CareManagement

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Vol. 22, No. 3 June/July 2016

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Gary S. Wolfe

The Zika Virus:
An International Health Crisis

The outbreak of the Zika virus disease is an international public health crisis. Case managers need to be knowledgeable about this disease as the disease spreads into the United States.

Key Facts

- Zika virus disease is caused by a virus transmitted primarily by *Aedes* mosquitoes.
- People with Zika virus disease can have symptoms including mild fever, skin rash, conjunctivitis, muscle and joint pain, malaise, or headache. These symptoms normally last for 2 to 7 days.
- There is scientific consensus that Zika virus is a cause of microcephaly and Guillain-Barré syndrome (GBS). Links to other neurological complications are also being investigated.

The Zika virus is not new. Here is some history. Zika virus is a mosquito-borne flavivirus that was first identified in Uganda in 1947 in monkeys through a network that monitored yellow fever. It was later identified in humans in 1952 in Uganda and the United Republic of Tanzania. Outbreaks of Zika virus disease have been recorded in Africa, the Americas, Asia, and the Pacific. From the 1960s to 1980s, human infections were found across Africa and Asia, typically accompanied by mild illness. The first large outbreak of disease caused by Zika infection was reported from the Island of Yap (Federated States of Micronesia) in 2007. In July 2015, Brazil reported an association between Zika virus infection and GBS. In October 2015, Brazil reported an association between Zika virus infection and microcephaly.

In January, 2016:

- The Hawaii Department of Health reported a baby with microcephaly in Hawaii, born to a woman who had resided in Brazil early in her pregnancy.
- El Salvador reported an unusual increase of GBS. From 1 December 2015 to 6 January 2016, 46 cases of the syndrome were reported, including 2 deaths.
- Brazil reported 3893 suspected cases of microcephaly, including 49 deaths. Of these, 3381 are under investigation. In 6 cases, Zika virus was detected in samples from newborns or stillbirths.
- Brazil reported that 1708 cases of GBS were registered by hospitals between January and November 2015. Most states reporting cases were experiencing simultaneous outbreaks of Zika, chikungunya, and dengue.

In February, 2016

- The United States reported a case of sexual transmission of Zika infection in Texas.
- Venezuela reported an increase in cases of GBS since the second week of January 2016. By the end of January, 252 GBS cases, associated in time and place with Zika, were reported.
- Two sexually transmitted cases of Zika virus in the United States were reported.

In March, 2016

- A study in Brazil of 88 pregnant women found that 72 women tested positive for Zika virus in their blood and/or urine. Abnormalities of the fetus were detected by ultrasound in 12 Zika-positive women. These findings add to the growing body of evidence linking Zika virus infection to fetal abnormalities.
- The United States reported 2 GBS cases with confirmed Zika virus infection. The first case, an elderly man with a recent

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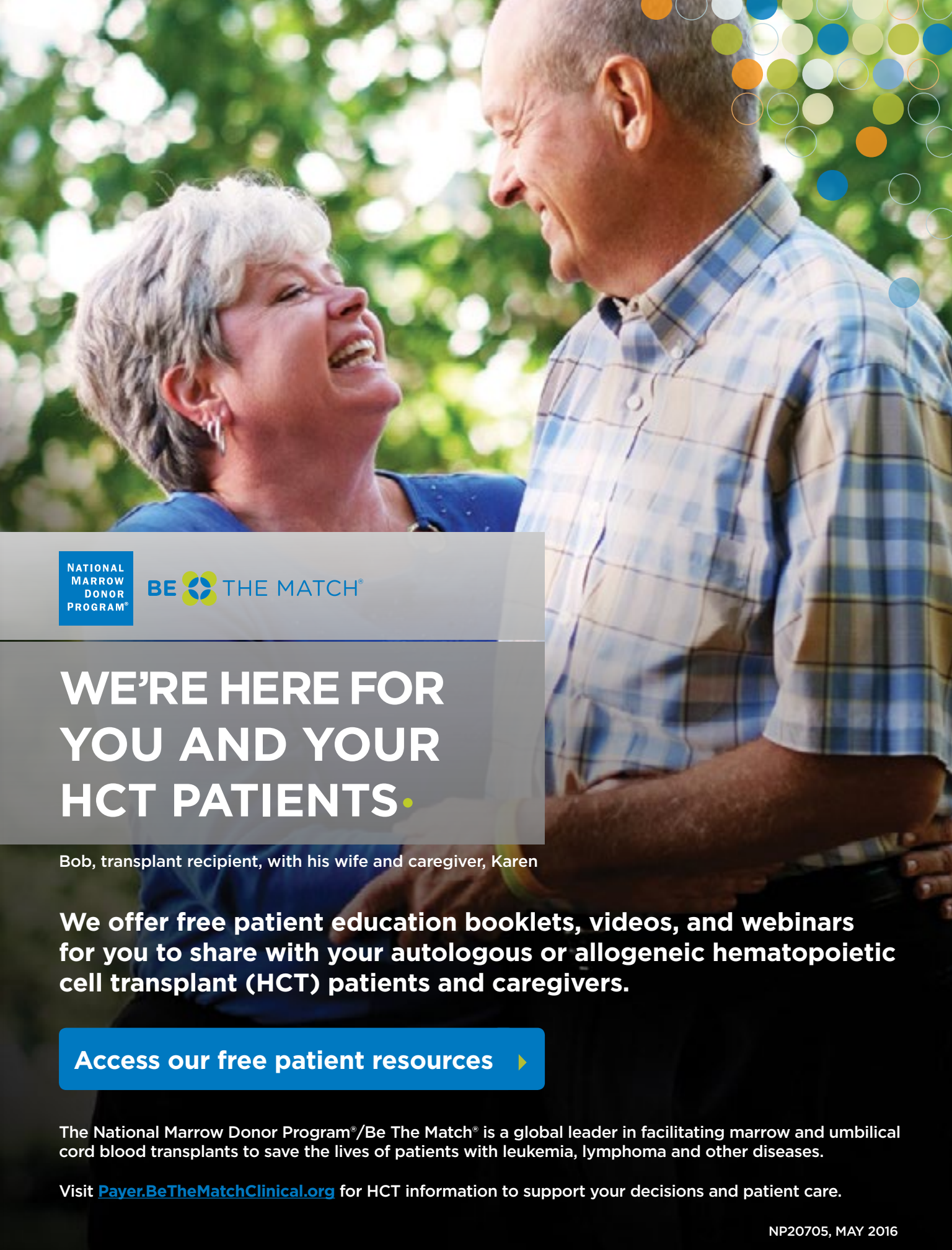

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The Zika Virus: An International Health Crisis *continued from page 2*

history of travel to El Salvador, died from sudden subarachnoid hemorrhage caused by a ruptured aneurysm. The second patient, a male resident of Haiti in his 30s, was diagnosed after he travelled to the US for treatment. He recovered fully after 5 days of treatment in hospital.

In June, 2016

- 60 countries and territories report continuing mosquito-borne transmission of which:
  - 46 countries are experiencing a first outbreak of Zika virus since 2015, with no previous evidence of circulation, and with ongoing transmission by mosquitos
  - 14 countries report evidence of Zika virus transmission between 2007 and 2014, with ongoing transmission.
- Microcephaly and other central nervous system (CNS) malformations potentially associated with Zika virus infection or suggestive of congenital infection have been reported by 11 countries or territories. Three of those reported microcephaly borne from mothers with a recent travel history to Brazil (Slovenia, US) and Colombia (Spain); for one additional case the precise country of travel in Latin America is not determined.

As you can see, just this year the Zika virus has spread dramatically around the world.

Prevention is key to controlling the spread of the Zika virus. Two practices are important in the control of the Zika virus.

Mosquito Bites

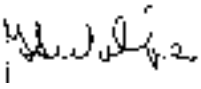
- Protection against mosquito bites is a key measure to prevent Zika virus infection. This can be done by wearing clothes (preferably light-colored) that cover as much of the body as possible; using physical barriers such as window screens or closing doors and windows; sleeping under mosquito nets; and using insect repellent containing DEET, IR3535, or icaridin according to the product label instructions. Special attention and help should be given to those who may not be able to protect themselves adequately, such as young children, sick individuals, or elderly people. Travellers and those living in affected areas should take the basic precautions described above to protect themselves from mosquito bites.

It is important to cover, empty, or clean potential mosquito breeding sites in and around houses such as buckets, drums, pots, gutters, and used tires.

Sexual Transmission

- Sexual transmission of Zika virus has been documented in several different countries. To reduce the risk of sexual transmission and potential pregnancy complications related to Zika virus infection, the sexual partners of pregnant women, living in or returning from areas where local transmission of Zika virus occurs, should practice safer sex (including using condoms) or abstain from sexual activity throughout the pregnancy.
- People living in areas where local transmission of Zika virus occurs should also practice safer sex or abstain from sexual activity. In addition, people returning from areas where local transmission of Zika virus occurs should adopt safer sexual practices or abstain from sex for at least 8 weeks after their return, even if they don't have symptoms. If men experience Zika virus symptoms, they should adopt safer sexual practices or consider abstinence for at least 6 months. Those planning a pregnancy should wait at least 8 weeks before trying to conceive if no symptoms of Zika virus infection appear, or 6 months if one or both members of the couple are symptomatic.
- Although Zika virus disease is just starting to be reported in the United States, we are just at the beginning of a pandemic. With the 2016 Olympic Games in Brazil, more people traveling and with the mosquito season upon us, we are assured of seeing more cases.

In this issue of *CareManagement*, we publish "Update: Guidance from the CDC on the Zika Virus" by Christine K. Olson, MD, MMOH; Jefferson M. Jones, MD, MPH; and John T. Brooks, MD. The case manager needs to stay informed and alert for Zika virus disease in our patient population.



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ACCM: Improving Case Management Practice through Education

Hospital Case Management: Patient-Centered, Team-Based

By Patrice V. Sminkey, RN, *CEO, Commission for Case Manager Certification*

Case managers, by the very nature of their roles, are team players. They work with individuals (patients or "clients" of case management services), families/support systems, physicians, nurses, social workers, pharmacists, and many other clinicians and providers of services. Today, there are new people on health care teams to whom case managers are responsible—people who understand, know, and manage the metrics that enhance patient outcomes and track financial impact. This is seen and experienced, specifically, in the acute-care setting. For hospital case managers, it is a complex role.

A recent Issue Brief, published by the Commission for Case Manager Certification, featured Dartmouth-Hitchcock Medical Center (DHMC), based in Lebanon, NH, where Amy M. Smith, RN, MSN, CCM, is the director of the Office of Care Management. In her position, Smith oversees care management and coordination, case management, social work, discharge planning, utilization management, lifeline services, community resources, and language and interpreter services. A large part of her responsibility is ensuring that patients receive the appropriate level of care by the appropriate-level professional.1

The example of DHMC illustrates the tremendous changes that have a direct impact on the professional case manager, who in the era of health care reform is seeing more challenges than ever before, including to enhance efficiency and effectiveness of care delivery. Specifically, today's focus on accountable care delivery and care transitions has expanded this role. As the Issue Brief highlights, three aspects have particular significance for professional case managers in the hospital setting:

The focus on reducing fragmentation and easing care transitions to prevent unnecessary readmissions is directly tied to a hospital's bottom line.

New team-based collaborative models challenge the status quo and could create new opportunities and greater need for defined roles and job requirements for the professional case manager. Optimizing the interdisciplinary health care team is critical in yielding positive patient outcomes.

A stronger emphasis on data, measures, and quality improvement underscores the need for case managers to be lifelong learners.

The focus on reducing fragmentation and easing care transitions to prevent unnecessary readmissions is directly tied to a hospital's bottom line. Now is the time to understand and demonstrate that the role of the professional case manager is essential.

The Issue Brief provides an in-depth portrait of DHMC's case management program and its policies across the institution.

