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Some months ago, I wrote an editorial which in part discussed Theranos, the entrepreneurial venture of wunderkind Elizabeth Holmes. A laboratory testing company with all-star backing (Sen. Bill Frist and Henry Kissinger to name a few of those stars), it promised the capability to perform hundreds of tests using only a few drops of blood rather than multiple vials. Theranos was hailed as revolutionary due to its technological innovation and promise to cut costs and improve patient experience. Walgreens partnered with Theranos to offer this convenience on every proverbial street corner. Elizabeth Holmes’ net worth shot to $4.5 billion on the basis of her 50 percent stake in the company.

Since then, the unicorn has been increasingly found to be a donkey dressed up in a party hat. In October, the Wall Street Journal raised concerns over the accuracy of the testing. Two years of results may have been inaccurate, and there may be lawsuits pending on behalf of patients who may have had inaccurate results, leading to unnecessary treatment or procedures. In addition, the Centers for Medicare and Medicaid Services reviewed these concerns and proposed banning Holmes from the industry altogether.

As of June 2, Forbes has recalculated Holmes’ net worth to be zero (the company is still worth $800 million, but if liquidated, her common shares will be worthless).

Theranos is a cautionary tale of business and medicine combining andcombusting, of secrets and lies, and of wanting so badly to believe that this dream could be possible. The full story will come out slowly but surely. Perhaps the technology is valid but wasn’t perfected before the rush to market; perhaps the science was good but the business angle corrupted its use. Perhaps the entire thing was a hoax, but that’s less likely. Hopefully patients have not suffered as a result. Investors no doubt will suffer. Elizabeth Holmes is luckily only 32 and has a lifetime to recover and reinvent herself and analyze what went wrong. I’m guessing that some of us have seen this story before in a different incarnation in our lives.

Medicine plus entrepreneurial ambition can be a boon or just a seductive siren song of hope. One thing remains firm through the years: If it sounds too good to be true, it probably is.

Dr. Paranjpe is an ophthalmologist and medical editor of the ACMS Bulletin. She can be reached at reshma_paranjpe@hotmail.com.

The opinion expressed in this column is that of the writer and does not necessarily reflect the opinion of the Editorial Board, the Bulletin, or the Allegheny County Medical Society.
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Bringing back the ‘Black Bag’

Great Jewish physician/philosopher Moses Maimonides in the “Oath of Maimonides” said: “May I never see in the patient anything but a fellow creature in pain.” He also said: “The physician should not treat the disease but the patient who is suffering from it.”

The practice of looking after the whole patient at home with the iconic black bag full of cures, the “Black Bag Model,” is coming back. The proverbial house calls which were routine around World War II slowly disappeared to almost nonexistent by the 1980s due to biomedical explosion, inefficiency and, of course, fear of litigation. Over the decades, the fault lines have appeared, showing aging demographics, a growing epidemic of chronic conditions and an unsustainable fiscal model. Many walls of bureaucracy have been put up, including paper work and third-party interference, and the doctor is being pushed further and further away from the patient. A resurgence of house calls brings the doctor back to the patient and, if properly utilized, can go a long way to improve the patient experience, reduce cost and heal the profession of medicine.

A traditional house call is defined as visiting a patient at his or her home, but this new version of a house call can be a team sport, including home health care, a personal care provider, a physical therapist, and palliative/hospice care all working in coordination toward the patient’s best interest. Multiple studies have shown that house calls for homebound, chronically ill and frail patients can improve patient satisfaction and build bonds between the patient and physician, which again helps the healing while lowering the cost of care.

The cost of care for the elderly was a major driver behind health care reform, and readmissions have become a major issue. A New England Journal of Medicine 2009 study showed that one in five elderly patients are readmitted within 30 days and a third of this number are readmitted within a week. While we can debate as to whether it is the failure of the physician, hospital or the societal health infrastructure, it is costing Medicare $26 billion annually, and $17 billion is spent on readmissions that are preventable. While there have been all kinds of innovative ideas, including post-discharge phone calls or earlier follow-ups, properly organized house calls can play a crucial role in fixing this problem. Actually, the Medicare Independence at Home

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bill, the only piece of legislation in health care reform that was unanimously passed, reflects the seriousness of this issue. Medicare has already saved $25 million within a year. Meanwhile, many innovative projects are underway to support house calls at home.

While support for traditional house calls is gaining momentum in professional bodies, policy boards and medical school curriculum, there is another version of house calls that is disrupting health care at the fringes. It is nicknamed the “Uberization” of medicine and involves seeking/providing health care through applications on a smartphone. Additionally, there has been an explosion of startups led by people like Oscar Salazar, co-founder of taxi service Uber, who is trying to commoditize house calls, much like a cab ride. He operates Heal, an app-based service in Los Angeles to help patients who do not have time to wait find board-certified physicians closer to their home using GPS for a flat fee. These services apparently save money and decompress emergency rooms, but it is not known if they improve health. Many cities have embraced these services with their own apps, like Mend (Dallas), Curb-sidecare (Philadelphia) and Dose (Nashville), and there is one coming in Pittsburgh. One hopes that these are not replacements for traditional doctor appointments but are meant for convenience and minor ailments only.

These are challenging times for the medical profession. While the science of medicine is exploding, the art of medicine is dying. The resurfacing of house calls in whatever form will find a niche in our health care model and can re-humanize medicine. Digitization and innovation is welcome but does not have to fragment and replace the humanity of medicine, rather it should be used to augment it. A truly personalized medical care of the future will not be just the right medicine for the right patient, but also the right medicine at the right place, i.e., the patient’s home. New and improved house calls, with all of the new gadgets, can heal medicine again.

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The opinion expressed in this column is that of the writer and does not necessarily reflect the opinion of the Editorial Board, the Bulletin, or the Allegheny County Medical Society.
The new Maintenance of Certification (MOC) requirements imposed unilaterally on physicians by the American Board of Internal Medicine (ABIM) several years ago have awakened a sleeping giant in the medical community. Opposition to MOC has united physicians like no other issue. Since the new regulations were instituted, a grassroots revolt by physicians has been steadily growing in size and momentum. In a recent Medical Economics poll, a staggering majority of doctors are dissatisfied with MOC (96 percent), feel that it does not make them better physicians (95 percent) and feel that there should be alternative methods for recertification (75 percent). Since the ABIM rolled out the new MOC system, they have come under fire not only from physicians but also state medical boards, the American Medical Association (AMA), physician organizations and even Newsweek.

