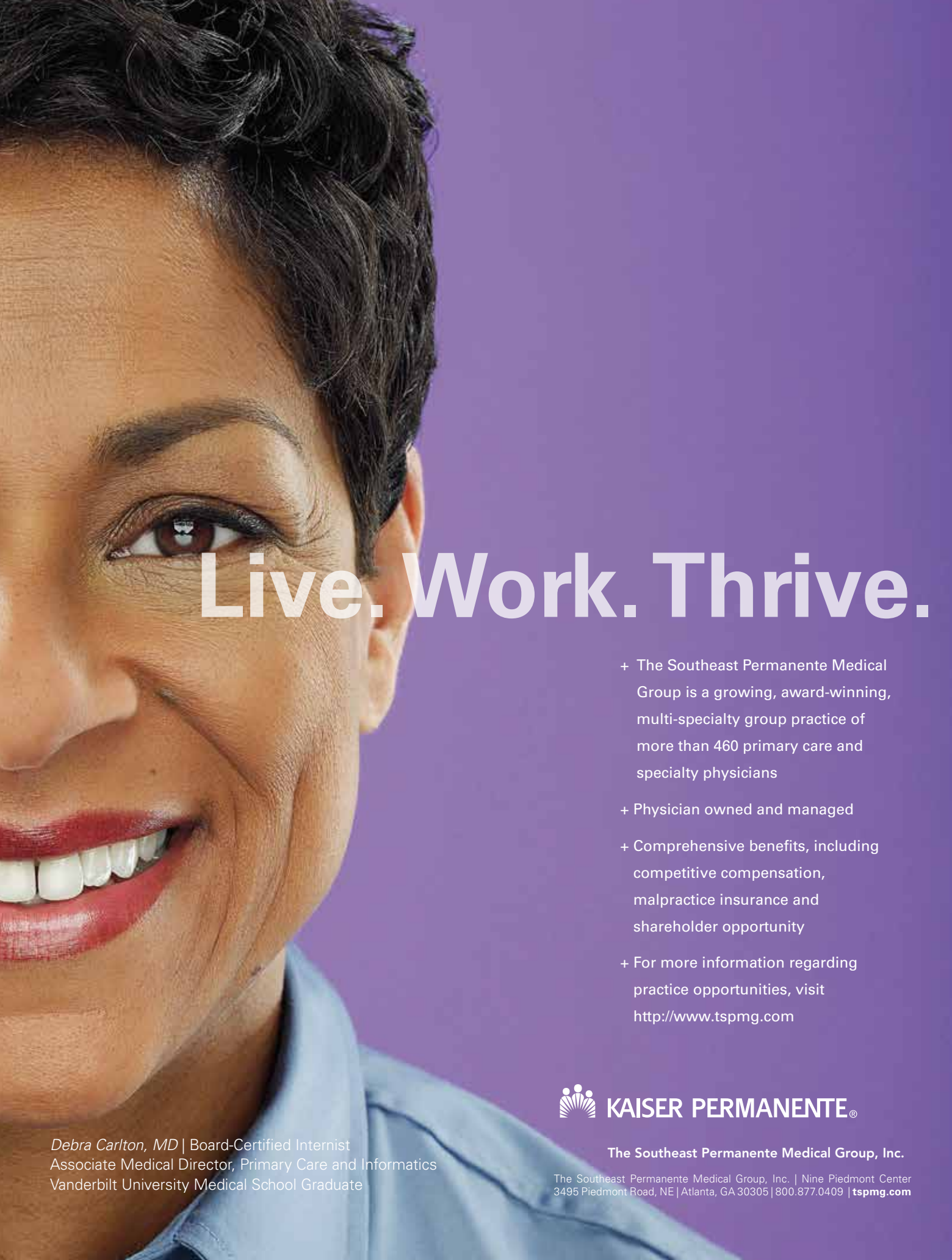
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Dr. Vincent Marconi (on left) is the Associate Medical Director of the Grady Health System's Infectious Disease Program

Is a Cure for HIV in Sight?

By Vincent C. Marconi, M.D., and Mirko Paiardini, Ph.D.

For the first time in almost three decades of AIDS research, the international scientific community has undertaken a large-scale, concerted effort to discover a cure for HIV.

Several anecdotal reports and small clinical studies have provided some optimistic insights into the feasibility of HIV eradication. In 2009, the dramatic case study of Timothy Brown (the Berlin patient) ushered in an era of cure fervor[1]. Brown was diagnosed with HIV in 1995, started antiretroviral therapy (ART) and did well for 11 years. Then in 2006, he was diagnosed with acute myelogenous leukemia (AML) and subsequently was treated with chemotherapy complicated by pneumonia and sepsis. His doctors then decided to try a different approach.

His doctors knew that a stem cell transplant might cure his AML. Using this opportunity, they chose a unique donor whose cells lacked the critical co-receptor (CCR5) necessary for the entry of HIV into cells. Their hope was to rebuild his immune system in such a way as to make his body resistant to HIV infection.

Shortly after receiving his "HIV-resistant" stem cell transplant, Mr. Brown stopped taking ART and has never

Although the promise of a cure and HIV eradication has been encouraging of late, this enthusiasm has been offset by many of the practical issues surrounding the pandemic at large.

looked back. Now almost seven years later, he remains free of HIV despite careful examination of samples of his blood, brain, liver, lymph nodes, cerebrospinal fluid, intestinal tract and bone marrow.