One interesting highlight is the DHMC care management program that is structured as a triad composed of case managers, social workers, and utilization review RNs. In addition, Smith describes the goal of having a case management process at as many points of entry as possible. Three such areas are:

- Emergency Department—RN case managers staff the emergency department and give evidence-based recommendations about which patients to admit, which to discharge, and which require observation services.
- Transfer Center—The transfer center is available 24/7 to help facilitate urgent/emergency transfers to DHMC.
- Operating Room—Dartmouth-Hitchcock performs approximately 20,000 surgeries a year. Each morning, utilization review RNs go over the operating room bookings to ensure each patient has an appropriate order.

As the Issue Brief states: "This 'front door' approach has led to more efficient and appropriate transfers, better compliance with Medicare regulations (which means fewer penalties), better communication across and within teams, and a more efficient and less stressful admissions process, regardless of point

continues on page 36

Patrice V. Sminkey, RN, *is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies case managers. To date, more than 60,000 case managers have been certified, and currently more than 40,000 case managers are board certified as Certified Case Managers.*

CARF Releases New Standards for Networks

Addressing the recent trend toward integration of business and service delivery models within the health and human services field, CARF International has released a new standards manual supplement for networks that is available for use in combination with all CARF standards manuals beginning in standards manual year 2016, effective July 1, 2016.

CARF defines a network as a legal entity that contracts with two or more organizations that deliver health or human services to persons served (participating providers) to coordinate functions between or on behalf of the participating providers. Various types of networks exist and they may have different purposes in the field. For example, business networks may be formed to establish strategic business arrangements with or among participating providers, and service delivery networks may establish an integrated system of service provision by participating providers to persons served. Other types of networks may combine the functions of business and service delivery networks. The network standards are available as a complimentary download at carf.org/OnlineStandards.

"Providers are forming a variety of relationships with one another due to recent economic incentives and an increasing focus on improving outcomes for individuals who access services across various primary, acute, and community-based care settings," says Sue Matthiesen, managing director of aging services for CARF. "CARF implemented the network standards to support networks' development toward continuity of services among multiple providers and to support quality when a legal entity does not own all participating providers within its network."

The new network standards replace CARF's previous Business and Services Management Network Standards Manual, which is now discontinued, and the standards for Aging Services Networks previously included in the Aging Services and CCRC standards manuals. An International Standards Advisory Committee (ISAC) collaborated to develop new network standards that are applicable across all of CARF's accreditation areas. The ISAC included representatives from a cross-section of networks including Central Florida Behavioral Health; VA Boston Healthcare System; Human Factor Consulting, LLC; Carolinas HealthCare System; naviHealth; Shepherd's Care Foundation; Mary Free Bed Rehabilitation; Children's Treatment Network of Simcoe York; and ROC Solutions.

Prior to adoption, CARF submitted the draft standards to its International Advisory Council (IAC) for review. CARF also conducted a public field review to invite comments from interested parties, including persons served and their families, to further refine the standards prior to publication. CARF's leadership in framing standards is backed by its 50-year history of accrediting health and human services. CM

CARF defines a network as a legal entity that contracts with two or more organizations that deliver health or human services to persons served (participating providers) to coordinate functions between or on behalf of the participating providers.

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Style guidelines for manuscripts are as follows:

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- Use AMA style for references
- The first page of the manuscript (the title page) should include manuscript title and a mini-abstract of 2–3 sentences summarizing the manuscript—please do not put author's names on the title page
- Suggested manuscript length is 2,500 to 3,000 words

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If You Recognize Yourself in this Article, Take Action!

By Elizabeth Hogue, Esq.

In 2015, we wrote about an article by Tom Jackman that appeared in the June 23, 2015, edition of *The Washington Post,* which was about a patient who made some surprising discoveries on the way home from a colonoscopy when he listened to a recording that he had accidentally made during the procedure. The patient was horrified to hear the surgical team mock and insult him while he was anesthetized. Among other things, the anesthesiologist referred to the patient as a "retard" and said that she wanted to punch him in the face while talking to him in pre-op. The physician performing the procedure openly instructed an assistant to lie about his availability after the procedure, including "misleading and avoiding" the man after he woke up.

We subsequently tweeted about a Texas hospice owner who sent employees a text that said, "You need to make this patient go bye-bye." Giving the owner every benefit of the doubt and allowing for misunderstandings that may arise from text messages, it seems impossible to justify this conduct. Well. (as George Will of the *The Washington Post* says) Here we go again!

ABC news reported on April 7, 2016, that a patient in Texas hid a recording device in her hair so that she could record the staff's conversation during her surgery. Again, big surprises! The staff in the operating room openly made fun of her, especially her belly button. They also repeatedly referred to her as "Precious," which the patient understood to be a derogatory reference to a character in a recent movie.

When almost everyone has a cell phone that is capable of recording audio and video, we must conclude that it is likely that someone is listening to every word we say and watching every move we make. The only way to be sure that no one is recording inappropriate conduct is simply to not engage in it.

As we acknowledged in our earlier article, there is no doubt that patients can sometimes be exasperating and infuriating…and that may be putting it charitably! As professionals, however, it is important to recognize that the kind of "talk" that went on in these instances is completely unacceptable. It's up to professionals to deal with frustrations in other, more appropriate ways. Even venting to colleagues by making derogatory statements about patients is inappropriate.

When almost everyone has a cell phone that is capable of recording audio and video, we must conclude that it is likely that someone is listening to every word we say and watching every move we make. The only way to be sure that no one is recording inappropriate conduct is simply to not engage in it.

The consequences of the above conduct may be severe. The jury awarded the man who accidentally recorded the conversation during his colonoscopy $500,000. Licensed professionals involved in any of the cases may face disciplinary action, including loss of licensure. If the owner of the hospice or anyone else took action to make the patient "go bye-bye," they may also face criminal prosecution.

SO, if you recognize yourself, take action. Get help of a professional nature, if necessary. If you continue to make inappropriate statements about patients, then perhaps it is time for you to do something else for a living. This is serious! CM

Elizabeth Hogue, Esquire, *is an attorney who represents health care providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.*

Readers

Have an idea for an article? Send your suggestions for editorial topics to: jennifer@jmaybin.com.

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CE 1

Motivating the Unmotivated Client

By Judith Hibbard, DrPH

Why are some chronic disease patients highly motivated to self-manage and others not so much? Why do some patients take a proactive approach to managing their health while others are very passive? The answers to these questions are critical for care managers. With most chronic diseases, it is the patient who largely determines, through their own actions and choices, the trajectory, severity, and impacts of the illness on the quality of their lives. Motivated and proactive patients are more likely to adhere to their treatment regimens, alter unhealthy behaviors, and monitor and self-manage their conditions. More motivated and skilled patients also tend to have better outcomes.

Alternatively, we might ask: why wouldn't patients be motivated? Doesn't everyone want to feel better and have fewer health crises, better health outcomes, and a higher quality of life? Based on our research, I believe the answer is that most patients, even those who appear to be unmotivated, actually are motivated, but for some, their motivation is "muted." Motivation becomes muted, when patients feel overwhelmed, when they experience multiple failures in trying to manage, and when they feel that what is being asked of them is beyond their capabilities.

Before we expand on this idea of "muted" motivation and how to unmute it, some background is necessary. Our research, using the Patient Activation Measure (PAM), is where these insights about motivation emerged. The PAM measures an individual's knowledge, skill, confidence, and motivation to manage one's health and health care.[1,2] The measure, based on the answers to 13 questions, assesses patients on a 0-100 scale. The 0-100 scale can be further broken down into 4 levels of activation (from low activation, level 1, to high activation, level 4). The levels can be used to tailor support to patients, and help them gain in their ability to self-manage.[3] The tool has strong measurement properties and is predictive of most health behaviors, many clinical outcomes, utilization, and health care costs.[4,5] The validity and the reliability of the PAM as a measurement tool has been confirmed in over 240 published articles from all over the world. The measure is now being used in care delivery systems to more fully understand patients, and both researchers and practitioners are using it around the globe.

We conducted in-depth interviews with chronic disease patients who measured at different points along the 0–100 point patient activation continuum. Our purpose was to explore differences in patient beliefs, experiences, coping approaches, and motivations. These interviews provided some very important insights. Patients who measured low on the PAM scale were much more likely to feel little or no confidence in their ability manage their health.[6] These patients were more likely to make statements like: "It doesn't really matter what I do, I can't have a positive impact on my health" or "I would rather not think about my health." These patients felt overwhelmed with the task of managing their health. Their experiences with failure in trying to do so had made them discouraged and passive. Further, these patients had limited problem-solving skill. When faced with a new problem or challenge, they were more likely to simply give up. Many understood their proper role as a patient was to be a passive recipient of care.

These insights suggest that patients who measured low on the PAM scale felt they were not capable of making behavioral changes and/or managing their health effectively on a day-to-day basis. That is to say, it is not that they were not motivated, but that they were afraid of further failure and felt that effective self-management was beyond their capabilities. That isn't to say that these patients didn't want to feel better or improve their quality of life or ability to function. It was more that they did not think they could. These perceptions, in effect, muted their motivation to try.

When patients are told that they need to change eight different things in their daily lives (not an uncommon scenario for chronically ill patients), how do you think they receive the message? For patients who are less activated and already feel overwhelmed and less confident, hearing a list of needed changes is a recipe for failure. And in the case of less activated patients, it is likely

Judith Hibbard, DrPh, *is professor of Health Policy at the University of Oregon where she has focused her research on consumer choices and behavior in health care.*

going to increase their already considerable experience with failure.

So the question becomes, how do you "unmute" people's motivation? How can we move away from setting patients up for failure and instead set them up for success? Our approach, which has proven to be effective, is to meet patients where they are. If they have little confidence and feel overwhelmed, then our approach addresses those issues, by giving them permission to not do everything they have been told they need to do—for now. The strategy is to encourage them to make only one or two small changes, changes that they are likely to succeed at. The point is to give them a chance to experience success. What we have observed is that by experiencing success, even small successes, it "unmutes" the patient's motivation. They become more motivated and begin to think that maybe taking care of their health is not beyond their reach.[7]

The approach, based on behavioral activation theory, is to encourage the patient to act, and the theory is that motivation will follow action. Research confirms this approach and shows that encouraging even a small behavior, results in greater motivation. That is, instead of trying to stimulate motivation, the focus is on stimulating behavior.[8]

What is a small step? It can be as small as deciding not to eat fast food for lunch on 2 days in the coming week. Of course, once the small step is achieved, then it is important to move on to the next small step challenge. In addition, to focusing on small steps, it is also recommended to work on problem-solving skills and to help patients understand the important role they can play in the care process.

Of course, not all patients are the same. Some are more proactive, skilled, motivated, and confident. For those patients, a different approach is needed. The key is to measure, to know where each patient is on the patient activation 0–100 continuum and meet each individual there.

FIGURE 1 **FOUR LEVELS OF PATIENT ACTIVATION AND SUPPORT**

Level 1: patients tend to be passive and feel overwhelmed with managing their own health

Level 2: patients may lack knowledge and confidence for managing their health

Level 3: patients appear to be beginning to take action but may still lack confidence and skill to support their behaviors

Level 4: people have adopted many of the behaviors to support their health but may not be able to maintain them in the face of life stressors

Tailoring Support to Activation Levels:

At level 1, focus on building self-awareness and understanding behavior patterns, and begin to build confidence through small steps

At level 2, work with patients to continue small steps and begin to build basic knowledge. Focus on problem solving

At level 3, work with patients to adopt new behaviors and to ensure some level of condition-specific knowledge and skills. Support the initiation of new "full" behaviors (eg, 30 minutes of exercise 3 times a week) and work on the development problem-solving skills

Tailored Coaching

Tailored coaching entails tailoring the support and focus of coaching to the client's activation level: it is about meeting patients where they are. Of course, this means being able to consistently and systematically assess the starting point for each patient. Measuring patients' activation levels (see Figure 1) gives clinicians and care managers three key advantages in supporting patients. First, it provides an assessment to help tailor the amount of support necessary for an individual patient. It lets care managers know where a patient is on this continuum and enables them to meet the patient there. Second, the score provides guidance on the type of support that is likely to be helpful to the patient. Third, the score provides a metric to track progress for an individual patient or a population of patients.

