The number of Americans who forgo or delay needed care has nearly doubled in the past decade. The scarce options for primary care mean that people will delay or fail to receive primary care services, putting them at risk for poor health.

Primary Care Shortage

Further complicating matters is the increasingly short supply of primary care physicians. According to a study by the Louisville Primary Care Association by 2020 Louisville, Ky., will need 455 new primary care doctors to replace current doctors who are expected to retire and to meet federal guidelines for serving the projected 2020 population. Those numbers include 220 new family practitioners, 192 general internists and 43 pediatricians.

Those numbers will be a challenge to meet. According to the Association of American Medical Colleges, in the past 15 years, the number of U.S. medical school seniors who pursued family medicine residencies fell to 8 percent last year. One reason why family medicine has been deemed unpopular is due to its “lower” salary. On average, primary care doctors are paid as little as half as much as specialist. Yet they are faced with more time demands with patients that people will delay or fail to receive primary care services, putting them at risk for poor health.

By Lynne Jeter

Demand for primary care has outpaced supply nationwide, leaving many communities with primary care providers who are absent, unaffordable or inaccessible because of distance, special healthcare needs, insurance status or cultural barriers.

“People who cannot navigate these obstacles are forced to forego or delay seeking care, leaving them with many unmet healthcare needs,” said Dan Hawkins, senior vice president for policy and research at the National Association of Community Health Centers (NACHC), who revealed the study, “Health Wanted: The State of Unmet Need for Primary Health Care in America,” on Capitol Hill. The briefing coincided with the two-year anniversary of the historic passage of the Affordable Care Act (ACA).

The NACHC 2012 report demonstrated how Americans are turning to the national network of Community Health Centers (CHCs) in greater numbers, yet the need for their services continues to outpace growth.

Region 6 representatives on the NACHC board of directors, pointed out that CHCs, also known as Federally Qualified Health Centers (FQHCs), serve 40 million Americans and operate more than 8,000 healthcare delivery sites in all 50 states. These health centers provide one-quarter of primary care visits for the nation’s low-income population, comprising a substantial share of the nation’s primary care infrastructure.

However, the number of Americans who forgo or delay needed care has nearly doubled in the past decade. The scarce options for primary care mean that people will delay or fail to receive primary care services, putting them at risk for poor health.

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Letter from the Publisher

May brings the MediStar Awards

The MediStar Awards is weeks away and we are very excited about this year’s event. A special thanks goes to our Editorial Board for judging the first round of nominees. We had a number of terrific nominees and I’m sure it was hard for the board to make final decisions. Congratulations to all the nominees and finalists.

The IGE Media family is excited about the big night and we hope that you all feel the same. Make sure to join the more than 500 healthcare leaders that will attend the MediStar Awards on May 22. For more information, please see the finalists listing on page 17 or visit www.MediStarAwards.com. Make sure you take the time and congratulate each of the MediStar Award winners.

One more word on celebrations: As you will see in this paper, this month we are celebrating the 20th Anniversary of Medical News. Over the past several months, we have been working with members of the healthcare community to look back on the industry, the newspaper and the changes that have taken place. We are honored to have been a small part of this exciting industry in Kentucky and Southern Indiana.

Please join us as we celebrate. Visit www.MedicalNews.md to share your thoughts on the changes in the healthcare industry over the past 20 years. You are the ones that make our community special.

I look forward to seeing you on May 22 at the MediStar Awards!

Sincerely yours,

Thoughts from the healthcare community

Insider Louisville @insiderlou:
Appalachian Regional Healthcare Center cutting Centene, Conventry demanding Medicaid managed-care payments – bit.ly/3bwMSd

Kentucky Chamber @KyChamber:
The No. 1 #BestPlacesKy in the large company for 2012 is… Genetech! So proud of all our great Kentucky companies.

Rob Edwards @robwardruby:
Louisville tonight prepin for a talk on ACA for Kentucky Assoc of Healthcare Underwriters in the am. Hat tip to Doc Crows for fried oysters.

Kentucky @RFKentucky:
UPDATE: Owensboro healthcare facility opens after scabies outbreak.

VA struggles to provide vets with mental health care; #NKU seeks to address psychiatric nursing shortage http://nkugradarticles.wordpress.com/2012/04/26/va-struggles-to-provide-vets-with-mental-health-care/.
His patients may not remember all the medicines they take. Fortunately, their electronic records do.

Dr. Stephen Besson knows just how valuable the Kentucky Health Information Exchange can be. Every day, with just one click of a button, he’s able to learn about his patients’ prescriptions, allergies and past medical procedures. “This helps me protect them against drug interactions. It helps me avoid ordering unnecessary tests. And it helps me quickly zero in on the right treatment option,” says Besson. You can enjoy the same benefits. Join our secure statewide exchange and see for yourself how your practice and patients can benefit.

For a limited time, there are financial incentives for your hospital or practice to join KHIE. Visit www.khie.ky.gov or call 502-564-7992 to learn more.
Unmet needs

Continued from page 1

Nurturing the family-practice pipeline

By Sharon H. Fitzgerald

Ensuring that there are enough family physicians to be inspirations in the future and to care for tomorrow’s swelling number of patients is a challenge for medicine today, yet leaders in academic medicine, as well as the president of the American Academy of Family Practitioners, said there are promising signs that primary care is – albeit slowly – growing in popularity with young medical students.

It can’t happen soon enough. AAFP projects a shortage of 40,000 primary-care physicians in America by 2020, a figure that’s exacerbated by the nation’s aging population. Should some provisions of the federal Affordable Care Act come to fruition, more than 32,000 additional Americans are expected to have health insurance coverage by 2019. However, noted Glen R. Stream, M.D., a family practitioner in Spokane, Wash., and AAFP president, insurance coverage and access are two different things – and that’s the crux of the challenge. What needs to happen, Stream said, is pushing more primary-care physicians into the market.

A Supportive Environment

Stream called on medical schools to tweak their entry processes to target students interested in primary care, particularly in rural and underserved areas, and to create “a supportive environment” for primary care. “In a lot of academic institutions, family medicine is looked down on, quite frankly,” he said. “We need to be nurturing rather than stamping out that interest during their medical school education.”

A Challenge to Medical Schools

Stream also challenged medical schools to grow the number of primary-care residency training spots. An insufficient number of such residency opportunities are creating a “bottleneck in production,” he noted.

“I absolutely believe that the healthcare reform debate really highlighted how important primary care is,” Stark continued, and the patient-centered medical home concept puts family practice at center stage. He highlighted how important primary care is, “We’ll just get further behind if we don’t start now,” he said.

Examples of new CHC applications that remain unfunded

• In Clark County, Nevada, population 2 million on the doorstep of Las Vegas, there are only two CHC grantees. A significant portion of Nevadans are uninsured because many of them work in places that don’t provide healthcare coverage, therefore overloading emergency rooms for routine care because they cannot pay cash for their healthcare needs.

• In Hardin County, Ohio, which is federally designated as a Primary Medical Care Health Professional Shortage Area and a Dental Health Shortage Area, residents must drive more than half an hour to a neighboring county, a round trip of 66 miles, to access care even though nearly half the population doesn’t own their own car and escalating gas prices have taken a toll on the ability to pay for gas to drive to an appointment.

• Health Partners of Western Ohio Community Health Center, which operates two sites in nearby counties, applied for a new access point in Hardin County. It didn’t receive funding.

and administrative burdens with paperwork, coupled with the stress of paying off large medical school loans.

Inflating Healthcare Costs Loom

With the looming primary care physician shortage present, CHCs continue to feel the pinch as patient loads increase.

“This trend among the medically underserved is drastically inflating healthcare costs,” said Hawkins. “Many people turn to hospital emergency departments for non-urgent care; as many as 30 percent of visits to hospital ERs could be treated in a primary care setting. If everyone could access needed primary care services when they need them, the U.S. healthcare system could save $67 billion a year.”

CHCs have been hindered by federal budget reductions. Communities across the nation submitted nearly 2,000 health center grant applications; fewer than 10 percent received funding. In fiscal year 2011, only 67 of 810 new health service centers were funded. The Health Resources and Services Administration (HRSA), the federal agency that oversees the CHCs, had originally planned to fund 350 grants before funding was significantly reduced.

CHCs aren’t present in more than one-quarter of the counties with unfavorable primary care needs, including barriers to care of affordability, availability and accessibility; poor health outcomes; and economic consequences.
Physician Spotlight

Meet John B. Roth M.D.