Since that time, two other patients with HIV in Boston have undergone stem cell transplants for lymphoma. They were found this year to be "HIV-free" after stopping ART, despite having donors who did express CCR5. Only time will tell if these two patients remain aviremic indefinitely like Timothy Brown.

Although stem cell transplants appear to be effective in achieving a cure, the associated patient risks and financial cost have not made transplants the most attractive option. But they have demonstrated that HIV eradication is possible.

Obstacles to Eradication

In 2003, Dr. J.D. Siliciano and colleagues from Johns Hopkins Hospital published a study that many believed could have ended all hope for a cure[2]. They showed that with current highly potent ART, it would take more than 70 years before all HIV-infected cells would completely disappear from the body. This observation was based on modeling the average decay rate of resting CD4 cells and other long-lived cells harboring HIV in a latent state. In the latent state, the HIV virus is integrated into the host genome as a provirus and is not transcriptionally active. These cells have an intrinsically long half-life, and because the provirus is not producing active virus, this HIV "reservoir" remains protected from ART and immunologic clearance.

Even more daunting, Dr. Nicolas Chomont et al. posited in 2009 that some cells could maintain this HIV reservoir indefinitely through homeostatic proliferation. In other words, infected cells could create copies of themselves, including both the host and HIV genome[3].

Such an immortalized state could make eradication of this population of cells even more challenging. Because of this, scientists spearheading the cure agenda have been divided on whether the goal should be to eradicate every last HIV-infected cell from patients or not. This goal, known as a "sterilizing" cure, may appear to be the ideal approach; however, it has been shown that only a small percentage of infected cells harbor a provirus that is even capable of productive infection.

Unfortunately, current methods to identify these cells are cumbersome and suboptimal. Therefore, a growing number of researchers are aiming for a less ambitious target of achieving a "functional" cure. A functional cure is analogous to conventional objectives for cancer chemotherapeutics. In this scenario, an individual would receive treatment that would reduce the reservoir to such an extent that ART could be stopped and the remaining HIV would be kept suppressed by the individual's immune system. Although this seems a somewhat radical approach, there are several examples where immunologic control of HIV occurs naturally or has happened after stopping ART.

Examples of HIV Control

In the absence of ART, the host anti-viral immune responses are incapable of controlling the virus, leading to a chronic infection that persists throughout life in most humans living with HIV. In contrast, a rare subset of individuals (<1 percent) infected with HIV, known as Elite Controllers (EC), can maintain undetectable viral loads for many years without ART.[4] These individuals are living proof that the human immune system is able to fully control HIV.

Further research has revealed that there are a variety of factors that contribute to the ability of ECs to maintain an undetectable viral load. These factors include the host immune response, host genetic factors[5] and viral factors. Understanding the main mechanisms allowing EC to control HIV replication without ART will, undoubtedly, represent an important step in HIV research. However, this knowledge will significantly impact HIV treatment and cure only if we can design therapeutic strategies and/or vaccines that induce these mechanisms of control in the general population living with HIV.

Two recent studies generated excitement and optimism in the field regarding the possibility of achieving a "functional" cure without very complex, risky and expensive procedures such as stem cell transplants. Both looked at individuals treated early after initial infection with HIV.

The first, a case study of a Mississippi baby[6], garnered tremendous media attention. An infant was treated with ART starting at 30 hours after birth owing to a high-risk exposure—the mother had a detectable viral load prior to delivery. Treatment was continued through 18 months of age because repeated testing by RNA and DNA met criteria for HIV infection, but treatment was then discontinued. At 30 months of age, the child has remained virologically

undetectable in plasma samples and peripheral blood mononuclear cells. Furthermore, HIV antibody testing has reverted to negative.

In the second study, Dr. Asier Sáez-Cirión and colleagues in the VISCONTI cohort showed that approximately 15 percent of individuals with HIV that initiated ART close to initial infection showed long-term control of viremia for several years after ART-interruption (median of 89 months)[7]. Interestingly, these individuals, known as post-treatment controllers (PTCs), do not have the strong HIV-specific immune responses nor the favorable genetic factors (protective HLA B alleles) characteristics of EC. Remarkably, not only did PTCs show a lower viral reservoir on therapy, but they were also able to maintain or even reduce their meager viral reservoir while off ART.

Examination of the reservoir in these individuals showed that the types of cells infected with HIV in the reservoir differed when compared to those that did not control HIV. In fact, relatively few long-lived central memory T cells were infected compared to the short-lived effector memory T cells. These findings are consistent with those generated in sooty mangabeys, an African monkey species that do not progress to AIDS despite many years of infection with Simian Immunodeficiency Virus,[8] suggesting that strategies aimed at functional cure will need to not only reduce the size but also affect the "quality" of the HIV reservoir.

Current Cure Strategies

At present, several strategies are being explored to achieve a cure of HIV. One approach involves inducing latently infected cells to produce the virus again with the goal of purging the viral reservoir. This would lead to expression of viral proteins on the cell surface, allowing the host immune system to target these cells for clearance. It could also initiate a cell-signaling cascade leading to programmed cell death in these cells.

Several existing FDA-approved drugs and other novel compounds are currently being investigated, including histone deacetylase inhibitors (HDACi) and disulfiram. Although an initial study by Dr. David Margolis et al. demonstrated conversion of latent to productive infection in the presence of a single dose of the HDACi vorinostat, there did not appear to be a significant change in the overall size of the reservoir[9]. This implied that despite reversing the latency step, there did not appear to be an increase in the death of these cells, at least over the period of observation in this study.