Segmenting the Patient Population to Optimize Resources

Tailoring can also be done at the population level. The primary strategy here is to identify patient segments that would benefit from different types of supports. Because less-activated patients are more passive about their health, the approach is to use a higher touch and more active outreach with these patients. Further, because activated patients are more ready and motivated to use information and community resources, the approach is to make existing resources more available or to push electronic resources out to these patients. Thus, the approach is to optimize resource usage by more effectively matching the needs of different patient segments with the types and intensity of resources that will help them. The examples below all have this common approach, but their focus and their specific strategies vary.

The Peace Health Patient-Centered Medical Home, using a team-based

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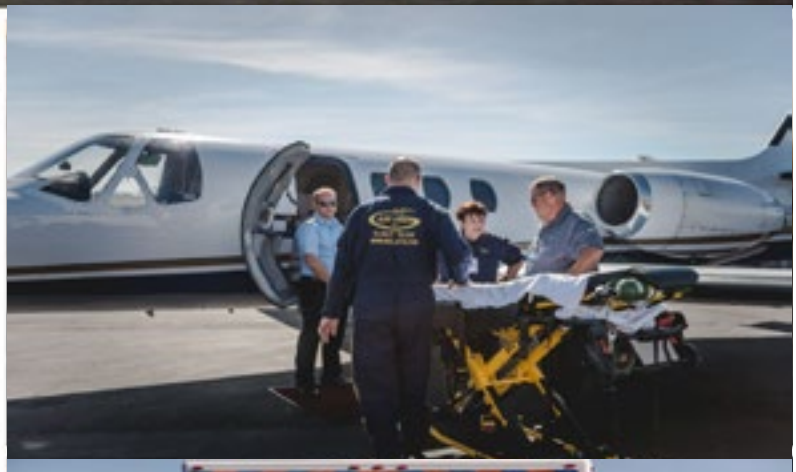

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approach, found that it is more efficient when resources are deployed according to specific needs of patients with chronic illnesses. For example, for more passive, less activated patients, they utilized staff to proactively reach out to them with a "high touch" approach. More highly activated patients, with the same level of disease, were provided electronic or community resources and peer support. The more highly activated patients are more motivated and ready to use relevant information supports and to pursue appropriate referrals. Figure 2 is a representation of this segmentation approach. It shows how resources are allocated more intensely to those patients with higher disease burden and fewer self-management skills (low activation). The Peace Health Patient-Centered Medical Home (PCMH) found that by stratifying patient populations by both activation level and disease burden, it is possible to achieve better outcomes with the same amount of resources.[9]

Healthcare organizations set up their segmentation strategies in different ways and aim them at different patient subgroups. For example, one large US national health insurance company uses an interactive voice response (IVR) system to call patients recently diagnosed with cancer and ask them to take the PAM. They recognize that these patients may need extra help in making treatment decisions, dealing with emotions, and/or navigating their care. The patients who score in the lower two levels of the PAM are immediately transferred to a live coach who begins to help them. Patients scoring in the higher two levels of the PAM are given several electronic choices via the IVR. The insurance company found that this approach not only helped them save operational costs, but also significantly increased overall customer satisfaction. This is an example of a strategy that is primarily aimed at helping less-activated patients get the care and help they need in a cost-efficient way.

Fairview Health Services triages support in several different ways to lower-activated patients. They have developed a series of activation level–specific care protocols. For example, when during the course of a visit it is determined that a female patient is due for a mammogram, the usual approach is to schedule that patient for a separate visit for that mammogram. However, if the patient has a low PAM score, she gets the mammogram that day at the clinic. The rationale for this is that it is not possible to do this for all patients, but for less-activated patients, there is a higher risk they will not return for that test. By accommodating the patient immediately, the clinic is appropriately using its resources to achieve better outcomes.

Hospitals all over the US are using the PAM to tailor support to patients as they transition from the hospital to home as a way to prevent readmissions. Research shows that less-activated patients have almost double the risk of a readmission in the posthospital period as compared to higher-activated patients.[5,10,11]

FIGURE 2 **SEGMENTING THE PATIENT POPULATION**

PAM LEVEL	DISEASE BURDEN	
	Low	**High**
High	**High-Tech Electronic Resources:** *Focus on Prevention*	**High-Tech Peer Support Electronic Resources:** *Focus on managing illness*
Low	**High Touch:** *Focus on Prevention*	**High Touch:** *Focus on developing skills to manage illness*

Conclusions

The key to successfully working with patients, regardless of their initial motivation level, is to meet them where they are. To do this in a consistent way and using standardized approaches, measurement is necessary. Measurement allows a kind of mass customization that enables personalizing care to patients' needs and, at the same time, systemizes care and makes it uniform for categories of patients.

The answer to the question posed earlier is that everyone is motivated to feel better, preserve functioning, and have a good quality of life. It is the job of the care manager to help "unmute" that motivation when patients are discouraged and frightened. **CE 1**

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References continue on page 36

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CE II

Updated Guidance from the CDC on Zika Virus

By Christine K. Olson, MD, MPH; Jefferson M. Jones, MD, MPH; John T. Brooks, MD

As we learn more about how the Zika virus is transmitted, healthcare providers need clear guidance to inform discussions with their patients about possible exposure to Zika virus and how to prevent its transmission to developing fetuses and sexual partners. A recent Webinar sponsored by the Centers for Disease Control and Prevention (CDC) provided health care providers with information about the updated CDC interim guidance for caring for reproductive age women and men with possible Zika exposure, CDC interim guidance for prevention of sexual transmission of Zika, preventing transmission of Zika virus in labor and delivery settings, interpreting pediatric testing guidance, and the US Zika pregnancy registry.

During this outbreak we have seen rapidly evolving information about Zika virus infection, its modes of transmission and its effects on pregnancy and birth outcomes. CDC has written an updated clinical guidance and developed tools and information for clinicians and the general public. In addition, CDC has created a national registry to collect information about Zika affected pregnancies and subsequent birth and infant outcomes.

Transmission

Zika virus disease is spread to people primarily through the bite of an infected *Aedes* species mosquito including *Aedes egyptis* and *albopictus*. These mosquitoes are aggressive daytime biters but they also bite at night. Data from previous outbreaks suggest most infections are mild and many are healthomatic. Symptoms last for several days to a week and include fever, maculopapular rash, arthralgia, and conjunctivitis. Myalgia and headache may also be present. Severe disease requiring hospitalization is uncommon.

Other documented modes of Zika virus transmission include intrauterine and perinatal transmission, sexual transmission, and laboratory exposures. Additionally there have been reports of potential Zika virus transmission through blood transfusion. And this mode of transmission is being investigated. There's also a theoretical concern of transmission through organ or tissue transplantation. And Zika virus RNA has been detected in breast milk but has not been documented to cause infection in a nursing infant. No instances of Zika virus transmission during fertility treatment have been documented. But transmission through donated gametes or embryos is theoretically possible given that Zika virus can be present in semen and sexual transmission has occurred. Sexual transmission of Zika virus will be discussed later in this article.

As of April 2016, there are 33 countries or territories in the Americas and 41 countries worldwide currently reporting active Zika virus transmission. Updates on areas with active Zika virus transmission are available online.

Local vectorborne transmission of Zika virus has not been reported in the 50 US states and DC, but local transmission has been reported in US territories. With the current outbreak in the Americas, the number of cases of Zika virus infection in US travelers will likely increase. Imported cases may result in virus introduction to states and DC, and local vectorborne transition might occur in some areas of the US.

On April 1, the CDC brought together state, tribal, local, territorial, and national stakeholders in Atlanta to discuss Zika preparedness and response activities. Through active investigation we are rapidly learning more information about Zika virus and pregnancy. Limited information demonstrates no evidence of increased susceptibility to Zika virus in pregnant women. Zika virus infection can occur in any trimester, but the incidence of Zika virus

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We recognize that in the face of limited information it is challenging for healthcare providers to counsel women about the risks of Zika virus in pregnancy.

infection in pregnant women is not known. There is no evidence that pregnant women have more severe disease compared with nonpregnant people.

Zika Effects on Fetal Development

An initial association between Zika and microcephaly was recognized in Brazil in May 2015 when an increased number of infants with microcephaly were reported following the onset of a Zika virus outbreak. Identified adverse pregnancy and birth outcomes include pregnancy loss, microcephaly, and fetal brain abnormalities and eye abnormalities. What is unknown is the level of risk of these adverse outcomes associated with Zika virus infection during pregnancy or around the time of conception.

We recognize that in the face of limited information it is challenging for healthcare providers to counsel women about the risks of Zika virus in pregnancy. For this reason, the CDC has proactively released and continually updates guidance as data emerge. Two recent studies provide some insight into the range of detected fetal abnormalities observed thus far. In Brazil among 42 women with laboratory-confirmed Zika virus infection, 29% had abnormal findings on prenatal ultrasounds including two who had intrauterine fetal deaths. Other findings included abnormalities in blood flow, growth, and amniotic fluid volume. Among the abnormalities detected, 17% had structural brain abnormalities including microcephaly, intracranial calcifications, ventriculomegaly, and brain atrophy. Many of these pregnancies were still ongoing at the time of publication; however, in one case prenatal ultrasound findings correlated with findings at birth and the infant had severe microcephaly, cerebral atrophy, and macular lesions.

In two of the pregnancies with prenatal diagnoses of microcephaly and intrauterine growth restriction, the infants were small for gestational age at birth. In a second study—a retrospective analysis of data from the 2013 to 2014 Zika virus outbreak in French Polynesia—prenatal Zika virus infection was associated with 8 cases of microcephaly. Mathematical modeling estimated that infection with Zika virus during the first trimester of pregnancy resulted in a risk of microcephaly of approximately 1%.

In a recent report from the United States, a woman who had traveled during her first trimester of pregnancy to areas with active Zika transmission reported symptoms consistent with Zika virus disease in her 12th week of gestation. Initial prenatal ultrasounds were reported to be normal and microcephaly was not identified. However, a decrease in fetal head circumference from the 47th to the 24th percentile was noted between 16 and 20 weeks' gestation. A fetal ultrasound at 19 weeks demonstrated significant intracranial abnormalities including cerebral atrophy, ventriculomegaly, possible intraventricular hemorrhage, and possible genesis of the corpus callosum. Subsequent to these ultrasound findings a fetal MRI was performed at 20 weeks and demonstrated brain abnormalities consistent with the ultrasound findings. A postmortem evaluation following elective termination demonstrated cerebral cortical thinning. In addition, the brain and other tissues contained high levels of Zika virus RNA, and virus was cultured for brain tissue.

Guideline Update

The following is a brief update to the published guidelines in regard to interim guidelines for prevention of sexual transmission of Zika virus in the United States.

The initial guidance first appeared in the *MMWR* on February 5, 2016. Since then, the CDC has continued to monitor and evaluate all available evidence in order to update recommendations as new information becomes available, which has resulted in the update that we published April 1, 2016.

CDC's updated guidelines have been informed by and continue to be informed by our close collaboration with clinicians, professional organizations, state and local health departments and many other stakeholders.

Sexual Transmission

So let's talk just a little bit about what we know about Zika virus and sexual transmission. We know that Zika virus can be sexually transmitted by a man to his sex partners, and that includes both male sex partners and female sex partners. But our concern, with regard to sexual transmission, is really around transmission to a woman during her pregnancy. All reported cases of sexual transmission to date have involved sex without a condom with a man who had or later developed symptoms.

