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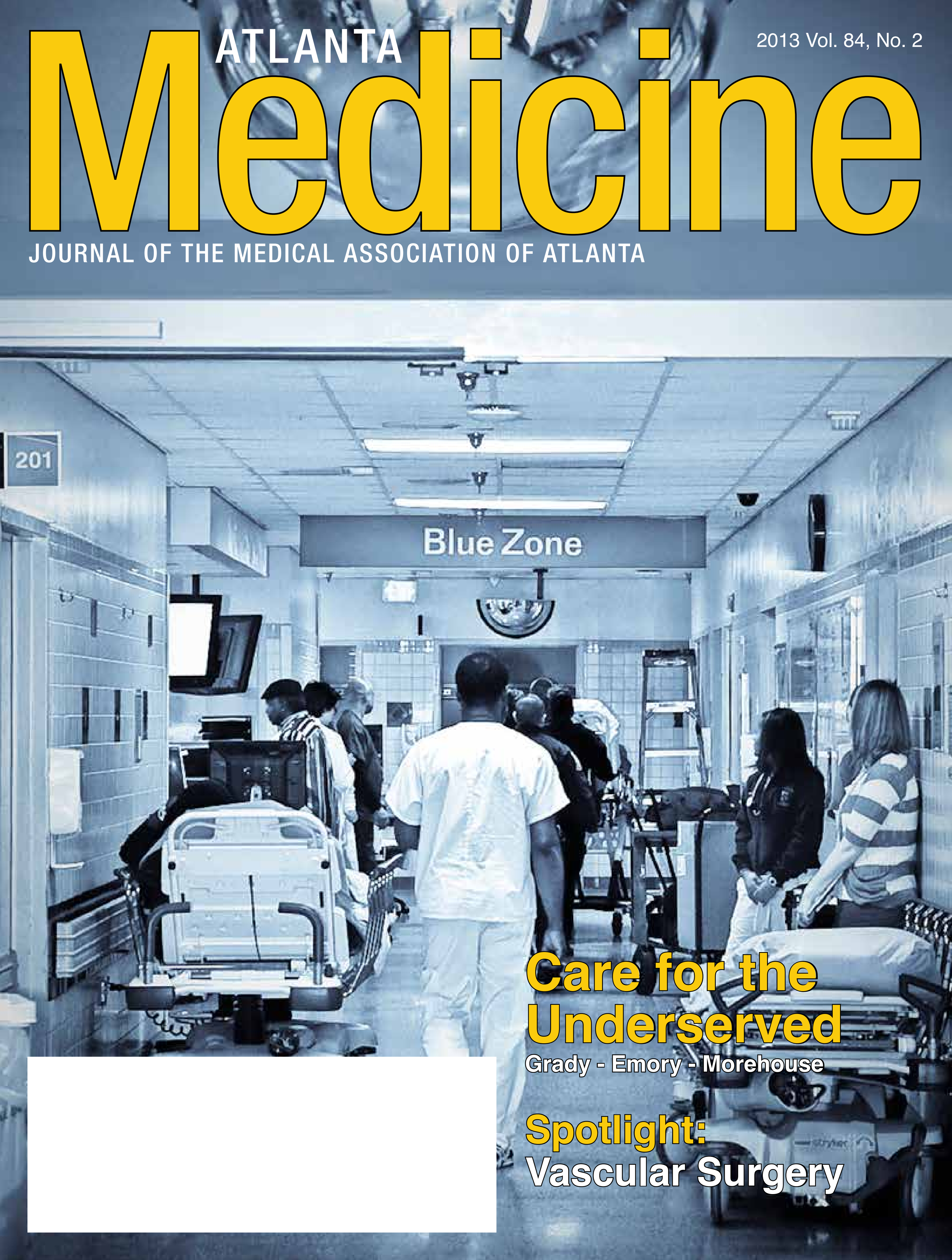

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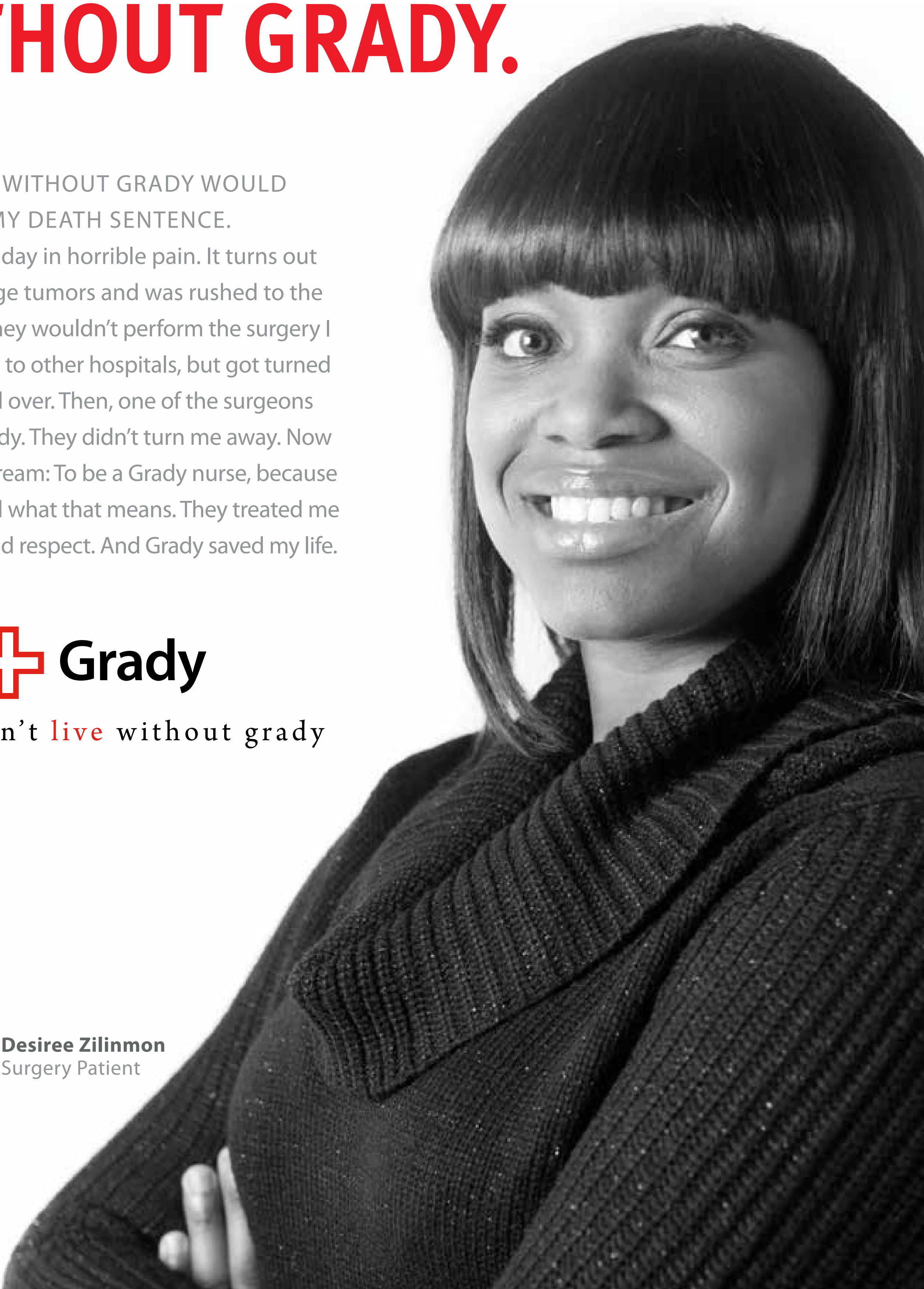

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Grady

atlanta can't live without grady

Desiree Zilinmon
Surgery Patient

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CARE FOR THE UNDERSERVED

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Medical Care With Limited Resources

By Dimitri Cassimatis, M.D., FACC

In 2011 the US Census Bureau reported that 48.6 million people (15.7 percent of the population) in the United States have no medical insurance, including 1.88 million in Georgia (19.6 percent of the Georgia population). The problem worldwide, primarily in less well-developed countries, is often significantly greater. Limited personal income and absence of healthcare coverage is often compounded by limitations in the health care delivery systems of poorer regions and countries, as many physicians leave their homes in search of better incomes for their families, leaving a small few to care for a great many.

Given the disparity of incomes between individuals and regions (nationally and internationally), there will likely always be a need for healthcare delivery in limited resource populations. Perhaps more importantly, though, is that we recognize that all resources face limits, and that healthcare cannot grow indefinitely in cost and size.

Bringing high-quality, low-cost care to as many as possible is the issue that comes to the forefront. But as one digs deeper, a great many questions arise: Who will fund such care? How can a system delivering care to people of different resources maintain fairness? Is it ethical to put limits on what will be offered? Can clinical research still be conducted in low resource populations without taking advantage of anyone's lack of resources? How can new doctors and medical students be taught in public hospital settings, without in any way disrespecting or being unfair to those who seek care in those hospitals? And despite all the difficulties at home even in wealthy countries, is there still a role for the people of wealthier nations to help their worldwide neighbors?

In this issue of Atlanta Medicine, we will examine some of these questions by reaching out to local physicians and leaders who devote themselves to caring for those with low resources. John Haupert, President and CEO of the Grady Health System, offers us a clear overview of the current state of indigent healthcare in Atlanta and Georgia, shining a light on the effects of recent legislative changes. Kimberly Manning, an award winning clinician-educator and internist at Grady Memorial Hospital, presents an intriguing case vignette-based reflection on teaching in a public hospital.

Jason Lesandrini, Grady Memorial Hospital's medical ethicist, and Neal Dickert, an Emory physician with a specialty in research ethics, offer a comprehensive and insightful article on the ethical challenges of clinical research in low resource populations. And Allen Dollar, the Chief of Cardiology at Grady Memorial Hospital, brings together four short essays by Grady and Emory physician faculty reflecting on the experiences, challenges, and accomplishments of rotating through a public hospital in Addis Ababa, Ethiopia.

In the end, our goal as physicians remains to provide the best care to the most people, with resources that are always going to have limits. The way in which this is done is forever evolving, and always worth reflecting upon. ■

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Answering the Call of Collaboration in Serving the Underserved

By Rachel Harris, M.D., MPH

The categorization of indigent in the United States has been the mainstay for many Americans as they are "deficient in what is required" to live long, happy and prosperous lives.[1] There are several dynamic elements which play integral roles in this ongoing game of chess, if you may, and delivery of healthcare is one piece among the set. The focus on the indigent has been a long road initially undertaken in the late 1700s to early 1800s and further refined by the 1900s. However, after over 300 years the predicament of caring for these vital members of society still remains a dilemma.

When one ponders who the indigent person is: a small business owner, the recently unemployed, an aspiring student, the mother of five children with a low paying job, or even a family member the call is overwhelming and clear. The unambiguous voice compels one to recognize each individual as the symbolic neighbor and a sense of obligation stems from the adage "For everyone to whom much is given, of him shall much be required."[2]

The resounding cacophony of lack of access, insufficient funds, and untrained healthcare workers to meet these needs can be replaced by the concerto of collaborative efforts by primary care providers, specialists, medical students, volunteers, community advocates, as well as hospitals and clinics who all pledge to deliver the best care possible in the most humanistic form imaginable.

Entrusting each generation of future physicians with the tools necessary to address the primary health care needs of the underserved is an essential mission of the Morehouse School of Medicine. Through programs in education, research, and service the torch is passed year after year. Since 1975, after establishing itself in the Atlanta University Center and forming fundamental relationships with Grady Memorial Hospital, Emory School of Medicine, Children's Healthcare of Atlanta, Georgia Institute of Technology, and most importantly numerous community and private entities, Morehouse School of Medicine strives to continue serving in this capacity.

In the articles from distinguished faculty, the passion is felt from those who care for the young pediatric patient and their family members at **Healthcare Without Walls: A Medical Home for Homeless Children,** to the pride of accomplishment in developing community programs with neighborhood involvement by the **Morehouse School of Medicine Preventive Research Center** and on to the hope of reducing and finally eliminating disparities that exist by focusing on neglected diseases and underserved populations led by the **Satcher Health Institute** and **Transdisciplinary Collaborative Center.** ■

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Rachel Harris, M.D., MPH joined the faculty of Morehouse School of Medicine, Section of Cardiology as an Assistant Professor in July 2011 and as Staff Cardiologist at the Atlanta VA Women's Center of Excellence East Point Outpatient Clinic in September 2012. Dr. Harris passionately enjoys teaching and also serves as one of the Morehouse School of Medicine Internal Medicine Residency Associate Program Directors. Dr. Harris is Board Certified in Cardiovascular Diseases, Internal Medicine, Nuclear Cardiology and Echocardiography. She serves as the Echocardiography Lab Co-Director at Grady Memorial Hospital in Atlanta, GA.

John M. Haupert, FACHE

The State of Indigent Healthcare in Atlanta and Georgia

The provision of healthcare services to the uninsured and underinsured in Atlanta is achieved by weaving together services from a broad array of diverse health service providers. This "safety net" is comprised of health systems, Federally Qualified Health Centers (FQHCs), not-for-profit clinics and county-supported health departments.

Safety net providers ensure core public health needs are met and carry out critical healthcare functions, including delivering essential community services, such as trauma and burn care, training tomorrow's healthcare workforce and providing uncompensated care to uninsured and underinsured patients. As the leading safety net provider in Georgia, Grady Health System provides 47 percent of healthcare services received by the uninsured in Fulton and DeKalb counties. Grady accomplishes this through its Neighborhood Health Centers, specialty clinics, emergency department, inpatient services and Crestview Rehabilitation and Nursing Center.