The criticisms against MOC are numerous. They include the excessive amount of busy work it imposes upon physicians which ultimately takes us away from patient care; the restrictions on acceptable CME; and the onerous 10-year exam. This high-stakes exam is very costly in time, money and stress. The relevance of this kind of testing has been challenged since the practice of medicine is changing quickly and access to up-to-date information is readily available through widespread access to the Internet. Studying for this test involves memorizing minutia which most will forget as soon as the test is over, learning information that may well be out of date, and trying to figure out what the “best” right answer is to test questions. Worst of all, not only do physicians spend thousands of dollars in MOC fees and tuition for courses that will “teach” them how to take the test, there also is no credible data that proves that MOC improves patient care or physician performance.

Our profession is one of compassion and respect for the individuality of each patient’s situation, yet we are ruled by an organization that has clearly forgotten or never learned this in the first place. The ABIM has unilaterally imposed stringent nonsensical rules on diplomates with which it is often difficult to comply. Like many physicians, my own interaction with the ABIM regarding CME requirements has been frustrating. I have obtained hundreds of hours of AMA PRA Category 1 CME which has been accepted by both my hospital and medical licensing board. The ABIM, however, will not accept this CME. The reason is not because it lacks credibility, but rather because the software of the organization awarding the CME is not compatible with the software at ABIM. A paper certificate or email from the organization is not acceptable. The solution the ABIM offered me was to attend conferences that offered CME that was acceptable to them. I work part-time and have a family including a child with special needs who needs me to drive to frequent therapy and doctor appointments; the “solution” to go out of town to attend a multiday conference is not an option for me. This will not only cost me thousands of dollars for the conferences but also the cost in lost wages from missing work. My difficulty is minor, though, as many medical blog sites, medical society meetings and news articles often have stories of the hardships many physicians experience trying to fulfill their MOC that are far worse than this. Grassroots anti-MOC physician groups have sprung up to push back against MOC and the stranglehold ABIM has on the medical community. A recent petition has more than 21,000 physicians’ signatures.
opposing MOC. We physicians have had enough. The good news is that we now have another option.

The National Board of Physicians and Surgeons (NBPAS – www.NBPAS.org) was created in 2015 to give physicians an alternative to the ABIM’s wildly unpopular recertification process. NBPAS was founded by Paul Teirstein, MD, of the Scripps Clinic, and promotes the idea of lifelong learning through earning CME credits that are chosen by the physicians based on relevancy to their practice. The requirements to recertify through NBPAS are reasonable and flexible. The rules are simple and include the stipulation that the physician must be certified initially through the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA), must hold a valid medical license, and must complete a minimum of 50 Accreditation Council for Continuing Medical Education (ACCME) accredited CME in two years. The cost is $169 for two years, which is far more reasonable than the thousands of dollars it can take to comply with MOC. The NBPAS board members are from well-respected institutions such as Harvard, Scripps Clinic, Mayo Clinic, Cedars Sinai, Columbia, American Diabetes Association and American Society of Gastroenterologists. Since its inception, the NBPAS is accepted by 30 hospital systems and has recertified more than 4,000 physicians.

Medicine is a profession that uses data and medical studies to guide our care of patients, yet one of the major criticisms of the MOC process is the lack of credible studies that show it improves patient care. Despite this dearth of evidence, our profession has for too long continued to spend our time, money and resources complying with a program that has no proven benefit for us or our patients. The ABIM states that patients are demanding recertification. We know from our own experiences that this is not true. Patients choose doctors based on parameters such as recommendations, insurance, location and physician likeability. In fact, in a recent Consumer Reports article analyzing “What Makes A Great Doctor,” of the nine criteria listed, recertification was nowhere to be found.

The ABIM, under intense pressure, has in recent months softened its rules for MOC. We physicians may be tempted to let our guard down thinking that the ABIM finally “gets it,” but I would like to point out that none of this happened until there was organized intense opposition from physicians, medical societies and the development of the NBPAS. The fear most physicians have in bucking the MOC process is that they will lose their license, hospital privileges and insurance contracts. This is understandable because we are in uncharted waters here. However, we are not alone in this battle. Since the backlash against the ABIM and MOC started, many positive inroads have been made. For example, the Washington State Medical Society now acknowledges the NBPAS as an acceptable path for recertification; the American Academy of Clinical Endocrinologists recommends to its members that they consider the NBPAS as an alternative recertification pathway; and the American Association of Physicians and Surgeons has filed a lawsuit against ABMS for restriction of trade. Most recently, the Oklahoma State legislature unanimously voted and the governor signed a bill that bans forced MOC. Kentucky already has a similar law. Missouri and Michigan are considering the same.

I, therefore, encourage my colleagues to help loosen this stranglehold the ABMS has on our profession and recertify through the NBPAS. We must put pressure on our hospitals, insurance companies and legislatures to not require MOC through ABMS as a requirement for licensure, hospital privileges and payment. The more physicians refuse to participate in MOC and instead choose to recertify through the NBPAS, the more likely we are to prevail. The Pennsylvania Medical Society (PAMED) to its credit has been highly critical of the MOC process. I encourage PAMED to support the grassroots effort and join the rapidly growing list of courageous organizations who oppose the onerous MOC and support NBPAS as a viable alternative. It is much easier when we approach the medical staff in our respective hospitals and the insurance companies we contract with to accept an NBPAS recertification if we have the support of PAMED. I see this as a modern-day David and Goliath struggle, one that will surely require a Herculean effort on all our parts. However, much more headway has been made on this issue in a short time than I would ever have thought.

Dr. Carignan is the director of General Medicine for the St. Barnabas Medical Center and the hospice director for the St. Barnabas Health System in Gibsonia, Pa. She can be reached at bulletin@acms.org.