Zika virus can be transmitted when the man has symptoms as well as days before symptoms start and days after

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symptoms end. Sexual transmission of many infections, including those caused by other viruses, is reduced by the consistent and correct use of latex condoms. There also are some things that we don't know. We don't know whether infected men who never develop symptoms can transmit Zika virus to their sex partners. We also don't know how long Zika virus persists in semen.

We know from 2 case reports that infectious virus that is culturable virus can be found in semen at least 14 days after symptoms of infection began. And we know from one other case report that virus particles have been detected in the semen in a man 62 days after symptoms of infection began. However, whether women can transmit Zika virus to their sex partners is unknown. And whether Zika virus can be transmitted from oral sex is also unknown. It is known that it's in semen, but we don't know if it's in saliva or vaginal fluid for instance.

So what are the changes in our guidance? For pregnant women there is no change in the existing guidance. We still recommend that couples in which the woman is pregnant use condoms consistently and correctly or choose to abstain from sex for the duration of the pregnancy. A pregnant woman should still ensure that her healthcare provider is aware of her male sexual partner's potential exposure or if he has been ill. And this kind of discussion usually requires sharing information around the potential exposure of a male sexual partner to the mosquito such as the duration and extent of exposure and the male's use of anti-mosquito measures such as insect repellent.

Providers can consult our guidelines for evaluation and testing of pregnant women. The real change comes here when we're talking about other couples who are not currently pregnant. So, if a man has confirmed Zika virus infection or clinical illness consistent with Zika virus disease, we recommend that the couple should use condoms or abstain from sex for at least 6 months after illness onset.

We consider this higher risk, and we recommend 6 months because this is 3 times the longest period that Zika virus RNA has been detected in semen after system onset. Actually it's greater than 3 times. We err on the side of caution here.

Now, if a man has traveled to an area with Zika—with active Zika virus transmission—but did not develop symptoms, we recommend that the couple should consider using condoms or abstaining from sex for at least 8 weeks after departure from the area. And this is 3 times the longest period that infectious Zika has been detected in the semen of men who were ill. So it's 3 times the longest time frame in which you would expect symptoms potentially to develop as well.

The more difficult consideration is for couples who reside in areas of active Zika virus transmission, and this really becomes a very nuanced discussion between the couple and their healthcare provider and between themselves. But we recommend that these couples might consider using condoms or abstaining from sex while active transmission persists in that area.

A little bit about testing with regard to determining whether risk of sexual transmission is possible. We do not recommend that any testing be conducted to determine whether there is risk of sexual transmission. And the reason for this are really twofold. The first is that the test to detect Zika virus in semen is not widely available, but of course that could change. What we're more concerned about is that we have very limited understanding of how to interpret results of semen testing. We really don't know much about how frequently men develop seminal shedding if they've been infected with Zika or for how long, so the incidence of that condition, how long it persists in the semen, and what the pattern of shedding is are unknown. There's always the concern that shedding could be intermittent, and we may collect a semen specimen during a period when shedding is not occurring and have a falsely negative and falsely reassuring results.

You know that talking about sex in general is hard for many people, and sexual transmission of Zika can be very complicated. Of course, anyone who's concerned about getting Zika virus from sex could choose to use condoms or choose not to have sex. And as always to be effective, condoms must be used correctly from start to finish every time during sex.

Sex by our definition includes vaginal sex. That's penis to vaginal contact, anal sex or penis–penis or penis–anal contact and oral sex or mouth to penis. In some places there may be barriers to accessing and using condoms, including availability, pricing, and one partner's ability to convince the other to use condoms. Couples who do not desire pregnancy should additionally use the most effective contraceptive method that they can use correctly and consistently in addition to condoms.

Religious beliefs can restrict a person's ability to use condoms or other contraception, and healthcare providers just have to bear that in mind when communicating to the general public.

Clinical Update for Women of Reproductive Age

Next, we would like to discuss the CDC's most recent guidance, which includes recommendations for women of reproductive age with possible Zika virus exposure. During the current Zika outbreak, the CDC has issued several guidance documents. Three of these guidance documents have focused on pregnant women and

As many of you know, the CDC has established the US Zika Pregnancy Registry, which will continue to provide critical information or inform updated guidance.

women of reproductive age.

Although Zika is not new, its potential effects on pregnancy have only recently been identified. We are learning more about Zika and what it means for pregnant women every day. The CDC has been rapidly translating new findings into updated clinical guidance, and we are committed to sharing what we know when we know it. As many of you know, the CDC has established the US Zika Pregnancy Registry, which will continue to provide critical information or inform updated guidance.

We know it can be difficult to stay current with updated recommendations. The CDC updates its recommendations when there are new data that can inform clinical and public health action.

The most recent guidance was released on March 25, 2016. The updated guidance includes new recommendations for women and couples who wish to conceive. This includes recommendations to individualize guidance based on the patient's circumstances including presence or absence of symptoms consistent with Zika virus disease. There are also new recommendations for women and couples undergoing infertility treatment and for pregnant women living along the US–Mexico border. And lastly, the updated guidance includes minor modifications to the pregnancy testing algorithm.

Before we move into the specific recommendations, it will be important to establish some clear definitions of terms used. Possible exposure includes travel to or residence in an area of active Zika virus transmission or sex—vaginal, anal, or oral—without a condom with a man who traveled to or resided in an area of active transmission.

Zika virus infection means laboratory confirmation of Zika virus infection including in persons who are asymptomatic. And Zika virus disease means a person has at least one of the following signs or symptoms: acute onset of fever, rash, arthralgia, or conjunctivitis and has laboratory confirmation of Zika virus infection.

People who have possible Zika virus exposure and display one or more signs or symptoms consistent with Zika virus disease but did not have testing performed should follow recommendations for persons with Zika virus disease.

We'll now go through the recommendations for different situations and then review the algorithm in the most recently issued guidance document. Women with possible exposure to Zika virus who do not reside in an area with active Zika virus transmission are the first group we'll discuss. Healthcare providers should discuss signs and symptoms of Zika virus and the potential adverse outcomes associated with infection during pregnancy with their patients. If Zika virus disease is diagnosed, a woman should wait at least 8 weeks after symptom onset to attempt conception. This recommendation takes into account the upper limit of the incubation period and the approximate tripling of the longest known period of viremia active symptom onset.

No data are available regarding the risk for congenital infection among pregnant women with asymptomatic infection. If the woman has a possible exposure but no symptoms consistent with Zika virus disease, she should also wait at least 8 weeks after the last date of exposure before attempting conception.

Healthcare providers counseling women and men interested in conceiving should provide information on ways their patients can prevent unintended pregnancies during the time after exposure or Zika virus disease that they are trying to avoid pregnancy. This includes discussion of the most effective contraceptive methods that can be used by the patient correctly and consistently. The patient should also be advised on a consistent and correct use of condoms for all vaginal and anal sex as well as fellatio to reduce the risk of sexual transmitted infections including Zika virus.

Let's shift now to discussing men. Some recommendations differ between men and women based on the information we have available at this time about persistence of virus and semen.

There have now been several laboratory-confirmed cases of sexually transmitted Zika virus disease from males to their partners. The duration and pattern of Zika virus persistence in semen is not fully characterized at this time and is under active investigation.

If a man with possible Zika virus exposure is diagnosed with Zika virus disease, he should wait at least 6 months after symptom onset before attempting to conceive. The applies to those men who are confirmed to have Zika virus disease through laboratory testing or those who have exposure and one or more signs or symptoms

consistent with Zika but did not have testing performed.

The 6-month interval, which is 3 times the longest period that Zika virus RNA has been detected in semen after symptom onset, allows enough of a time interval that the risk of sexual transmission is believed to be minimal. If a man has a possible exposure but no symptoms consistent with Zika virus disease developed, he should wait at least 8 weeks after exposure to attempt conception with his partner.

Again during the time after exposure to Zika virus disease, it is very important to discuss effective contraceptive methods and also advise patients on a consistent and correct use of condoms to reduce the risk of sexual transmission. It's recognized that counseling women and men who reside in areas with active Zika virus transmission is challenging and that multiple factors need to be taken into consideration.

It is recommended that couples in these areas talk with their healthcare provider if they're interested in conceiving. Counseling and discussion by the healthcare provider should include subjects that will aid in decision making. These include the woman or couple's reproductive life plan: for example, age, reproductive history, medical history, fertility, and personal values and preferences. Counseling should also include an assessment of the risk of Zika virus exposure and a discussion about the prevention of both mosquito bites and sexual transmission of Zika virus.

Areas to review include their environment—whether the home environment has air conditioning and window screens, and is an area with a high density of mosquitoes. The same should be discussed about the work environment. The current level of Zika virus transmission at a local area should also be discussed.

Personal measures to prevent mosquito bites are important to discuss. This includes the use of protective clothing—long sleeves, pants, and permethrin-treated clothing—use of EPA registered insect repellents as directed and emptying or removing standing water in containers.

Personal measures to prevent sexual transmission of Zika virus should be emphasized. This includes the patient's willingness to use condoms or to abstain from sex for the duration of a pregnancy. It is important to counsel these patients about signs and symptoms of Zika virus disease as well as the possible adverse consequences of Zika virus infection during pregnancy and the need to wait until the risk of for viremia or viral shedding in semen is minimal to attempt conception. Risks and benefits of pregnancy at the current time should be discussed with the couple.

The CDC has created a tool to aid healthcare providers in counseling women and men who were interested in conceiving and live in areas of active Zika virus transmission. This guide includes recommendations from the updated guidance, key questions to ask patients, and sample scripts to help facilitate discussion.

After discussion, if couples decide to attempt a conception, the healthcare provider should discuss the following: recommendations to use EPA-registered insect repellents that are safe to use while trying to conceive and during pregnancy. Use of insect repellents according to the instructions (including reapplication as directed) should also be emphasized.

It's important to discuss with patients interested in conceiving the recommendations to wait to attempt conception if one or both members of the couple have Zika virus disease. Recommendations are that women who have Zika virus disease wait at least 8 weeks after onset of symptoms before attempting to conceive and that men who have Zika virus disease wait for at least 6 months before attempting conception. Healthcare providers should advise couples to wait to conceive until the risk for viremia or viral shedding in semen is minimal. And this will involve discussion and judgment particularly in areas of active transmission. And importantly, male partners should correctly and consistently use condoms or abstain from sex for the entire duration of the pregnancy once pregnancy is achieved, as this is the best way to avoid even a minimal risk for sexual transmission and the potential serious adverse fetal effects of Zika virus infection during pregnancy.

If couples decide to wait to conceive, healthcare providers should ensure that they discuss the best strategies for their patients to prevent an unintended pregnancy including use of the most effective contraceptive methods and the role of the use of condoms in reducing the risk for sexually transmitted infections including Zika.

Special Circumstances

There have been no documented cases of Zika virus transmission during infertility treatment, although from what we know transmission via donated gametes or embryos is theoretically possible. Zika virus is unlikely to be destroyed by cryopreservation, so if present it may persist. Treatment for couples who are sexually intimate and use their own gametes and embryos should follow the timing recommendations for those couples who are attempting conception. Based on patient circumstances, you may need to individualize care.

The FDA has developed guidance for donated tissues in the context of a Zika virus outbreak. Living donors are ineligible for anonymous donation if they have at least one of the following: a medical diagnosis of Zika virus infection in the past 6 months, they resided

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in or traveled to an area with active Zika virus transmissions within the past 6 months, or within the past 6 months they had sex with a male partner who during the previous 6 months was diagnosed with or experienced an illness consistent with Zika virus disease or had traveled to an area of active Zika virus transmission. Areas of active Zika virus transmission in parts of Mexico that do not directly border the United States have been reported. Healthcare providers who care for pregnant women who reside along the US–Mexico border should assess their patients' travel histories including frequency of cross-border travel and destinations. They should also inquire about the travel of their patients' sexual partners as that exposure could also pose a risk.