Other significant providers of care to the uninsured and underinsured include a robust network of FQHCs including Oakhurst Medical Centers, St. Joseph Mercy Care Services, Southside Medical Center and West End Medical Centers. Atlanta is fortunate to have such a strong and competent network of FQHCs providing excellent care primarily to Medicaid and uninsured citizens. Not all metropolitan areas have such a healthy network of care providers to serve the underserved. Grady Health System and the FQHCs are forging a collaborative working relationship that includes the creation of a health information exchange that will enable providers to share clinical information regarding care delivered to patients who receive care in multiple locations.

Rounding out the Atlanta safety net are other health systems that serve a significant number of Medicaid and uninsured patients, including Children's Healthcare of Atlanta, Emory Healthcare and Tenet Healthcare Corporation. In addition, a very broad network of not-for-profit independent health clinics provide much-needed primary, specialty, dental and podiatry services to the uninsured. One such clinic is the HEAL Clinic, founded by Grady and Emory otolaryngologist Dr. Charles Moore. And finally, both DeKalb and Fulton counties provide a broad array of essential primary care and mental health services. Together, all of these providers come together to meet the needs of the uninsured and underinsured in the greater Atlanta area.

As a network of healthcare providers, all of these entities are working together to create much-needed medical homes for the indigent. Together, these healthcare providers believe that the right care should be provided in the right place at the right time for all people. By placing needed primary care services within the community, disease can be detected and treated earlier, patients can develop relationships with consistent and reliable providers, cost-effective and equitable care can be made available to more individuals and the overall health of the community can be improved.

This same story is being repeated throughout Georgia. Groups of health systems, FQHCs, not-for-profit clinics and county health departments are coming together to piece together a safety net for all Georgians. These networks have emerged in an effort to meet the healthcare needs of the uninsured of Georgia. 19.4 percent of Georgians, 1.9 million people, lacked insurance coverage in 2010 compared with 16.3 percent of Americans nationwide. Numerous studies have shown the clear benefits of health coverage. For example, a recent The *New England Journal of Medicine* article found that Medicaid coverage can decrease mortality rates, improve access to healthcare service and improve general well–being.[1] The Institute of Medicine (IOM) found that a lack of coverage leads to adults forgoing critical preventive services that can reduce illness and premature death, an increased likelihood of being diagnosed with end-stage cancers and higher mortality rates among those hospitalized for trauma or other serious conditions. IOM also found that uninsured adults who suffer from chronic conditions are more likely to suffer poorer outcomes, greater limitations in quality of life and premature death.[2]

The Affordable Care Act (ACA), as originally approved by Congress, would have provided the majority of Georgia's 1.9 million uninsured with some form of coverage, either through the proposed expansion of Medicaid or through the establishment of Health Insurance Exchanges. Estimates from the Centers for Medicaid and Medicare Services show that 700,000 Georgians are eligible for coverage under the expansion of Medicaid and 600,000 Georgians are eligible for coverage through the to-be-formed health insurance exchange. It is estimated that 600,000 Georgians, primarily the undocumented, would still have no insurance coverage.

The Supreme Court ruled this past summer that states could not be forced to expand their Medicaid programs through the ACA. Georgia is one of the states that has determined that it simply cannot afford the costs of expanding Medicaid at this time. That decision creates quite a conundrum for the safety net health systems and hospitals in the State of Georgia. The ACA calls for substantial cuts in Medicaid disproportionate share hospital (DSH) payments starting in October 2013 as one of the Federal funding sources for Medicaid expansion. These payments – a key source of support for hospitals shouldering uncompensated care costs generated by Medicaid and uninsured patients – will be reduced by significant amounts according to the current ACA law. By FY2019, the federal government will cut its support of this critical program by about half. Thus, the conundrum for Georgia hospitals that provide high volumes of care to Medicaid and uninsured patients.

Annual Medicaid Disproportionate Share Hospital (DSH) funding allocations from the Center for Medicare and Medicaid Services (CMS) are awarded to states for the purpose of supplementing payments to those hospitals that provide a particularly high level of care to low-income and uninsured individuals. The DSH program was created in 1981 when Congress recognized that hospitals serving a disproportionate share of the nation's poor needed additional financial support to fulfill their missions. In 2012, Georgia received $275 million in federal DSH funds. When matched with state funds and intergovernmental transfers, DSH supported nearly $416 million in care to the needy.

The original intent of the ACA utilizing DSH payments to fund the expansion of Medicaid was that the reduction in DSH funding would be offset by revenues from previously uninsured patients being covered under the Medicaid program. The safety net providers in Georgia now find themselves faced with significant funding cuts without any offsetting revenues through Medicaid expansion. What does this mean for the provision of healthcare to the indigent in Georgia? It means reductions in access to healthcare services and reductions in the scope of clinical services available to uninsured and Medicaid Georgians.

For Grady Health System, it means $45 million in reduced funding per year. If something does change in this complex equation, Grady Health System will find itself making some very difficult decisions regarding what clinical services it can no longer afford to provide to the citizens of Fulton and DeKalb counties. Hometown Health, a network of rural hospitals and healthcare providers in Georgia, anticipates several rural hospitals will have to close their doors if this vital funding is truly reduced, leaving many counties without access to hospital services and a significant loss of employment in these rural communities as these hospitals are often the largest employers in their region.

So, what to do? Some part of this equation has to change or Georgia will find itself in worse shape post-ACA than it did pre-ACA. Either the State of Georgia has to expand Medicaid, or the federal government has to reconsider the significant cuts to DSH outlined in the ACA. As previously mentioned, the State of Georgia has already determined that it cannot afford to expand Medicaid. That leaves us with one option, DSH funding must be reinstated to hospitals that provide high levels of care to Medicaid and unfunded patients.

While the aggregate amount of Medicaid DSH cuts is hardwired into current law, the Secretary of the U.S. Department of Health and Human Services has discretion in the distribution of cuts across states. Given this discretion, it is crucial for regulatory decisions to address the uncertainties created by the imbalance between anticipated uncompensated care needs and the level of federal support to hospitals that shoulder the majority of this work.

The threat of an even greater imbalance created by voluntary Medicaid expansion and guaranteed DSH cuts cannot be justified. If allowed to move forward, this imbalance will have disastrous consequences on the indigent patients of Atlanta and Georgia. The safety net providers across Georgia have come together to address this issue and stand ready to work with Congress to revisit the Medicaid DSH cuts included in the ACA. Specifically, the safety net providers of Georgia believe DSH funding cuts by the ACA should be restored so that we can continue to provide and expand needed services to the uninsured and underinsured of Georgia.

With adequate funding in place, the current network of safety net providers in Atlanta will be better armed to address the healthcare needs of the indigent population. There is much work to be done. Georgia has some of the highest incidence rates for obesity, diabetes, congestive heart failure and AIDS. It is only through a tightly woven network of dedicated and qualified healthcare entities and providers working together to address the root causes of these conditions that we can continue to improve the overall health in Atlanta and Georgia. ■

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John Haupert is President and CEO of Grady Health System in Atlanta. Prior to becoming CEO at Grady in 2011 he was in Texas, where his career in healthcare management began at Methodist Health System in Dallas in 1992. He served for 14 years in various roles, including president of one of the system's hospitals and as executive vice president for corporate services and business development. In October 2006, Haupert left the Methodist Health System to become the COO at Parkland. He is a Fellow in the American College of Healthcare Executives and recipient of the ACHE Regent's Leadership Award.

5 Biggest Challenges Physicians Face Today

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Informing and Influencing Health Policy and Practice

The Satcher Health Leadership Institute's Transdisciplinary Collaborative Center for Health Disparities

By Rachel Harris, M.D., MPH, Elizabeth Ofili, M.D., FACC and David Satcher, M.D., Ph.D

The Determinants of Health are the "range of personal, social, economic and environmental factors that influence health status" and involve the interaction between policy making, social factors, health services, individual behavior and biology/genetics.[1] The World Health Organization, Centers for Disease Control and Prevention, Department of Health and Human Services, as well as numerous state and local level agencies have led the way in redefining care of healthy populations to include social factors that address inequities and the physical conditions in the environment in which people are born, live, learn, play, work and age.[2,3]

The 2011 National Healthcare Quality Report by the Agency for Healthcare Research and Quality (AHRQ) found overall healthcare quality has improved for the general population between the years of 2002 to 2008. However, of the 250 healthcare measures tracked, there are persistent challenges in access to healthcare among racial and ethnic minorities, with 50 percent showing no improvement in this population as well as 40 percent of the core measures in this group declining.[4]

Keeping with the mission to reduce and ultimately eliminate disparities in health

The Satcher Health Leadership Institute (SHLI) at Morehouse School of Medicine (MSM) was established in 2006 to develop a diverse group of public health leaders, foster and support leadership strategies, and influence policies toward the reduction and ultimate elimination of disparities in health. Led by David Satcher, M.D., Ph.D., and a team of dedicated faculty and staff, the Institute has several programs, including the Center of Excellence for Sexual Health; Community Voices: Healthcare for the Underserved; the Division of Behavioral Health; the Division of Health Policy; and the Division of Health Promotion and Disease Prevention.

The role of SHLI/MSM in caring for the underserved is a pivotal one, not simply from the individual provider-patient standpoint, but also from the national and local perspective of healthcare leadership and policy. In keeping with the mission to reduce and ultimately eliminate disparities in health, the formula for continued success is by focusing on neglected diseases and underserved populations, while giving priority to health promotion and disease prevention.

In examining underserved populations, there are several factors that contribute to inequities: Individuals with inadequate access to healthcare providers who meet their needs, low socioeconomic status, lack of insurance or affordable access to medical care, and limited English proficiency and health literacy have the most health disparities, with ethnic and racial minority groups frequently found among this population.[4]

The SHLI/MSM will implement a regional approach to address persistent health inequities by leading a Health Policy Transdisciplinary Collaborative Center (TCC) for Health Disparities Research, with the unifying theme of a comprehensive and meaningful approach to the development, advancement and implementation of health policy that harnesses the power of collaboration to bolster innovation, cost reduction and health equity. This recent award by the National Institute on Minority Health and Health Disparities (NIMHD) has been an honor and great achievement by the faculty, researchers and community at large. The TCC will focus on collaborations in the Health and Human Services' (HHS) region IV, which encompasses Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee.

The SHLI/MSM TCC and its partners will address social inequities that affect child outcomes, mental health and health outcomes in vulnerable and high-risk populations, as well as continued implementation of health information technology "meaningful use" through academic/community partnerships.

Child Outcomes

Actions to reduce health disparities must start before birth and continue through the lifespan to reduce inequities due to socioeconomic status or disparate opportunities that deprive a fair and healthy start for all children. Evidence has shown a strong association between poverty and health disparities, including mental health, education and child outcomes.[5] Additional evidence from neuroscience and early childhood development research has shown that early childhood, particularly a child's first five years, lays the foundation necessary for the complex skills they will need as adults to become successfully employed, lawful, cooperative and productive.[6]

Demonstrable evidence shows that even when policies are in place, written policies alone do not adequately address health inequities until they are supported with effective local delivery systems and community participatory action. Thus, to effectively reduce and ultimately eliminate disparities, the SHLI/MSM TCC will engage nine states' members of the Centers for Disease Control and Prevention's Racial and Ethnic Health Disparities Action Institute (REHDAI) to evaluate the extent to which the outcomes of quality parenting impacts healthy child development, and how state and local policies ensure that every child receives quality parenting and early child development through supportive programs and public service delivery systems with community participation in decision-making.

Mental Health and Health Outcomes

Addressing the multi-faceted health and mental health needs of the U.S. population is a complex issue that warrants attention from policymakers, clinicians, researchers, scientists and public health professionals that can offer unique perspectives and strategies to support efforts for greater well-being among individuals.

With growing diversity concerning different ethnicities, nationalities and sexual orientation and with significant changes in the constellation of the myriad of risk factors that can influence health and health outcomes, it is imperative that we delineate strategic health policies, focused community-based programs and innovative research that include an examination of evidence-based models that can improve individuals' longevity and quality of life. These issues have particular relevance for vulnerable and high-risk populations, including veterans, ex-offenders, uninsured, homeless individuals; lesbian, gay, bi-sexual and transgender individuals (LGBT); and racial/ethnic minorities.

There are several key pieces of federal legislation passed by Congress that were designed to have positive health and behavioral health implications for underserved populations, including the Mental Health Parity Act (1996), Second Chance Act (2008), Mental Health Parity and Addiction Equity Act (2008), and the Patient Protection and Affordable Care Act (2010). Although collectively these health policies support the promotion of better access and utilization of health and behavioral healthcare services, the extent to which policies related to these legislative mandates are implemented remains questionable, and health disparities continue to plague our communities. The SHLI/TCC will implement strategies that integrate mental health in primary care practice settings. Through novel culturally centered approaches targeted to ethnically and culturally diverse adults, the goals of reducing health and mental health disparities, improving health equity and enhancing the quality of life for individuals, families and communities will be accomplished.

Health Information Technology

Using shared learning to enhance academic/community partnerships by leveraging Health Information Technology (HIT) is crucial in developing, informing and implementing public policies that impact health disparities relative to healthcare quality improvement. The use of shared information in underserved or understudied populations has been successfully implemented in a multi-institutional, multidisciplinary collaboratory model with a focus on key diseases and health conditions that disproportionately and adversely exist among racial and ethnic minorities.[7]

This model of information sharing has helped in professional validation, transdisciplinary integration and improved communication/interventions and as a result has had policy implications and improved health outcomes.[8] Key areas for quality improvement measures include insurance delivery and payment system reforms, health promotion and disease prevention, appropriate data collection and reporting, and comparative effectiveness research based on the health equity agenda of the Affordable Care Act.

Future Leaders

The SHLI currently has two SHLI health policy training programs: SHLI Health Policy Leadership Fellowship Program for postdoctoral professionals and the SHLI Community Health Leadership Program for community leaders and students.