Is it different than what you thought? If so, how?

While medicine is a profession that is constantly seeking to eliminate the cause of its existence with constant scientific advancements and treatments, the core of being a doctor has remained the same. It is the personal relationship between doctor and patient that is as important today as it was when I graduated from medical school.

What is the biggest misconception about your field?

A misconception that many people have about pediatrics is that pediatricians only treat infants and young children. In reality we see adolescents and young adults of college age as well, and often find our relationship with these patients to be quite gratifying as well as challenging.

What is the one thing you wish patients knew and/or understood about doctors?

One thing I wish that patients knew about doctors is that many are struggling with the increasing regulation of the profession, the corporatization of medicine, and the frustration with the business of managed care both private and government.

What is your opinion of electronic medical records (EMR) and how will this affect you and your practice?

While the adoption of electronic medical records has many positive aspects, such as being able to read the doctor’s notes, there are many potential pitfalls as related to patient privacy. In addition, with thousands of EMR systems, there is little interoperability and consistency on a national level. The cost of implementation and the time required to truly learn the “system” are really quite daunting. Undoubtedly doctors will have to adopt these systems, but they will not be a panacea for controlling costs or insuring quality.

What’s the best advice you ever received? Who gave it to you?

Some of the best advice I received in my training came from a family practice physician turned psychiatrist, who said to never use my profession as an excuse to be unavailable to family and friends, and to never be afraid to admit when I didn’t know something.

What’s the last good book you read? “Cutting for Stone” by Abraham Verghese.

Know a physician who deserves a chance in the spotlight?

Email: melanie@igemedia.com and find out how you or someone you know can be considered for an upcoming Physician Spotlight profile.
NEWS
in brief

The Kentucky Institute of Aging
goals, priorities

The Kentucky Institute for Aging was created in 1974 under KRS 194A.090 Citizen Advisory Bodies—Public Health Services Advisory and was amended in July 2000. The mandate of the Institute is "...to advise the Secretary of the Cabinet for Health and Family Services and other officials of the Commonwealth on policy matters related to the development and delivery of services to the aged." The Institute operates in partnership with the Department for Aging and Independent Living.

Goals of the Institute

- Assess, review and appraise services and programs for older adults within the commonwealth and nation.
- Recommend priorities for the state.
- Increase awareness within the commonwealth of issues related to aging.

Priorities

- Fostering workforce development.
- Increasing access to services.
- Facilitating service program development.
- Enhancing the quality of nursing facilities.
- Generating revenue and program funding.
- Promoting future planning.
- Improving communication.
- Disseminating information.
- Encouraging innovation.

Breast Center designated Breast Imaging Center of Excellence

The Breast Center on the Norton Hospital campus has been designated a Breast Imaging Center of Excellence by the American College of Radiology (ACR). This accreditation includes mammography, stereotactic breast biopsy, breast ultrasound and ultrasound-guided breast biopsy. Accreditation is granted by the ACR to facilities that have achieved high practice standards in image quality, personnel qualifications, facility equipment, quality control procedures and quality assurance programs.

Board-certified experts from the ACR conducted an intensive peer review of the Norton Healthcare facility. Assessments were made on image quality, personnel qualifications, adequacy of facility equipment, quality control procedures and quality assurance programs. Upon completion of the review, the Breast Center was awarded the ACR gold seal of accreditation, representing the highest level of image quality and patient safety. The Breast Center has thus been named a Breast Imaging Center of Excellence and was granted a three-year accreditation term in stereotactic and ultrasound-guided breast biopsy.

Lourdes pharmacists provide bedside care

Paducah, Ky.-based Lourdes Hospital celebrated the one year anniversary of partnering with the inpatient pharmacy to expand its multi-disciplinary care at the bedside. Adding a pharmacist to the team ensures patients and their families receive education regarding the importance of compliance with medication regimens.

Lourdes inpatient pharmacists are actively reviewing patients’ medication profiles, closely following lab values and reviewing patient medical histories to make recommendations on drug therapies.

Involving the patient in this process allows them to be an active participant in their care and equips them to be successful in managing their medications after discharge.

More than 5,000 patients have received education since the program started in 2011.
American Association of Colleges of Nursing
Jane Kirschling, dean of the University of Kentucky College of Nursing, has been elected to serve a two-year term as president of the American Association of Colleges of Nursing (AACN).

Jewish Hospital HealthCare
Louis I. Waterman was elected chairperson of the Jewish Hospital HealthCare Services board of trustees.

Sandra Barr Hammond was elected to serve as vice chair of the Jewish Hospital HealthCare Services board of trustees.

Lourdes Hospital
Lourdes welcomes Lee Syphus to the position of Kentucky region executive director for Mercy Medical Associates.

Mercy Medical Associates, Lourdes’ employed physician practice, welcomes Dr. Terri H. Telle to the medical staff.

Seven Counties Services, Inc.
Seven Counties Services, Inc. added Donnie Sash, office manager, to its staff of professionals.

University of Louisville
Karunarathna “K.B.” Kulasekera, Ph.D., joins the University of Louisville School of Public Health and Information Sciences as the chair of biostatistics and bioinformatics.

Craig J. McClain, M.D., professor of medicine at the University of Louisville, is among four new members appointed to the National Advisory Council on Alcohol Abuse and Alcoholism of the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

Western Baptist Hospital
Dona Rains, director of marketing and planning at Western Baptist Hospital, is one of 53 Kentuckians selected for the 2012 class of Leadership Kentucky.
Louisville health charities recognize outstanding volunteers

Local health charities recognized their most dedicated volunteers at the 15th Annual Champions in Health Awards Celebration.

The highest honor of the evening went to E. Joseph Steier III, president and CEO of Signature Health CARE, LLC. He was presented with the 2012 Champion in Health Leadership Award for his commitment to push the healthcare industry to pursue higher standards of care.

For 15 years, Community Health Charities of Kentucky has hosted the event to recognize those who have served as advocates for health and wellness in the community.

Cheri Hauber was also honored as a dedicated advocate for Ovarian Awareness of Kentucky and an ovarian cancer survivor. She was named OAK’s Volunteer of the Year for her efforts to educate women on the importance of knowing their family medical history and the signs and symptoms of ovarian cancer.

ICD-10 readiness survey results

The Workgroup for Electronic Data Interchange (WEDI), Reston, Va., announced submission of the latest ICD-10 industry readiness survey results to the Centers for Medicare & Medicaid Services (CMS). WEDI’s report revealed that much of the industry is not on track to meet the October 2013 compliance date.

Since 2009, WEDI has conducted ICD-10 readiness surveys to measure the progress of industry compliance. As an advisor under the Health Insurance Portability and Accountability Act (HIPAA), WEDI brings to the attention of CMS issues that it believes warrant review and consideration from the Secretary of Health and Human Services.

WEDI’s current assessment of industry readiness is derived from survey responses collected from more than 2,600 providers, health plans and vendors during February 2012. Based on the premise that impact assessments should have been completed in 2011 and other key milestones, survey results show evidence that the industry is falling behind with ICD-10 compliance. Significant data collected from the survey include:

Survey Findings
- Nearly 1/2 of the provider respondents indicated that they did not know when they would complete their impact assessment.
- Although 1/3 of providers expected to begin external testing in 2013, another 1/2 responded that they did not know when testing would occur.
- Most health plans do not expect to begin external testing until 2013.
- Over 1/3 of health plans have completed their assessment, but 1/4 are less than halfway done.
- About 1/2 of vendors are less than halfway complete with product development.

Public affairs manager honored

Marcelline Coots was one of the first individuals to be hired at Passport Health Plan in 1997. Almost fifteen years later, Coots continues to pay dividends for Passport, and the people they serve. Coots was named the 2012 Making A Difference award winner by the Association for Community Affiliated Plans (ACAP).

ACAP selected Coots from a pool of candidates submitted by the national organization’s 57 affiliated health plans located throughout 27 states. Combined, ACAP’s members serve more than 10 million Medicaid and CHIP members across the country.

To honor Coots, ACAP is presenting a $500 donation to her charity of her choice, the Ohio Valley Educational Cooperative Head Start (OVEC) program.

Baptist receives Acorn award

Louisville, Ky.-based Baptist Hospital East was recognized for its “green” leadership among large corporations in Metro Louisville with an Acorn Award. The award, given annually by Operation Brightside, are sponsored by The Green Building.