The opinion expressed in this column is that of the writer and does not necessarily reflect the opinion of the Editorial Board, the Bulletin, or the Allegheny County Medical Society.
Cancer has been a scourge on mankind since the beginning of recorded history. While mankind has made remarkable advances in the health of our population to include better public health (sanitation and drinking water), food preparation (preservatives, refrigeration, pasteurization), infectious disease (antibiotics, antifungals, antivirals and vaccines), cardiovascular health (anti-hypertensives, statins, B-blockers), cancer remains a most difficult and vexing foe. Yet, even here we have made progress based upon recent publications of cancer death rates.

Hopefully, we live in an age where this is only the beginning.

Historically, we have relied upon the three pillars of cancer therapy: surgery, radiation and chemotherapy. Over the last five decades, we have vastly improved surgical techniques, allowing for organ- and limb-sparing procedures for malignancies such as head and neck cancer and sarcoma. We have used scientific study to decrease the morbidity of surgery while preserving outcome such as with lumpectomy rather than mastectomy and sentinel lymph nodes rather than complete axillary dissection and other numerous advances that cannot all be elaborated upon here. We have honed our ability to deliver curative radiation therapy with mind-bending precision, avoiding toxicities to neighboring organs and allowing for increased dose intensity. Finally, we have developed improved chemotherapies with greater efficacy and less toxicity as well as better supportive care agents to minimize side effects. With these tools alone, we have made significant advances in the cure rate of cancer, mostly in the adjuvant setting but also with striking examples in disseminated diseases such as testicular cancer, lymphomas and leukemias.

Advances in the last 15 years have vastly increased our understanding of the mechanisms by which cancers develop and grow and have therefore allowed for the development of novel therapeutics that affect these newly discovered pathways. Here, we will present just a few of these achievements which give hope to those of us who either care for or suffer from this disease.

Targeted therapy

Extensive research into cellular signaling systems has led to advances in understanding what informs a cell to...
divide. Almost always in cancer cells, these signals are mutated leading to constitutive stimulation and cell division. Targeted therapy blocks the growth of cancer cells by interfering with specific targeted molecules needed for carcinogenesis and tumor growth.

These therapies may be biologic molecules (antibodies) which are administered via infusion, or small molecules (kinase inhibitors) which often are able to be absorbed orally. The poster child of targeted therapy is the medication imatinib (Gleevec® STI-371), used to treat chronic myelocytic leukemia (CML). Prior to 2000, CML inexorably progressed from chronic phase to accelerated phase to blast crisis to demise over an average of five years. The disease could be slowed by interferon or occasionally cured by allogeneic transplant, but for most patients it was a terminal disease. In 1961, it was discovered that CML was associated with the Philadelphia Chromosome, a 9-14 translocation. Subsequent study determined that this translocation caused constitutive activation of the ABL kinase which was key to cellular regulation. Dr. Brian Drucker discovered a tyrosine kinase, then known only by the research name STI-571, which blocked this kinase activation and essentially stopped cellular division. Now called imatinib, this 400mg pill taken once daily has changed a once deadly disease into a chronic condition that is contained in 85 percent of all patients.

Other targeted agents are well known to the medical community and work through varied targeted mechanisms to slow or inhibit malignant cell growth. Examples include the biologics such as bevacizumab (VEG-F inhibitor), rituximab (CD 20 antibody) and pertuzumab (HER-2 antibody), as well as the small molecules such as ibritinib (Bruton kinase inhibitor for CLL), erlotinib (EGFR inhibitor, NSCLC), vemurafenib (Braf inhibitor, melanoma) and numerous others. This class of therapeutics has resulted in significant improvements in disease-free survival and overall survival for numerous cancers with only modest toxicity. We anticipate that many new agents will be developed as we learn more of the biology of malignancy.

Continued on Page 226
A major challenge in our fight against cancer is that cancers have a proclivity for mutation, meaning that the cancer that lies within one patient has multiple different cell lines each with distinct genetic signatures resulting in some cells being resistant to the targeted treatment.

**Immunotherapy**

This exciting new approach is based upon the premise that cancers grow because they have figured out a way to avoid immune surveillance. Immunotherapies are promising as, by their nature, they should be effective regardless of mutation status of the tumor as virtually all mutations cause the development of foreign antigens on the cell surface. It has been discovered that in many instances, cancer cells take advantage of naturally occurring “Checkpoint” inhibitors which exist to protect normal cells from inadvertent destruction by our own immune system.
Cancer cells develop the capability of stimulating these inhibitors to protect themselves from immune destruction. Two known checkpoint inhibitors are CTLA-4 and PD-1/PD-L1. By activating either the CTLA-4 or PD-1 receptor, cancer cells inhibit either the priming of T-cells or the effectiveness of T-cell induced cytotoxicity. Investigators have developed antibodies against those receptors to block this “Checkpoint” inhibition, allowing for an enhanced immune response to the cancer antigens and the cells upon which they reside. While all patients do not respond, this is particularly effective treatment in the highly immunogenic malignancies melanoma and NSCLC, but the use is rapidly expanding into other diseases. Examples of this class of agents are ipilimumab (antibody to CTLA-4), pembrolizumab (antibody to PD-L1) and nivolumab (antibody to PD-1).

Along with these therapies came a new set of toxicities, mainly immune-mediated inflammation of various organs causing pneumonitis, hepatitis, colitis, hypophysitis and others. We are learning to manage these side effects, and most patients do quite well with these new medications.

As we learn more about cancer cell growth and mechanisms for immune activation and de-activation, expect better and more sophisticated therapies in the near future such as CAR T-cells and even viral therapies.

There are many reasons to have hope for a future where, even if we cannot cure cancer, we can control it and live with it.

Dr. Ellis is deputy director, Clinical Services, and associate chief medical officer at UPMC Cancer Center; clinical professor of Medicine at the University of Pittsburgh School of Medicine; and a member of the ACMS Board of Directors. He can be reached at ellisp@upmc.edu.

Help your patients talk to you about their BMI

Allegheny County Medical Society is offering free posters explaining body mass index (BMI) and showing a colorful, easy-to-read BMI chart. The posters can be used in your office to help you talk about weight loss and management with your patients.

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Dr. Houda is a board-certified thoracic surgeon with specialty expertise in minimally invasive and robotic surgical techniques for lung, esophageal, mediastinal, endoscopy, laparoscopy and hiatal hernia repair.