There are currently no reports of active Zika virus transmission along the US–Mexico border. However, if active transmission occurs, local health officials should determine when to implement testing of asymptomatic pregnant women based on information about local levels of Zika virus transmission and current laboratory capacity.

Testing Recommendations

The CDC recommends the following Zika virus diagnostic testing when testing is indicated. Reverse transcription polymerase chain reaction (RTPCR) detects viral RNA, and serum and should be collected within 7 days after symptom onset. Because viremia decreases over time, a negative RTPCR result from serum collected 5 to 7 days after onset of symptoms does not exclude Zika virus infection. Therefore, serologic testing for Zika virus IGM should be performed if the specimen was collected 4 or more days after illness onset. Healthcare providers should work with their state, local, or territorial health departments for facilitation and interpretation of testing.

Serologic testing for Zika virus can be offered to asymptomatic pregnant women with possible Zika virus exposure including travel to or residence in an area with ongoing Zika virus transmission. A negative immunoglubin M (IgM) result within 2 to 12 weeks after exposure could suggest that a recent infection did not occur and could obviate the need for serial ultrasound. However, a negative serologic result cannot definitively rule out Zika virus infection. Information about the performance of testing in asymptomatic persons is limited.

The CDC has updated recommendations about whom to test. Pregnant women with possible Zika virus exposure who do not reside in an area with active Zika virus transmission should be evaluated by their healthcare providers for possible Zika virus infection. This includes inquiring about exposure through travel or sexual activity, symptoms consistent with Zika virus infection, and physical examination. If the pregnant patient has been ill with one or more signs or symptoms consistent with Zika virus disease within 2 weeks of travel to an affected area, serum testing should be performed.

Healthcare providers should work with their state, local, or territorial health departments to order and interpret testing. Testing can be offered if the woman does not report clinical illness consistent with Zika virus disease but did have possible exposure including history of travel to an area with active Zika virus transmission or sex without a condom with a male partner who had symptoms consistent with Zika virus disease. Testing is not currently recommended for pregnant women with possible sexual exposure to Zika virus if both partners are asymptomatic.

As more has been learned about the fetal abnormalities associated with Zika virus, language around the findings on fetal ultrasound that may indicate congenital Zika virus infection has been broadened. In addition to microcephaly and intracranial calcifications, abnormally formed or absent brain structures, micro-ophthalmia, cataracts, and other eye abnormalities have been detected. The algorithm was therefore modified to reflect this.

In addition, amniocentesis was removed from the algorithm. Amniocentesis may be used in the evaluation of a patient, but clinical decisions about the use of amniocentesis will need to be individualized according to patient circumstances. The CDC has also updated recommendations for pregnant women residing in an area with active Zika virus transmission. The pregnant woman should be evaluated and if she has been ill with one or more signs or symptoms of Zika virus disease, testing should be performed at that time.

If the woman does not report signs or symptoms of Zika virus disease, then serum testing for Zika virus can be offered during the pregnancy. IGM can be offered upon the initiation of prenatal care. And if that test is negative repeat testing with IGM can be considered in the mid-second trimester because of the ongoing risks of Zika virus exposure and infection during pregnancy in an area with active transmission.

As with women residing in areas without active Zika virus transmission, if clinical illness consistent with Zika virus disease develops at any point in pregnancy, repeat Zika virus testing is warranted. Testing is not recommended in the setting of possible sexual exposure if both partners are asymptomatic.

As with the algorithm for pregnant women with possible Zika virus exposure but not residing in an area of active transmission similar changes were made. These included removal of the amniocentesis language as well

as broadening the language used for finding some fetal ultrasounds that may indicate congenital infection with Zika virus.

Next, we'll switch gears and discuss guidance that was issued about infection control in the labor and delivery setting through use of standard precautions in the context of Zika virus. Zika virus has been detected in multiple body fluids including blood, amniotic fluid, urine, saliva and semen as previously mentioned. At this time there have been no reports of transmission of Zika virus from infected patients to healthcare personnel or other patients.

Labor and delivery settings have the potential for exposure to large volumes of body fluids due to the nature of the care provided. Healthcare personnel working in these settings must adhere to standard precautions as they should in all healthcare settings.

The CDC recommends standard precautions in all healthcare settings to protect both healthcare personnel and patients from infection with Zika virus, as well as from other blood-borne pathogens for example HIV and hepatitis C virus. Standard precautions that are basic measures all healthcare personnel should take to prevent infection and apply to all patient care settings.

The goals of standard precautions include preventing contact between a patient's body fluids and healthcare personnel's mucous membranes including eyes, skin, and clothing; preventing healthcare personnel from transmitting potentially infectious material from one patient to another; and avoiding unnecessary exposure to contaminated sharp implements.

Standard precautions include hand hygiene, use of Personal Protective Equipment (PPE), safe injection practices, and safe handling of potentially contaminated equipment or surfaces in the patient's environment.

Healthcare personnel must assess their personal risk for exposure to blood and body fluids based on the type of patient contact and the nature of the clinical procedure activity and select the appropriate PPE based on that information. PPE includes gloves with double gloving having the potential to reduce percutaneous injuries when handling sharps, impermeable gowns, masks, eye protection either goggles or face shields, and knee-high impermeable shoe covers.

Examples of procedures that require increasing levels of PPE in the labor and delivery setting include vaginal examinations particularly during amniotomy or rupturing membranes when exposure to fluids will be expected, performing a vaginal delivery or manual removal of a plus-of a placenta when exposure to larger volumes of fluids would be routine and procedures in an operating room setting where clothing, skin and mucous membrane and protection should be maintained. Healthcare personnel should consider the anticipated exposure to blood and body fluids and the opportunities for splashes of these fluids. Appropriate PPEs should be worn to protect mucous membranes including the eyes accordingly.

In addition, all healthcare personnel on a team that are involved in the same procedures should use the same level of PPE. In addition to use of PPE by healthcare personnel, placement of disposable absorbent material on the floor around the procedure and delivery area to absorb fluid can reduce the risk for splash exposure to body fluids. Infection control supplies should be available and accessible in all patient care areas where they will be needed. Standard cleaning and disinfection procedures for environmental services using EPA registered hospital disinfectants should be followed.

It is important for all occupational exposures to be reported to a facility's occupational health clinic so that appropriate assessment of healthcare personnel can occur and any system-systemic safety risk can be promptly addressed. Ongoing education and training of all healthcare personnel about standard precautions and the use of appropriate PPE help ensure that infection control policies and procedures are understood and followed.

Any barriers to the routine use of standard precautions and appropriate PPE should be addressed immediately when identified. Facility nursing and obstetric leadership is critical for instituting infection prevention policies and promoting routine use of and adherence to standard precautions.

Algorithm for Evaluation of Infants

The algorithm for the evaluation and testing of infants can be found on the CDC website. The guidance represented by this algorithm is still current. However, it's important to highlight some areas that are influenced by the updated guidance for women of reproductive age with possible Zika virus exposure. These updated guidelines apply to infants particularly in two important ways.

In addition to travel to a residence in an area of active Zika virus transmission, mothers of infants can be exposed to Zika virus through sex without a condom as previously described. And in addition to microcephaly and intracranial calcifications, abnormalities consistent with Zika virus disease also include brain and eye abnormalities.

US Zika Pregnancy Registry

As we have discussed, Zika virus infection during pregnancy has been linked to adverse outcomes. Despite these observations very little is known about the risks of Zika virus infection during pregnancy. CDC has established the US Zika Pregnancy

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PharmaFacts for Case Managers

New Approvals

Nuplazid (pimavanserin) tablets, for oral use

Indications and Usage

Nuplazid is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Dosage and Administration

The recommended dose of Nuplazid is 34 mg, taken orally as two 17 mg strength tablets once daily, without titration. Nuplazid can be taken with or without food.

The recommended dose of Nuplazid when coadministered with strong CYP3A4 inhibitors (eg, ketoconazole) is 17 mg, taken orally as one tablet once daily. Monitor patients for reduced efficacy if Nuplazid is used concomitantly with strong CYP3A4 inducers; an increase in Nuplazid dosage may be needed

Dosage Forms and Strengths

Nuplazid (pimavanserin) is available as 17 mg strength tablets. The white to off-white, round, coated tablets are debossed on one side with a "P" and "17" on the reverse side.

Contraindications

None.

Warnings and Precautions

Warning: Increased Mortality in Elderly Patients With Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Nuplazid is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

Increased Mortality in Elderly Patients With Dementia-Related Psychosis

Antipsychotic drugs increase the all-cause risk of death in elderly patients with dementia-related psychosis. Analyses of 17 dementia-related psychosis placebo-controlled trials (modal duration of 10 weeks and largely in patients taking atypical antipsychotic drugs) revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in placebo-treated patients.

Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Nuplazid is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

QT-Interval Prolongation

Nuplazid prolongs the QT interval. The use of Nuplazid should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics (eg, quinidine, procainamide) or Class 3 antiarrhythmics (eg, amiodarone, sotalol), certain antipsychotic medications (eg, ziprasidone, chlorpromazine, thioridazine), and certain antibiotics (eg, gatifloxacin, moxifloxacin). Nuplazid should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.

Use in Specific Populations

Pregnancy

There are no data on Nuplazid use in pregnant women that would allow assessment of the drug-associated risk of major congenital malformations or miscarriage. In animal reproduction studies, no adverse developmental effects were seen when pimavanserin was administered orally to rats or rabbits during the period of organogenesis at doses up to 10 or 12 times the maximum recommended human dose (MRHD) of 34 mg/day, respectively. Administration of pimavanserin to pregnant rats during pregnancy and lactation resulted in maternal toxicity and lower pup survival and body weight at doses which are 2 times the MRHD of 34 mg/day.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively.

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Drug Abuse and Dependence

Controlled Substance

Nuplazid is not a controlled substance.

Abuse

Nuplazid has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence.

While short-term, placebo-controlled and long-term, open-label clinical trials did not reveal increases in drug- seeking behavior, the limited experience from the clinical trials do not predict the extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed.

Overdosage

The premarketing clinical trials involving Nuplazid in approximately 1200 subjects and patients do not provide information regarding symptoms with overdose. In healthy subject studies, dose-limiting nausea and vomiting were observed.

Management of Overdose

There are no known specific antidotes for Nuplazid. In managing overdose, cardiovascular monitoring should commence immediately and should include continuous ECG monitoring to detect possible arrhythmias. If antiarrhythmic therapy is administered, disopyramide, procainamide, and quinidine should not be used, as they have the potential for QT-prolonging effects that might be additive to those of Nuplazid. Consider the long plasma half-life of pimavanserin (about 57 hours) and the possibility of multiple drug involvement. Consult a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice.

Pimavanserin was not teratogenic in pregnant rats when administered during the period of organogenesis at oral doses of 0.9, 8.5, and 51 mg/kg/day, which are 0.2 and 10 times the maximum recommended human dose (MRHD) of 34 mg/day based on AUC at mid and high doses, respectively. Maternal toxicity included reduction in body weight and food consumption at the highest dose.

Administration of pimavanserin to pregnant rats during pregnancy and lactation at oral doses of 8.5, 26, and 51 mg/kg/day, which are 0.14 to 14 times the MRHD of 34 mg/day based on AUC, caused maternal toxicity, including mortality, clinical signs including dehydration, hunched posture, and rales, and decreases in body weight, and/or food consumption at doses ≥ 26 mg/kg/day (2 times the MRHD based on AUC). At these maternally toxic doses there was a decrease in pup survival, reduced litter size, and reduced pup weights, and food consumption. Pimavanserin had no effect on sexual maturation, neurobehavioral function including learning and memory, or reproductive function in the first generation pups up to 14-times the MHRD of 34 mg/day based on AUC.

Pimavanserin was not teratogenic in pregnant rabbits during the period of organogenesis at oral doses of 4.3, 43, and 85 mg/kg/day, which are 0.2 to 12 times the MHRD of 34 mg/day based on AUC. Maternal toxicity, including mortality, clinical signs of dyspnea and rales, decreases in body weight and/or food consumption, and abortions occurred at doses 12 times the MRHD of 34 mg/day based on AUC.