Since its inception, the SHLI Health Policy Leadership Fellowship 10-month program for postdoctoral professionals has 13 alumni and five current fellows, with numerous additional previous summer program and workshop attendees. It is the goal of the fellowship program to develop a diverse group of health leaders who "care enough, know enough, do enough and are persistent enough" to help realize global health equity.

The Community Health Leadership Program (CHLP) is a 12-session program focused on developing community health leaders with an interactive and community-based curriculum. An important part of the CHLP curriculum is its community-based research and practicum component. The community participants and MSM MPH students partner in developing community projects that must be relevant to community needs, show evidence of sustainability and impact health disparities.

Through a coordinated effort to identify health policy leaders' training needs for developing, implementing and changing policies to address disparities in health, the SHLI will continue to work on the behalf of millions of Americans who are affected daily by disparate health challenges and outcomes.

Reducing health inequities is, for the Commission on Social Determinants of Health, an ethical imperative that is shared by the Satcher Health Leadership Institute. The SHLI/MSM TCC proposes transformative health policy goals that will positively impact and sustain health equity across this regional transdisciplinary collaborative.

The ultimate goal of the SHLI is emerging as the preeminent, national health policy center focused on innovation, cost reduction and health equity; emerging as the 'collaborator of choice' in leading-edge health policy research focused on health equity; training the next generation of leaders in health policy research; and expanding the diversity of the health policy workforce. SHLI TCC and its partners across HHS Region IV will significantly impact the health outcomes of participating communities through policy development and implementation. ■

For more information, visit www.msm.edu/research/research_centersandinstitutes/SHLI.aspx.

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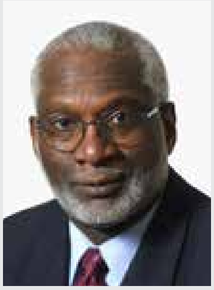
Rachel Harris, M.D., MPH, joined the faculty of Morehouse School of Medicine, Section of Cardiology as an Assistant Professor in July 2011 and as Staff Cardiologist at the Atlanta VA Women's Center of Excellence East Point Outpatient Clinic in September 2012. She serves as one of the Morehouse School of Medicine Internal Medicine Residency Associate Program Directors. Dr. Harris is Board Certified in Cardiovascular Diseases, Internal Medicine, Nuclear Cardiology and Echocardiography. She serves as the Echocardiography Lab Co-Director at Grady Memorial Hospital.



David Satcher, M.D., PhD is Director of The Satcher Health Leadership Institute which was established in 2006 at the Morehouse School of Medicine in Atlanta, Georgia. Dr. Satcher was sworn in as the 16th Surgeon General of the United States in 1998 and served until 2002. He also served as the 10th Assistant Secretary for Health in the Department of Health and Human Services making him only the second person in history to have held both positions simultaneously. His tenure of public service also includes serving as Director of the Centers for Disease Control and Prevention (CDC). Dr. Satcher has held top leadership positions at the Charles R. Drew University for Medicine and Science, Meharry Medical College, and the Morehouse School of Medicine.

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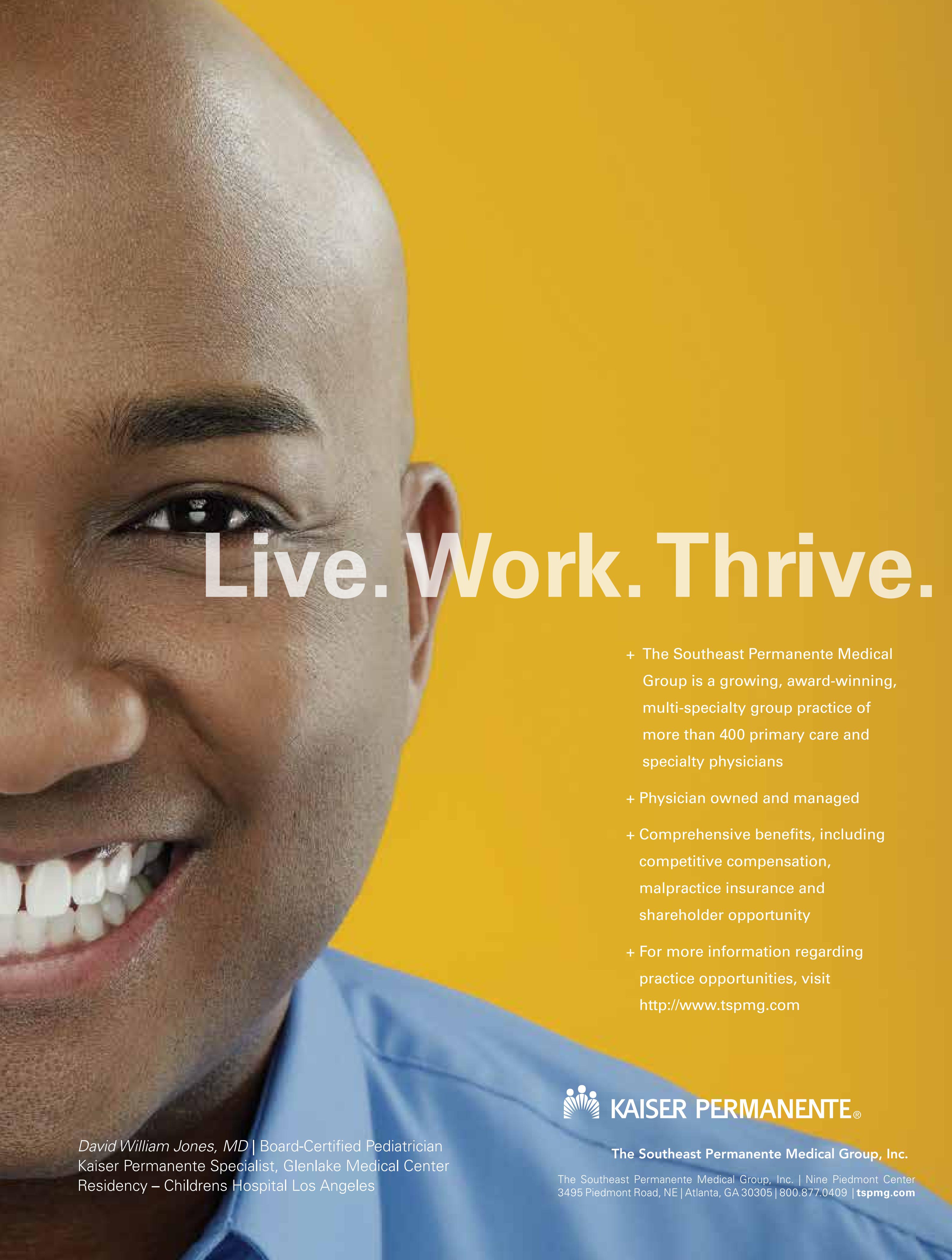
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Morehouse School of Medicine Prevention Research Center

Collaborating with Neighborhoods to Develop Community-Based Participatory Approaches to Address Health Disparities in Metropolitan Atlanta

By Tabia Henry Akintobi, PhD, MPH, Lisa M. Goodin, MBA and LaShawn M. Hoffman

Socioeconomic status and ethnicity have been associated with a variety of health outcomes. Blacks have disproportionately higher morbidity and mortality associated with cardiovascular disease, cancer, homicide, diabetes and HIV/AIDS. These persistent trends help to explain the increased focus of public health research agendas on ethnic disparities in health.

Many clinicians and researchers agree that social and environmental factors are crucial to understanding and addressing the determinants of health outcomes that increase the likelihood of mortality and morbidity across the lifespan. Historically, academic research in communities existed in which the academic institution received significant benefit; however, the community held no control of research projects and tended not to receive any benefit.

Often times, this led to the community's distrust of researchers in communities and the communities' ultimate lack of participation in research programs[1]. The evolution and application of community-based participatory research (CBPR) in communities has led to increased research participation and community ownership globally. The Morehouse School of Medicine Prevention Research Center (PRC) has empowered representatives of metropolitan Atlanta Neighborhood Planning Units (NPUs) to define their research, service and education needs to address the health of their neighborhoods.

The PRC was established in 1998 and based on the applied definition of CBPR, where research is conducted with communities in a partnership relationship. This contrasts with the older approach to community-based research in which research was conducted on communities in an arrangement that often resulted in exploitation of the communities.

This positioning of communities as central to identifying their own health priorities is directly aligned with Morehouse School of Medicine's prioritization of service to the underserved. The PRC's research partner communities are located within City of Atlanta NPUs V, X, Y and Z. Each City of Atlanta NPU contains five to 10 well-defined neighborhoods. Each elects officers and holds monthly public meetings to discuss relevant and timely issues of importance to its residents (i.e. city zoning, economic and civic development, etc). The total population of PRC's partnering communities in NPU V, X, Y and Z is 55,757, with 89.3 percent (48,701) being African Americans. 40.9 percent of African-American households within the four aforementioned NPUs live below the poverty level[2].

Community-Prioritized Governance in Setting Health Agendas

The PRC's partnering NPUs have been faced with increased poverty for decades, a lack of neighborhood resources and a plague of chronic diseases, so historically they have maintained a basic distrust in the research process. Several residents expressed their apprehension about participating in yet another partnership with an academic institution to conduct more meaningless research in their neighborhoods[3]. So at the outset, the PRC created a governance model in which the community would serve as the "senior partner" in its relationship with the medical school and other academic and agency collaborators.

The PRC is governed by a Community Coalition Board (CCB), to which all the identified partners belong, but community representatives hold the preponderance of power, literally putting them at the forefront of all CBPR and related approaches. Board members, including academic, agency and neighborhood representatives, truly represent the community and its priorities. Academic representatives include the faculty and staff that are frequently engaged in carrying out the research service or training initiatives affiliated with the PRC. Agency staff (e.g., health department staff, school board representative) may not live in the community where they work, but their agencies serve the communities. Their input has value but represents the goals and objectives of their organization, rather than the lived experience of a resident. Residents of the community – "neighborhood representatives" – are in the majority, and one always serves as Board Chair, as opposed to agency or academic members of the CCB. The PRC'S CCB serves as a policy-making board– not an advisory board, which has created an opportunity for community partners to have an active voice in directing the operations of and sustainability for the Center.

Morehouse School of Medicine
PREVENTION RESEARCH CENTER

The roles of The CCB are to: (a) set policy and oversee the operations of the center; (b) identify priorities and approve projects; (c) provide information on center activities to the organizations and agencies represented on the Board; and (d) develop a strategic plan by which the Center may achieve its long-term objectives. The CCB established and ratified bylaws that provide a written blueprint for the governing body. Subsequently, the CCB articulated its values and priorities through the development, adoption and enforcement of community values, research priorities and evaluation criteria for projects.

The governance of the research partnership is largely through consensus decision making, in which CCB members prioritize critical needs, review them, discuss appropriate solutions and cast a vote during its bimonthly meetings. All decisions are based upon the Board's charge that all research – past, present and future – is packaged in simple ways for everyone to understand and is disseminated to individuals, communities, organizations and institutions in partnership with the PRC and its partners. Therefore, projects, if successful: 1) will contribute to a reduction in the disparity in health status between the white population and the African American or other minority population; 2) will contribute to improving the health status of African American males; and 3) will reduce injustice, including environmental injustice.

Establishment of a governing body that ensures community-engaged research can be challenging when: 1) academicians have not previously been guided by neighborhood experts in the evolution of a community's own natural environment, 2) community members have not led discussions regarding their health priorities, or 3) academic, agency and neighborhood experts have not historically worked together as a single body with established rules guiding roles and function. The PRC, however, has successfully engaged in community-research partnerships that have been sustained for more than a decade[3].

According to the former CCB Chair, Ella Heard Trammell, community members allow researchers conditional access to communities in order to engage in research, training and/or service initiatives with established community benefit. To that end, engagement of community partners involves an investment of time, dialogue, compromise and consensus toward selective participation in activities with bi-directional value. The PRC's ability to actively engage the CCB in a meaningful way (where they see value in the Center's work and positive impacts within their communities) has led to the retention of community partners since the PRC was founded.

Community health priorities assessment surveys are conducted by the PRC staff and partnering communities at least every two years. CCB members are trained to conduct the surveys in their communities, and the results are disseminated throughout community-based venues, e.g., CCB and NPU meetings; PRC newsletters, website; and via CCB member communication in their communities.

PRC core research and other PRC projects are also developed specifically in response to priorities identified through the assessment surveys. The most recent (and prior) community health needs assessments identified HIV/AIDS prevention as the top priority, with cancer and heart disease/stroke prevention following closely. Therefore all MSM PRC core research projects target HIV/AIDS prevention among African Americans including the projects titled HIV/AIDS Prevention among African American Women [1998-2004]; HIV/AIDS Risk Reduction among Heterosexually Active African American Men and Women: A Risk Reduction Prevention Project (2004-2009); and Prevention Intervention: Meeting Them at the Gate (An African American male targeted detainee release HIV/AIDS prevention project, 2004-2014). Cancer research projects were also sought, written with CCB review and recommendations, resulting in funding of cancer-focused projects like the Cancer Prevention and Control Research Network (2004-2009), Ethno-cultural and Regional Variations in Prostate Cancer Knowledge, Attitudes and Screening Behaviors of African American and Jamaican Black Men (2006-2010), and the Southeastern United States Collaborative Center for the Elimination of Health Disparities (SUCCEED), which focused on breast and cervical cancer screening (2007-2012), and the Colorectal Cancer Screening Intervention Project (2004-2009).

These projects were incorporated into the expansion of the PRC research design by developing the PRC Community-based Cancer Unit, which is also advised by the CCB and works in tandem with the Atlanta Cancer Awareness Partnership (a city-wide community board that guides cancer research efforts) to increase its cancer-focused outreach in communities.