He earned his medical degree at the University of Pittsburgh, School of Medicine. He completed his general surgery residency at UPMC Mercy Hospital in Pittsburgh, Pa., serving as chief resident. He went on to complete his cardiothoracic surgery residency at Allegheny General Hospital in Pittsburgh, serving as chief resident. He is certified by the American Board of Thoracic Surgery.

He most recently was in practice with Cardiothoracic Surgery Associates at Miami Valley Hospital in Dayton, Ohio. Dr. Houda was also appointed as clinical assistant professor of surgery at Wright State University, Boonshoft School of Medicine. Dr. Houda holds memberships with numerous professional societies including the American Medical Association, the American College of Surgeons, the American College of Cardiology and the Society of Thoracic Surgeons to name a few.

He has medical staff privileges at Allegheny General, West Penn, Forbes, Allegheny Valley, Canonsburg, and Jefferson hospitals.

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ACMS to sponsor publication of First History of Medicine in Allegheny County

The Allegheny County Medical Society (ACMS) is pleased to announce its sponsorship of a comprehensive History of the Practice of Medicine in Allegheny County. This will be a fully illustrated, hard-cover book that will chronicle the achievements of the medical community in Allegheny County, beginning with the first practicing physician and continuing to the present. Our medical community is recognized as one of the finest in the world, and this book will document and illustrate how and why that reputation has been earned and is so deserved.

Building on the 150th anniversary of ACMS, this book will not only recognize the pioneers of our medical society who have established a legacy of caring, dedication and skilled treatment that we continue to proudly build upon, but also will provide an opportunity for our membership to include their own practice history.

The book will be published by Legacy Publishing Co. of Birmingham, Ala., an experienced publisher of medical histories.

Look for more information in future Bulletins.

Practice Managers Section program announced

The ACMS Practice Managers Section will host “Volume to Value – the ABC’s of Payment Reform” on Thursday, August 4, from 8:30 to 10:30 a.m. at the ACMS building.

The program will focus on the latest information concerning payment reform and what that means to you as a practice. Topics include: Move from Quantity to Quality; Components of MACRA; How Will MIPS Apply to You; and How to Prepare NOW for the Future.

The presenter will be Linda Benner, CPC, CPMA,CAS-CC, COBGC; AHIMA-approved ICD-10 CM/PCS trainer; and principal/owner of Your Healthcare Consultant, LLC.

For more information or to register, visit www.acms.org/events.

HIPAA, OIG program planned at ACMS

ACMS will host “Annual Check-up – HIPAA and OIG Compliance,” from 8:30 a.m. to 12 p.m. Thursday, August 18, at the ACMS building.

Joe Suchocki, president of Eagle Associates, Inc., returns to Pittsburgh to help you get your practice ready for regulatory compliance.

The program will cover HIPAA Privacy, Security, and Breach Notification; and Implementing OIG Fraud and Abuse Prevention.

For more information or to register, visit www.acms.org/events.

Happy Hour set for ACMS Young Physicians

The ACMS Young Physicians Section is hosting an Over the Hump Happy Hour from 6:30 to 8:30 p.m. Wednesday, July 13, at the Industry Public House in Lawrenceville.

A $10 ticket includes appetizers and a drink ticket (wine or beer). Guests are welcome.

For more information or to register, visit www.acms.org/yps, call (412) 321-5030, or email yps@acms.org.
Allegheny County Medical Society members:

The new world of Health Care ushered in by the Patient Protection and Affordable Care Act (ACA) has created uncertainty and confusion for most people. There are new regulations and requirements. Individual and employer mandates. Penalties for not purchasing coverage. On Exchange and Off Exchange access. As an Allegheny County Medical Society member, you have help.

Talk to USI Affinity, the ACMS’s endorsed insurance broker and partner. Our benefits specialists are experts in Health Care Reform. We can help you choose a health plan that provides the best coverage and value while ensuring you will be in compliance with complex new IRS and Department of Labor regulations. We’ll also provide you the kind of world class service and support you need to make sure you get the most out of your health care benefits after you buy.

You can also check out the NEW Allegheny County Medical Society Insurance Exchange, a convenient and secure online portal where you can find competitively priced insurance coverage for all your needs, including a wide variety of medical and dental plans.

To learn more, contact USI Affinity today!

Call 800.327.1550, or visit the ACMS Insurance Exchange at www.usiaffinityex.com/acms
**2017 Board and Delegate Nominations**

A Candidate for the ACMS Board of Directors:
- Represents physicians on issues impacting the practice of medicine and makes policy decisions for the medical society.
- Meets four times per year, special meetings as needed.

<table>
<thead>
<tr>
<th>Please print name</th>
<th>I am interested in the Board of Directors (Phone)</th>
</tr>
</thead>
</table>

A Candidate for the ACMS Delegation to the PAMED:
- Represents physicians of Allegheny County in creating statewide policy on issues impacting physicians, patients and the practice of medicine.
- Meets as necessary prior to attending House of Delegates in October in Hershey, PA.

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<thead>
<tr>
<th>Please print name</th>
<th>I am interested in the ACMS Delegation (Phone)</th>
</tr>
</thead>
</table>

I would like to recommend the following individual(s) [Please print.]

| __________________________________________________________ | Board Delegate |
| __________________________________________________________ | for Board Delegate |

Please FAX completed form to (412) 321-5323 by Friday, July 29.

---

**Thank you for your membership in the Allegheny County Medical Society**

The ACMS Membership Committee appreciates your support. Your membership strengthens the society and helps protect our patients.

Please make your medical society stronger by encouraging your colleagues to become members of the ACMS. For information, call the membership department at (412) 321-5030, ext. 110, or email membership@acms.org.
ACMS member receives Cushing Award

L. Dade Lunsford, MD, was presented with the 2016 Cushing Award for Technical Excellence and Innovation in Neurosurgery by the American Association of Neurological Surgery (AANS) at the group’s recently held annual meeting in Chicago, Ill.

Dr. Lunsford is the Lars Leksell Distinguished Professor of Neurological Surgery at the University of Pittsburgh and director of the UPMC Center for Image-Guided Neurosurgery.