Baptist East was selected based on several environmentally-friendly initiatives such as the design of Park Tower, an eight-story addition to the hospital that is wrapped in glass to maximize natural light and views.

The Baptist Eastpoint Cancer Center achieved Leadership in Energy and Environmental Design (LEED) certification from the U.S. Green Building Council. The certification identifies the center as a “pioneering example of sustainable design, demonstrating leadership in transforming the building industry.”

Baptist East also has an employee Green Team, which coordinates the recycling of some non-invasive surgical equipment such as blood pressure cuffs, gauze, sponges, basins and needle holders which are donated to Supplies Over Seas, a local organization, which ships healthcare supplies to needed areas across the globe.

UK students present research

Twenty undergraduates were selected by the University of Kentucky Office of Undergraduate Research to attend the National Conference on Undergraduate Research (NCUR) at Weber State University in Ogden, Utah.

NCUR is an annual conference for students dedicated to encouraging undergraduate research, scholarship and creativity in all fields of study.

Alyssa Fountain, an agricultural biotechnology major from Roswell, Ga., is one of the students who attended NCUR. Working with professor Luke Bradley in the UK Department of Anatomy and Neurobiology, her project focuses on investigating the protective mechanism of a small molecule that has potential interest for developing treatments for neurodegenerative disorders, including Parkinson’s disease.

To be selected by NCUR, students were required to submit an abstract that stated their central research question and the purpose of their research, a brief discussion of their research methodology, and their final or anticipated conclusions. These abstracts were reviewed by faculty across UK and the top 21 were selected for attendance.

BrightStar Care awarded accreditation

BrightStar Care of Louisville, a full-service healthcare staffing agency that provides non-medical homecare, has been accredited by The Joint Commission, a not-for-profit organization that accredits and certifies more than 19,000 healthcare organizations and programs in the United States. The BrightStar location earned The Joint Commission’s Gold Seal of Approval. The accreditation is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards.

As the only non-medical home health agency certified in Kentucky, this achievement puts BrightStar Care of Louisville within the elite group of less than 10 percent of homecare agencies nationwide that have achieved this accreditation.
Harrington co-edits new book

A scholarly anthology covering advances in the field of eHealth applications, co-edited by University of Kentucky communication professor Nancy Harrington, has been published by Routledge. Harrington collaborated on the book with former UK faculty member Seth Noar, now an associate professor in the School of Journalism and Mass Communication at the University of North Carolina at Chapel Hill.

The book, “eHealth Applications: Promising Strategies for Behavior Change,” provides an overview of technological applications in contemporary health communication research, exploring the history and current uses of eHealth applications in disease prevention and management. It focuses on the use of these technology-based interventions for public health promotion and explores the rapid growth of an innovative interdisciplinary field.

UK HealthCare, Norton Healthcare formalize collaboration

UK HealthCare and Norton Healthcare officials announced the creation of a new, not-for-profit membership corporation—composed of leading officials from both institutions—to deliver outreach, education and research opportunities across the Commonwealth of Kentucky and beyond. The Norton Healthcare-UK HealthCare Partnership for Quality will initially focus on improving population health in the areas of cancer care, stroke and heart disease.

During the inaugural meeting of the Norton Healthcare-UK HealthCare Partnership for Quality, the board of directors moved forward on a number of initiatives, including:

- Authorized a Memorandum of Understanding between the UK Markey Cancer Center and the Norton Cancer Institute and the Partnership for Quality to develop joint educational and outreach programs to reduce the incidence of cancer in Kentucky, to develop systems of care between Markey and Norton Cancer Institute for cancer care, and to collaborate in research efforts—specifically investigator initiated trials.
- Approved programs in research to support epidemiologic studies, biospecimen-collection and an expansion of the stroke patient registry to include other high incidence diseases in Kentucky.
- Approved a budget of $595,000 to grow outreach in stroke outreach and education, and launch new programs in acute myocardial infarction care and cancer.

Local physicians give back

As high school seniors approach the end of the school year, there is often more on their minds than just prom and graduation. For many graduates, college lies ahead. But with tuition costs rising, many find themselves with no choice but to take on extensive student loans. For the 21st year, physicians associated with Jewish Hospital & St. Mary’s HealthCare, a part of KentuckyOne Health, are helping to lighten the load by offering college scholarships.

The scholarship program, which began in 1991 as a Sts. Mary & Elizabeth Hospital medical staff initiative, will award at least 12 one-time scholarships in the amount of $3,000 each. The program is open to all students who live in the primary service areas of the Jewish Hospital & St. Mary’s HealthCare campuses. At least two will be awarded to JHSMH employee or a member of a JHSMH employee’s family.

As part of the application process, students are asked to submit an essay distinguishing themselves from other students, detailing how the scholarship will allow them to reach their long-term goals or explaining how they’ve persevered through hardships in life. Applicants were also asked to provide information about their academic achievements, family demographics, community service and teacher recommendations.

The scholarship may be used for tuition, room and board and books at the college of the recipient’s choice. To date, the medical staff has awarded $263,000 in scholarships.

ULP research featured at medical education conference

Research by Ryan Kingery, Ph.D., M.Ed., manager of technical training for University of Louisville Physicians (ULP), was selected as a Best Practices in Medical Education oral presentation for the 2012 Southern Group on Educational Affairs (SGEA) conference.

Participants of the SGEA annual conference for medical educators, held this past April 19-21 in Lexington, come from 46 southern medical schools.

SGEA is a professional development organization affiliated with the Association of American Medical Colleges. This is the first year an educator from ULP has been selected to present at the conference.

Kingery’s proposal, “Continuing Medical Education for Physicians: Needs Assessment for Electronic Health Record Courses with Meaningful Use Implications,” explored the need for specialized training as more and more doctors adopt electronic health records (EHR) technology.

Meaningful Use guidelines and related reimbursement have served as an impetus to the current upswing in electronic health record adoptions. These implemented measures impact providers significantly and training is needed for these providers.

However, not all meaningful use measures impact providers equally. To determine a priority of training needs, Kingery conducted a needs assessment. In it, providers reported that their past technology experiences, technical prowess and area of practice all should determine details of EHR training course content, especially when it relates to meaningful use.

The 2012 SGEA conference theme was “Best Practices in Medical Education: Bring Us Your Best.” The conference featured the very best initiatives and practices in place at medical schools across the southern United States delivered through oral presentations, small group discussions, workshops, demonstrations and poster sessions.
OMHS joins Audubon International Signature Program

Owensboro Medical Health System (OMHS) registered its new, replacement hospital — opening in the summer of 2013 — as a member of the Audubon International Signature Program. OMHS is the first member in Kentucky and the first and only hospital worldwide to become a member.

Audubon International is a not-for-profit environmental organization dedicated to educating, assisting and inspiring millions of people to protect and sustain the land, water, wildlife and other natural resources around them.

OMHS sought a relationship with Audubon because of the new hospital project and its interest in maintaining an environmentally friendly structure and grounds.

Floyd Memorial announces new health needs assessment

Floyd Memorial Hospital and Health Services, New Albany, Ind., unveiled a new community health needs assessment tool that includes more than 100 nationally recognized measurements rating the overall health status of Floyd County residents.

The health needs assessment, available to the public on www.floydfoundation.org uses data compiled from governmental and non-governmental agencies and is automatically updated as the most recent data becomes available.

The assessment is divided into categories derived from the social determinants of health, including economy, education, environment, government and politics, public safety, social environment, and transportation. Each indicator is scientifically rated and accompanied with a colored gauge, with a needle showing how well Floyd county is doing compared to other Indiana counties, and in some cases the Louisville Metro area.

It also rates the county’s progress toward the national standards of health and wellness established by the Centers for Disease Control’s Healthy People 2020 initiative.

Floyd Memorial also coordinated an effort to capture qualitative primary data from Floyd county residents and leaders. First, a focus group session was held consisting of representatives from various community groups and agencies in Floyd County. Then, a community-wide health needs assessment survey was conducted over a one month period to collect the perceived needs from community’s residents.

King’s Daughters Health Foundation receives gift

King’s Daughters Health Foundation, Ashland, Ky., received a gift of $440,000 from the Mansbach Foundation in support of the medical center’s mobile health initiative.

Jane Blankenship, executive director of King’s Daughters Health Foundation, said the medical center determined last fall that its only mobile health unit, which had logged more than 100,000 miles, was wearing out and no longer able to keep up with the healthcare needs of the communities KDMC serves.