The PRC is an award-winning center that has been nationally recognized for its sustained collaborations with the CCB in effective community-based participatory research (CBPR). The organization Community-Campus Partnerships for Health honored the PRC in 2002 in recognition of the

Mr. David Collins, Assistant Director for Community Development, interacting with new CCB members

Center's community partnership's "exemplary contribution towards improving health professions education, civic responsibility, and the overall health of communities." A Certificate of Appreciation for "outstanding dedication to communities with the REACH for Wellness Program" was awarded by the Fulton County Department of Health and Wellness in 2005. Georgia Healthcare Foundation's presented the PRC with its 2010 Joseph D. Greene Community Service Award for "continued extraordinary commitment to improving the quality of health."

The PRC also received four Centers for Disease Control and Prevention (CDC) awards: Outstanding Community-Based Participatory Research Award in 2004, Award for Excellence in Community-Based Research in 2005[4]; an award for effective implementation of CBPR in 2010, and Best Practice Award in Community-Based Participatory Research in April 2011.

Community Partner Benefits

The employment of community persons on the core HIV research projects is a tangible benefit of the community's participation as a partner. Other benefits community members have gained are research development, training and evaluation of core HIV research skills through training by PRC researchers and staff. Further, community-based radio broadcasts on a local Atlanta radio station, WYZE 1480 AM, have facilitated real-time dialogue between metropolitan Atlanta community members and researchers to increase awareness regarding HIV and other community health issues through which communities can be empowered to improve their health. Other benefits have been the creation or expansion of jobs and health promotion initiatives through grants for community-led health initiatives, like the recent award of the Minority Men's Oral Health and Dental Access Program – a community-campus project led by a community-based organizations, funded to increase an understanding of oral health issues and to increase access to oral healthcare among African-American men living in NPUs V, X, Y and Z.

An expansion of the research goals beyond HIV afforded the PRC with an opportunity to apply for and receive diverse grant funding, resulting in other projects benefitting the community. One such program involved decreasing the "digital divide" among communities in which few people had computers. Now the community area has a technology center that is still operational. This allows people in the community who did not have access to computers and the internet with the opportunity to expand their knowledge and develop skills to improve their standard of living. The Colorectal Cancer Screening Intervention Project involved seniors in an education series on colon cancer screening tests. The information was disseminated to senior citizens facilities, recreational centers, YMCAs and churches in PRC's partnering communities. The funding of evaluation projects has led to the establishment of our Evaluation Unit, in which evaluation leadership in partnership with community-based organizations has resulted in communities' capacity to assess their own programs.

Academic Partner Benefits

The implementation of the CBPR model has been the cornerstone of the PRC's success in building effective community-campus partnerships. This model is being used as the guide for other federally and privately funded grants that foster community-driven health initiatives designed to

LaShawn Hoffman, MSM PRC CCB Chair, interacting with community residents at Meet and Greet.

addressing health disparities and to also guide researchers on the processes critical to effective CBPR.

For example, the Community Engagement and Research Program (CERP), through the Atlanta Clinical and Translational Science Institute, funded by the National Institutes of Health to Emory University, is led by the PRC. CERP unites existing academic community research partnerships, develops new bi-directional collaborations and seeks to transform research from a scientist-subject interaction that generates publishable data to a more equitable partnership - one in which the process of research, as well as the outcomes, benefit both the researchers and the community.

The PRC also leads the Community Engagement Core for the National Institutes of Health-funded Center of Excellence in Health Disparities-Reducing Health Disparities in Vulnerable African American Families and Communities. The grant has the overriding goal of building the capacity of partner communities to reduce racial and ethnic health disparities through systematic engagement in the planning, implementation and evaluation of CBPR through health priority assessment, advising community-engaged research, and connecting families to medical homes.

Researchers that work with community coalitions utilizing a participatory approach build trust and a sense of ownership of the prioritized health issues through identifying the most culturally relevant approaches. While not without challenges due to differing priorities and being accountabilities[5], major lessons learned are that: 1) community partnerships are developed over months or years, and therefore should not ideally depend on a single grant, and 2) genuine partnership means resources and control are shared and that academic partners must be prepared to share funds or to serve in a support role with communities serving as fiscal agents for the health initiatives that they lead[6].

The effective use of CBPR has helped the PRC and the CCB to develop collaborative solutions that have brought the community and the institution together as equal partners in developing targeted approaches to addressing health disparities. ■

For more information, visit www.msm.edu/prc.

Acknowledgement

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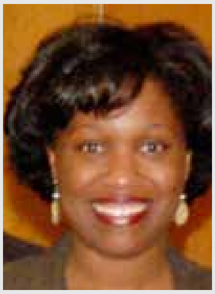

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LaShawn M. Hoffman is one of Atlanta’s most distinguished young civic leaders. He currently serves as Chief Executive Officer of the Pittsburgh Community Improvement Association, Inc. (PCIA) a neighborhood-based not for profit community development corporation. Through his leadership, PCIA is preparing for thoughtful development, both human and physical, as the Pittsburgh community embraces a city that is constantly changing. LaShawn’s other numerous civic activities includes Chairperson for the Morehouse School of Medicine Prevention Research Coalition Community Board.

Healthcare Without Walls

A Medical Home for Homeless Children

By Debra Hughes, MS and Yasmin Tyler-Hill, M.D., FAAP

Dr. Tyler-Hill in clinic with newborn

**Imagine you have no home.
Your daughter is sick.
Where do you take her?**

For most homeless women, the local emergency room is the healthcare provider of choice for one simple reason: they have no other choice.

For women at the Mary Hall Freedom House – who have previously lived on the street, in tent cities, with friends or in their cars – their children have Healthcare Without Walls: A Medical Home for Homeless Children.

Healthcare Without Walls is a medical home with both heart and passion, and its most passionate proponents are I. Leslie Rubin, M.D., president and founder of the Innovative Solutions for Disadvantage and Disability (formerly Institute for the Study of Disadvantage and Disability), an Atlanta-based private, not-for-profit institute, and research associate professor in the department of pediatrics at Morehouse School of Medicine; Lucy Hall-Gainer, founder and president, Mary Hall Freedom House, Inc.; Yasmin Tyler-Hill, M.D., interim chair of the department of pediatrics at Morehouse School of Medicine; and Janice Nodvin, program director for ISDD and administrator of the Healthcare Without Walls Project.

In areas of affluence, there are pockets of poverty. For Dr. Rubin, this was most telling in the homeless children he treated with developmental disabilities including cerebral palsy, one of his areas of specialty. He found that children who are homeless are at high risk for adverse health, developmental, educational and social outcomes because they are likely to have been exposed to stresses before, during and after birth and also face multiple physical, emotional and social hazards. In addition, children treated in the emergency room do not receive comprehensive care, including immunizations or health or developmental screenings.

For Lucy Hall, her experience was personal. Her mother, Mary Hall, for whom the program is named, died of alcoholism when Lucy was six years old. She left seven children, some of whom later lost their lives to substance abuse. Lucy herself abused drugs and alcohol for 10 years, but when she became pregnant with her daughter, she became sober and to date has helped more than 3,500 women and children break the cycle of generational addiction, poverty and homelessness.

And for Dr. Tyler-Hill, it simply made sense to provide healthcare services for children who otherwise would have none, except for trips to the emergency room.

Their collaboration began when a Mary Hall Freedom House board member told Dr. Rubin about Lucy Hall; Hall subsequently attended a “Break the Cycle” conference put on by ISDD. When she met Dr. Rubin, they decided to work together to improve the health and well being of the children living with their mothers at the Mary Hall Freedom House.

“From the day I met him, I kept telling him about the services that these children needed,” Hall says. Drs. Rubin and Tyler-Hill “fell in love with the concept,” Hall adds, and they decided to seek a grant.

On March 1, 2010, the Maternal and Child Health Bureau of the U.S. Health Resources Services Administration and the American Academy of Pediatrics awarded a five-year, $250,000 Healthy Tomorrows grant to the ISDD, for Healthcare Without Walls: A Medical Home for Homeless Children, the first such grant awarded to Georgia in 17 years.

The goal of the Healthy Tomorrows grant is to provide seed money for an unusual idea that will flourish through involvement from community partners. Healthcare Without Walls is now in its fourth year collaborating with the Department of Pediatrics at Morehouse School of Medicine, Children's Healthcare of Atlanta – Hughes Spalding Hospital (CHOA), and the Rollins School of Public Health at Emory University to provide a medical home for children, both at the Mary Hall Freedom House in Sandy Springs and CHOA Hughes-Spalding clinics. In addition, they are working with Childkind (a social service and support program in Atlanta) to train mothers in health literacy so they know when their children are sick and how to navigate the healthcare system.

Dr. Rubin and Dr. Dunston – Dr. Rubin receiving AAP Calvin C.J. Sia Community Pediatrics Medical Home Leadership and Advocacy Award (summer 2012)

The program employs the American Academy of Pediatrics Medical Home practices and Bright Futures guidelines to help ensure this group of vulnerable children receives healthcare that is consistent, continuous, coordinated, comprehensive, community-based, family-centered and culturally sensitive.

"Our goal is to try to build into our program a sense of continuity, to build into the lives of the women and children confidence and empowerment and to redirect their energies so they focus on their children, rather than the lifestyles into which they had drifted," says Dr. Rubin.

The mothers who reside at the Mary Hall Freedom House – which is, in fact, several residences throughout the Atlanta metropolitan area comprising emergency, transitional and permanent housing for homeless women – love their children and try to do their best for them, says Dr. Tyler-Hill, who runs the Mary Hall Freedom House and CHOA clinics. But most are struggling with the effects of psychological, physical and sexual abuse; unmet mental health needs; and self-medicating substance abuse.

In some cases, the abuse – and substance abuse – is multigenerational, and the mothers may never have learned tactics to care for their children. A two-year-old girl with behavioral problems was diagnosed as hard of hearing after her mother failed to pick up cues she wasn't acting normally, Dr. Tyler-Hill says. A boy of six who was incontinent and had undergone extensive testing in the emergency room with normal results was taught to ask to go to the bathroom and his mother advised to be less fixated on his behavior, with successful results.

Some women may have limited formal schooling. Others may be frightened they will be judged to be unfit and their children will be taken away. Still others may have been incarcerated and are being reunited with their children. Women who participate in the behavioral health program offered at Mary Hill Freedom House are either recommended or commit themselves to the program to end their substance abuse. According to Nodvin, it is one of the few programs where mothers can keep their children with them.

As a pediatrician, Dr. Tyler-Hill not only provides healthcare for children but helps the mothers understand what a relationship with a doctor should be like: to expect respect, have their care managed and have high expectations of a medical system. Morehouse School of Medicine pediatric residents also provide care at the clinics, which in effect serve as training sites, says Nodvin.

Feedback from the mothers suggest that they feel comfortable with a physician, many for the first time.

"Dr. Hill has been great to my son … and answered all of my questions," says Lisa, a resident at the Mary Hall Freedom House.

During the first clinic visit, each child undergoes an initial examination, including questionnaires to determine if he or she has any unmet acute or chronic medical needs. Plans are drawn up to address long-term healthcare concerns, such as developmental issues, and referrals are made to specialists.

Lula Cullen, assistant program director for Healthcare Without Walls who lives at Mary Hall Freedom House in Sandy Springs, serves as the onsite coordinator between the mothers and Dr. Tyler-Hill so that any immediate needs can be addressed. For example, one evening during the middle of the flu season, Dr. Tyler-Hill, who lives in the area, added an unscheduled clinic to examine seven children, saving them all a trip to the emergency room.

A key to ongoing success is maternal health literacy training. To ensure mothers become more proficient in healthcare, Childkind social workers Joe Sarra and Christina Mahoney provide a curriculum that focuses on access to medical services, good prenatal care, nutritional issues, healthcare for infants, toddlers and children, and that helps differentiate between illnesses that do and do not require emergency care.

To date, Healthcare Without Walls has served approximately 100 mothers and 130 children, which has included helping them secure Medicaid insurance. The majority of women reside at the Mary Hall Freedom House from six months to a year. Once they leave, however, their children can continue to be seen at the Healthcare Without Walls clinics.

Laurie Gaydos, Ph.D., assistant professor of health policy and management at the Rollins School of Public Health, is using formal questionnaires to evaluate the effect the supportive services provided by Healthcare Without Walls has on the women. A future goal is to develop a permanent community-based clinic continuing the theme of A Medical Home for Homeless Children to provide continuous, coordinated care. Hall urges professionals to leave their traditional settings to bring services to those who need them.

The ISDD is a recipient of the Rollins School of Public Health 2013 Martin Luther King Jr. Community Service Award and, in October 2012, Dr. Rubin received the American Academy of Pediatrics Calvin C. J. Sia, M.D., Community Pediatrics Medical Home Leadership & Advocacy Award.

Founded by Dr. Rubin in 2004, ISDD's mission is to promote health equity among children living in social and economic disadvantage with or at risk for disability. In addition to Healthcare Without Walls, ISDD is home to Project GRANDD, a program that provides a network of support to grandparents in the greater metropolitan Atlanta who are raising grandchildren who have disabilities, chronic illness and behavior or learning difficulties. ISDD also has an annual program called Break the Cycle, which invites university students to develop projects that will break the cycle of disadvantage and disability and help children who live in an environment of social and economic disadvantage to lead healthier and more productive lives. ■

For more information: www.isdd-home.org.

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Ethical Challenges in Clinical Research with Low-Resource Populations

By Jason Lesandrini, MA and Neal Dickert, M.D., Ph.D.

Clinical research in low-resource settings involves numerous ethical complexities. The legacy of clear historical abuses such as the infamous Tuskegee Syphilis Experiments cannot be ignored, but today's researchers working to address important problems in underserved populations face challenges that are more subtle and that sometimes lack obvious solutions.