The Cushing Award is given to an AANS member for technical prowess and skill and/or innovation in the development of new procedures that have become part of the arsenal neurosurgeons use to treat disease or trauma.

In announcing the award, the AANS cited Dr. Lunsford for his “ability to improve the delivery of neurosurgical care by enhancing safety and efficacy and by making the field of neurosurgery safer, more accessible, more efficient and more effective.” The award is one of the highest recognitions bestowed upon a neurosurgeon.

Dr. Lunsford is an internationally recognized authority on stereotactic surgery, radiosurgery and minimally invasive surgery. In 1987, he was responsible for bringing the Gamma Knife to then Presbyterian University Hospital, the first hospital in North America to offer the innovative form of brain surgery.

In the nearly 30 years since its installation, more than 13,500 patients have undergone radiosurgery in the department’s Gamma Knife units. Dr. Lunsford’s team has published numerous books and more than 400 peer reviewed outcome studies, and his team has trained more than 1,700 physicians and physicists from around the world in the role, methods and long-term outcomes of Gamma Knife radiosurgery.

Dr. Lunsford also has played a leading role in assisting Gamma Knife manufacturer Elekta develop further models of the Gamma Knife.

Fox Rothschild’s Health Law Practice reflects an intimate knowledge of the special needs, circumstances and sensitivities of physicians in the constantly changing world of health care. With significant experience and a comprehensive, proactive approach to issues, we successfully meet the challenges faced by health care providers in this competitive, highly regulated environment.

After all, we’re not your ordinary health care attorneys.
On May 10, the Allegheny County Medical Society (ACMS) Alliance concluded its 90th year (1925-2015/16) of continuous community service in partnership with the ACMS. The Alliance Governing Board and general membership completed the planned agenda of the Annual Business Meeting, including affirmation of appointed leadership for the coming 2016-17 year.

The Meet and Greet social segment of the afternoon provided wonderful fundraising opportunities with vendor Paititi Intl-Peruvian Art and Hand Crafts, along with gorgeous, high-value gift clusters for the raffle and 50/50 drawing. A luscious luncheon was served. Convivial table talk was enjoyed by members and guests. Lovely background entertainment by pianist/vocalist Gerri Werl Newcamp enhanced the festive mood throughout the exquisite afternoon at Pittsburgh Golf Club in Schenley Park.

Kudos to energetic event Chairman Mrs. Alan Barnett and gracious Co-Chair Rose Kunkel Roarty with imaginative and dedicated committee members Mrs. John DaCosta, Mrs. Eugene Delserone, Mrs. Marshall Levy, Mrs. Augusto Martinez, Mrs. Samuel Mines, Mrs. Donald Orr, Mrs. Lawrence Purpura, Mrs. Chandra Reshmi and Mrs. LeRoy Wible. Special recognition and heartfelt thanks to raffle item contributors, the entire committee, and Mrs. Hugo Cerri and Mrs. George Gerneth. Other significant support was derived via direct monetary donation by Mrs. John Burkholder, Mrs. Cleon Cornes, Mrs. Anthony Colatrella, Mrs. George Gerneth, Mr. John G. Krah, Mrs. Michael Kutsenkow, Mrs. Robert Lee, Mrs. Chandra Reshmi and Mrs. LeRoy Wible. From the community at large came a gift certificate from Aladdin’s Eatery in Squirrel Hill and Fox Chapel Day Spa; and performance tickets to La Traviata from Pittsburgh Opera. Thanks, too, to Mrs. LeRoy Wible for wonderful door prizes. We extend appreciation to William Hetrick, MD, for his charming company and participation as photographer of our event.

Net proceeds from the Annual Meeting and Luncheon 2015-16 will benefit the ACMS Foundation to advance home and community environments which nurture and develop healthy children and families for a healthy Allegheny County! Most sincere thanks and appreciation to all for a very enjoyable afternoon out with colleagues, family, friends and guests, all the while serving a purpose in partnership with Allegheny County Medical Society.

Call Alliance at (412) 321-5030 for Alliance membership, Alliance event details and RSVP information.

Content and text by Kathleen Jennings Reshmi
Peter M. Winter, MD, 81, of Issaquah, Wash., formerly of Pittsburgh, died Saturday, May 14, 2016.

Dr. Winter graduated in medicine from the University of Rochester, N.Y.; served his residency at Harvard Medical School/Massachusetts General Hospital; and served an internship at University of Utah School of Medicine. He was awarded the Buswell Fellowship at SUNY Buffalo.

He decided to pursue a medical career after serving in a medic unit in the U.S. Army during the Korean War.

Dr. Winter was a clinician and researcher in anesthesiology, serving as chair of the University of Pittsburgh Department of Anesthesiology and Critical Care Medicine from 1976-1996.

He was credited with promoting life-support methods that resulted in anesthesia-related deaths decreasing to nearly zero.

After he led his department at Pitt to invest in training with human simulation and established a simulation center, The Peter M. Winter Institute for Simulation, Education and Research (WISER) was named in his honor in 2001.

Surviving are a son, Chris Winter (Kristin); daughters Karin McCloskey (Leo), Lia Winter and Tori Winter; three grandchildren, Kylie, Nadia and Carys; and his former wife, Madge.

A private memorial service was held in Issaquah.

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Dr. Keddie graduated in medicine from the University of Pittsburgh and served his internship at St. Joseph Hospital in Pittsburgh. He also graduated from the University of Pittsburgh School of Law.

He was a U.S. Navy veteran, serving during World War II and the Korean Conflict.

Dr. Keddie practiced both medicine and law for many years and was instrumental in the passage of the original Pennsylvania seat belt legislation. He was considered a pioneer in trauma medicine and served as the director of multiple emergency departments in Western Pennsylvania.

He also founded the Chartiers Valley Medical Center in Bridgeville, which he operated until his retirement in 2001.

Surviving are his wife, Suzanne; three daughters, Karen Keddie, Rosemary Keddie and Dawn Keddie (Aaron Riley); five sons, Chip Keddie (Stella), Tom Keddie (Susan), Rob Keddie, Mike Keddie (Debbie) and Andy Keddie (Paula); 13 grandchildren; and 10 great-grandchildren.

Deceased are a brother, Harvey; and a son, Kevin Keddie.