The first of the new mobile health units, a blue one, was on the road in November 2011 with help from a major gift from King’s Daughters Medical Center’s Auxiliary. The second unit, which is red, features specialized cardiac testing and can accommodate a variety of mobile health programs.

In honor of its major gift, the Mansbach Foundation was given naming rights to the red mobile health unit, Blankenship noted. As a result, it has been dedicated in memory of Donald H. Putnam Jr. and Samuel Mansbach. Both served on King’s Daughters Medical Center’s board.

Event calendar

Event: The 2012 MediStar Awards
Info: The MediStar Awards is the region’s premier venue for recognizing excellence in the business of healthcare. MediStar Awards features substantial networking with more than 500 healthcare professionals and executives along with the presentation of eight awards to the “best of the best” in our region.
Date: Tuesday, May 22, 2012
Time: 4:30 p.m. networking; 5 p.m. awards; 6 p.m. cocktail reception
Location: Hyatt Regency Louisville, Regency Ballroom, Louisville, Ky.
Cost: $50 individual; $500 sponsored table of 10
To register: www.medistarawards.com/tickets
Learn more: www.medistarawards.com

Event: Spring Zing 2012
Info: Zoom Group’s signature annual fundraiser. All proceeds from Spring Zing go to support Zoom Group’s mission to help adults with developmental disabilities experience a sense of belonging in our community.
Date: Wednesday, May 23, 2012
Time: 6-9 p.m.
Location: The Olmstead, 3701 Frankfort Ave., Louisville, Ky.
To register: 502-894-9768
Learn more: www.zoomgroup.org

Event: 14th Annual NIH SBIR/STTR Conference
Info: “The Changing Face of SBIR/STTR” will focus on topics targeted for those who are new to the SBIR/STTR programs as well as those who are more experienced. Attendees will gain understanding of the nuts and bolts of SBIR and STTR programs from NIH staff.
Date: May 30-June 1, 2012
Location: Louisville Marriott Downtown, 280 W. Jefferson St., Louisville, Ky.
Life science conversation

Kentucky biotech executives discuss their industry’s growth potential, challenges and successes.

By Melanie Wolkoff Wachsman

Biotechnology is one of the fastest growing industries in the United States, and Kentucky is to thank. It’s no secret that over the past decade Kentucky has invested heavily in biotechnology. The successful “Bucks for Brains” program, which matches public dollars with private donations to encourage academic research, has attracted top researchers from around the world to the bluegrass state. In fact, more than 75 percent of new biotech companies have spun out of either the University of Kentucky or The University of Louisville.

Medical News sat down with Kentucky biotech executives including Randall Riggs, president and CEO, Advanced Cancer Therapeutics (ACT) in Louisville, Ky.; Ted Kalbfleisch, Ph.D., founder and CEO, Intrepid Bioinformatics; Gina Lankswert, vice president, business operations and development, Intrepid BioInformatics Solutions, in Louisville, Ky.; Eric Ostertag, president and CEO, Transposagen, in Lexington, Ky.; Bryce Johnson, CEO, Peptides International, in Louisville, Ky.; and Keith Schneider, managing director, BioLOGIC, Covington, Ky., who shared their thoughts.

MN: What are some of the biggest challenges that face the pharmaceutical and biotechnology industries today?

Randall Riggs: Enormous strength of payers (e.g., CMS) is having a draconian price control effect on novel therapeutic drug pricing, which then discourages innovation because of the unbalanced ratio of high risk/high reward now becoming high risk/low reward.

In addition, since late 2007, sources of capital funding for innovative biotech companies have dried up and large pharma is becoming highly risk averse as well when risk taking and innovation is required of them now more than ever. Lastly, significant advances in human biology has been lackluster, leading to further failures among many drugs in development.

Eric Ostertag: Funding from most sources is significantly more difficult to obtain than a few years ago. Also, we sell to larger pharmaceutical and biotech companies, which have been making big budget and employee cuts.

Bryce Johnson: Large costs and long times to develop therapeutic drugs and the availability of research funding from NIH and others to our customers.

Keith Schneider: I think the regulatory environment will always pose a challenge for the type of work we do. Especially in the start-up world where little pieces of funding need to carry an idea a great distance. That said funding is another key piece. More specifically for our region, we need to continue to strengthen the talent pool. By that I do not only mean people that can work for these companies, but also potential entrepreneurs from all stages of life that can contribute ideas and intellect.

Ted Kalbfleisch: The challenge in the bioinformatics industries lies in developing systems that can handle big data sets and organize the information in a manner that enables scientists to quickly and easily realize the full potential of their data.

MN: What are some of the biggest misconceptions about your field?

Gina Lankswert: In general, many people do not understand what bioinformatics is. Bioinformatics is a relatively young discipline (20 years) that has evolved through the melding of the fields of biology, computer science and information technology.

The ultimate goal of bioinformatics is to use information science to drive the discovery of new biological insights that may result in better understanding of the causes and progression of illness, resistance to disease, and development of targeted drugs and cures.

Bioinformatics includes the development of tools and algorithms that allow for the analysis of various types of biological and genomic information as well as support for efficient access and long-term management of those datasets.
K.S.: A misconception I often preach to is that life science companies are a riskier investment than other options. Although to call this a misconception is a bit of a stretch as there is a great deal of risk associated with life science start-ups, with anything the risk lessens when some key components are added to the mix. Things like a strong set of advisors, industry expertise, and like-minded people help lessen the risk.

As long as you have a few people that understand the science and can translate it to the business end then I believe your chances to hit a home run with a company like Surgical Energetics, for example, are at least as good as hitting a homerun by seeking the next Facebook or Papa John's. It may involve different nuts, but the bolts are the same—an addressable market, a strong team, IP and executable business model. bioLOGIC's goal is to bring the bolts to the table as we uncover great and launch opportunities.

R.R.: Biotech companies have secretly discovered cures for many human diseases, but we hide them so we can sell our products each year to people. Another misconception is that drugs from biotech companies are a drain on our economy because of their costs, when in reality if we can improve the quality of someone's life so that they can work and live a “normal life” and stay out of the hospital, then we have provided great value to our economy, the patient and their family.

E.O.: It's not easy to make it big, especially if you are not willing to dedicate all of your time to your company.

B.J.: Biotech is not recession proof and can be very competitive.

M.N.: What accomplishments are you most proud of to date?

E.O.: I started with no money, no equipment, no lab space, no intellectual property and no employees and have built a biotech company that currently employs more than 15 full-time employees, has a very large IP portfolio, and generates revenue greater than $1 million per year. Most importantly, we are offering products and services that lead to new therapeutics to improve the quality of people's lives.

R.R.: We [ACT] started from scratch in late 2007, and we are about to start a Phase I human clinical trial with a novel, first-in-class anti-cancer drug that works by choking off a key fuel source cancer consumes for its growth and metastasis. And, we did this with 1/5 to 1/10 of the resources that is commonly used within the pharmaceutical industry to accomplish this outstanding achievement.

B.J.: Development by our employees of a quality management system that has earned ISO certification and made it through some tough audits.

T.K.: I am most proud of the relationships that I have been able to build in Louisville, and across the nation to find the technological and business acumen necessary to start and sustain Intrepid.

Equally important have been the scientific ties that I have been able to foster with government, academic and commercial scientists. These scientific, technological, and business relationships provide a solid foundation for Intrepid, and position us well to sustain our growth.

G.L.: I am most proud of the partnership I have been able to build with our founder and CEO. The blending of strong scientific and business expertise allows Intrepid to deliver superior returns to all its constituents.

M.N.: What advice can you give someone who would like to pursue a career
within the pharmaceutical and biotechnology industries?

B.J.: A broad technical experience creates the best perspective for pursuing an MBA or other business degree in the biotech area.

R.R.: Have passion for breakthrough discoveries, but the persistence to face many daunting challenges and still move forward with confidence.

T.K.: The technology in the life sciences is improving at an incredible rate. Staying at the leading edge of technology is more difficult now than it has ever been. Keep your eyes and your mind as open as possible to identify and evaluate new opportunities. The people who are able to be creative in such a dynamic environment are the ones in the best position to lead us to the essential improvements in therapeutics and diagnostics for the benefit of our healthcare system.

E.O.: Being a biotech entrepreneur will require enormous personal sacrifices and dedication, so don’t try it unless you are passionate about it.