There is, for example, a clear need to include all types of individuals in research in order to ensure that data are generalizable to populations in whom the treatment will be used. Under-enrollment of poor and often minority patients in clinical trials thus may have scientific consequences and may result in lack of access to important innovations. Moreover, many conditions preferentially affect low-income populations; including those populations in research is essential to advancement of care. There are, however, important ethical challenges – many related to potential for exploitation – of which researchers are acutely aware and which require careful attention in balancing the need for research with the need for appropriate protections.

The challenges of research in low-resource settings are made more difficult by the lack of guidance provided by either federal regulations or major guideline documents. In many respects, those in low-resource settings may be considered vulnerable, with "diminished ability to protect [their] own interest, manifested by a compromised capacity to give informed consent" (Grady, 2009). Guidelines call for extra protections for vulnerable participants to guard against exploitation or maltreatment. However, the extent to which low-income populations are appropriately considered vulnerable has been the subject of some dispute, and it is often challenging to define appropriate and necessary levels of protection (Iltis, Wall, Lesandrini, Rangel, & Chibnall, 2009).

The following examples represent some of the ethically challenging situations that researchers commonly encounter when conducting clinical research in low-resource settings. Importantly, they illustrate some of the complexities of these situations and the particular challenges of disentangling the ethical challenges of research from background injustice and disadvantage.

Payment for research participation

A 35-year-old African-American woman (Suzie) with lupus, hypertension and recurrent GI bleeds is considering enrolling in a Phase III, placebo-controlled trial of drug X in treatment of lupus to which her primary care physician, Dr. Smith, has referred her. Suzie currently does not have insurance and does not qualify for Medicaid or Medicare. She has no children, never completed high school and has a part-time job making minimum wage. Her last primary care visit cost her $300 out of pocket, with $100 for the office visit and the rest going to labs for lupus workup.

Suzie reads over the consent form for the study, and it appears that the drug being studied has shown promise in reducing lupus flares in preliminary human studies. Moreover, it appears to be relatively safe; the most significant side effect appears to be that a small number of patients in early-phase studies were found to have low blood counts (mild bone marrow suppression) that appeared to resolve after the drug was stopped. She also notices that the study will cover the cost of her office visits for the two-year study period and involves routine monitoring of labs for which she normally has to pay. Finally, she will receive $50 per visit for participation.

She decides to sign up for the study, principally because she can get regular care for free with some potential for disease improvement if the study drug is helpful and some extra money that she can certainly use to help cover her expenses. Suzie thinks research is a good idea in general, but she would not have signed up for the study in the absence of payment or free healthcare. She knows that this represents a good deal for her and feels she can't turn it down.

Situations like Suzie's are common when potential subjects have limited financial resources or access to healthcare services. These situations cause thoughtful investigators and review board members significant worry. Excluding patients like Suzie seems inappropriate because it denies an opportunity to participate in research, runs the risk of under-representing important segments of the population in clinical trials, and fails to respect Suzie's ability to make decisions for herself. However, many worry that patients like Suzie are being exploited or "unduly induced" to participate. Concerns about exploitation and undue inducement are central considerations, but they are different concerns, and appreciating them as distinct can help to clarify when there is a problem.

Exploitation has been most clearly defined as "taking unfair advantage"(Wertheimer, 1996) of another person. Exploitative situations are classically those in which people with few resources are "paid" less than their services are worth (e.g. sweatshop labor). The key issue in determining whether Suzie is being exploited, then, is whether the research study somehow represents an unfair distribution of benefits, burdens and risks.

In Suzie's case, the study covers all of her expenses associated with the trial, offers a small payment for her time and does not appear to pose inordinate or inappropriate risks. It does not seem to be "taking unfair advantage" of her by offering her less than is ethically required simply because Suzie is poor and in a bad bargaining position. The key practical issue in determining whether a study is exploitative is generally sorting out whether a study offers subjects enough in the way of benefits rather than whether it offers too much. While the fact that someone is poor makes them more vulnerable to exploitation, it does not make a situation exploitative unless the offer is unfair.

People may take inordinate risks in exchange for monetary benefit

Undue inducement concerns, on the other hand, center around whether offers of study participation are so attractive that they somehow lead people to make uninformed decisions about participation or compromise the extent to which enrollment decisions are voluntary. It was assumed for years that any kind of payment to patients like Suzie represented undue inducement. After all, how could Suzie refuse participation when it offers her free healthcare and extra money that she badly needs?

In fact, Suzie's own reasoning could be seen to support this claim; she feels she "can't turn this down." However, there is nothing to suggest that Suzie doesn't understand the study; rather, she seems clear about what it involves. Similarly, in recognizing that she can't turn it down, she isn't necessarily acting involuntarily; she simply recognizes that participation makes sense given her situation. Most importantly, removing this opportunity by excluding her from enrollment because of her financial situation hardly expands her options and fails to recognize her ability to make decisions and weigh risks and benefits for herself. Similarly, lowering the "offer" to make it less attractive runs the risk of making a previously fair offer exploitative and, from Suzie's perspective, hardly does her any favors. How many of us, if offered an opportunity to make extra money performing a clinical service, for example, would appreciate having the payment reduced so that we are not unduly induced to accept the offer?

Interestingly, while the impact of payment and other offers on research enrollment decisions is not well-studied, available data in recent years do suggest that payment for research participation in fact may not distort decision-making or reduce subjects' understanding of trials in which they enroll. In fact, several studies have suggested that potential subjects may take more time reviewing information or may consider risks to be higher when they are offered money to participate (Halpern, 2011). More data on these issues are needed, but the claim that payment, in whatever form, to patients like Suzie necessarily represents undue inducement is not supported by evidence.

In addition to issues of exploitation and undue inducement, there are concerns that payment may lead people to hide relevant information about themselves in order to be eligible for a study. There are also concerns that people may take inordinate risks in exchange for monetary benefit or act in ways that violate important values that they hold.

These issues all warrant further study and do require careful attention, but there are several key lessons from considering cases like Suzie. First, concerns about undue inducement and exploitation exist in tension with each other, and neither is fixed by denying the opportunity to participate. Second, people of all financial positions make tradeoffs between benefits and burdens routinely. Respecting research subjects requires that we recognize this. Finally, studies should be evaluated primarily on whether the risks are justified by the benefits (to science and to enrolled patients); focusing on whether the research is ethically appropriate and safe is probably much more important to protecting subjects than focusing on the extent of payment (Denny & Grady, 2007; Dickert & Grady, 2008).

Consent Issues

A 47-year old wheelchair-bound homeless man, Mr. Holmes, with diabetes mellitus notices a flyer for a study to treat depression in the lobby of his psychiatrist's office building. When he meets his psychiatrist that afternoon he asks her about the study, and she provides him with the name and number to contact for the researcher conducting the study. The study is a Phase III trial of a new combination drug that treats dysthymia. Mr. Holmes has tried antidepressants in the past, but he did not like the side effects, e.g., dry mouth, weight gain, abdominal pain and sexual side effects.

After contacting the researchers, he meets them to complete the necessary forms to enroll in the trial. The researcher provides him with the consent form that details the standard requirements for consent in their research setting (the purpose of the study, risks, potential benefits, appropriate alternative treatments, a confidentiality statement, a statement about incidental findings and highlighted section about when the subject may be removed from the study or how they may leave the study at any time). For example, the form states, "Your participation in this research project may be terminated by your doctor without your consent if you are not benefiting from the treatment/procedure, or if the treatment/procedure is determined to be inappropriate to your case. You may also be terminated from participation at any time, at the study physician's discretion, for any reason he/she deems appropriate" (Paasche-Orlow, Taylor, & Brancati, 2003).

Consent forms use boilerplate language that is written beyond the American health literacy level.

After reviewing the form for three minutes and being asked if he has questions, Mr. Holmes signs the form and agrees to participate in the trial. The primary investigator (PI) conducting the study later learns that Mr. Holmes' has enrolled in the trial and is worried about Mr. Holmes' ability to understand the study, especially some of the specifics in the consent form. While not Mr. Holmes' psychiatrist, the PI knows of Mr. Holmes via interdisciplinary rounds at the local hospital where Mr. Holmes has been admitted for inpatient psychiatric treatment. The PI knows that the patient completed only third grade, doesn't maintain a job and has been recognized at the hospital to have "low health literacy." While he does not want to arbitrarily exclude Mr. Holmes from the study, particularly given the potential for benefit from the new medication, the PI is concerned that Mr. Holmes may not have given adequate consent.

Performing research with patients that have minimal resources commonly creates encounters like the one above. The PI is rightfully worried about including him in the study if he lacks the ability to comprehend the information provided in the consent document, particularly given the fact that the consent document is likely incomprehensible to patients with low health literacy. In addition, the PI is also concerned about the informed consent process, as it appears that Mr. Holmes signed the form without much interaction with the researcher and without much dialogue. Particularly if the conversation did not adequately supplement the consent form, Mr. Holmes may not have provided meaningful consent to participate.

The process of informed consent is often mistakenly thought to be synonymous with the signing of the consent form. However, signing the form is a poor marker for any of the three components of the informed consent process, namely information, comprehension and voluntariness (Flory & Emanuel, 2004). In Mr. Holmes' case, legitimate concerns may arise about all three elements, but perhaps the central concern is whether he has appreciated the information provided to him and evaluated whether the risk and potential benefits associated with the trial are acceptable to him.

It is tempting, in some respects, to assume that someone with Mr. Holmes' level of education, socioeconomic disadvantage and background psychiatric disease is not able to make such a decision. However, decision-making capacity is task-specific and not an all-or-nothing phenomenon. Mr. Holmes' capacity to make this specific decision must be assessed according to the risks, benefits and complexities of the research under consideration (Ganzini, Volicer, Nelson, Fox, & Derse, 2005).

It is all too common that consent forms use boilerplate language that is written beyond the average American health literacy level. One review of IRB consent form templates found that the average readability score of text provided by the IRB was at a 10.6 grade level on a Flesch Kincaid scale (Paasche-Orlow, et al., 2003). Interestingly, despite the fact that IRBs' standards for boilerplate language in consent forms is an eighth grade level or less, "only 8 percent met their own goal, the mean exceeding the stated standard by 2.8 grade levels" (Paasche-Orlow, et al., 2003).

When one considers that the health literacy level of those with limited financial resources is typically basic, such that they have the ability to understand medical instructions written at a fifth grade level or lower (Kutner, United States. Dept. of Education., & National Center for Education Statistics., 2006), enrolling them in research with complex consent forms is a potential problem. This is not to say participants like Mr. Holmes cannot enroll in trials like those described above. Rather, it places an obligation on the researcher to ensure that the consent form and the consent process are adequate to ensure comprehension.

To ensure that adequate informed consent has taken place, the researcher should consider informed consent as a process that includes a dialogue between the researcher and subject. In doing so, the researcher provides space for the participant to engage the researcher with questions, uncertainties and particularities about their situation. Participating in this type of process versus merely having the participant sign a consent form, "has more potential for active engagement and responsiveness to the individual needs of the research participant" (Flory & Emanuel,

2004). Indeed, studies suggest that providing more time for conversation, as well as using tools such as teach-back methods to allow participants to demonstrate their understanding, may improve understanding and thus the validity of consent (Flory & Emanuel, 2004; Kripalani, Bengtzen, Henderson, & Jacobson, 2008).

Ensuring consent in low-resource populations is challenging, but it is a misperception that patients in low-resource settings are unable to provide adequate consent for research trials. Rather, the key is to refocus the consent process away from the form. Unfortunately, other elements of the consent process can often be difficult to monitor. The principal responsibility is thus with investigators to assess whether participants have the cognitive ability to understand the trial and to ensure that conversations adequately communicate relevant trial information in a way that participants can understand.

Do clinical investigators have an obligation to help meet these unmet needs?

Post-trial treatment and ancillary care responsibilities

The infectious disease division of a local urban medical center is conducting an industry-funded Phase II open-label preliminary efficacy study of a new anti-retroviral medication for HIV in patients whose disease has been resistant to standard therapy. The study involves 12 months of treatment, during which subjects are monitored for side effects and for lab parameters of disease activity (CD4 counts and viral load). The trial is nearing completion, and the preliminary data are promising. Many patients appear to have had a significant reduction in their viral load and improvements in CD4 counts, though some have continued to have disease progression and have even developed opportunistic infections during the study period.

The investigators are now concerned about two issues. First, they wonder what their obligations are to patients who have had a good response to the drug at the end of the trial period. Second, they wonder what their obligations are to provide treatment for opportunistic infections or other conditions that have developed, particularly in patients with poor response to the study drug.

These issues commonly arise when research subjects have few other options for receiving care. Interestingly, they have been most thoroughly discussed in the context of conducting research in the developing world, but they pose important challenges for domestic researchers as well. The issue of post-trial access to study medications is complex (Shah, Elmer, & Grady, 2009). First, provision of investigational medication that has not yet been approved raises regulatory concerns and is typically not within the purview of the individual investigator to decide. Second, the duration of treatment for a chronic disease such as HIV is difficult to define. Any limit to the term of treatment seems arbitrary, as the individual may have an indefinite need for the medication. At the same time, treatment for any period, if the alternative is no treatment, appears to be a benefit to the patient. Finally, the reasons for drug resistance in the first place may include non-adherence; patients' ability to take the drug successfully outside of the study context may not be clear, and there may be real concerns about further drug resistance.

The issue of whether investigators have responsibilities to treat conditions such as opportunistic infections that arise over the course of a research study has also been discussed in recent years but has troubled researchers for a long time. This type of medical care has been termed "ancillary care," and it importantly refers not to side effects, toxicities or other research injuries (Belsky & Richardson, 2004; Dickert & Wendler, 2009). Rather, ancillary care addresses health needs (not caused by the study itself) that arise during the course of research participation.