Services were held May 26 at Beinhauers, McMurray.
Combating Opioid Abuse in Pennsylvania

Pennsylvania Medical Society’s (PAMED) Opioid Education and Resources

“Addressing Pennsylvania’s Opioid Crisis: What Health Care Teams Need to Know”—Multimedia education with video interviews, statistics, prescribing guidelines, scenario-based learning, and more

- CME credits available
- Free for PAMED members

Long-acting and extended-release opioids online courses—Learn about prescribing, monitoring, assessment, and documentation

- CME credits available
- Free for all prescribers in Pennsylvania

Opioid Prescription Checklist—Use this checklist to start the conversation about pain management with your patients. Includes a list of things to consider when taking pain medication and is printed in the form of a prescription notepad.

Visit PAMED’s opioids resource center for the latest news, education, and tools.

www.pamedsoc.org/opioidresources
Insulin updates: New agents on the market and those coming soon

AMANDA MARTIN, PHARM.D

Introduction

Insulin is the cornerstone of therapy for those with Type 1 diabetes and very frequently used in patients with uncontrolled Type 2 diabetes as well. Insulin therapy has progressed significantly since its discovery in the early 1920s. We have moved away from the use of bovine and porcine sources and transitioned into the age of recombinant technology. Insulin therapy and the use of insulin analogs has brought us closer than ever to mimicking the body’s natural production of insulin with the use of the long-acting basal products in combination with short- or rapid-acting mealtime boluses. Recently, two new agents, Toujeo® (insulin glargine) and Tresiba® (insulin degludec), were approved by the FDA and are gaining a significant share of the patient base. Here we present a brief overview of the new products.

Toujeo® (insulin glargine, 300 units/ml)

The first of the two new products is not a new molecular entity but a new dosage formulation. Toujeo® is long-acting basal insulin, insulin glargine, and the same analog as Lantus®. The only difference is that Lantus® is available in concentration of 100units/mL (U-100) whereas Toujeo® is available as 300units/mL (U-300). They are created by the same manufacturer, Sanofi, and it could be concluded that the release of Toujeo® came conveniently when the patent on Lantus® was expiring.

Toujeo® is still dosed once daily, and the unit conversion from Lantus® or Levemir® is 1:1. For example, if a patient is currently taking 50 units of Lantus® at bedtime, they would be transitioned to 50 units of Toujeo® at bedtime. The difference is in the volume of their injection: The patient injecting 50 units of Lantus® will be using 0.5mL whereas the patient using Toujeo® will only inject 0.16mL, a much smaller volume. The benefit therefore in changing a patient from Lantus® or Levemir® to Toujeo® is in the injection volume, and thus switching is recommended for patients who are using large amounts of basal insulin. The other consideration for providers is that Sanofi is no longer providing samples of Lantus® but instead Toujeo®, so if you have a patient who you sample frequently or who needs financial assistance, the manufacturer support is now stronger with Toujeo®.

Clinical trial summary

The safety and efficacy of Toujeo® was compared to Lantus® in several open-label, randomized, active-control parallel studies of up to 26 weeks in patients with both Type 1 (n=546) and Type 2 diabetes (n=804). The reduction of HbA1C and fasting plasma glucose was similar and met non-inferiority standards. At the end of the trials, patients were generally receiving a higher dose of Toujeo® than Lantus®.

Tresiba® (insulin degludec)

The second of the two new products is a new molecular entity, an ultra-long-acting insulin analog, insulin degludec. Manufactured by Novo Nordisk, this basal insulin touts an extra-long half-life of 42 hours.

It is still recommended to be dosed once daily with the unit equivalent of the total daily long or intermediate insulin dose. For example, if you have a patient who is using 25 units of Lantus® twice daily, you could convert them to Tresiba® at a dose of 50 units once daily. This product may be a good choice in patients who struggle with compliance as they will have continued control over a longer period of time.

It is available in two different pen strengths, the traditional U-100 and also U-200. The trials garnering approval demonstrated non-inferiority to insulin glargine in both Type 1 and Type 2 patients and also reported significantly lower rates of nocturnal hypoglycemia in all groups.

Clinical trial summary

The efficacy of Tresiba® was studied in Type 1 patients in three randomized, open-label, treat-to-target, active-control trials for a duration of up to 52 weeks as compared to Lantus® (n=1,122) or Levemir® (n=455) and met the non-inferiority margins for HbA1C reduction. Similarly, Tresiba® was studied in Type 2 patients in a 52 week randomized, open-label, multicenter trial as compared to Lantus® (n=1030) and met the non-inferiority...
Other up-and-coming insulin products

- **Humulin® R U-500 KwikPen®** – Eli Lilly has finally manufactured U-500 in a pen in an attempt to decrease the number of dosing errors with U-500 vial and syringe
- **Ryzodeg® (insulin degludec/insulin aspart)** – manufactured by Novo Nordisk, a 70/30 mix of basal and bolus insulin for twice daily dosing, approved September 2015 with anticipated availability currently undetermined
- **Basaglar®** (insulin glargine) – manufactured by Eli Lilly, attained bio-similar status in Europe but has been approved by the FDA as a “follow-on” biologic, reported to be available in December 2016 as a less expensive alternative to Lantus®
- **Xultophy®** (insulin degludec/liraglutide) – manufactured by Novo Nordisk, approved in the EU and filed for regulatory review in the United States, a combination of basal insulin plus a GLP-1 agonist, Phase 3 studies demonstrated a lower mean A1C and greater proportion of patients reaching target A1C at eight and 12 weeks as compared with the individual components alone, most likely not available until 2017 if approved
- **Faster-acting insulin aspart** – Novo Nordisk submitted an NDA for this product, has two new excipients to ensure early and fast absorption, shown to improve postprandial control versus insulin aspart and attain an equal A1C reduction in all populations but had a significantly larger drop in A1C as compared to insulin aspart in Type 1 patients, most likely will not be available until 2017 if approval is attained, keep your eyes open for pharmacokinetic data to be presented in 2016

**Summary**

In summary, insulin has come to play a major role in therapy for diabetes and the options are only improving. With more choices for patients and providers, success is more likely and therapy can be tailored to the individual. While neither of these new agents demonstrates clinical superiority to other available options, they do provide additional choices for specific patient populations. Additionally, the insulin products in the pipeline offer even more options for individualized regimens.