Another approach has been under consideration since the mid-1980s. Researchers have explored methods to enhance an HIV-infected individual's immune response to their own HIV, employing what have been called therapeutic vaccines. A form of "passive immunity" is also

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It has become apparent that using multiple approaches will likely be required to achieve even a functional cure.

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being considered. As one example, antibodies engineered to target HIV-infected cells and deliver a cytotoxin are currently under investigation.

Chronic HIV infection leads to chronic immune activation, as the immune system is continually fighting a pathogen. This leads to many of the comorbid conditions seen in those with HIV disease (for example, early heart disease) and plays a major role in CD4 cell loss.

In contrast to enhancing the immune system, some scientists have considered various methods to reduce this ongoing inflammatory state. By tempering this inflammation, expression of viral proteins and CCR5 are decreased, resulting in less effective HIV replication. In addition, less immune activation will have an effect of reducing bystander apoptosis of HIV-uninfected CD4 cells, potentially preserving critical immune function. Studies with a variety of biologic agents have been performed and are ongoing to pursue this possibility.

Gene therapy has shown some promise for the cure agenda as well. One particular strategy has been to render host cells resistant to HIV infection using zinc-finger nucleases[10]. These proteins essentially disrupt expression of CCR5. In a sense, this recreates the conditions experienced by Timothy Brown after his stem cell transplantation.

A very practical approach to a cure has been to "optimize" ART. By diagnosing and treating individuals soon after infection, the goal is to replicate the experiences of the VISCONTI cohort. This, coupled with better antiretroviral drugs with greater penetration into body sites and greater activity against resting CD4 cells and macrophages, may lead to a functional cure.

Ultimately, if anything has been constant throughout the past three decades of research and clinical care, it is that effective strategies are those that work in combination. It has become apparent that using multiple approaches will likely be required to achieve even a functional cure.

Currently, the concept of "kick and kill" is one such combination approach, wherein the latent reservoir is purged with medications like HDACi and subsequently targeted for cell death using therapeutic vaccines or immunotherapy. This could be coupled with improved ART and biological agents aimed at reducing chronic inflammation.

Although the promise of a cure and HIV eradication has been encouraging of late, this enthusiasm has been offset by many of the practical issues surrounding the pandemic at large. The costs associated with both discovery and implementation strategies must be balanced by the urgent need to get existing individuals living with HIV diagnosed, linked and retained on existing ART. For now, it is unclear precisely how or when this effort will be successful, but it is clear that it will succeed. ■

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MAA Debate Topic

Yes or No: The Patient's Compensation Ststem as proposed in SB 141 should replace the current Medical Tort Liability System.

MEDICAL ASSOCIATION OF ATLANTA
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6:30 PM Dinner
7:00 PM - Debate

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Donald J. Palmisano Jr.
Executive Director / CEO
Medical Association of Georgia

Donald J. Palmisano Jr. is the executive director and CEO of the Medical Association of Georgia, which is the leading voice for the medical profession in the state. Palmisano served as general counsel and then general counsel and director of government relations for MAG between 2005 and 2010. He represented individual physicians and hospitals and nursing homes as a private practice attorney in Louisiana from 1999 to 2005 and developed a specialized practice in insurance fraud litigation. Palmisano graduated magna cum laude from Loyola University in New Orleans, while he received his law degree from Loyola University's School of Law. He is a member of the State Bar of Georgia, the Louisiana State Bar Association, the Lawyers Club of Atlanta, Leadership Atlanta, the American Bar Association and the American Society of Medical Association Counsel. In 2012, Palmisano was listed as "On the Rise" by the Fulton County Daily Report, and one of the fourteen attorneys to watch in Georgia. Palmisano resides in Atlanta with his wife, Ana, and their four children.

Richard L. Jackson
Chairman, Patients for Fair Compensation

Richard L. Jackson serves as Chairman of Patients for Fair Compensation and Patients for Fair Compensation Institute. Jackson is Chairman and Chief Executive Officer of Jackson Healthcare. Jackson Healthcare provides hospitals with physicians, clinicians and allied health professionals to ensure the delivery of timely, high quality patient care.

For the past 34 years, Jackson has been instrumental in conceptualizing and developing more than 25 healthcare companies.

Driven by a personal mission to inject hope and opportunity into the lives of underserved children, Jackson actively supports numerous local and international charitable organizations. In 2010, he established a national Hospital Charitable Service Awards program - the only recognition program in the healthcare industry celebrating hospital accomplishments at the program level.

Jackson serves on the board of directors of the Georgia Department of Community Health and the Metro Atlanta Chamber of Commerce.

HIV and Cancer

By Clifford Gunthel, M.D., Minh Ly Nguyen, M.D.

Antiretroviral therapy (ART) has increased the lifespan of people living with HIV/AIDS (PLWHA). While ART has led to a marked reduction in the incidence of AIDS-defining illnesses, a variety of HIV-associated non-AIDS (HANA) conditions are becoming increasingly commonplace in individuals with long-standing HIV infection. Key among these is the increased incidence of HIV-associated malignancies.

Why are PLWHA at risk for cancer?