While discussion of ancillary care responsibilities has focused on research in the developing world, these issues frequently arise when domestic research subjects have important unmet health needs. Local investigators working with economically disadvantaged patients know these struggles well. In addition to potentially developing opportunistic infections, these patients may have diabetes or hypertension, for example, and no access to care for these co-morbidities. Do clinical investigators have an obligation to help meet these unmet needs?

There are no settled approaches to issues of post-trial access or ancillary care responsibilities, in part because the role of clinical researchers is ambiguous and incorporates elements of both clinical care and research. Because most clinical investigators are clinicians, they feel some obligation to attend to clinical needs when possible. The problem is that those needs are often significant, can require substantial resources and can cripple limited research budgets. Moreover, like issues regarding payment, the principal challenge is the difficult set of background conditions (poor access to care and other resources) that is not caused by the research. In fact, the research is in many cases specifically working to improve these conditions with regard to healthcare. In short, these issues warrant careful attention and planning but can be difficult and illustrate the extent to which clinical research is inextricably intertwined with deep social challenges.

The above three examples are designed to illustrate the ways in which research in low-resource settings is complicated by background social situations that in many cases raise real concerns about injustice. As the case with Suzie and the case about ancillary care show, research participation is intertwined with subjects' real lives in ways that demand attention. That said, clinical research cannot fix income inequalities and is not the solution to poor access to primary care. The consent case shows that requirements, forms and processes that researchers and institutions put in place can compound issues of comprehension.

Ultimately, all three issues require further study regarding how best to address these ethical tensions. Moreover, all three demonstrate the hard work that many of our community's clinical investigators must do in conducting their important work addressing the needs of some of Atlanta's most vulnerable patients. ■

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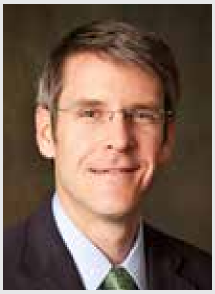

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Reflections of a Clinician-Educator in a Public Teaching Hospital

By Kimberly D. Manning, M.D., FACP, FAAP

As a medical student, I felt this deep affinity for the county hospital during my clinical rotations. In my very junior mind, I believed that training in those metaphorical trenches filled with the underserved was where the "real" learning and growing would take place. The patients would be sicker, more needy of my assistance and ultimately more memorable.

This was my perception, not only as a student, but also well into my residency. For this reason, my entire postgraduate training was spent almost exclusively in an indigent care setting. I wanted to be where the action was.

Alas, there is nothing new under the sun. After more than a decade of teaching medical students and residents at one of our nation's largest public hospitals, I still hear similar sentiments from our students. Heartfelt declarations of how the brick and mortar walls of our county hospital have won them over and how all other experiences pale in comparison.

Twenty years later, I now see it differently. Certainly my fondness for caring for and teaching learners in an indigent care setting hasn't waned, but today I better recognize the unique qualities of the public hospital for what they are. I see it less as some competition between university and privately insured environments. Instead, I know this for certain: Teaching and learning amongst a primarily underserved and low-resource patient population fosters a deeply symbiotic relationship between the patients and their caregivers. We need each other to survive.

It is no secret that public hospitals are known as destinations for patients with limited incomes, our immigrant population and oft times the elderly. For this reason, disease is often captured de novo with remarkable physical findings and presentations. This is sure to enamor even the most stoic learner and is the part that is frequently lauded between them.

There is so much to be learned, however, from the journey each patient took to reach us. Lessons in cultural competence, systems issues, psychosocial factors and even history further paint the landscape to make indigent care settings more than just "cool." When put together, this explains what I couldn't fully appreciate as a student. I hope this true story of caring and teaching in a public hospital will, too.

The Accomplice

Grady Inpatient Service, early 2007

"11:41 a.m.!" I announced to my ward team while walking backwards. I spun on my heel and turned into the corridor leading to the emergency department. My long, brisk strides signaled urgency to all around. The team – made up of one senior resident, two interns and three medical students – shuffled quickly to keep up.

It had been a long morning of rounds, and we were finally approaching the bedside of the last of 10 new patients admitted to our team on call the evening before. On our "post call" days, it was a struggle to get everything done. As the attending, it was my responsibility to see every patient with the team, seize teachable moments along the way and finish in a manner timely enough to dismiss the house staff to the lunchtime teaching conference.

We were nearly three weeks into the month, and by now our team dynamic was relaxed and familiar. The learning environment was good – safe, collegial and interactive. I worked hard to keep the group engaged and to avoid the stagnant, endless rounds that I occasionally experienced as a trainee. I slowed my pace just long enough to scan the patient board in the ED for our patient's initials and room number.

"She's in 208," I spoke while pointing down the hall. The pack swiftly marched ahead; all of our eyes locked on room 208. As soon as we reached the room, like a well-oiled machine, everyone did their part. One intern stepped into the doorway and quickly murmured to the patient that we would be in shortly. Another industriously flitted about the nurses' station searching for the hospital chart.

Closing the door carefully, I pulled out a billing card and positioned my pen. Like clockwork, the team formed an arc around me as Evan, the third-year medical student, stepped forward to begin his patient presentation.

I scanned the faces and body language of the group; the shifting feet, shoulder rolls and quick glances at the clock made it clear to me that we needed to soon wrap up. I smiled and nodded in Evan's direction. He began speaking in a HIPAA-sensitive voice. "So last but not least, Ms. Harris is a 36-year-old African-American female who presented with a two-hour history of chest pain after using crack cocaine."

He looked over at Mitchell, the senior resident, who let out an exasperated sigh. Evan continued. "She's had two admissions this year for similar symptoms and also has a history of hypertension and tobacco use. She's nonadherant to her medications. Her chest pain started retrosternally and then radiated to her right arm. There was no associated …."

Mitchell groaned and then interrupted. "Can I please just give you the thumbnail version? Basically, Dr. M, it's just another crack-chest-pain. Totally not typical for cardiac causes, EKG was negative, enzymes negative, exam unremarkable, totally non-compliant and 100 percent uninterested in taking any of her meds other than crack." Mitchell reached out and gave Evan a half-hearted pat on the shoulder. "Sorry, buddy, it's getting really close to noon, and I'm sure Dr. M has reached her crack-chest-pain-limit for the day." The group collectively released a nervous chuckle.

A fine ripple of discontent ran through me – not the kind that mobilizes you to scream in protest, but just enough to make you take pause. I wasn't sure what was worse – referring to this patient, this person as "just another crack-chest-pain" or the fact that I had created this climate that allowed my resident to do so. I searched myself for some poignant but quick statement that I could make as the attending to point out this faux pas to my learners, but came up with nothing.

"So do you want to pop in there together or would it be okay if you saw her alone?" Mitch made an exaggerated lean backward, stretching out his back after a late evening on call and a long morning on rounds. I was still processing the "crack-chest-pain" statement. "Dr. Manning? Dr. M, you with me?" Startled, I sheepishly acknowledged that my mind had drifted and agreed to reconvene with them later.

I began looking through Ms. Harris' chart as the group prepared to leave. Just then, I overheard the team chatting amongst themselves. "Dude! What the heck is up with all of these crack-chest-pain admissions?" This was the rhetorical question thrown out by one of the interns.

Mitchell shook his head and snickered. "I know, right? It's the blue plate special. Chest pain with a side of crack."

Again, the coalescent eruption of giggles and, again, my ripple of discontent.

"Hey, Dr. Manning," Mitchell said with a mischievous grin, "I have an important suggestion for you to bring to the powers that be." I braced myself for what I knew would be anything but. He playfully stood up and straightened the lapels on his lab coat whimsically. "We need a crack-team at this hospital."

The entire team exploded in laughter, some leaning over the nurses' station, others slapping their legs. This only egged him on. "There could be a crack-pager, and somebody could be on crack-call in a crack-unit. Oh, and when they leave the hospital, they can all just follow up in the crack-clinic."

By this time, tears were rolling down his face, and others on the team could barely catch their breath. Their boisterous mirth continued down the hall as they waved goodbye and disappeared around the corner.

I stood there with the same nondescript expression that I had from the moment the first "crack comment" was made. It felt like I had just made a wrong turn down a dark alley and witnessed a mugging. Instead of leaping to the defense of the victim, I was paralyzed with uncertainty on how best to proceed. And by doing nothing, I felt like an accomplice.

When I entered the patient's tiny room in the emergency department, she was leaning over the tray-table drawing a picture. The nasal cannulas initially given to her in triage was now perched atop her hair like clear rubber headband. She looked up at me and smiled. I returned the gesture, pulled up a chair, and sat beside her bed.

I learned that she was 36, just like me, and that her family was originally from the south, just like my own. She told me about her four children, two sons and two daughters, none of which were in her custody.

"Do you have kids?" she asked me earnestly. I responded by showing her a picture of my two sons on my cell phone, and again we shared a smile. A boyfriend had suggested she try crack cocaine when she was only 21 years old, and she "got hooked from the jump." I eventually came to the history of present illness, followed by a physical examination, which yielded very little.

Methodically, I explained that she didn't have a heart attack, and she could probably be discharged from the hospital today with plans to follow up in our primary care clinic. "That sounds good, doc," she said, again flashing the same dingy grin.

My eyes rested on the sketch that sat before her. "Do you mind if I look at this?" I asked. She nodded in acknowledgment, as I inspected the carefully penciled drawing of a mother holding a baby. The intense love between mother and child was captured beautifully – from the glistening eyes to the details of the mother's embrace. "Wow. This is awesome," I uttered aloud, completely sincere.

"Yeah," she spoke softly, "I always loved drawing pictures."

I reflected on my own interests and quietly replied, "Me, too." I enveloped her right hand in both of mine, encouraged her to keep drawing and to keep her appointments. Then I told her it was wonderful meeting her. I meant that.

Later that afternoon, I met up with my team to solidify the plans on our patients.

"Anything earth-shattering when you saw that lady in 208?" Mitch asked lightly. I stared at her name on the billing card and said nothing initially. The team waited respectfully in the pregnant pause.

I looked up and gave them a half-smile. An unexplained tension mounted in the room; I chose my words carefully. "Miss Darlene Harris is originally from Demopolis, Alabama. She has four kids – two boys and two girls – Dwayne, DeRon, Denise and DeShon. 'D' is for her grandmother's name, Dorinda. Her grandma raised her since both her parents struggled with health problems and alcohol." I looked up for a moment at the group, some shifted nervously in their chairs while others just sat, mummified and quiet. I cleared my throat and went on. "She loves to draw, and wow, y'all … she's really good. She was only 21 when she got addicted to crack, and she wishes she wasn't. Oh yeah, and I also learned she's the same age as me – 36."

I could see Ms. Harris' smiling face, warm and genuine. I felt an unexpected wave of emotion pushing against the backs of my eyes. I swallowed hard and willed myself to keep my composure. "So yeah … I guess what I learned was kind of earth-shattering for me. I guess I learned that she isn't just another crack-chest-pain." I scanned the faces of my learners, earnest and thoughtful. I suddenly felt my face grow warm with shame and dropped my head, identical to that of my children when they've knowingly done something wrong.

Had I? Had I done something wrong?

In this moment, I had the undivided attention of my team, just as I had many, many times that month. That told me my answer. As the attending physician, it was I who had set the tone for that team. The foundation for what was and wasn't acceptable had been laid by me. Any action or indifference I'd demonstrated had sent a mighty message to those learners.

It wasn't like I had this egregiously unprofessional resident that month. He was a good resident, really, but somehow, some way as their role model, I'd dropped my guard and allowed things to go awry. This was clearly evident in his comfort in delivering that stand up "crack" routine.

I studied my chicken scratch notes again, shook my head and sighed. "We're taking care of real people, y'all. I'm sorry for not slowing down more to help us remember that. I promise to do better. Look … let's just all try to do better, okay?"

When I looked up, the first thing I noticed was one of the medical students, silently crying.

The value of the indigent patient setting for learning

In this vignette, a team of doctors are exposed to the forces of psychosocial and systemic factors in healthcare – both very common in indigent care settings. Though the learning could have been focused on concrete physical examination techniques, evidence-based discussion points and management decisions, what takes place instead underscores why this environment is so critical to medical education. A patient with a lifestyle that likely does not mirror that of her caregivers is ultimately seen as a person. Attitudes are explored and self-reflection takes place, not only with the most junior learners, but with the most senior person as well.

Certainly each patient encountered at a place like Grady Hospital won't be struggling with substance abuse or be faced with some less than socially unacceptable situation. Instead, this unfiltered gateway brings everyone to our doorsteps. From the senior who once played in the Negro baseball league and marched shoulder to shoulder with Dr. King to the immigrant working three jobs to make ends meet for a family both here and abroad, to the newly laid off college-educated engineer who never imagined being without insurance – providers and their learners are exposed to the full spectrum of society. Therefore, even with the most "bread and butter" patients, there is always something to teach and, at every level, something to learn.

Of course there are those who still might argue that it is the sheer volume of patients, many of who are challenging and without other alternatives to care, that sets public teaching hospitals and indigent clinical centers apart from their counterparts. This was the part that wooed me as a student some 20 years ago, but now I know differently. There is so much more.

All of our clinical learning environments are important to the growth of our future workforce. But in my experience, the greatest strength of ours is this: Caring for underserved populations shines a light onto humanity – that of our patients and of ourselves. This, perhaps, has been and shall always be the greatest educator of them all. ■

Kimberly Dyan Manning, M.D. joined the faculty at the Emory University School of Medicine in 2001 after completing residency in combined training Internal Medicine and Pediatrics, and is now an associate professor in the department of medicine. She divides her professional time between teaching pre-clinical medical students, training medical residents and patient care primarily at Grady Memorial Hospital. Dr. Manning serves as residency program director for the Transitional Year Residency Program. She is also an avid writer, whose writings include a blog ("Reflections of a Grady Doctor") that was named in 2010 by 'O' The Oprah Magazine as one of "four top medical blogs you should read."