**Dr. Martin is a PGY-1 pharmacy resident, ambulatory care focus, Allegheny General Hospital, Allegheny Health Network. She can be reached at bulletin@acms.org.**

References

The Centers for Medicare & Medicaid Services (CMS) has finalized the 60-day overpayment rule and clearly indicated its expectation that providers establish robust compliance plans and promptly investigate credible overpayment allegations.

**Statutory background**

As with most health care regulations, it takes CMS a while to adopt regulations. The 60-day repayment rule was implemented by the § 6402 of the Affordable Care Act (ACA) in 2010, which is 28 U.S.C. § 1128j(d). The 60-day repayment rule requires:

“person to report and return any Medicaid and Medicare overpayment by the later of either (a) the date which is 60 days after the overpayment was identified or (b) the date when the corresponding cost report is due.

“Failure to return the overpayment will subject the person to civil money penalties of $5,500 to $11,000 per claim plus for treble damages in addition to potential state claims if there are Medicaid claims involved.”

The final regulations actually consist of three separate but similar regulations applying to Part A (Hospital Payment) and Part B (Physician Payment) of Medicare, Part C (Medicare Advantage) and Part D (Prescription Drug) of Medicare. The regulations can be accessed at this link: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-11.html.

**Key issues**

The key issues are the definition of overpayments, the process for identification of overpayments and the “Six-Year Look Back Period.”

1. **Definition of overpayment**

   CMS defines “overpayment” as “any funds that a person has received or retained under title XVIII of the [Social Security Act] to which the person, after applicable reconciliation, is not entitled under such title.” The obligation to report and return an overpayment exists regardless of whether that overpayment resulted from intentional or unintentional conduct. CMS makes clear in the preamble to the rule it believes overpayment includes claims resulting from Anti-Kickback Statute or physician self-referral law violations or claims for items and services furnished by an excluded person.

2. **Determining when an overpayment is identified**

   Regulations clarify “identification” as occurring when “the person has, or should have through the exercise of reasonable diligence, determined that the person has received the overpayment and quantified the amount of the overpayment.” Identification does not occur until the provider has quantified the amount of the overpayment identifying the substance of the illegality and quantifying the substance of the amount, which is intended to allow providers to have sufficient time to fully investigate and calculate an overpayment before the 60 days. CMS explains in the preamble that reasonable diligence means both:
   - proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments, and
   - investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of potential overpayment.

3. **Six-Year Look Back Period**

   The rule also finalized the issue of defining the “look back period,” which originally was proposed to be 10 years. This obviously means if you identify an overpayment that occurred in 2016, and you have been billing the same way for the last six years, then you need to look back for six years and return any proceeds obtained using the process now deemed improper.

**Exceptions to 60-day repayment rule**

CMS has provided the following exceptions to the 60-day rule:

1. Submission to the OIG Self-Disclosure Protocol suspends repayment until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.

2. Submission to the CMS Voluntary Self-Referral Disclosure Protocol suspends payment until such time as a settlement agreement is entered, the person withdraws from the CMS Voluntary Self-Referral Disclosure Protocol, or the person is removed from the CMS Voluntary Self-Referral Protocol.

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Michael A. Cassidy, Esq.
Disclosure Protocol.

3. Payment is suspended if the parties are negotiating an extended repayment schedule under 42 C.F.R. § 401.603, and remains suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

Conclusion

Although there never was any legitimacy to the idea that physicians were not required to return mistaken payments, this makes it both official and very expensive.

Mr. Cassidy is a shareholder with Tucker Arensberg and is chair of the firm’s Healthcare Practice Group; he also serves as legal counsel to ACMS. He can be reached at (412) 594-5515 or mcassidy@tuckerlaw.com.
As the population of older adults continues to grow within Allegheny County, more health and social care services will be needed to support their well-being. While institutional-based care, like a nursing or personal care facility, can be an option, most adults prefer to remain in their own homes. Those who have financial means can pay for in-home supports, care management and other services. The Living Independence for the Elderly (LIFE) program exists to give the same option to lower-income older adults, so they, too, can remain in their homes for as long as possible and as safely as possible.

Known nationally as the Program for the All-Inclusive Care for the Elderly (PACE), the model started in the Chinatown community of San Francisco, Calif. On Lok opened in 1973 as an adult day care center and also provided home meals for the elderly. On Lok was developed by Chinese-American families because they valued community care and believed nursing homes were an unnatural place for their loved ones to age.

Today, there are more than 116 PACE programs across the country. In Pennsylvania, PACE is known as LIFE. Extending beyond the original On Lok model, LIFE provides coordinated acute, chronic care and long-term services within an interdisciplinary team that includes a physician, nurse, social worker, physical therapist, occupational therapist, dietician, in-home services coordinator, recreational therapist and transportation coordinator.

Several research papers have studied the LIFE program’s outcomes and found that they are an effective alternative to institutional care. The results show:

1. LIFE reduces the need for costly long-term nursing home care.

   “Despite the fact that 100% of the PACE/LIFE participants were nursing facility eligible, the risk of being admitted to a nursing home long term following enrollment from the community is low.” (Friedman, S.; Steinwachs, D.; Rathouz, P.; Burton, L.; & Mukamel, D. (2005). Characteristics predicting nursing home admission in the program of all-inclusive care for elderly people. The Gerontologist, Vol. 45, No. 2, pp. 157-166.)

2. PACE/LIFE prevents and/or significantly reduces preventable hospitalizations. PACE/LIFE enrollees had fewer hospital admissions, preventable hospital admissions, hospital days, emergency room visits and preventable emergency room visits than a comparable population enrolled in the Wisconsin Partnership Program. (Kane, R. L.; Homayak, P.; Bershadsky, B; & Flood, S. (2006). Variations on a theme called PACE/LIFE. Journal of Gerontology Series A, Vol., 61, No. 7, pp. 689-693.)

3. LIFE is effective and efficient in treating individuals with multiple and complex health care needs.

   “LIFE was one of the three chronic care models identified that include processes that improve the effectiveness and efficiency of complex primary care.” (Boul, C. & Wieland, G.D. (2010). Comprehensive primary care

LIFE programs can keep families together, enabling elderly family members to stay at home rather than move into a nursing home or personal care facility.