K.S.: Find a mentor. So many people I work with, whether at the CEO level or a lab rat, are so willing to share their time and insight. Set up a time to chat and bring them caffeine. You will gain a wealth of knowledge.

Executive confessions

Sure, they may be executives, but they are not afraid to share. Below are some fun revelations our panelist said their colleagues would be surprised to learn about them.

“I have always wanted to be the President of the United States at some point in my life because I truly believe we need a non-politician running this country that has demonstrated integrity over his life and achieved success through hard work and passion.”

— Randall Riggs, president and CEO, Advanced Cancer Therapeutics

“I can bench press significantly more than I weigh.”

— Eric Ostertag, president and CEO, Transposagen

“I started out as a chemistry professor at the University of Louisville.”

— Bryce Johnson, CEO, Peptides International

“Most people are surprised to learn I have no background in life science other than assisting a few companies with funding opportunities. To date, this has been an asset to me. It is so easy for a scientist or innovator to fall in love with their ideas and technologies, but if they can’t explain it to a guy like me it will be a long road to ruin.”

— Keith Schneider, managing director, bioLOGIC

What happened 20 years ago in healthcare?

Twenty years ago, Cardinal Hill Rehabilitation Hospital opened the general rehabilitation unit. Our hospital not only remodeled the spinal cord unit, but increased the bed capacity. Soon after, we opened the first Young Adult Day Program in Central Kentucky and the Lyman V. Ginger Pediatric. We’ve started new programs, built new care centers and continue to serve the Commonwealth of Kentucky. We serve five inpatient units and strive to maintain our mission of being a benchmark in the nation for excellence in physical rehabilitation services.
Why Owensboro is poised to be the global center of the PMP revolution

By Madison C. Silvert

The story that has not been told is the story of how Owensboro created a system of supports to keep the industry alive following the collapse of Large Scale Biology, and how this network of supports will help Large Scale’s successor company, Kentucky BioProcessing, create an industry that, up until now, did not truly exist.

In 2007, following the acquisition of the physical plant (and ultimately the intellectual property) of Large Scale Biology by Owensboro Medical Health System, the Greater Owensboro Economic Development Corporation (GO-EDC) was in its first year of a new strategic plan. Dr. Nicholas Brake, GO-EDC’s new CEO, wanted to do things differently, and saw the potential in KBP and the PMP industry. Dr. Brake and the GO-EDC board saw this as an opportunity to not only support PMP’s, but also as an opportunity to support high-tech start-ups in general.

But Owensboro did not stop with connections to the ICC network and the state’s funding infrastructure—it created a fund of its own. In 2008, the City of Owensboro decided to commit a significant portion of its dividend from Riverport operations to the eMerging Ventures Seed Fund, which is dedicated to high-tech start-ups. Though the investments from the eMerging Ventures Seed Fund tend to be small, it is often a company’s first investment dollar in the door.

The Innovation Act of 2000 had created a successful network of Innovation and Commercialization Centers, under the leadership of the Office of the New Economy (now the Office of Commercialization and Innovation) and the Kentucky Science and Technology Corporation. Remarkably, though one of Kentucky’s largest cities, Owensboro was not granted an office in the ICC network. This changed in 2007, first recognizing Owensboro’s eMerging Ventures Center for Innovation as a satellite office of the Western Kentucky University ICC, and now, as of July 1st of this year, the Owensboro office will have full status as an ICC. This provides better access to services needed by high-tech start-ups as well as a more direct line to the Commonwealth’s cadre of high-tech funds, including the Kentucky Enterprise Fund, the Commonwealth Seed Capital Fund, the unique SBIR/STTR matching fund, and the state’s High-Tech Pool fund.

What happened 20 years ago in healthcare?

Spencerian College celebrates its 120th birthday this year. Since our inception in 1892, we’ve remained true to our roots. Our mission is to provide people with the quality training in the business, technical and healthcare professions. In the history book Beginning of the Business School, author Charles G. Reigner said the name Spencerian is a name well known among American people; that it’s an honored name. It’s been an honor serving our students and we hope for many more years to come.

While the protocol has remained the same, it has been frustrating that medications have not changed much in recent years.

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CHALLENGE: When Dr. Navalgund came out of medical school, he had all the right medical training. But when he decided to open his own practice, he needed something new — an education in the business side of medicine.

SOLUTION: Dr. Navalgund had the Cash Flow Conversation with his PNC Healthcare Business Banker, who put his industry knowledge to work. Together, they tailored a set of solutions to strengthen his cash flow: loans for real estate and equipment along with a line of credit to grow his practice, plus remote deposit to help speed up receivables.

ACHIEVEMENT: DNA Advanced Pain Treatment Center now has four private practices and a growing list of patients. And Dr. Navalgund has a place to turn for all his banking needs, allowing him to focus on what he does best.

WATCH DR. NAVALGUND’S FULL STORY at pnc.com/cfo and see how The PNC Advantage for Healthcare Professionals can help solve your practice’s challenges, too. Or call one of these PNC Healthcare Business Bankers to start your own Cash Flow Conversation today:

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ACCELERATE RECEIVABLES
IMPROVE PAYMENT PRACTICES
INVEST EXCESS CASH
LEVERAGE ONLINE TECHNOLOGY
ENSURE ACCESS TO CREDIT
Easily Owensboro’s biggest investment in PMP’s is the Centre for Business and Research. Opened in 2011, the 47,000 square foot business incubator is dedicated to the life sciences. The $2.5 million project was developed in consultation with scientists from KBP as well as the Owensboro Cancer Research Program. The facility, developed in a 100-year-old abandoned tobacco warehouse, boasts roughly 2,000 square feet of biosafety level 2 laboratory space and nearly $1 million worth of equipment.

The equipment, paid for by a generous contribution from the Daviess County Fiscal Court and a grant from the Economic Development Administration, includes, among other things, auto-sampling HPLC’s, a capillary electrophoresis, freezers, centrifuges and tissue culture and sanitization equipment.

This allows a life science start-up to greatly reduce its costs to start R&D, and provides them a place to work among other researchers and entrepreneurs. KBP will also have a space in the labs to help PMP developers better use and understand their unique manufacturing system.

Owensboro’s commitment to PMPs and the life sciences is clear. With access to consulting and commercialization services, start-up capital, labs and equipment, Owensboro is poised to be the global center of the PMP revolution.

Madison C. Silvert is director of the Owensboro ICC and interim director of the Kentucky BioAlliance.
Meet Your 2012 MediStar Award Finalists

**The ARGI Financial Physician of the Year Award**
Presented to a physician who has demonstrated outstanding leadership on a local, state or national level to improve accessibility, affordability and quality of healthcare in our region.
- Scott Hedges, M.D., Seven Counties Services
- Kerri Remmel, M.D., Ph.D., University of Louisville Hospital Stroke Center
- Madonna Ringswald, D.O., Baptist Hospital Northeast

**The Hall Render Leadership in Healthcare Award**
Presented to an individual or organization demonstrating outstanding leadership in the business of healthcare.
- Michael W. Bukosky, University of Louisville Physicians
- Helen Overfield, American Diabetes Association

**The Crowe Horwath Innovation Award**
Presented to an individual or organization that has positively impacted healthcare delivery costs through the development, design or implementation of new technology.
- Roberto Bolli, M.D., Jewish Hospital & St. Mary’s Healthcare, a part of KentuckyOne Health
- Kentucky Health Information Exchange
- UofL Health Care Supply Chain

**The Seven Counties Services Healthcare Advocacy Award**
Presented to an individual or organization that is an effective advocate at the local, state or national level concerning issues such as, but not limited to, access to care initiatives that support healthy lifestyles.
- Vasti Broadstone, M.D., Floyd Memorial Joslin Diabetes Center Affiliate
- Foundation for a Healthy Kentucky
- Therese Sirles, Kosair Children’s Hospital

**The Facility Design Award**
Presented to an individual or organization that has designed, built or implemented the most innovative facility within the region.
- Home of the Innocents, designed by Michael Koch & Associates
- Kosair Children's Medical Center, designed by LMH Architecture
- University of Louisville School of Dentistry, designed by Luckett & Farley

**The Governor’s Dignity of Humanity Award**
Presented to an individual or organization that through its mission and its actions has improved availability and/or access to healthcare services for our region’s underserved or vulnerable populations.
- Christian Care Communities
- Kelly Gunning, NAMI Lexington
- Supplies Overseas
- UofL School of Dentistry/RAM

**The AHIP Consumer First Award**
Presented to an individual or organization that has demonstrated the most “consumer friendly” program or facility.
- James Graham Brown Cancer Center Mobile Mammography Unit
- CenterOne, Seven Counties Services
- Mary Haynes, Nazareth Home
- Recovery Mall at Eastern State Hospital

**The A.O. Sullivan Award for Excellence in Education**
Presented to an individual or organization that has developed and implemented programs which increase the level of knowledge, education, and career opportunity in healthcare.
- Carol Fout-Zignani, Norton Healthcare
- ULH Nurse Residency Program
- UofL Pediatrics – Forensic Medicine

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The new cloud over the future of personalized medicine

The future of personalized medicine, or the tailoring of healthcare decisions and practices to individual patients, recently became a lot cloudier. On March 20, 2012, the U.S. Supreme Court issued its decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., U.S., No. 10-1150, 3/20/2012, and invalidated patent claims directed to methods of optimizing patient treatment in which drug metabolite levels were measured and then used to adjust dosage levels. The ruling in Mayo, however, extends beyond the simple measurement of drug metabolite levels, and has the potential to make a significant impact in healthcare and the life sciences.