Lactation

There is no information regarding the presence of pimavanserin in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Nuplazid and any potential adverse effects on the breastfed infant from Nuplazid or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness of Nuplazid have not been established in pediatric patients.

Geriatric Use

No dose adjustment is required for elderly patients.

Parkinson's disease is a disorder occurring primarily in individuals over 55 years of age. The mean age of patients enrolled in the 6-week clinical studies with Nuplazid was 71 years, with 49% 65–75 years old and 31% > 75 years old. In the pooled population of patients enrolled in 6-week, placebo-controlled studies (N = 614), 27% had MMSE scores from 21 to 24 compared to 73% with scores ≥ 25. No clinically meaningful differences in safety or effectiveness were noted between these two groups.

Renal Impairment

No dosage adjustment for Nuplazid is needed in patients with mild to moderate (CrCL ≥ 30 mL/min, Cockcroft-Gault) renal impairment

Use of Nuplazid is not recommended in patients with severe renal impairment (CrCL < 30 mL/min, Cockcroft-Gault). Nuplazid has not been evaluated in this patient population.

Hepatic Impairment

Use of Nuplazid is not recommended in patients with hepatic impairment. Nuplazid has not been evaluated in this patient population.

Other Specific Populations

No dosage adjustment is required based on patient's age, sex, ethnicity, or weight. These factors do not affect the pharmacokinetics of Nuplazid.

Clinical Studies

The efficacy of Nuplazid 34 mg as a treatment of hallucinations and delusions associated with Parkinson's disease psychosis was demonstrated in a 6-week, randomized, placebo-controlled, parallel-group study. In this outpatient study, 199 patients were randomized in a 1:1 ratio to Nuplazid 34 mg or placebo once daily.

Study patients (male or female and aged 40 years or older) had a diagnosis of Parkinson's disease (PD) established at least 1 year prior to study entry and had psychotic symptoms (hallucinations

and/or delusions) that started after the PD diagnosis and that were severe and frequent enough to warrant treatment with an antipsychotic. At entry, patients were required to have a Mini-Mental State Examination (MMSE) score ≥ 21 and to be able to self-report symptoms. The majority of patients were on PD medications at entry; these medications were required to be stable for at least 30 days prior to study start and throughout the study period.

The PD-adapted Scale for the Assessment of Positive Symptoms (SAPS-PD) was used to evaluate the efficacy of Nuplazid 34 mg. SAPS-PD is a 9-item scale adapted for PD from the Hallucinations and Delusions domains of the SAPS. Each item is scored on a scale of 0-5, with 0 being none and 5 representing severe and frequent symptoms. Therefore, the SAPS-PD total score can range from 0 to 45 with higher scores reflecting greater severity of illness. A negative change in score indicates improvement. Primary efficacy was evaluated based on change from baseline to Week 6 in SAPS-PD total score.

Nuplazid 34 mg (n = 95) was statistically significantly superior to placebo (n = 90) in decreasing the frequency and/or severity of hallucinations and delusions in patients with PDP as measured by central, independent, and blinded raters using the SAPS-PD scale. An effect was seen on both the hallucinations and delusions components of the SAPS-PD.

Motor Function in Patients with Hallucinations and Delusions Associated with Parkinson's Disease Psychosis Nuplazid 34 mg did not show an effect compared to placebo on motor function, as measured using the Unified Parkinson's Disease Rating Scale Parts II and III (UPDRS Parts II+III). A negative change in score indicates improvement. The UPDRS Parts II+III was used to assess the patient's Parkinson's disease state during the 6-week double-blind treatment period. The UPDRS score was calculated as the sum of the 40 items from activities of daily living and motor examination, with a range of 0 to 160.

How Supplied/Storage and Handling

Nuplazid (pimavanserin) tablets are available as:

- A 17-mg white to off-white, round, coated tablet debossed with "P" on one side and "17" on the reverse.
- Bottle of 60: NDC 63090-170-60

Storage

Store at 20°C–25°C (68°F–77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).

Nuplazid is distributed by ACADIA Pharmaceuticals Inc. San Diego, CA

Cabometyx™ (cabozantinib) tablets, for oral use

Indications and Usage

Cabometyxis is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

Dosage and Administration

Do not substitute Cabometyx tablets with cabozantinib capsules.

The recommended daily dose of Cabometyx is 60 mg. Do not administer Cabometyx with food. Instruct patients not to eat for at least 2 hours before and at least 1 hour after taking CABOMETYX. Continue treatment until patient no longer experiences clinical benefit or experiences unacceptable toxicity.

Swallow Cabometyx tablets whole. Do not crush Cabometyx tablets. Do not take a missed dose within 12 hours of the next dose.

Do not ingest foods (e.g., grapefruit, grapefruit juice) or nutritional supplements that are known to inhibit cytochrome P450 during Cabometyx treatment.

For Patients Undergoing Surgery

Stop treatment with Cabometyx at least 28 days prior to scheduled surgery, including dental surgery.

For Adverse Reactions

Withhold Cabometyx for NCI CTCAE Grade 4 adverse reactions, and for Grade 3 or intolerable Grade 2 adverse reactions that cannot be managed with a dose reduction or supportive care.

Upon resolution/improvement (ie, return to baseline or resolution to Grade 1) of an adverse reaction, reduce the dose as follows:

- If previously receiving 60 mg daily dose, resume treatment at 40 mg daily
- If previously receiving 40 mg daily dose, resume treatment at 20 mg daily
- If previously receiving 20 mg daily dose, resume at 20 mg if tolerated, otherwise, discontinue CABOMETYX

Permanently discontinue Cabometyx for any of the following:

- Development of unmanageable fistula or GI perforation
- Severe hemorrhage arterial thromboembolic event (eg, myocardial infarction, cerebral infarction)
- hypertensive crisis or severe hypertension despite optimal medical management
- nephrotic syndrome
- reversible posterior leukoencephalopathy syndrome

In Patients Concurrently Taking a Strong CYP3A4 Inhibitor

Reduce the daily Cabometyx dose by 20 mg (for example, from 60 mg to 40 mg daily or from 40 mg to 20 mg daily). Resume the dose that was used prior to initiating the CYP3A4 inhibitor 2 to 3 days after discontinuation of the strong inhibitor.

In Patients Concurrently Taking a Strong CYP3A4 Inducer

Increase the daily Cabometyx dose by 20 mg (for example, from 60 mg to 80 mg daily or from 40 mg to 60 mg daily) as tolerated. Resume the dose that was used prior to initiating the CYP3A4 inducer 2 to 3 days after discontinuation of the strong inducer. The daily dose of Cabometyx should not exceed 80 mg.

In Patients With Hepatic Impairment

Reduce the starting dose of Cabometyx to 40 mg once daily in

patients with mild or moderate hepatic impairment. Cabometyx is not recommended for use in patients with severe hepatic impairment.

Dosage Forms and Strength

- 60-mg Cabometyx tablets are yellow film-coated, oval shaped with no score, and debossed with "XL" on one side and "60" on the other side.
- 40-mg Cabometyx tablets are yellow film-coated, triangle shaped with no score, and debossed with "XL" on one side and "40" on the other side.
- 20-mg Cabometyx tablets are yellow film-coated, round with no score, and debossed with "XL" on one side and "20" on the other side.

Contraindications

None.

Warnings and Precautions

Hemorrhage

Severe hemorrhage occurred with Cabometyx. The incidence of Grade ≥ 3 hemorrhagic events was 2.1% in Cabometyx -treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program.

Do not administer Cabometyx to patients that have or are at risk for severe hemorrhage.

GI Perforations and Fistulas

In a randomized study in renal cell carcinoma, fistulas were reported in 1.2% (including 0.6% anal fistula) of Cabometyx -treated patients and 0% of everolimus-treated patients.

Gastrointestinal (GI) perforations were reported in 0.9% of Cabometyx-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program.

Monitor patients for symptoms of fistulas and perforations. Discontinue Cabometyxin patients who experience a fistula which cannot be appropriately managed or a GI perforation.

Thrombotic Events

Cabometyx treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program.

Discontinue Cabometyx in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

Hypertension and Hypertensive Crisis

Cabometyx treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥ 3) of Cabometyx-treated patients and 7.1% (3.1% Grade ≥ 3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during Cabometyx treatment. Withhold Cabometyx for hypertension that is not adequately controlled with medical management; when controlled, resume Cabometyx at a reduced dose. Discontinue Cabometyx for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue Cabometyx if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

Diarrhea

Diarrhea occurred in 74% of patients treated with Cabometyx and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of Cabometyx-treated patients and in 2% of everolimus-treated patients. Withhold Cabometyx in patients who develop intolerable Grade 2 diarrhea or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume Cabometyx at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

Palmar-Plantar Erythrodysesthesia Syndrome

Palmar-plantar erythrodysesthesia syndrome (PPES) occurred in 42% of patients treated with Cabometyx and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX-treated patients and in <1% of everolimus-treated patients. Withhold Cabometyx in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume Cabometyx at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

Reversible Posterior Leukoencephalopathy Syndrome

Reversible Posterior Leukoencephalopathy Syndrome (RPLS), a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion or altered mental function. Discontinue Cabometyx in patients who develop RPLS.

Embryo-fetal Toxicity

Based on data from animal studies and its mechanism of action, Cabometyx can cause fetal harm when administered to a pregnant woman. Cabozantinib administration to pregnant animals during organogenesis resulted in embryo lethality at exposures below those occurring clinically at the recommended dose, and in increased incidences of skeletal variations in rats and visceral variations and malformations in rabbits. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Cabometyx and for 4 months after the last dose.

Adverse Reactions

- Hemorrhage
- GI Perforations and Fistulas
- Thrombotic Events

- Hypertension and Hypertensive Crisis Diarrhea
- Palmar-plantar erythrodysesthesia syndrome
- Reversible Posterior Leukoencephalopathy Syndrome

Drug Interactions

Use in Specific Populations

CLINICALLY SIGNIFICANT DRUG INTERACTIONS INVOLVING DRUGS THAT AFFECT CABOZANTINIB

Strong CYP3A4 Inhibitors	
Clinical Implications:	Concomitant use of Cabometyx with a strong CYP3A4 inhibitor increased the exposure of cabozantinib compared to the use of Cabometyx alone Increased cabozantinib exposure may increase the risk of exposure-related toxicity.
Prevention or Management:	Reduce the dosage of Cabometyx if concomitant use with strong CYP3A4 inhibitors cannot be avoided.
Examples:	Boceprevir, clarithromycin, conivaptan, grapefruit juice, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telithromycin, and voriconazole
Strong CYP3A4 Inducers	
Clinical Implications:	Concomitant use of Cabometyx with a strong CYP3A4 inducer decreased the exposure of cabozantinib compared to the use of Cabometyx. Decreased cabozantinib exposure may lead to reduced efficacy.
Prevention or Management:	Increase the dosage of Cabometyx if concomitant use with strong CYP3A4 inducers cannot be avoided.
Examples:	Rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

Pregnancy

Based on findings from animal studies and its mechanism of action, Cabometyx can cause fetal harm when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal developmental and reproductive toxicology studies administration of cabozantinib to pregnant rats and rabbits during organogenesis resulted in embryofetal lethality and structural anomalies at exposures that were below those occurring clinically at the recommended dose. Advise pregnant women or women of childbearing potential of the potential hazard to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

In an embryo-fetal development study in pregnant rats, daily oral administration of cabozantinib throughout organogenesis caused increased embryo-fetal lethality compared to controls at a dose of 0.03 mg/kg (approximately 0.12-fold of human AUC at the recommended dose). Findings included delayed ossification and skeletal variations at a dose of 0.01 mg/kg/day (approximately 0.04-fold of human AUC at the recommended dose).