Many factors account for the increased incidence of HIV-associated malignancies. First, in a healthy patient, the immune system controls and regulates the development of cancer cells. In an HIV-infected patient, the immune system and its ability to fight cancer cells is impaired. Second, although ART allows PLWHA to live longer, healthier lives, their immune systems remain in a state of chronic activation. As a result, inflammatory pathways and coagulation pathways are persistently activated, which is known to increase the risk of developing cancer[1]. Second, cancers that are diagnosed commonly in older individuals will have an opportunity to manifest themselves as PLWHA age. Third, the HIV virus has a synergistic effect on other chronic viral infections, leading to a decreased capability for the immune system to control other viruses. This is important because many neoplastic processes are a result of viral processes. In an HIV-infected person, these viral-associated cancers can develop and progress faster than in healthy people. The most significant oncogenic viruses are:

- (KSHV), which is the cause of Kaposi sarcoma.
- Epstein Barr virus (EBV), which causes some subtypes of non-Hodgkin's and Hodgkin's lymphoma.
- Human papillomavirus (HPV), which causes cervical cancer and some types of anal, penile, vaginal, vulvar and head and neck cancer.
- Hepatitis B virus (HBV) and hepatitis C virus (HCV), which can both cause liver cancer.

In addition, there are higher rates of tobacco use in the HIV-infected population than in the HIV-negative population. It is estimated that 60 percent to 70 percent of people with HIV drink or smoke, which further contributes to the development of smoking-associated cancers such as lung cancer.

What are the types of cancer commonly encountered in PLWHA?

The landscape of HIV/AIDS-associated malignancies has evolved with the advent of the widespread use of ART. Prior to effective ART, AIDS-associated malignancies, or those associated with severe immune deficiency, were common. Since then, rates of these malignancies has dramatically decreased, in particular Kaposi's sarcoma and non-Hodgkin's lymphoma[1-4]. In contrast, non-AIDS associated malignancies have become more prevalent, including lung cancer, head and neck cancer, anal cancer and Hodgkin's lymphoma[1-5]. These cancers are summarized below.

The most common AIDS-associated cancers are Kaposi's sarcoma (KS) and non-Hodgkin's lymphoma. Each is associated with an oncogenic virus. KS is associated with human herpesvirus-8 (HHV-8) also known as Kaposi's sarcoma herpes virus (KSHV).

KS was among the first conditions that alerted astute clinicians to the presence of a new disease in the United States. Since the initial era of the HIV epidemic, when KS was commonly seen, the disease has become rare in most urban centers. Within the Grady Infectious Disease Program, however, KS remains relatively common, an indication of the late stage at which our patients in Atlanta present; on average a new case is diagnosed nearly once a week.

Although skin lesions are the most common manifestation of this disease, lymphadenopathic and visceral (mainly pulmonary) involvements are frequently encountered at our center. For limited disease, immune reconstitution with antiretroviral therapy is usually sufficient to cause regression of lesions.

There is little role for treating the HHV-8 virus once disease is established. Instead, more extensive disease requires systemic chemotherapy; liposomal doxorubicin or paclitaxel are standard agents used in treating Kaposi sarcoma.

HHV-8/KSHV also leads to another condition known as multicentric Castleman's disease. Although not a true malignancy, this disease often presents with constitutional symptoms, diffuse lymphadenopathy, and a sepsis-like syndrome. These manifestations are mainly due to the elaboration of cytokines, predominantly interleukin-6.

The diagnosis of Castleman's disease is established by distinct pathologic findings. Interestingly, this disease is seen in patients with higher CD4 counts, and the incidence has increased in the current era of effective ART.

Treatment with ART is not very effective in the short-term management of Castleman's disease. Very limited success has been obtained using direct anti-KSHV treatment with valganciclovir or cytotoxic chemotherapy. The disease does, however, respond to therapy with rituximab.

Non-Hodgkin's lymphomas (NHLs) are also considered AIDS-associated malignancies and are commonly associated with Epstein Barr virus (EBV). NHL presents most commonly as either isolated CNS disease (primary CNS lymphomas) or with systemic involvement. AIDS-associated primary CNS lymphomas are virtually all EBV-associated. This disease usually presents in the most severely immunocompromised patients, often with CD4 counts less than 50.

Fortunately the incidence of this lymphoma has declined significantly in the combined antiretroviral era. Our clinic experience has paralleled this national trend. Treatment goals are usually supportive and often include palliative radiation therapy. For patients with a good performance status, high-dose methotrexate-based regimens are tolerable and have resulted in prolonged disease-free survival when combined with antiretroviral therapy.

The systemic non-Hodgkin's lymphomas are heterogeneous in persons with AIDS. They are mainly comprised of high-grade B-cell lymphomas, and the majority of them are EBV-associated. The most common pathologic types are diffuse large B-cell lymphoma and Burkitt's lymphoma. They are managed with combination chemotherapy. Rituximab is tolerable in those patients with higher CD4 counts. For those patients with refractory or recurrent disease, intensive chemotherapy with stem cell rescue is an option and has been administered by colleagues at Emory.

Photo Credit: Debra Jansen, DebJansenPhotography.com

George Rankins does blood work on a patient at Grady Health Systems' Ponce de Leon Center

Primary effusion lymphoma is a rare, unique cancer that is virtually all KSHV-associated. The majority of these lymphomas also harbor EBV.

Among the non-AIDS associated cancers (NADC), infection with oncogenic virus- associated cancers are more frequently encountered[5]. In a retrospective study comparing the rate of cancers encountered at the Grady Infectious Diseases Clinic and that of the Metro Atlanta area from 2000-2007, the adjusted rate of anorectal squamous cell carcinoma (SCC) was 67.6, Hodgkin's lymphoma (HL) 19.7, hepatocellular cancer (HCC) 9.5, head and neck cancer (HNCC) 8.7, and lung cancer 4.5 times higher in PLWA at the IDP. The rate of breast cancer in our HIV population is similar to that in the general population, and that of prostate cancer is lower.