DRUGS
FLEEMAN'S PHARMA
Concord Community Pharmacy
drop off
pick up

Emory Residents and Fellows Go Abroad

By Allen L. Dollar, M.D., FACC, FACP, Dominique Cosco, M.D., Patricia A. Hudgins, M.D., FACR, Annette Esper M.D, MSc and Jennifer A Goedken, M.D.

A year ago, Dean Thomas J. Lawley of Emory's School of Medicine established and funded a unique program to enable Emory resident and fellowship trainees from all disciplines to spend a month of training outside of the United States. Prior to the establishment of this program, Emory's Department of Medicine had for five years funded six or seven third-year internal medicine residents to go abroad for a month at a time.

Emory has long had an international health presence through the Hubert Department of Global Health at the Rollins School of Public Health, a university-wide Global Health Institute dedicated to research, training and partnerships abroad, and significant international collaboration with the Centers for Disease Control and Prevention and the Carter Center. These more recent programs, however, are the first to provide opportunities for residents and fellows to go abroad.

Over the past year, postgraduate trainees from Emory's programs in internal medicine, surgery, radiology, pediatrics, dermatology, anesthesiology, pathology, gynecology and obstetrics, family and preventative medicine and rehabilitation medicine have had the opportunity to spend a month in Ethiopia. Emory faculty members are also sent to accompany the trainees. Eventually, this program will diversify to other countries, but keeping it initially limited to one country has greatly simplified organization.

Most of these trainees have spent their month at the Black Lion Hospital, the main teaching hospital of the Addis Ababa University School of Medicine (AAU) in the Ethiopian capitol city. The Black Lion Hospital in many ways resembles Grady Memorial Hospital; it is a large public safety-net hospital serving the 3.5 million people who live in Addis.

Ethiopia, with 86 million people, is the second most populous of the 57 African nations and also one of the poorest in the world. Depending on which statistics you believe, there are between one and 2.6 physicians per 100,000 population in Ethiopia, placing it in the bottom five countries in the world for physician supply. In comparison, most first- and second-world countries average around 350 physicians per 100,000 people. Part of the Ethiopian physician shortage has to do with the number of medical schools, but the larger part is a tremendous efflux of physicians leaving the country. Because the quality of medical education in Ethiopia is quite good and all Ethiopian physicians receive their education in English, it is easy for Ethiopian medical school graduates to find employment outside of Ethiopia. With relatively few medical jobs in Ethiopia and very low pay (physicians in Ethiopia earn around $3,600/year on the average), there is tremendous incentive for physicians to leave their home country. Estimates are that at least 50 percent of Ethiopia's medical graduates leave Ethiopia soon after training.

Below are four reports from Emory faculty who have had the opportunity to travel to Ethiopia under this new program over the last year, illustrating some of the challenges faced in Ethiopia and highlighting some of the efforts made towards positive change.

Allen L. Dollar, M.D., FACC, FACP

Dr. Dollar has been in practice in Atlanta for the past 20 years. He was in private practice at Piedmont for 13 years, and now he is on faculty at Emory. He serves as the Chief of Cardiology at Grady Memorial Hospital.

Internal Medicine

Emory's Internal Medicine Residency program established a Global Health Initiative in 2007 to support resident interest in global health and to provide selected residents with an opportunity to learn how to practice medicine in a resource-limited environment. Since its inception in 2007, the Internal Medicine Residency program has supported approximately 35 residents in pursuing experiences in global health.

Emory Internal Medicine residents join the Internal Medicine residents at Addis Ababa University (AAU) at Black Lion Hospital on inpatient ward teams, and round daily with attending faculty. Emory residents also have an opportunity to round with limited sub-specialty services such as Infectious Disease and Hematology/Oncology. Black Lion does have ICU capabilities, but the hospital only has two ventilators for the medical ICUs. Many times, these ventilators are being used by the surgical ICUs, leaving the medical ICU with no mechanical ventilation capabilities.

Two years ago, the Emory residents started rotating through the newly opened Emergency Room at Black Lion, which proved to be a valuable learning experience. The Emergency Department is staffed by Internal Medicine residents and physicians and has approximately 15 beds. The patients on the inpatient medicine wards tend to have long stays at Black Lion, so rounds in the ER allowed Emory residents the opportunity to see many new patients. The patients that present to the ER and subsequently are admitted to Medicine teams may remain in the ER for up to two days waiting on a floor bed.

Internal Medicine residents and physicians in Ethiopia are extremely knowledgeable. In fact, most Internal Medicine residents read Harrison's cover to cover, and they are readily able to quote directly from it. However, the residents do lack access to major journals and therefore may not be well-versed in the latest studies and patient care guidelines.

I have found that AAU Internal Medicine residents often ask questions about how to use medication in daily patient management. For example, on my first visit to Black Lion Hospital in 2008, the residents asked me how to choose which statin you would use for a diabetic patient. The residents knew all the pharmacokinetics and indications to use statins, but the practical prescribing information interested them as they did not have access to statins at Black Lion Hospital.

On my visit in 2011, Black Lion had just acquired access to metformin, which was a big step forward as there has been a huge increase in the incidence of diabetes in urban areas within Ethiopia with the introduction of a more "westernized" diet.

There is a wide spectrum of disease on the inpatient medicine wards at Black Lion. There is a large HIV population, and these patients tend to present with advanced opportunistic infections. Tuberculosis is also prevalent in Ethiopia, especially within the HIV population. In fact, tuberculosis is automatically on the differential diagnosis for any patient with an abnormal chest X-ray, regardless of their immune status. There are no isolation beds or rooms at Black Lion Hospital, so large, open windows serve as the infection control for patients with tuberculosis. Rheumatic heart disease is also quite prevalent in Ethiopia. There are many young patients on the medicine wards with very advanced heart failure secondary to rheumatic heart disease, and their inpatient stays for heart failure management tend to be quite prolonged. Cardiac surgery is currently unavailable in Ethiopia.

The experiences gained for Emory's Internal Medicine residents during their travels and clinical experiences in Ethiopia are immeasurable. Residents not only come to view medicine through a wider lens, but they also gain a greater appreciation for the art of the history and physical exam. The residents learn how to make management decisions in a limited resource environment. Finally, this unique opportunity illustrates to residents how global health encompasses not only medicine, but also the culture, religion and social norms of a country.

Dominique Cosco, M.D.

Dr. Dominique Cosco graduated from Tulane University School of Medicine and completed her internal medicine residency training at Emory University. Upon completion of residency, Dr. Cosco joined the faculty of the Division of General Medicine at Grady Hospital. Dr. Cosco serves as one of the associate program directors for Emory's Internal Medicine Residency training program. She also directs the Global Health Distinctions Program for the internal medicine residents.

Radiology

Historically, the role of diagnostic imaging in global health has been under-represented, likely due to the perception that radiology volunteer work requires expensive imaging equipment not available in developing countries. Of the myriad international healthcare efforts, few involve radiologists or radiology technologists. As the gap between technology and production costs closes, the role of radiology in global health work has grown.

In 2010, Dr. Patricia Hudgins, professor of radiology at Emory, and Dr. Ali Tahvildari, radiology resident, spent a month at the Black Lion teaching hospital in Addis Ababa. It was an incredible experience and the beginning of an enduring friendship and collaboration.

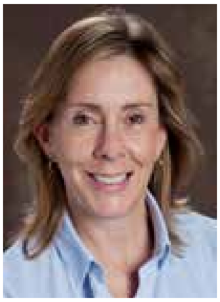
There are approximately 125 radiologists in Ethiopia (one radiologist per 680,000 people). AAU has the sole radiology residency, staffed by nine attendings and 30 residents in a three-year program.

The radiologists were welcoming and knowledgeable. The residents are well read and eager to learn new imaging techniques. Drs. Hudgins and Tahvildari participated in the daily read-outs of plain film, fluoroscopy, IVP, ultrasound and CT. There are three MRI machines in the entire country, all at private imaging centers, and some patients are referred to AAU with their MRI for interpretation.

The diversity of pathologies that we observed was astounding. Because patients have limited access to healthcare, many diseases are imaged in advanced stages. The prevalence of aggressive HPV-associated cervical cancer is especially high. Among infectious diseases, HIV, tuberculosis, schistosomiasis, malaria and echinococcus are commonly seen.

During our visit, we gave multi-subspecialty case conferences and formal didactics, all of which were enthusiastically received. We were also fortunate to have the company of an Emory Internal Medicine team concurrently in Addis. Together, we rounded on clinical services in the emergency room and in the intensive care unit, which greatly complemented our time in the reading room.

From the inception of this project, it has been our goal to create a partnership with our Ethiopian colleagues and to establish a yearly resident and faculty rotation. In 2013 we will visit for the third time, taking three senior radiology residents to Black Lion Hospital, where each will spend one month. Dr. Aarti Sekhar, an Emory abdominal imaging attending, also now travels to Ethiopia to help supervise the radiology residents and offer her expertise. She introduced CT-guided fine needle aspiration to the Black Lion radiologists, and under her tutelage the first CT-guided procedures were done.



Patricia A. Hudgins, M.D., FACR

Dr. Patricia Hudgins is Professor of Radiology at Emory University in Atlanta, where she is Director of Head and Neck Radiology. Her clinical practice includes all of neuroradiology, with an emphasis on head and neck imaging. She is interested in improving radiology services in under-served populations.

Pulmonary Medicine

Medical subspecialists are limited in Ethiopia, and subspecialty training is relatively a new thing. AAU started out with fellowships in neurology, infectious disease and cardiology and in 2012 added hematology, endocrine and gastrointestinal fellowships. Due to the many patients with pulmonary disease, the faculty identified a great need and role for pulmonary medicine at Black Lion Hospital, which led to an interest in developing a pulmonary training program. The Pulmonary Division at Emory was asked to assist in doing an initial needs assessment to determine the feasibility of developing such a program at AAU's teaching hospital, Black Lion.

There is currently one pulmonologist in the entire country of Ethiopia who practices in a private clinic in Addis. He was formerly a member of the Internal Medicine faculty at AAU and returns on specified days to supervise bronchoscopies performed by one of the internists. Currently, pulmonary consults are performed by Dr. Amsalu Binegdie, an internist and faculty member at AAU who has an interest in pulmonary medicine. He also staffs the pulmonary clinic in addition to running the chest unit, where procedures such as bronchoscopies are performed.

My experience at Black Lion with Dr. Amsalu was tremendous. There, I had the opportunity to observe the diagnosis and management of disease states in a limited resource setting. As expected, I encountered many cases of tuberculosis (TB), both pulmonary and extrapulmonary. Due to the patient population, the suspicion for TB is always high when patients come in with respiratory symptoms and characteristic radiological findings. Interestingly, many patients are started on anti-TB medications empirically as lab data is unreliable. Furthermore, infection control measures such as isolation procedures and hand hygiene are minimal to nonexistent.

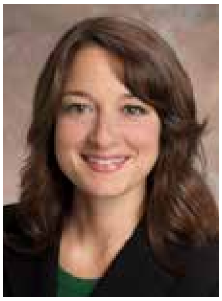
Although infectious diseases are the most common pulmonary diseases encountered, there has been a rise in non-communicable diseases such as lung cancer, asthma, COPD and interstitial lung disease. The management of these diseases is limited due to limited therapeutics. I encountered patients in the pulmonary clinic with a variety of pulmonary problems, including lung masses, asthma and interstitial lung disease.

In addition to the lack of subspecialists, the availability of both diagnostic and therapeutic resources is quite limited. Although the hospital has had a number of pieces of equipment donated, there is a lack of understanding of how to properly use or maintain them. Thus, in addition to the need for subspecialists, there is a great need for biomedical engineers.

Many diagnostic tests are not available to patients if they are not able to afford them, making diagnosis even more challenging. Hospital resources are limited, including such basic equipment as pulse oximetry, ABG analyzers, ventilators and pulmonary function equipment. At the time of my visit, there were only two functioning ventilators in the entire hospital. Although the hospital does have the capability to perform bronchoscopies, the equipment is old and limited. Biopsies are not typically performed due to the lack of working biopsy forceps. Moderate sedation is not used during these procedures due to the lack of monitoring equipment.

The physicians that I interacted with at Black Lion Hospital were passionate and enthusiastic about their work and their role as teachers. I learned a great deal from them during discussions about various cases. Due to limited resources, they are faced with great challenges in managing their patients, but they know how to best utilize what they have to provide the best care given the circumstances.

There is a great need for pulmonologists in Ethiopia, and with the support of the World Lung Foundation, the first pulmonary fellowship at Black Lion Hospital/AAU is set to begin in early 2013. Volunteer faculty from various institutions, including Emory attending physicians and fellows, will be traveling to Ethiopia to participate in the training program and serve as visiting faculty.



Annette Esper M.D, MSc

Dr. Esper is Assistant Professor of Medicine in the Division of Pulmonary, Allergy and Critical Care at Emory University. She serves as the Assistant Director of the Medical and Coronary Intensive Care Unit and Medical Director of the Step-down Unit at Grady Memorial Hospital. Dr. Esper's research interests include clinical and translational studies in critically ill patients with sepsis and ARDS. In addition to her clinical and research interests at Emory, Dr. Esper is a member of the Global Health Residency Scholars Program Advisory Committee, involved in enhancing collaborations between Emory and Ethiopian institutions, and she will participate as faculty for the East Africa Training Initiative in Pulmonary Medicine.