In pregnant rabbits, daily oral administration of cabozantinib throughout organogenesis resulted in findings of visceral malformations and variations including reduced spleen size and missing lung lobe at 3 mg/kg (approximately 1.1-fold of the human AUC at the recommended dose).

In a pre- and postnatal study in rats, cabozantinib was administered orally from gestation day 10 through postnatal day 20. Cabozantinib did not produce adverse maternal toxicity or affect pregnancy, parturition or lactation of female rats, and did not affect the survival, growth or postnatal development of the offspring at doses up to 0.3 mg/kg/day (0.05-fold of the maximum recommended clinical dose).

Lactation

There is no information regarding the presence of cabozantinib or its metabolites in human milk, or their effects on the breastfed infant, or milk production. Because of the potential for serious adverse reactions in a breastfed infant from Cabometyx, advise a lactating woman not to breastfeed during treatment with Cabometyx and for 4 months after the final dose.

Females and Males of Reproductive Potential

Cabometyx can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Cabometyx and for 4 months after the final dose.

Based on findings in animals, Cabometyx may impair fertility in females and males of reproductive potential.

Pediatric Use

The safety and effectiveness of Cabometyx in pediatric patients have not been studied.

Juvenile rats were administered cabozantinib daily at doses of 1 or 2 mg/kg/day from Postnatal Day 12 (comparable to less than 2 years in humans) through Postnatal Day 35 or 70. Mortalities occurred at doses equal and greater than 1 mg/kg/day (approximately 0.16 times the clinical dose of 60 mg/day based on body surface area). Hypoactivity was observed at both doses tested on Postnatal Day 22. Targets were generally similar to those seen in adult animals, occurred at both doses, and included the kidney (nephropathy, glomerulonephritis), reproductive organs, gastrointestinal tract (cystic dilatation and hyperplasia in Brunner's gland and inflammation of duodenum; and epithelial hyperplasia of colon and cecum), bone marrow (hypocellularity and lymphoid depletion), and liver. Tooth abnormalities and whitening as well as effects

continues on page 35

LITSCAN FOR CASE MANAGERS

LitScan for Case Managers reviews medical literature and reports abstracts that are of particular interest to case managers in an easy-to-read format. Each abstract includes information to locate the full-text article if there is an interest. This member benefit is designed to assist case managers in keeping current with clinical breakthroughs in a time-effective manner.

J Hepatol. 2016 May 12. pii: S0168-8278(16)30184-2. doi: 10.1016/j.jhep.2016.04.031. [Epub ahead of print]

Alcohol intake increases the risk of hepatocellular carcinoma in patients with hepatitis C virus-related compensated cirrhosis: a prospective study.

Vandenbulcke H, Moreno C, Colle I, et al.

Whether alcohol intake increases the risk of complications in patients with HCV-related cirrhosis remains unclear. AIM: To determine the impact of alcohol intake and viral eradication on the risk of hepatocellular carcinoma (HCC), decompensation of cirrhosis and death. PATIENTS AND METHODS: Data on alcohol intake and viral eradication were prospectively collected in 192 patients with compensated HCV-related cirrhosis. RESULTS: 74 patients consumed alcohol (median alcohol intake: 15 g/day); 68 reached viral eradication. During a median follow-up of 58 months, 33 patients developed HCC, 53 experienced at least one decompensation event, and 39 died. The 5-year cumulative incidence rate of HCC was 10.6% (95% CI: 4.6-16.6) in abstainers vs. 23.8% (95% CI: 13.5-34.1) in consumers (p = 0.087), and 2.0% (95% CI: 0-5.8) vs. 21.7% (95% CI: 14.2-29.2) in patients with and without viral eradication (p = 0.002), respectively. The lowest risk of HCC was observed for patients without alcohol intake and with viral eradication (0%) followed by patients with alcohol intake and viral eradication (6.2% [95% CI: 0-18.4]), patients without alcohol intake and no viral eradication (15.9% [95% CI: 7.1-24.7]), and patients with alcohol intake and no viral eradication (29.2% [95% CI: 16.5-41.9]) (p = 0.009). In multivariate analysis, lack of viral eradication and alcohol consumption were associated with the risk of HCC (hazard ratio for alcohol consumption: 3.43, 95% CI: 1.49-7.92, p = 0.004). Alcohol intake did not influence the risk of decompensation or death. CONCLUSION: Light-to-moderate alcohol intake increases the risk of HCC in patients with HCV-related cirrhosis. Patient care should include measures to ensure abstinence.

Cancer. 2016 May 17. doi: 10.1002/cncr.30052. [Epub ahead of print]

Disparities in cancer treatment among patients infected with the human immunodeficiency virus.

Suneja G, Lin CC, Simard EP, et al.

BACKGROUND: Patients with cancer who are infected with the human immunodeficiency virus (HIV) are less likely to receive cancer treatment compared with HIV-uninfected individuals. However, to the authors' knowledge, the impact of insurance status and comorbidities is unknown. METHODS: Data from the National Cancer Data Base were used to study nonelderly adults diagnosed with several common cancers from 2003 to 2011. Cancer treatment was defined as chemotherapy, surgery, radiotherapy, or any combination during the first course of treatment. Multivariate logistic regression was used to examine associations between HIV status and lack of cancer treatment, and identify predictors for lack of treatment among HIV-infected patients. RESULTS: A total of 10,265 HIV-infected and 2,219,232 HIV-uninfected cases were included. In multivariate analysis, HIV-infected patients with cancer were found to be more likely to lack cancer treatment for cancers of the head and neck (adjusted odds ratio [aOR], 1.48; 95% confidence interval [95% CI], 1.09-2.01), upper gastrointestinal tract (aOR, 2.62; 95% CI, 2.04-3.37), colorectum (aOR, 1.70; 95% CI, 1.17-2.48), lung (aOR, 2.46; 95% CI, 2.19-2.76), breast (aOR, 2.14; 95% CI, 1.16-3.98), cervix (aOR, 2.81; 95% CI, 1.77-4.45), prostate (aOR, 2.16; 95% CI, 1.69-2.76), Hodgkin lymphoma (aOR, 1.92; 95% CI, 1.66-2.22), and diffuse large B-cell lymphoma (aOR, 1.82; 95% CI, 1.65-2.00). Predictors of a lack of cancer treatment among HIV-infected individuals varied by tumor type (solid tumor vs lymphoma), but black race and a lack of private insurance were found to be predictors for both groups. CONCLUSIONS: In the United States, HIV-infected patients with cancer appear to be less likely to receive cancer treatment regardless of insurance and

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comorbidities. To the authors' knowledge, the current study is the largest study of cancer treatment in HIV-infected patients with cancer in the United States and provides evidence of cancer treatment disparities even after controlling for differences with regard to insurance status and comorbidities. Further work should focus on addressing differential cancer treatment.

Am J Epidemiol. 2016 May 8. pii: kwv296. [Epub ahead of print]

Neighborhood environments and incident hypertension in the multi-ethnic study of atherosclerosis.

Kaiser P, Diez Roux AV, Mujahid M, et al.
We examined relationships between neighborhood physical and social environments and incidence of hypertension in a cohort of 3,382 adults at 6 sites in the United States over 10 years of follow-up (2000-2011), using data from the Multi-Ethnic Study of Atherosclerosis. The sample was aged 45-84 years (mean = 59 years) and free of clinical cardiovascular disease and hypertension at baseline. Of the participants, 51% were female, 44% white, 23% Hispanic, 21% black, and 13% Chinese-American; 39% of participants developed hypertension during an average of 7.2 years of follow-up. Cox models were used to estimate associations of time-varying cumulative average neighborhood features (survey-based healthy food availability, walking environment, social cohesion, safety, and geographic information system-based density of favorable food stores and recreational resources) with incident hypertension. After adjustment for individual and neighborhood-level covariates, a 1-standard-deviation increase in healthy food availability was associated with a 12% lower rate of hypertension (hazard ratio = 0.88, 95% confidence interval: 0.82, 0.95). Other neighborhood features were not related to incidence of hypertension. The neighborhood food environment is related to the risk of hypertension.HIV Med. 2016 May 17. doi: 10.1111/hiv.12357. [Epub ahead of print]

Systemic inflammation and liver damage in HIV/hepatitis C virus coinfection.

Shmagel KV, Saidakova EV, Shmagel NG, et al.
OBJECTIVES: Chronic hepatitis C virus (HCV) and HIV viral infections are characterized by systemic inflammation. Yet the relative levels, drivers and correlates of inflammation in these settings are not well defined. METHODS: Seventy-nine HIV-infected patients who had been receiving antiretroviral therapy (ART) for more than 2 years and who had suppressed plasma HIV levels (< 50 HIV-1 RNA copies/mL) were included in the study. Two patient groups, HCV-positive/HIV-positive and HCV-negative/HIV-positive, and a control group comprised of healthy volunteers (n = 20) were examined. Markers of systemic inflammation [interleukin (IL)-6, interferon gamma-induced protein (IP)-10, soluble tumour necrosis factor receptor-I (sTNF-RI) and sTNF-RII], monocyte/macrophage activation [soluble CD163 (sCD163), soluble CD14 and neopterin], intestinal epithelial barrier loss [intestinal fatty acid binding protein (I-FABP) and lipopolysaccharide (LPS)] and coagulation (d-dimers) were analysed. CD4 naïve T cells and CD4 recent thymic emigrants (RTEs) were enumerated. RESULTS: Plasma levels of IP-10, neopterin and sCD163 were higher in HCV/HIV coinfection than in HIV monoinfection and were positively correlated with indices of hepatic damage [aspartate aminotransferase (AST), alanine aminotransferase (ALT) and the AST to platelet ratio index (APRI)]. Levels of I-FABP were comparably increased in HIV monoinfection and HIV/HCV coinfection but LPS concentrations were highest in HCV/HIV coinfection, suggesting impaired hepatic clearance of LPS. Plasma HCV levels were not related to any inflammatory indices except sCD163. In coinfected subjects, a previously recognized relationship of CD4 naïve T-cell and RTE counts to hepatocellular injury was defined more mechanistically by an inverse relationship to sCD163. CONCLUSIONS: Hepatocellular injury in HCV/HIV coinfection is linked to elevated levels of certain inflammatory cytokines and an apparent failure to clear systemically translocated microbial products. A related decrease in CD4 naïve T cells and RTEs also merits further exploration.

BMJ. 2016 May 17;353:i2351. doi: 10.1136/bmj.i2351.

Potato intake and incidence of hypertension: results from three prospective US cohort studies.

Borgi L, Rimm EB, Willett WC, Forman JP.
OBJECTIVE: To determine whether higher intake of baked or boiled potatoes, French fries, or potato chips is associated with incidence of hypertension. DESIGN: Prospective longitudinal cohort studies. SETTING: Healthcare providers in the United States. PARTICIPANTS: 62,175 women in Nurses' Health Study, 88,475 women in Nurses' Health Study II, and 36,803 men in Health Professionals Follow-up Study who were non-hypertensive at baseline. MAIN OUTCOME MEASURE: Incident cases

of hypertension (self-reported diagnosis by healthcare provider). RESULTS: Compared with consumption of less than one serving a month, the random effects pooled hazard ratios for four or more servings a week were 1.11 (95% confidence interval 0.96 to 1.28; P for trend = 0.05) for baked, boiled, or mashed potatoes, 1.17 (1.07 to 1.27; P for trend =0.001) for French fries, and 0.97 (0.87 to 1.08; P for trend = 0.98) for potato chips. In substitution analyses, replacing one serving a day of baked, boiled, or mashed potatoes with one serving a day of non-starchy vegetables was associated with decreased risk of hypertension (hazard ratio 0.93, 0.89 to 0.96). CONCLUSION: Higher intake of baked, boiled, or mashed potatoes and French fries was independently and prospectively associated with an increased risk of developing hypertension in three large cohorts of adult men and women.