Prevention of cancer in HIV-infected persons

A number of measures can help with early detection or prevention of cancer in the HIV-infected population and are routinely performed at IDP.

Cervical cancer screening in PLWHA: Yearly cervical pap smears for HIV-infected women are recommended, and early signs of cervical dysplasia should be referred for colposcopy.

Current recommendations published by the United States Preventive Services Task Force (USPSTF) for the general population recommend that all women should be screened with Pap testing within three years of the onset of sexual activity or at age 21, and that follow-up screening occur every three years (www.uspreventiveservicestaskforce.org). However, HIV-specific guidelines proposed by the Centers for Disease Control and Prevention, which suggest more frequent Pap testing, have not changed and recommend Pap testing upon HIV diagnosis, at six months after diagnosis and then annually. (www.hivguidelines.org/ clinical-guidelines/adults/ neoplastic-complications-of-hiv-infection). It is likely, however, that HIV-infected women on a stable ART regimen with viral suppression can be safely monitored in a fashion similar to HIV-uninfected women[6]. Although strategies utilizing HPV testing have shown merit in the general population, there is little evidence to suggest any advantage in HIV-infected women, as the baseline prevalence of high-risk HPV strains are high, limiting the discriminatory power of testing[7].

Anal cancer screening in PLWHA is controversial. No randomized control trials have been performed to guide screening methods for anal cancer, although a large multicenter trial is planned. There are also no guidelines for anal cancer screening in the general population. Yearly digital rectal exams [DRE] are recommended in high-risk patients. Patients with abnormal findings are best evaluated by high-resolution anoscopy if available. As in cervical cancer, the role of HPV testing in screening for anal cancer is of limited benefit among PLWHA. The New York State AIDS Institute has recommended baseline and annual screening with anal cytology in HIV-infected MSM, women and persons with a history of anal condylomata. Additionally, DRE is recommended in all persons with HIV on an annual basis (www.hivguidelines.org/clinical-guidelines/adults/neoplastic-complications-of-hiv-infection). However, since the incidence of anal cancer in HIV-infected persons is significant, screening of high-risk groups with cytology or high-resolution anoscopy should be considered while further studies of the harms and benefits are underway[7].

Screening for hepatocellular carcinoma (HCC): HCC is seen most commonly in those with underlying viral hepatitis, including hepatitis B and C. Several commonly used antiretroviral agents for treatment of HIV also are effective to treat Hepatitis B.

In addition, treatment for hepatitis C is evolving rapidly with improving success in the HIV-coinfected population. Treating these two viral hepatitides is an important preventive measure for HCC. For those with evidence of cirrhosis in hepatitis C and in all Hepatitis B coinfected patients, annual liver ultrasound to screen for HCC is recommended. Vaccination against hepatitis B is an important preventive measure to prevent hepatitis B and therefore HCC in those without hepatitis B infection.

Smoking cessation programs are an important adjunct for prevention of smoking-related cancers including lung cancer and should not be overlooked. Early diagnosis of HIV with treatment to prevent immunosuppression is also an effective measure[8].

HIV testing

Studies in the era of ART have showed improved survival of PLWA with cancer if both the HIV infection and the cancer are treated concomitantly[9-11]. Furthermore, early diagnosis of HIV can prevent the development of AIDS-associated malignancies. This underlines the importance of diagnosing HIV infection early. All adults age 15-65 should be screened for HIV with opt-out language, now a Grade A recommendation by the USPSTF (www.uspreventiveservicestaskforce.org/uspstf13/hiv/hivfinalrs.htm).

In addition, all individuals with cancers associated with HIV should be tested. For example in the Grady Healthcare System, of those patients with newly diagnosed cancers from 2000-2010, 33 percent of lung cancer patients were tested for HIV and 6.4 percent of all lung cancer patients were HIV-infected. During that same period, 66 percent of the Hodgkin's lymphoma patients were tested for HIV and 30 percent were HIV-infected. Similarly, from 1991 to 2006, 30 percent of head and neck cancer patients were tested for HIV and 8 percent were positive. These numbers might represent an underestimate, as only a small percent was tested for HIV.

Effective and tolerable ART has allowed PLWHA to live longer but also to develop cancers that are typically encountered at advanced age. The most frequently encountered non-AIDS associated cancers are those associated with oncogenic viruses: anal cancer, head and neck cancer, Hodgkin's lymphoma and hepatocellular cancer.

In our clinic, there is a disproportionate rate of AIDS-associated cancers. Greater effort should be devoted in diagnosing HIV early and to get PLWHA into care early to prevent the occurrence of AIDS-defining malignancies. ■

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Clifford Gunthel, MD

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Minh Ly Nguyen ,MD,MPH,FACP

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A New Model of Mental Health Care

By Eugene Farber, Ph.D, Amit Shahane, Ph.D. and Sanjay M. Sharma, M.D.

Jeff is a 34-year-old male with AIDS who was diagnosed with HIV in 2009. He is presently re-enrolling in clinical services at the Infectious Disease Program (IDP) of Grady Health System after dropping out of care due to depression. Prior to that, his health was stable with good overall virologic control.

Now his CD4 count has declined substantially and his viral load is very high. In addition to his current medical issues, Jeff presents complaining of feeling "tired" and "run down." He describes feeling "down all the time" and reports sleep difficulties, impaired concentration/focus, poor appetite with associated weight loss, decreased motivation, social withdrawal/isolation, and he notes he is "not enjoying the things I used to do."