Patricia and Ralph Chasey experienced failing health and a fall that placed them in separate nursing homes. With limited incomes, they were unable to pay for in-home services or the complicated medication regimen needed to keep their independence. At the suggestion of a nursing home social worker, Patricia was willing to meet with a LIFE Pittsburgh social worker to learn more about the program.

“It sounded too good to be true,” Patricia said.

It was hard to believe that all of the services offered would be at no cost to them if they met the financial criteria. Immediately after being discharged from the nursing home, Patricia and Ralph were enrolled. They now have in-home care (including housecleaning and laundry services), they visit the...
Day Health Center three times a week, and they have transportation to and from the center and other medical appointments. Most importantly, they are home together.

“This place works wonders!” Ralph said.

The LIFE Program not only assists the elderly, but is able to alleviate the burdens placed on family and caregivers which often is overwhelming. Because the LIFE interdisciplinary health care team authorizes and coordinates all the health care services, the program becomes a one-stop alternative that simplifies access to health care.

One participant, Willie, had always been independent and a provider for his family; however, in recent years, he experienced several medical setbacks making it increasingly difficult to live alone.

Willie moved in with his daughter, Demita, and her family. Demita, sandwiched between family and workplace needs, required more supports to make sure her father was safe and well cared for during the day.

Willie joined Community LIFE and attends the Day Health Center five days a week. While at the center, Willie can see his medical doctor, receive physical therapy and participate in recreational activities. Demita doesn’t have to worry about getting her father to the center because Community LIFE provides the transportation needed.

“It is a tremendous stress relief to know Dad is safe. I am so impressed with the changes it has made in my dad,” Demita said.

For more information on LIFE Pittsburgh, visit www.lifepittsburgh.org.

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### Reportable Diseases

**Allegheny County Health Department**

**Quarterly (Q) Selected Reportable Diseases**

<table>
<thead>
<tr>
<th>Disease*</th>
<th>2014 Q1</th>
<th>2015 Q1</th>
<th>2016 Q1**</th>
</tr>
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<tbody>
<tr>
<td>Campylobacteriosis</td>
<td>16</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td>Cryptosporidiosis</td>
<td>6</td>
<td>5</td>
<td>1</td>
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<tr>
<td>Giardiasis</td>
<td>29</td>
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<td>12</td>
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<tr>
<td>Guillain-Barre</td>
<td>4</td>
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<td>2</td>
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<tr>
<td>Invasive Haemophilus influenzae</td>
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<td>1</td>
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<tr>
<td>S. pneumoniae Invasive</td>
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<td>16</td>
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<tr>
<td>West Nile Virus Infection</td>
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<td>0</td>
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</tbody>
</table>

*Case classifications reflect definitions utilized by CDC Morbidity and Mortality Weekly Report.

**These counts do not reflect official case counts as current year numbers are not yet finalized. Inaccuracies in working case counts may be due to reporting/investigation lag.

NOTE: Disease reports should be filed electronically through PA-NEDSS. For diseases that are immediately reportable, call (412) 687-2243.

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There is currently an opening on the *Bulletin* Editorial Board for an **ASSOCIATE EDITOR**. The position requires an interest and flair for writing and the willingness to contribute an editorial column of 500-900 words twice per year. Associate editor terms are for two years; they may serve three consecutive terms. Selection of the final candidate will be made by the Editorial Board and the ACMS Board of Directors. Please email or fax a short letter and a writing sample to *Bulletin* Managing Editor Meagan Welling at mwelling@acms.org, or fax (412) 321-5323.
Here have been three confirmed cases of Zika virus infection in Allegheny County as of June 3, 2016. All are males who traveled to Zika-affected areas and developed symptoms.

The Zika virus outbreak in the Americas is primarily due to transmission by Aedes aegypti mosquitoes. Allegheny County has pockets of Aedes albopictus mosquitoes, which are competent vectors, but the risk for local transmission is unknown. Sexual transmission from symptomatic men to their sex partners has been documented. It is unknown whether women or asymptomatic men can transmit the virus through sex.

To manage this burgeoning public health issue, health care providers can take the following steps:

- Determine if testing is appropriate based on symptoms and exposure history. Currently, the following persons are eligible for testing:
  a. Pregnant women who have traveled to a Zika-affected area while pregnant or shortly before becoming pregnant, regardless of symptoms. Asymptomatic pregnant women should be tested two to 12 weeks after possible exposure.
  b. Travelers to Zika-affected areas with at least one symptom of Zika virus infection (fever, maculopapular rash, arthralgia, nonpurulent conjunctivitis) within two weeks of travel.
  c. Symptomatic sex partners of travelers with Zika symptoms or a positive Zika test.
  d. Infants with microcephaly or intracranial calcifications born to women who traveled to or resided in an area with Zika virus transmission while pregnant, or infants born to mothers with positive or inconclusive test results for Zika virus infection
- Contact the Health Department to get approval for testing at CDC. Call the Allegheny County Health Department (ACHD) at (412) 687-2243 for Allegheny County residents and the Pennsylvania Department of Health at 1-877-724-3258 for residents of other counties. Testing for the virus by RT-PCR can be done on urine and serum collected within 14 days of symptom onset. For asymptomatic persons, testing for IgM antibodies can be done two to 12 weeks after exposure. A commercial RT-PCR test is available, but only for symptomatic travelers tested within 7 days of illness onset.
- Counsel pregnant woman not to travel to Zika-affected areas. Couples trying to get pregnant should wait two months after either partner has traveled, or six months if a male has traveled and has had symptoms. Testing asymptomatic travelers before trying to conceive is not indicated at this time.
- Counsel travelers to avoid mosquitoes in Allegheny County for three weeks after their return to prevent infection of local mosquitoes, even if travelers are asymptomatic.

For more information, call the ACHD at (412) 687-2243.
APPLICATION FOR MEMBERSHIP

Within the last 5 years, have you been the subject of any disciplinary action by any governmental body, medical organization, or hospital staff?

Date: ____________________________________________

Signature: _______________________________________

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