Under the U.S. patent system, it has long been recognized that patents can not be obtained for fundamental laws of nature, such as Albert Einstein’s theory of relativity (E=mc^2) or Sir Isaac Newton’s law of gravity. At the same time, the U.S. Supreme Court has repeatedly stated that applications of such laws of nature are eligible for patent protection. Indeed, practitioners and researchers in healthcare and the life sciences have often relied on the ability to patent applications of natural laws in order to protect innovations that have led to a number of medical cures and breakthroughs. The Supreme Court has now made it clear in Mayo that such applications of laws of nature are not always eligible for patent protection.

The Mayo Decision

In Mayo, a unanimous (9-0) Supreme Court held that the personalized medicine dosing process invented by Prometheus was not eligible for patent protection because the process was effectively an unpatentable law of nature. The Court reasoned that the relationship between the drug metabolites found in the patient and the dosage administered was a consequence of the way in which the drug was being metabolized in the body or, in other words,
Aspirin therapy update

The jury’s still out for primary prevention.

By Sharon H. Fitzgerald

Just like the phrase “take two aspirin and call me in the morning” implies, acetylsalicylic acid is a medical mainstay, one of the world’s most frequently prescribed and least expensive drugs. In fact, 100 billion aspirin tablets are produced worldwide each year. That said, there’s still a lot we don’t know about aspirin, particularly when it comes to heart-attack prevention.

“I think aspirin is still a fascinating topic because it’s a commonly used medication, both in terms of doctors recommending it and also patients sometimes just taking it over the counter for a variety of indications. However, given how widespread its use is, it’s actually amazing that in 2012 there are still a lot of unanswered questions about aspirin,” said Deepak L. Bhatt, M.D., chief of cardiology at the VA Boston Healthcare System and director of the Integrated Interventional Cardiovascular Program at Brigham and Women’s Hospital.

Secondary Prevention

Nonetheless, some things are certain. For secondary prevention, when patients have already suffered a heart attack or certain types of strokes or have undergone a heart bypass or other procedure, aspirin is a proven therapy. “Taking aspirin is the right thing to do for the vast majority of those patients unless they have some serious bleeding problems. They really should be on aspirin, and it’s unfortunate that a proportion of such patients aren’t,” Bhatt said. “Typically, as is the case with all medicines, patients don’t always adhere to what’s recommended, especially once they’re feeling well and once time has passed from the index event.”

Echoing that notion is Stephen L. Kopecky, M.D., professor of cardiology at the Mayo Clinic and president-elect of the American Society for Preventive Cardiology. “For people who have heart disease, aspirin clearly is beneficial, and it lowers their risk for having a recurrent heart attack, and if they do have a heart attack, it lowers their chance of dying,” he said. Yet Kopecky bemoaned the fact that patients don’t loyally adhere to aspirin regimens— or regimes of any medication, for that matter.

Patients Lack Adherence

To underscore his point, Kopecky referenced a study published in late 2011 in the New England Journal of Medicine that examined patients’ adherence to a drug therapy after a heart attack. Even when the patients in the study received free of charge the drug that may prevent a recurrent heart attack, only about half the patients stuck with the therapy for three years. “You would think that those patients would be the most motivated,” he said.

Then there’s the problem of ensuring that those patients who should be taking aspirin for secondary prevention are indeed informed.

Bhatt was on the research team of the international REACH study, which wrapped up its findings in 2010 and documented the underutilization of aspirin. It concluded that about 14 percent of patients who had strong indications to be on aspirin for secondary prevention weren’t.

“Some proportion of that might have been side effects or problems with bleeding, but I don’t think that explains that whole percentage,” Bhatt said.

Primary Prevention

Yet, when it comes to aspirin for primary prevention, the jury is still out, even for patients with multiple risk factors such as advancing age, diabetes, smoking, high blood pressure and high cholesterol. While some physicians believe a low-dose daily aspirin for such patients is appropriate, provided those patients don’t have a history of problems taking aspirin, other physicians are shying away until more concrete, evidence-based data are available.

“There are certainly are some studies that show reductions in nonfatal heart
“Aspirin is the most used drug, most prescribed drug for the most common disease that is the biggest killer in the world—coronary artery disease. Yet we’ve never had a study that has told us what dose to use.”

– Stephen L. Kopecky, M.D., professor of cardiology at the Mayo Clinic and president-elect of the American Society for Preventive Cardiology

attacks, but it’s not been absolutely shown with certainty in any large, contemporary, randomized, clinical trial that aspirin for primary prevention (in high-risk patients) does reduce events like death and heart attack,” Bhatt said.

And the downside, he added, can be devastating. Gastrointestinal bleeding increases with an aspirin regimen, and there’s also a very small, but very real, risk of bleeding into the brain. “That’s why it creates a dilemma,” Bhatt said.

As for Kopecky, he said he does recommend aspirin for primary prevention if a patient presents with more than two risk factors and especially if there’s evidence of narrowing of arteries to the heart or anywhere in the body. He said he sometimes orders a CT scan to pinpoint whether there’s calcium in the arteries to the heart. “Then we know those patients have a process that is damaging the lining of their arteries, so we get those people on aspirin,” he said.

There are a number of large, randomized, clinical trials ongoing that should be reporting in the next few years and should nail down the role of aspirin in primary prevention.

Meanwhile, both Kopecky and Bhatt said physicians should consider each patient’s particular circumstances when deciding whether to recommend an aspirin therapy.

“It’s a complex decision, and it really should be individualized,” Bhatt said, adding, “I think it’s actually an error for patients to just start taking aspirin on their own for primary prevention without consulting with their doctor, even though it’s cheap, over the counter and is a familiar medicine.”

**Patient Immunity**

Could patients become immune to aspirin? Such a phenomenon hasn’t been demonstrated, and Kopecky said patients don’t become immune in the same way that they would develop a tolerance for an antibiotic.

“However, we do know that if you take aspirin and you still have a heart attack, then you’re higher risk and you probably need something more than aspirin next time,” he said.

Yet, there’s something about aspirin that Kopecky would really like to know, and it’s something research has yet to tell him. “Aspirin is the most used drug, most prescribed drug for the most common disease that is the biggest killer in the world – coronary artery disease. Yet we’ve never had a study that has told us what dose to use,” he said.

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“Patient Immunity”

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THIS IS AN ADVERTISEMENT
Genetic testing challenges

Studies show physicians concerned about cost, lack of familiarity, support.

By Lynne Jeter

Greater use of genetic testing would occur if physicians had the necessary tools, according to a new study by UnitedHealth Group’s Center for Health Reform & Modernization.

The report, “Personalized Medicine: Trends and Prospects for the New Science of Genetic Testing and Molecular Diagnostics,” presents new findings on how genetic tests may facilitate disease diagnosis, target prevention, and ensure that patients receive the medicines that will best treat their conditions.

“IT’s our sense that genetics is rapidly moving from the era of ‘genetic exceptionalism’ to simply being ‘medicine,’”
— Reed Tuckson, M.D., chief of medical affairs at UnitedHealth Group

“A commitment to lifelong learning is an obvious responsibility for a health professional,” he said. “Physicians must be supported with actionable information at the point of care, and they’ll need to learn how to use this information in the most appropriate way. Finally, it’s the responsibility of all healthcare stakeholders to help physicians to have convenient access to the data, analytics and actionable intelligence necessary to meet their professional obligations, and let’s not forget that, especially in genetic medicine, the patient’s values and perspectives are essential to the clinical decision making process.”