He denies any active thoughts or intention to harm himself. Jeff also describes using alcohol in increasing amounts and "a little" cocaine to "help me feel better." He reports that his relationships have been negatively affected due to his current state. He also feels that he may lose his job in the near future as he has been missing work recently. This leads him to worry that he may eventually be evicted and become homeless.

After attending to his immediate medical issues, his primary care provider, seeking consultation, refers Jeff for further mental health and substance abuse evaluation and treatment services within the IDP.

Jeff's story is all too familiar. His case illustrates how the intersection of mental health, substance abuse and medical issues can negatively impact engagement, retention and adherence to HIV care, leading to poor HIV/AIDS health outcomes. Many people living with HIV/AIDS (PLWHA) experience a host of mental health and substance abuse problems that negatively affect their HIV status and lives. A national sample has indicated that approximately 50 percent of PLWHA meet criteria for a psychiatric disorder with major depressive and generalized anxiety disorders being almost five and eight times greater than the general population respectively (Bing et al., 2001). Furthermore, the same national sample indicated that approximately 40 percent of PLWHA reported illicit drug use.

The consequences of these high prevalence rates of mental health and substance abuse disorders within PLWHA are far reaching. Comorbid HIV and mental health disorders, such as depression, are associated

Photo Credit: Debra Jansen, DebJansenPhotography.com

Within the IDP, mental health and substance abuse services are not only co-located with other services offered through the program, but also are integral components of a patient's overall HIV medical care and treatment plan.

with both clinical and immunological HIV disease progression, even in the era of effective combination antiretroviral therapy. (Lesserman, 2008). In addition, PLWHA with a mental health and/or substance abuse disorder are more likely to engage in behaviors associated with higher HIV transmission risk (Meade & Sikkema, 2005).

These statistics clearly demonstrate the need for mental health and substance abuse services to move beyond the traditional medical model approach to mental health care. Jeff's case further underscores the need for integrated medical and mental health/substance abuse services. At the Grady IDP, we have made an effort to develop an integrated medical and mental health system to help people like Jeff.

Within the IDP, mental health and substance abuse services are not only co-located with other services offered through the program, but also are integral components of a patient's overall HIV medical care and treatment plan. IDP mental health and substance abuse services are grounded within a biopsychosocial approach to mental health evaluation, consultation and treatment.

The biopsychosocial model conceptualizes health and illness in the context of the interactions among various biomedical, psychological and psychosocial factors (Engel, 1978), many of which then influence a patient's HIV adherence, retention, overall health, functioning and well-being. The primary emphasis within this approach is on understanding and treating the patient holistically. This dynamic framework reminds providers to consider the patient's overall illness within the whole of the patient's life and to respond to disruptions and impairments at each of these levels; in this sense, the biopsychosocial model sharply contrasts with the biomedical model of healthcare, which is purely disease-focused in both assessment and treatment.

Understanding the importance of all of these facets of patient care, the mental health and substance abuse services at IDP are designed to meet the multidimensional needs of patients like Jeff through uniform integration with the primary care clinics, including general adult services, the women's health clinic and pediatric/adolescent specialty services (infants, children, youth and families). Primary mental health and substance abuse services and programming are delivered within the IDP's Center for Well Being and Transition Center.

The Center for Well Being consists of a general outpatient mental health clinic that provides both mental health and substance abuse intervention for clients with co-occurring psychiatric disorders and HIV/AIDS. Within the Center for Well Being, an interdisciplinary team of psychiatrists, psychologists, psychiatric nurses and mental health/substance abuse counselors work in balance to create a comprehensive network of collaborative care. This includes our program for those with substance abuse, which offers individual- and group-based treatment services, including a daily core adult program and specialty programming for subsets of patients with additional challenges.

Some patients require less traditional, less structured services. We have responded to the biopsychosocial needs of these patients by creating alternate paradigms to meet the needs of patients with unique challenges. The Transition Center (TC) at IDP is an example of this.

The TC accepts patients with serious mental illness, substance dependence and chronic psychosocial instability who are failing the standard clinic structure. The TC provides a more flexible structure and a nurturing personalized environment with highly integrated care. Consistent with a biopsychosocial model of care, the TC utilizes a multidisciplinary team consisting of medical and specialized psychiatric nurses, a chaplain, psychologist, mental health/substance counselor and pharmacist. A study of adherence to HIV therapy for patients in the TC compared to their adherence in the standard clinic showed that participants were virologically controlled significantly more often than they were in the standard of care clinic.

The provision of a wide variety of services allows the integrated model to be successful. We believe this is critically important to successful HIV care with retention of patients in care. In sum, this requires (1) evaluation services, including routine, urgent and emergency comprehensive diagnostic assessments and treatment planning, neuropsychiatric evaluation and pediatric neurodevelopmental testing; (2) consultative services, including collaboration medical care providers to reduce psychiatric/behavioral barriers to medical treatment adherence and consultation with support agencies such as case management, housing services, etc. and consultation with schools and education-related client advocacy for pediatric and adolescent clients; and (3) treatment services, including individual, couple, family and group psychotherapy; mental health and wellness programs (e.g., HIV risk prevention practices, HIV medical adherence, stress management, yoga); psychiatric medication management/counseling; treatment of HIV-related neuropsychiatric complications; spiritual/religious counseling; and crisis intervention.