Gynecology

In 2010, Emory University was granted a $100,000 award from the Bill and Melinda Gates Foundation (BMGF) to partner with Addis Ababa University (AAU). The charge was to work with AAU to implement a program focused on the Millennium Development Goal (M.D.G) to improve maternal health with a specific goal of reducing maternal mortality by three quarters by 2015.

For women in developing countries, the average lifetime risk of death from pregnancy-related causes is between 1 in 15 and 1 in 50. For women in industrialized countries, that risk is only 1 in 4,000 to 1 in 10,000. No other public health statistic reflects a greater disparity between rich and poor countries.

Ethiopia is one of six countries (along with India, Nigeria, Pakistan, Afghanistan and Democratic Republic of Congo) that together account for more than 50 percent of maternal deaths worldwide. With more than 60 percent of the population of 85 million in Ethiopia being under the age of 25, the birth rate is a staggering 2.8 million births yearly with 14,000 maternal deaths, 118,000 neonatal deaths and 500,000 cases of maternal morbidity yearly.

Globally, pre-eclampsia and eclampsia occur at a rate of five to 10 per one hundred pregnancies and account for greater than 50,000 maternal deaths every year. Pre-eclampsia/eclampsia is among the top five causes of maternal mortality in Ethiopia, accounting for more than 10 percent of maternal deaths. Whereas most of the pre-eclampsia seen in the developed world is mild and rarely progresses, in Ethiopia, there is a much higher proportion of severe pre-eclampsia and full-blown eclampsia.

There is extensive evidence in the medical literature that magnesium sulfate (MgSO4) is the drug of choice not only for preventing the progression of pre-eclampsia to eclampsia but also for the treatment of eclamptic seizures. Sadly though, MgSO4 remains largely unavailable in many developing countries, and until very recently all women with pre-eclampsia or eclampsia in Ethiopia were treated with diazepam.

The AAU-Emory group, supported by the BMGF grant, conducted a Knowledge Attitude and Practice survey in 90/110 public hospitals in Ethiopia. The results of this survey helped to create educational materials that were distributed during the training of midwives, nurses and physicians. Strategic collaborations between the Ethiopian Society of Obstetrics and Gynecology (ESOG), the Federal Ministry of Health of Ethiopia (FMOH), UNICEF and the Pharmaceutical Fund and Supply Agency [PFSA] resulted in the introduction of MgSO4 into the mainstream clinical services at more than 100 government hospitals within Ethiopia.

At the beginning of the project, there was essentially no MgSO4 available in Ethiopia. Despite the fact that there are now more than 500,000 vials available, the success of this intervention has been quite limited, because nearly 90 percent of deliveries are conducted at home and most women will never make it to the hospital to receive lifesaving MgS04.

On another note, our collaboration with the department of obstetrics and gynecology of AAU drew the attention of the Emory community, and a small amount of funding was acquired from the Woodruff Fund with the focus of decreasing cancer-related deaths. In Ethiopia, the estimated incidence rate of cervical cancer is 11.2 per 100,000, making it the second most common cancer in women there, second only to breast cancer. However, with an estimated mortality of 3,235 women per year, it is the leading cause of cancer-related deaths with a mortality rate of 8.0 per 100,000.

Declining cervical cancer-related mortality in the United States demonstrates that adequate screening can play a huge role in reducing the number of cervical cancer related deaths. However, screening with our pap smear-focused approach requires significant resources, as well as intensive follow up. Such programs rarely exist in areas with limited resources. Our AAU collaborators were keenly interested in developing a cervical cancer screening program in their institutions, as well as in training their residents in such skills.

To address the issue of cervical cancer prevention in low-resource areas, a safe, acceptable and feasible single-visit screen and treatment modality has been designed and implemented successfully in many countries. This method involves visual inspection of the cervix with acetic acid, known as VIA, combined with cryotherapy treatment of visualized lesions. Conveniently, cryoablation does not require electricity, and CO2 or NO are usually readily available even in rural areas.

A knowledge, attitude and practice (KAP) survey was performed at three public hospitals associated with AAU. Three hundred and thirty-four healthcare professionals completed the survey. Eighty-nine percent of respondents thought that a cervical cancer screening program should be started in their community, but only 22 percent of healthcare providers reported having performed a pap smear. Even fewer healthcare providers, only 11 percent, reported experience with VIA.

We embarked on the development and implementation of a VIA-based cervical cancer screening training program. In total, three obstetric and gynecology faculty members, nine chief residents and three nurses completed the training facilitated by an Emory faculty.

At the end of the course, all the participants demonstrated competency. Anonymous evaluations and focus groups revealed the majority of trainees felt confident performing VIA and cryotherapy. The KAP survey readministered four months after the conclusion of training revealed that 90 percent of trainees were very likely to conduct screening on future patients.

A total of 127 women have been screened thus far at the two involved clinics since the training program began. Of those screened, 12 percent had a positive VIA result and all but two, whose lesions were too large, underwent cryotherapy. Patient surveys administered at the completion of the visit indicated the majority of women deemed both VIA and cryotherapy very acceptable. Though the two clinics are still functioning, both have faced challenges in increasing services mostly due to constraints of time on the few trained faculty and limited nurses capable of supervising the activities. Further training and funding are needed to increase the capability of this desperately needed intervention.

Jennifer A Goedken, M.D.

Dr. Goedken graduated from University of Wisconsin Medical School and completed residency training in obstetrics and gynecology at the University of Massachusetts. She is an assistant professor of gynecology and obstetrics at Emory University, Chief of Gynecology at the Atlanta VA Medical Center and a member of the medical staff at Grady Memorial Hospital. She has been the Ob/Gyn clerkship director since 2000. Her research focus and special interests are education, global health and ethics.

Joseph Ricotta, M.D., of Northside Vascular Surgery

Vascular Surgery

By Helen Kelley

New minimally invasive techniques and custom-made endografts are making a difference for high-risk patients in the arena of vascular surgery. Several of Atlanta's vascular surgeons are performing procedures that result in improved outcomes and shortened hospital stays for patients with abdominal aortic aneurysms.

Fenestrated aortic endografts for high-risk patients

It is estimated that 1.7 million Americans suffer from abdominal aortic aneurysms, a bulge in the main blood vessel that runs through the stomach and carries blood from the heart to the rest of the body. More than 50,000 repairs are performed annually in the United States on patients with this condition.

The condition, which can be life-threatening if the aneurysm bursts and causes severe internal bleeding, is relatively common in men and those 65 and over. Despite this, approximately half of those with abdominal aortic aneurysms may not be candidates for traditional repairs due to other risk factors and health conditions.

Those at risk for developing an abdominal aortic aneurysm include people who smoke, have a family history of aortic aneurysms and have high blood pressure, high cholesterol or a plaque buildup in and on artery walls restricting blood flow (atherosclerosis). Infection and trauma also can cause abdominal aortic aneurysms, according to the Centers for Disease Control and Prevention.

A new procedure, a fenestrated aortic stent-graft (or endograft) can help these high-risk patients get the life-saving aortic aneurysm repair they need.

"Until now, repairing complex or ruptured abdominal aneurysms was risky," says Eyal Ben-Arie, M.D., a vascular surgeon with Piedmont Heart Institute who has a particular interest in aneurysm repair. "With this minimally invasive procedure, a fenestrated aortic stent-graft is used to reinforce openings and maintain blood flow to vessels that lead to other organs in the body."

Instead of making a large incision in the stomach, doctors performing a fenestrated aortic endograft make a small cut near each hip. A small, fabric tube called a graft is inserted into the arteries and positioned in the appropriate blood vessel. Once in place, the graft seals off the aneurysm and makes a new path through which the blood flows.

"Patients who get this new procedure may go home after a very short hospital stay, generally do not require an ICU stay or a transfusion, and experience minimal pain after surgery," says Dr. Ben-Arie.

Dr. Ben-Arie performed the procedure for the first time at Piedmont Atlanta Hospital on Feb. 6, 2013, in collaboration with the hospital's entire vascular team.

Custom-modified endografts reduce wait time for patients in need

Joseph Ricotta, M.D., of Northside Vascular Surgery, is the first and only surgeon in the United States with FDA approval for an Investigational Device Exemption (IDE) to create and implant custom-modified endografts for high-risk patients with thoracoabdominal aortic aneurysms (TAAA). Dr. Ricotta performed his first case, as part of his new MOSTEGRA (MOdified STEnt GRAft) clinical trial, Feb. 12, 2013, at Northside Hospital-Forsyth in Cumming.

Dr. Ricotta, who can make a custom-modified endograft in the OR in as little as 30 minutes, says one of the procedure's advantages is the ability to treat patients quickly.

"We keep all the necessary supplies and tools to make the endografts on hand and ready in the OR," he says. "When a patient is admitted for TAAA, we can make a customized graft immediately, which is especially helpful in emergency situations."

Since the entire aneurysm is repaired from the inside of the aorta, rather than cutting open the chest and abdomen, patients have a much shorter hospital stay and a quicker recovery time. In Dr. Ricotta's February 12 case, the patient was removed from the ventilator at the conclusion of the operation before she left the operating room and went home just two days after surgery. A traditional open surgical procedure would have left her in the hospital for more than one week and on oxygen for most of that time.

However, construction of these devices requires that they be custom-made to fit the specific anatomy of each patient.

"The kidney arteries and intestinal artery all arise from different positions off the aorta," Dr. Ricotta explains. "Angles, curvature and locations can differ from patient to patient – no two people are the same in terms of their blood vessels and aortic anatomy."

Ricotta says that his technique has evolved since he began making custom-modified endografts in 2007 and will continue to change as new methods are discovered.

"The foundation of what I do is the same, but the way I do it has changed a lot in the last six years. You learn over time how to make improvements," he says. "We're always looking for ways to make the procedures quicker, safer and easier for the patient."

Minimally invasive treatment for Aortic Stenosis

With an ever-aging population, identification and treatment of heart valve disease has become a primary focus in the treatment of cardiovascular disease. Aortic valve stenosis is of particular concern given the dismal prognosis of this condition as the valve worsens.

The normal aortic valve allows blood to freely exit the left ventricle, the main pumping chamber of the heart. In aortic stenosis, the valve does not fully open, due to heavy calcium build-up, which decreases blood flow from the heart.

Without treatment, approximately 50 percent of severe aortic stenosis patients will not survive more than two years from the onset of symptoms. Historically, treatment was via open-heart surgery, which requires a large incision or cutting through the entire breastbone. Yet a patient's advanced age or the presence of other medical conditions might often preclude them from traditional aortic valve replacement surgery.

Amar Patel, M.D., an interventional cardiologist and medical director of WellStar Hospital System's Structural Heart and Valve Program, along with fellow interventional cardiologist Arthur Reitman, M.D. and cardiothoracic surgeons William Cooper, M.D. and Richard Myung, M.D., offers these patients a life-saving alternative called Transcatheter Aortic Valve Replacement (TAVR).

TAVR is an FDA-approved catheter-based procedure in which the new prosthetic aortic valve is implanted via a minimally invasive approach by either going through a small incision in the groin or left chest, underneath a rib. The TAVR approach greatly increases a patient's survival rate, alleviates debilitating symptoms, reduces the likelihood of repeat hospitalizations and improves the quality of life for aortic stenosis patients who have no other treatment options.

Dr. Patel says that performing the procedure as a team of CT surgeons and interventional cardiologists is a critical part of a successful outcome for the patient.

"We do these procedures as a team," he says, "because one of the most important aspects of the TAVR procedure is a true multidisciplinary approach to managing the patient."

In comparing like patients who do undergo TAVR versus surgical aortic valve replacement (SAVR), the length of stay and recovery time is shorter with similar procedure success, stroke risk and death. However, Dr. Patel warns that the TAVR procedure is not without its own risks.

"Vascular complications were higher in the TAVR group given the large sheaths that are used during the procedure, when the valve is replaced by going through an artery in the leg," he says. "Also, medical conditions such as significant heart failure, renal insufficiency, lung disease, liver disease and frailty may adversely impact the success of the procedure or post-procedural recovery." ■

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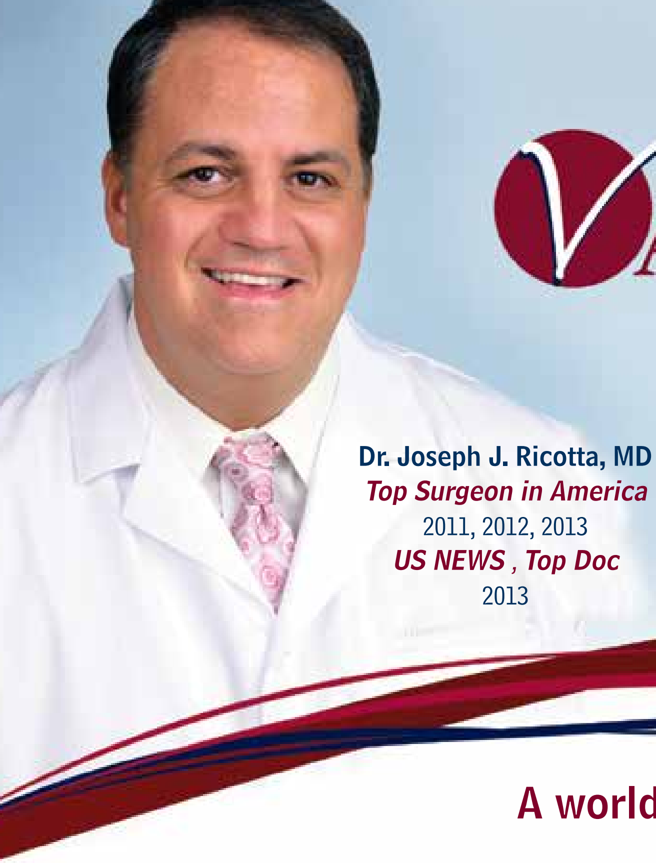

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