Rising Costs

Some $5 billion is being spent annually on genetic testing in the United States; costs may easily increase to $25 billion by 2021. Genetic testing is currently optional for roughly 2,500 conditions, including cancers and communicable diseases. Full genome sequencing, which maps an individual’s entire genetic code, is also expected to become widely available, possibly beginning as soon as later this year.

“Genetic science offers unprecedented potential to prevent disease and improve diagnosis and treatment, ushering in an era of truly personalized care,” said Simon Stevens, executive vice president of UnitedHealth Group, and chairman of the UnitedHealth Center for Health Reform & Modernization.

“But for patients to realize these practical benefits, we’ll also need new models of research and care delivery combined with informed choice and appropriate consumer safeguards.”

Oris Brawley, M.D., chief medical officer of the American Cancer Society, said advancing genetic testing is “one of the greatest contributions we can make to the future of personalized medicine. Doing it conscientiously requires taking a close look at the challenges ahead with a focus on bringing to consumers the full benefits that this new technology promises.”

Doing the Math

On average, physicians report having recommended genetic testing for 4 percent of their patients over the past year. Looking ahead five years, physicians on average feel that 14 percent of their patients will have had a genetic test; however, nearly three-in-five doctors say that they’re very concerned about the cost of genetic tests.

“We hope that, when used properly and appropriately, (genetic testing) will enhance the precision in which healthcare is delivered; thereby, increasing healthcare quality and lowering costs,” said Tuckson. “However, today’s delivery system is too often characterized by misuse and inappropriate use of healthcare assets. Genetic-based technologies will increase the complexity of clinical decisions and could, without concerted

Report Recommendations

The report makes six recommendations to ensure that patients and physicians benefit from the new science:

1. Protecting and supporting patients through data confidentiality, nondiscrimination safeguards and decision support;
2. Strengthening clinical evidence to inform patients and physicians about which tests work best, for specific conditions;
3. Better aligning of reimbursement incentives to encourage innovation and appropriateness in test development and usage;
4. Improving care monitoring and transparency of test coding practices;
5. Ensuring that lab tests are performed safely and accurately; and
efforts, lead to further waste in health-care delivery. As such, it’s important to have specificity regarding the appropriateness criteria and clinical guidance for genetic tests and effective point-of-care decision making aids for clinicians and patients.”

A stumbling block: the coding system used nationwide to monitor medical tests offers few codes to describe genetic tests for specific diseases.

Some $5 billion is being spent annually on genetic testing in the United States; costs may easily increase to $25 billion by 2021.

“Most physicians see the largest barrier to use of genetic testing from the M.D. perspective as cost and reimbursement for tests,” said Tuckson, noting the working paper discusses how payers make coverage decisions for genetic testing. “In general, public and private payers cover the costs of diagnostic testing as broadly defined, and may have specific medical policies in this area of genetic testing, depending upon the clinical evidence for a specific test.”

Tuckson said it’s reasonable to expect variability across health coverage plans for the near future. “The goal will be to standardize our understanding of which patients are appropriate for what interventions,” he noted.

**Report Recommendations**

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• Better aligning of reimbursement incentives to encourage innovation and appropriateness in test development and usage;

• Improving care monitoring and transparency of test coding practices;

• Ensuring that lab tests are performed safely and accurately; and

• Making it easier for health professionals to stay abreast of new developments in genetic science.

“We discuss in the paper ways to make it easier for health professionals to stay up-to-date as genetic science evolves,” said Tuckson. “Those include greater use of genetic counselors, improvements and updates to existing guidelines and guidelines review, cross-training opportunities with individuals in the bioinformatics field and health information technology applications that could keep clinicians informed about new tests and their clinical applications.”

Certainly, the mapping of the human genome and use of genetic testing in diagnosing and treating diseases are landmark breakthroughs in modern medicine, said Tuckson. “It’s now up to all of us to foster an environment that encourages innovation in these tests and related treatments,” he said, “as well as their responsible use, to bring about real-world improvements in care.”

**Going Mainstream**

It’s not a matter of if genetic testing will become the norm, but when, said Tuckson.

“It’s our sense that genetics is rapidly moving from the era of ‘genetic exceptionalism’ to simply being ‘medicine,’” he said. “Predictions on timelines when this will be fully realized must be considered in the context of a continuum. This continuum, based upon the already extraordinary number of genetic-based tests and related expenditures, has already begun.”

By Tony Felts

By 2020, it is predicted the U.S. will have a shortage of more than 40,000 primary care physicians. Kentucky is hard-hit, especially in rural areas of the Commonwealth.

In response to this problem, last month WellPoint, the parent company of Anthem Blue Cross and Blue Shield in Kentucky, announced the launch of an innovative reimbursement initiative, partnering with primary care physicians to improve quality and reduce medical costs.

In the Wall Street Journal, WellPoint executive vice president of comprehensive health solutions Dr. Harlan Levine said, "This will fundamentally change our relationship with primary care physicians."

Under the initiative, participating physicians will be able to share in this program through a general increase to the regular fees paid to physicians practices for specific services; through payment for "non-visit" services currently not reimbursed, with an initial focus on compensation for preparing care plans for patients with multiple and complex conditions; and through shared saving payments for quality outcomes and reduced medical costs.

WellPoint anticipates that primary care practices that participate in the program can earn 30 to 50 percent more from WellPoint’s affiliated health plans than they do currently.

The initiative will be implemented by Anthem Blue Cross and Blue Shield in Kentucky’s primary care network by the end of 2014, according to Mike Lorch, Anthem’s regional vice president for provider engagement and contracting.

"In many ways, Kentucky is in the forefront of this focus on primary care," Lorch said. "We realized that evaluation and management (E&M) services are the most common revenue source for primary care providers. So back in 2009, Anthem started looking for a way to increase our allowances for primary care, without diluting the effort by increasing specialty evaluation and management, which is usually a lesser part of specialty practices."

Primary Care Fee Schedule

This resulted in Anthem’s introduction of a Primary Care Fee Schedule that is separate and distinct from the fee schedules for other medical specialties.

"For each year since 2009, Anthem has placed the majority of our fee schedule increases on the primary care side," Lorch said. "Today, our allowance for evaluation and management services to primary care is 17 percent higher than other specialties."

"This is an exciting time in Kentucky. We have the opportunity to further our goals for primary care recognition, and develop our processes for maximum impact, both in quality care and cost efficiency."

— Mike Lorch, Anthem’s regional vice president for provider engagement and contracting

"In many ways, Kentucky is in the forefront of this focus on primary care," Lorch said. "We realized that evaluation and management (E&M) services are the most common revenue source for primary care providers. So back in 2009, Anthem started looking for a way to increase our allowances for primary care, without diluting the effort by increasing specialty evaluation and management, which is usually a lesser part of specialty practices."

Shared-Savings Model

Later this year, Anthem will begin to share quality data derived from its claims data. This will be practice specific. The standards will include criteria developed by the National Committee on Quality Assurance, the American Academy of Pediatrics, the American Academy of Pediatrics, and others. Measurements against these standards will be introduced to differentiate reimbursement levels in a quality-based purchasing process. In addition, Anthem will enhance the links between the physician’s office services and their own case-management activities to ensure coordinated approaches to at-risk patients.

Anthem will also share data on how primary care can achieve overall medical cost savings by providing information on facility costs, referral guidelines, and practice-specific information such as generic prescribing compared to peers, and patient ER usage.

"To initiate a true shared-savings model, there must be sufficient scale to ensure that results are stable and significant," Lorch said. "That means that as a rule of thumb, a practice should have at least 5,000 Anthem patients in order to stabilize the measurement outcomes. For a smaller state like Kentucky, those numbers may be difficult to achieve. However, we will still seek ways to integrate these underlying principles of patient centered medical homes into our relationships with physicians."

"This is an exciting time in Kentucky," he continued. "We have the opportunity to further our goals for primary care recognition, and develop our processes for maximum impact, both in quality care and cost efficiency."

— Mike Lorch, Anthem’s regional vice president for provider engagement and contracting
A walking miracle
How rehab saved patient after 100-foot fall.

By Angie Kinsey

Daniel Dunn has no doubt his ongoing recovery from a near-fatal fall nine months ago is a miracle.