In evaluating Jeff's case, his mental health provider examines the various pertinent issues and experiences affecting Jeff's overall health, function and well-being, as

The Center for Well Being consists of a general outpatient mental health clinic that provides both mental health and substance abuse intervention for clients with co-occurring psychiatric disorders and HIV/AIDS.

well as his adherence and retention in care. In this case, the pertinent biopsychosocial aspects to consider include: (i) biomedical factors including HIV/AIDS and its potential neuropsychiatric impact, major depression and substance use; (ii) psychological factors including depression, emotional distress, personality-related issues, coping skills and maladaptive behavior patterns; (iii) psychosocial factors including social support networks/systems, relationships, spiritual/cultural beliefs, financial/material resources, housing assistance/resources and attitudes/perceptions/ belief systems (HIV/AIDS-related and other).

Working together, Jeff and his mental health provider formulate an initial holistic treatment plan based upon his initial assessment. This treatment plan includes the following: (i) biomedical – educating Jeff about his major depression and initiating him on an antidepressant medication, educating him about the deleterious and potentially dangerous effects of ongoing substance use and creating a recovery plan in this context, and following-up and working collaboratively with his medical provider to ensure adherence in this area; (ii) psychological – providing Jeff with regular psychotherapy, both individual and group, to address maladaptive behavior patterns, develop problem-solving strategies and reinforce positive/healthy coping skills; (iii) psychosocial – connecting Jeff with active case management services to address issues such as housing assistance, financial resources and psychosocial support.

Additionally, Jeff is introduced to several of the health and wellness programs offered through the Center for Well Being. These sessions complement the overall treatment plan and cover a wide range of subjects and areas, including adherence, relapse prevention, stress management and financial information sessions.

Over time, Jeff remains actively engaged in his overall treatment plan and shows improvements in all aspects of his health and well-being, including medically, psychologically, emotionally, psychosocially and functionally.

At the IDP, the multiple biopsychosocial dimensions of a patient's care, as illustrated in Jeff's case, are explored, assessed and treated in unison. The biopsychosocial approach to patient care also leads to both enhanced collaboration among providers and between patients and providers. By using this model of integrated care, the IDP has developed unique programming and systems of service delivery that serve to increase engagement, retention and adherence to overall HIV/AIDS care and wellness. ■

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Hospice and Palliative Care

By Helen K. Kelley

Specialized care for terminally ill and seriously ill patients is a rapidly growing area of healthcare that requires a partnership and collaboration between patients, physicians and other care providers.

Increase in Use of Hospice and Palliative Care Corresponds to Population Trends

The use of hospice and palliative care is on the rise, both in Georgia and nationally. That increase can be attributed to many factors, most of them population trends, according to Jennifer Hale, executive director of the Georgia Hospice and Palliative Care Organization.

"There is a gap in care delivery. That gap isn't new, but what is new is that people who are coming out of the acute care setting are often much sicker and much more frail than ever before," says Hale. "So, there's been a corresponding increase in use of hospice and palliative care, especially for patients whose prognosis is not really certain. Now we're seeing trends such as patients receiving hospice care and getting stabilized, processes being put into place to help families support their loved ones and an increase in live discharges from hospice."

The most notable trend is that as our population ages — including the vast baby boomer segment — chronic diseases have also broadened and become more complex. This complexity is driving an increase in the need for specialized care of patients with terminal and long-term serious illnesses.

"Twenty-five years ago, if you had heart disease, there was a way to manage it. Today, there is no simple way to manage it — now a heart patient is also likely to have kidney or vascular involvement, diabetes or other additional health issues," Hale explains. "The complexity of managing all those multiple diseases makes it difficult for patients to be informed about medications, know when to follow up with primary care or specialists, and whether or not their physicians communicate with each other. Increasing numbers of older people are frailer, need more care and need more assistance in managing that care. These issues have developed from our very fragmented healthcare system."

Hospice and palliative care help fill this gap in care delivery by providing an opportunity for the majority of these patients to receive care at home.

"Many people still believe hospice is an actual place to go

and that being admitted to hospice signifies that the patient only has days or hours to live. That's a big misconception," says Hale. "Facilities are intended only for very short-term acute care for patients with issues such as uncontrollable pain, respiratory distress or a diagnosis that the hospice team can't manage in home setting. If a patient in acute hospice care is stabilized, they return home."

Hale adds that there is also an increased frequency in the use of hospice physicians.

"The emphasis on physician involvement has actually come from the federal government," she says. "More frequent hospice physician involvement often results in either longer length of stay or shorter length of stay for these terminally or seriously ill patients than in the past. And sometimes, the hospice physician sees that a patient no longer has a shortened life expectancy."

Resources for Information About Hospice and Palliative Care

Georgia Hospice and Palliative Care Organization
Web: ghpco.org
Phone: 877-924-6073

National Hospice and Palliative Care Organization
Web: nhpco.org
Phone: 703-837-1500

The University of Georgia College of Public Health's Institute of Gerontology
Web: training.geron.uga.edu/
Phone: 706-425-3222

POLST Initiative Designed to Improve End-of-Life Care

The Physician Orders for Life-Sustaining Treatment (POLST) national initiative is designed to improve the quality of care people receive at the end of life, providing patients an opportunity in advance to determine their own medical care.

Here in Georgia, a POLST form developed by the Georgia Department of Public Health provides that "Any person who acts in good faith in accordance with a Physician Order for Life-sustaining treatment developed pursuant to subsection (l) of this Code section shall have all of the immunity granted pursuant to Code Section 31-32-10." O.C.G.A. § 31-32-10 provides, in pertinent part: "Each health care provider, health care facility, and any other person who acts in good faith reliance … shall be protected and released to the same extent as though such person had interacted directly with the [patient] as a fully competent person."

According to Dr. Pam Erdman, Medical Director of Crossroads Hospice in Tucker, POLST is an opportunity for the patient, while still able to make his or her own decisions, to direct the course of care and to state whether or not they wish to remain at home.

"The patient makes the determination in advance about whether or not they want life-prolonging efforts like IV fluids or tube feeding before it comes to the moment of decision when there are no remaining medical options available," she says. "It's a lot easier for the family to then say, 'we'll keep our loved one at home because we know that's what they wanted.' The POLST initiative allows the patient to choose a more comfortable, meaningful remainder of their life, while lifting the burden of decision-making off the family."

The POLST form is similar in some ways to an Advanced Directive, but is more extensive. It's filled out when the physician believes the patient is likely to die within the next 12 months.

Erdman encourages doctors to think of ways to incorporate the use of the form into routine visits with terminally ill patients so that quality of life issues are addressed while the person is still able to make decisions about their own care.

"Once the physician understands the patient's wishes and those are entered on the form, then some time must be allotted to go through the form and

Dr. Pam Erdman

get the patient's informed consent," she says. "Then the physician signs the form and it becomes an order, so that if and when the patient ends up at a hospital, they don't receive treatments they don't want."

Physicians may download the POLST form on the Georgia Department of Public Health's website: http://dph.georgia.gov/POLST.

Innovative Fellowship Program Prepares Nurses to Provide Specialized Care

The Helene Fuld Health Trust has donated $6.5 million to establish an innovative palliative care fellowship program at Emory University's Nell Hodgson Woodruff School of Nursing and the Emory Palliative Care Center. The program aims to develop nurse leaders who can make an impact in palliative care, an area of healthcare that is rapidly growing as more Americans are facing life-threatening and chronic illnesses.

This grant will create the Fuld Palliative Care Fellowship Program to prepare nursing students to work collaboratively with physicians, social workers, physical therapists and chaplains to provide specialized holistic palliative care, which is a unique care model that provides patients with relief from the symptoms, pain and stress often associated with serious illnesses, with the ultimate goal of improving the quality of life for patients and their families.

About POLST

The National POLST (Physician Orders for Life-Sustaining Treatment) Paradigm is an approach to end-of-life planning based on conversations between patients, loved ones and medical providers. The POLST Paradigm is designed to ensure that seriously ill patients can choose the treatments they want and that medical providers honor their wishes.

The POLST initiative is based on:

- effective communication of patient wishes
- documentation of signed medical orders on an official form
- a promise by healthcare professionals to honor these wishes
- protocols for transportability to assure that the form travels with patients across settings

For more information, visit www.POLST.org.

This grant will provide program support and scholarships to select students each year to become immersed in palliative care clinical initiatives, research and policy development by working with the Emory Palliative Care Center, an organization that provides team-based palliative care to nearly 5,000 adult and pediatric patients each year. The new program will enroll its inaugural students this summer.

"This fellowship is transformative in the training of nurses seeking careers in palliative care. Palliative care advanced practice nurses are central to the success of our interdisciplinary clinical teams and the delivery of the highest quality comprehensive care," says Tammie Quest, M.D., director of the Emory Palliative Care Center. "These Fellows will define the key research question in the field and innovate in the area of education to students of all disciplines. They will be role models to others in their clinical knowledge, skill and contributions to the field to ensure patients and families facing serious illness have the highest quality care focused on quality of life." ■

Medical Association of Atlanta Board Members

In every issue, *ATLANA Medicine* will feature a couple of the association's board members. If you would like to consider becoming a board member, please contact David Waldrep at dwaldrep@maa-assn.org.

W. Cody McClatchey, M.D., FACP, is an internist at Piedmont Physicians in Buckhead, where he has practiced for 13 years. He currently serves on the Boards of Piedmont Medical Care Corporation and the Piedmont Foundation. He is a graduate of the Georgia Physician Leadership Academy and serves as Treasurer and member of the Health and Public Policy Committee of the Georgia Chapter of the American College of Physicians. He has been named a Fellow of the American College of Physicians. He has a Bachelor of Arts in History from Duke University, Doctor of Medicine from Emory University, and completed his internal medicine residency at Wake Forest University.

Dr. Sumayah Taliaferro graduated with honors from Brown University and Alpert Brown Medical School. Her career began with residency training in the Yale Primary Care Internal Medicine Program, followed by residency in dermatology at Howard University. A board-certified dermatologist with Dermatology Affiliates, Dr. Taliaferro specializes in pigmentary disorders, medical dermatology, surgery, and cosmetic dermatology. She is a fellow of the American Academy of Dermatology and an active member of the Women's Dermatologic Society, the Atlanta Association for Dermatology and Dermatologic Surgery, and the Atlanta Medical Association. She serves on the Board for the Medical Association of Atlanta and leads their new Residency Mentorship Program.

Thomas Bat, M.D. founded his medical practice North Atlanta Primary Care 25 years ago. The practice has grown to five locations in Alpharetta, Cumming, John's Creek, Sandy Springs and Woodstock.

As medical director at NAPC he oversees a provider staff of 30 family physicians, internists, and physician assistants seeing over 125,000 patients annually. The practice has been recognized by HIMSS for its use of information technology with the Nathan Davies award in 2005. The practice was Georgia's first recognized private multi-site primary care practice Patient Centered Medical Home by NCQA in 2012. Dr. Bat received his medical degree from the University of Mississippi and his post graduate training at the University of Tennessee in Family Medicine.

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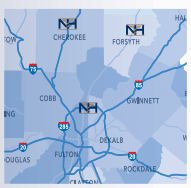

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