“All of the doctors are amazed at what’s taken place. I had to learn how to walk again.”

—Daniel Dunn, patient

“It’s a whole bunch of miracles,” said Dunn, 37, of Melber, Ky. “All of the doctors are amazed at what’s taken place. I had to learn how to walk again.”

Dunn, an avid outdoorsman, was hiking last Memorial Day at Burden Falls in southern Illinois when his life changed forever. In an attempt to rescue a friend who was falling, they both fell 75 to 100 feet over the waterfall and were airlifted to a hospital in Evansville, Ind. They both suffered life-threatening injuries.

“I had multiple transfusions and almost died a couple of times,” he said. “I had hundreds of breaks. I didn’t have any feeling in my legs.”

Slow Healing Process

After multiple surgeries, including a craniotomy, Dunn began the slow process of healing, with parents Ron and Margaret Dunn and brother Robert by his side.

Dunn was able to leave the hospital in July, with 24-hour care, and began rehabilitation at Paducah’s Baptist Rehab Center in October. He is now able to walk with a cane and live on his own.

“Daniel has worked really hard and has made tremendous progress,” said physical therapy clinical manager Tony Bohannon. “When he first came to us, he needed someone close to him with any walking or transfers because his balance was so bad. He was dizzy all the time and didn’t have much strength in one of his legs, and the other leg didn’t have any sensation. He can walk and transfer by himself now with much better safety.”

Bohannon used equipment such as Balance Master and a vibrating platform to assist Dunn’s therapy. “The main things we worked on were vestibular rehab to help his dizziness. We also worked a lot on balance, gait training and core strengthening exercises,” said Bohannon.

Bohannon said Dunn benefited from physical and occupational therapy at one place. “It meant that he didn’t have to go to multiple places to get help, but we could meet all his needs here,” Bohannon said.

“We focus on getting to the heart of the problem and not just treating their symptoms.”

—Tony Bohannon, Baptist Rehab physical therapy clinical manager

The center also offers speech therapy – helpful especially to stroke victims who may need all three services. “We focus on getting to the heart of the problem and not just treating their symptoms,” said Bohannon. “We want our patients to know that if they give 100 percent, we will be right there with them every step.”

In Dunn’s case that’s exactly what happened. Although, Bohannon admits Dunn’s determination escalated his recovery. “He was such a go-getter and never complained. He always worked on his exercises at home,” he said.

Angie Kinsey is communications coordinator at Western Baptist Hospital, Paducah, Ky.

R egulatory overhauls are in full swing, particularly in the areas of reimbursement, technology, and accountability. Concern over the changing landscape has renewed health care providers’ interest in discussions regarding collaboration and consolidation. One certainty is that those who adapt to change will be best suited to thrive in a new payment environment.

Bundled Payment Programs Are On The Horizon

Bundled Payment Programs are one of the centerpieces of healthcare reform. The goal of these programs is to reduce duplication of services and improve quality. Bundled payments will be designed to incentivize providers to keep the cost of an episode of care below the lump sum payment. This model comes with the potential for both great risk and great reward. It is driving providers to change historic relationships and may change the overall framework through which care is provided.

Collaboration and Consolidation Come With Risks

We know we will see increased collaboration and consolidation across the provider spectrum. It is already here. Of course, changing relationships implicate a tangled web of legal issues, including antitrust, anti-kickback, and the Stark Law.

With Heightened Enforcement, Providers Must Stay Compliant

Enforcement of federal healthcare fraud and abuse laws has escalated in recent years, with recoveries reaching an all-time high in 2011. The laws on self-reporting and returning overpayments are changing, and compliance requires heightened vigilance. Organizations should strive to keep overpayment and self-disclosure policies in line with developing regulations.

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Kentucky’s new Medicaid problem

By Dr. Jason Wallace

It seems as though we’ve swapped one Medicaid problem for another. This time, it’s the 540,000 Kentuckians on the program who are feeling the pain. There’s no doubt something had to be done to fix the budget black hole that was Kentucky’s fee for service Medicaid program. The costs were spiraling out of control and fiscal responsibility demanded a solution. Managed care may well end up being the right move, but it is certainly experiencing some trouble out of the gate.

Kentucky’s Medicaid managed care organizations (MCO’s) are putting profits ahead of patients and risking the health and well-being of Kentucky’s most vulnerable citizens. As an independent pharmacist, I see my patients dealing with it every day.

Nearly one-fifth of Kentuckians cannot afford or qualify for private insurance leaving Medicaid as their only option. We cannot allow private companies to take advantage of them. Pharmacists are often forced into the very difficult position of telling their patients why their insurance company has denied them the medicines prescribed by their doctor. Medicaid patients deserve the same access to life-saving medications as commercially-insured patients.

Unfortunately, the MCOs’ complicated prior-authorization processes and mandatory step-therapy/fail first policies often force patients to go without prescribed medications. These are usually patients that aren’t able to iterate their complaints to the MCOs.

Another troubling trend is the practice of MCO pharmacy benefit managers (PBMs) requiring patients to use mail order pharmacies to access what they have determined are “specialty drugs.” This forces people away from their trusted local pharmacist and can mean significant delays in getting medications. This often impacts patient communities who can least afford a change in their treatment regimen, including those with cancer, mental and behavioral health, issues and chronic pain.

Another threat to patients is just beginning to rear its head. Kentucky’s independent pharmacists are struggling to keep their doors open as MCOs look to balance profits on their backs by slashing reimbursement rates and dispensing fees. Many independent pharmacies are forced to fill prescriptions for less than what they pay to buy the drugs needed to fill them. The MCOs use a draconian reimbursement formula that lacks transparency. The result is an unsustainable negative income for pharmacies that provide a critical service to Kentucky’s Medicaid population.

Immediate changes are needed in the way MCOs approve patient medications and in the way they work with healthcare providers. MCOs must clean up their complicated prior-authorization processes and be more transparent when it comes to fail first policies that are forcing patients to go without prescribed medications. They must also pay fair and reasonable reimbursement rates and dispensing fees for the critical services independent pharmacists provide.

If the MCO’s are allowed to continue these aggressive practices, Kentucky’s Medicaid population will suffer. Not only will they lose access to life-saving medications, but they may very well lose access to the pharmacies they know and trust. This is unacceptable. We must fix the problem before it’s too late.

Dr. Jason Wallace is an independent Kentucky pharmacist and owner of three pharmacies in rural Grant County.
The new cloud over the future of personalized medicine

Continued from page 18

was the consequence of an entirely natural process. Additionally, because methods for determining drug metabolite levels were well known, the Court stated that the claimed processes were simply telling others “to engage in well-understood, routine, conventional activity previously engaged in by researchers in the field.” Mayo, 566 U.S. ___ (2012), Slip Opinion at p. 4.

Natural Law Patent Protection Uncertain

As a result of the Supreme Court’s decision in Mayo, the question inevitably becomes, what types of applications of natural laws are going to be eligible for patent protection in the future? The Court in Mayo made it clear that an application of a law of nature may continue to be deserving of patent protection. However, the Court also made it clear that “well understood, routine, conventional” applications are not going to be sufficient to confer patent protection, such that the decision in Mayo can potentially be extended to the patent eligibility of a variety of different discoveries in the field of personalized medicine.

For example, the discovery of the presence or absence of specific proteins in certain disease states are routinely the subject of diagnostic method patents whose claims include steps of determining levels of the proteins in the blood of a patient and correlating those levels to a particular disease state. Likewise, the discovery of specific gene mutations, such as those gene mutations found in breast cancer patients that are now the subject of the well known Assn. For Molecular Pathology v. Myriad Genetics case (often referred to as “the gene patent case”), are frequently relied on to support patent claims directed to methods for assessing a risk of disease in a particular patient by determining the presence or absence of the gene mutation. Under Mayo, each of these personalized medicine approaches are almost certainly implicated and may ineligible for patent protection if they are found to make use of “well understood, routine, conventional” ways to identify the particular protein marker or the gene mutation.

Moving forward, the extent to which a law of nature will need to be applied and, consequently, the extent of the effect that the Mayo decision will ultimately have on healthcare and the life sciences is unclear. Because of the potentially broad implications of the Mayo decision, however, the decision will certainly change how companies and research institutions invest in or pursue protection for new discoveries in the field of personalized medicine.

Indeed, on the day the Court issued the decision in the Mayo case, the stock for Myriad Genetics, the holder of the patent in the gene patent case, dropped by a full 5 percent.

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