Int J Cardiol. 2016 May 3;217:122-127. doi: 10.1016/j.ijcard.2016.04.174. [Epub ahead of print]

Association between retinal vein occlusion and risk of heart failure: A 12-year nationwide cohort study.

Rim RH, Oh J, Kang SM, Kim SS.

BACKGROUNDS: Retinal vein occlusion (RVO) is one of the major causes of visual impairment in elderly people. Risk factors for RVO are also common risk factors for cardiovascular disease, including heart failure (HF). However, the association between RVO and HF has not been evaluated. METHODS AND RESULTS: A retrospective propensity-score matched cohort study was conducted using national representative 1 million samples from the Korea National Health Insurance Service. The RVO group included patients with a first diagnosis of either central or branch RVO (n = 1754) and the comparison group included randomly selected patients (n = 8749) who were matched to sociodemographic factors and the year of RVO diagnosis. In the longitudinal cohort, HF developed in 11.6% and 8.0% of patients in the RVO and comparison groups, respectively, (p <0.001) during the 11-year follow-up period (median, 7.6 years). RVO was significantly associated with an increased risk of HF after multivariable adjustment (HR = 1.36; 95% CI, 1.16-1.60). In terms of HF subtypes, RVO was associated with the risk of ischemic HF but not with the risk of non-ischemic HF. The effect size (~HR) for HF by RVO was larger in patients without each comorbidity than in patients with each comorbidity. CONCLUSIONS: Our observational study on nationwide data suggests that RVO is associated with an increased risk of the incidence of HF, especially ischemic HF. An optimal surveillance strategy and referring from ophthalmologists to cardiologists should be considered in the presence of one or more additional HF risk factors in patients with RVO.

HIV Med. 2016 May 17. doi: 10.1111/hiv.12357. [Epub ahead of print]

Systemic inflammation and liver damage in HIV/hepatitis C virus coinfection.

Shmagel KV, Saidakova EV, Shmagel NG, et al.

OBJECTIVES: Chronic hepatitis C virus (HCV) and HIV viral infections are characterized by systemic inflammation. Yet the relative levels, drivers and correlates of inflammation in these settings are not well defined. METHODS: Seventy-nine HIV-infected patients who had been receiving antiretroviral therapy (ART) for more than 2 years and who had suppressed plasma HIV levels (< 50 HIV-1 RNA copies/mL) were included in the study. Two patient groups, HCV-positive/HIV-positive and HCV-negative/HIV-positive, and a control group comprised of healthy volunteers (n = 20) were examined. Markers of systemic inflammation [interleukin (IL)-6, interferon gamma-induced protein (IP)-10, soluble tumour necrosis factor receptor-I (sTNF-RI) and sTNF-RII], monocyte/macrophage activation [soluble CD163 (sCD163), soluble CD14 and neopterin], intestinal epithelial barrier loss [intestinal fatty acid binding protein (I-FABP) and lipopolysaccharide (LPS)] and coagulation (d-dimers) were analysed. CD4 naïve T cells and CD4 recent thymic emigrants (RTEs) were enumerated. RESULTS: Plasma levels of IP-10, neopterin and sCD163 were higher in HCV/HIV coinfection than in HIV monoinfection and were positively correlated with indices of hepatic damage [aspartate aminotransferase (AST), alanine aminotransferase (ALT) and the AST to platelet ratio index (APRI)]. Levels of I-FABP were comparably increased in HIV monoinfection and HIV/HCV coinfection but LPS concentrations were highest in HCV/HIV coinfection, suggesting impaired hepatic clearance of LPS. Plasma HCV levels were not related to any inflammatory indices except sCD163. In coinfected subjects, a previously recognized relationship of CD4 naïve T-cell and RTE counts to hepatocellular injury was defined more mechanistically by an inverse relationship to sCD163. CONCLUSIONS: Hepatocellular injury in HCV/HIV coinfection is linked to elevated levels of certain inflammatory cytokines and an apparent failure to clear systemically translocated microbial products. A related decrease in CD4 naïve T cells and RTEs also merits further exploration.

LITSCAN
FOR CASE MANAGERS

Arch Pathol Lab Med. 2016 May 19. [Epub ahead of print]

Liquid biopsy in lung cancer: a perspective from members of the Pulmonary Pathology Society.

Sholl LM, Aisner CL, Allen TC, et al.
Liquid biopsy has received extensive media coverage and has been called the holy grail of cancer detection. Attempts at circulating tumor cell and genetic material capture have been progressing for several years, and recent financially and technically feasible improvements of cell capture devices, plasma isolation techniques, and highly sensitive polymerase chain reaction- and sequencing-based methods have advanced the possibility of liquid biopsy of solid tumors. Although practical use of circulating RNA-based testing has been hindered by the need to fractionate blood to enrich for RNAs, the detection of circulating tumor cells has profited from advances in cell capture technology. In fact, the US Food and Drug Administration has approved one circulating tumor cell selection platform, the CellSearch System. Although the use of liquid biopsy in a patient population with a genomically defined solid tumor may potentially be clinically useful, it currently does not supersede conventional pretreatment tissue diagnosis of lung cancer. Liquid biopsy has not been validated for lung cancer diagnosis, and its lower sensitivity could lead to significant diagnostic delay if liquid biopsy were to be used in lieu of tissue biopsy. Ultimately, notwithstanding the enthusiasm encompassing liquid biopsy, its clinical utility remains unproven.

Pediatrics. 2016 Jan;137(1). doi: 10.1542/peds.2015-0851. Epub 2015 Dec 1.

A multicenter collaborative to reduce unnecessary care in inpatient bronchiolitis.

Ralston SL, Garber MD, Rice-Conboy E, et al; Value in Inpatient Pediatrics Network Quality Collaborative for Improving Hospital Compliance with AAP Bronchiolitis Guideline (BQIP).
BACKGROUND AND OBJECTIVE: Evidence-based Guidelines for acute viral bronchiolitis recommend primarily supportive care, but unnecessary care remains well documented. Published quality improvement work has been accomplished in children's hospitals, but little broad dissemination has been reported outside of those settings. We sought to use a voluntary collaborative strategy to disseminate best practices to reduce overuse of unnecessary care in children hospitalized for bronchiolitis in community settings. METHODS: This project was a quality improvement collaborative consisting of monthly interactive webinars with online data collection and feedback. Data were collected by chart review for 2 bronchiolitis seasons, defined as January, February, and March of 2013 and 2014. Patients aged < 24 months hospitalized for bronchiolitis and without chronic illness, prematurity, or intensive care use were included. Results were analyzed using run charting, analysis of means, and nonparametric statistics. RESULTS: There were 21 participating hospitals contributing a total of 1869 chart reviews to the project, 995 preintervention and 874 postintervention. Mean use of any bronchodilator declined by 29% (P = .03) and doses per patient decreased 45% (P < .01). Mean use of any steroids declined by 68% (P < .01), and doses per patient decreased 35% (P = .04). Chest radiography use declined by 44% (P = .05). Length of stay decreased 5 hours (P < .01), and readmissions remained unchanged. CONCLUSIONS: A voluntary collaborative was effective in reducing unnecessary care among a cohort of primarily community hospitals. Such a strategy may be generalizable to the settings where the majority of children are hospitalized in the United States.

Br J Cancer. 2016 Jan 12;114(1):110-117. doi: 10.1038/bjc.2015.438.

Male pattern baldness and risk of colorectal neoplasia.

Keum N, Cao Y, Lee DH, et al.
BACKGROUND: Male pattern baldness is positively associated with androgens as well as insulin-like growth factor 1 (IGF-1) and insulin, all of which are implicated in pathogenesis of colorectal neoplasia. METHODS: From 1992 through 2010, we prospectively followed participants in the Health Professionals Follow-Up Study. Hair pattern at age 45 years was assessed at baseline with five image categories (no baldness, frontal-only baldness, frontal-plus-mild-vertex baldness, frontal-plus-moderate-vertex baldness, and frontal-plus-severe-vertex baldness). Cancer analysis included 32 782 men and used Cox proportional hazards models to estimate hazard ratios (HRs) and 95% confidence intervals (CIs). Restricted to men who underwent at least one endoscopy over the study period, adenoma analysis included 29 770 men and used logistic regressions for clustered data to estimate odds ratios (ORs) and 95% CIs. RESULTS: Over the mean follow-up of 15.6 years,

continues on page 37

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LONG-TERM CARE COSTS CONTINUE TO RISE

Long-term care in a private nursing home room is now close to $100,000 per year. The costs of home health aides and assisted living communities is also rising, but costs for adult day care have fallen slightly in the past year. With these rising costs come rising insurance rates for long-term care insurance. Assisted living costs now average about $43, 500 per year while in-home health aids cost about $46,300 per year. Adult day care rates are about $17,700 annually.

Government and Private Sector Seek to Reduce Organ Transplant Waiting List

Research efforts to increase the number of transplants by 2,000 a year have brought together transplant centers who will share information on kidney transplant for patients who are difficult to match, a $160 million Pentagon program to develop ways to repair and replace cells and tissue, and a study of organ transplants between donors and recipients who are HIV-positive. Read more on *The Washington Post* website. ■

Emergency Response to Mass Shootings

Jay Kaplan, president of the American College of Emergency Physicians (ACEP) has called for more patient injury data and improved emergency response measures to better treat victims of gun violence following the mass shooting in Orlando. Listen to the video recording at Modern Healthcare. Is your hospital prepared? ■

How Do Social Factors Affect Health Care?

Good health is not just a matter of receiving care from the best doctors, nurses, and other members of health care teams. Studies show that social, environmental, and behavioral factors account for 60% of determinants of good health. Genetics account for a mere 20%. The quality of health care accounts for the remaining 20%. Interested in learning more about how social factors determine population health? Read the free ebook from Xerox. ■

ANTIBIOTIC OVERUSE IS FOCUS ON NEW CMS MANDATE

The same rule that proposes stronger antidiscrimination policies also mandates that hospitals must develop infection prevention and control and antibiotic stewardship programs for surveillance, prevention, and control of health care–associated infections and other infectious diseases and for the appropriate use of antibiotics. ■

Elevating Mental Health in Election Year Dialogue

Former congressman from Rhode Island and son of the late Sen. Ted Kennedy, Patrick Kennedy is calling for conversation during the presidential elections to focus on the mental health crisis in America. Vital treatment for mental health is a forgotten civil right, according to many mental health advocates and care providers. Nearly $100 billion is lost in productivity per year because of untreated or undertreated mental illness. How can you move the conversation forward? ■

Migraine–Vitamin Deficiency Link

A study by researchers at Cincinnati Children's Hospital Medical Center found that many children, teens, and young adults with migraines have deficiencies (albeit mild) in vitamin D, coenzyme Q10, and riboflavin. Research findings were reported at the 58th Annual Scientific Meeting of the American Headache Society this month. ■

Stress May Be a Precursor to Alzheimer's

Stress, according to researchers, is a major contributing factor to pre-dementia, which can lead to Alzheimer's disease. A recent study of 2,000 seniors showed that those who were contantly stressed out by small, daily hassles were twice as likely to be at risk for mild brain impairment. Read more at Life Lessons. ■

Those With Mental Illness Rarely Involved in Gun Violence Toward Others

A study by researchers at Johns Hopkins Bloomberg School of Public Health finds that those with mental illness are unfairly portrayed by the media as being responsible for gun violence toward others. Schizophrenia is most commonly connected to violence in media reports. The full report is available in this month's issue of *Health Affairs*. ■

CMS Reaffirms That Insurers Can't Impose Waiting Periods for Benefits

Plans that provide mandated benefits under the Affordable Care Act cannot require beneficiaries to wait before using the benefits. This includes pediatric orthodontia. ■

PILOT PROGRAM WILL FORCE PREAUTHORIZATION FOR HOME HEALTH

CMS is moving forward with a 3-year demonstration project rolled out in 5 states that will require preapproval for home health services. The states include Florida, Illinois, Massachusetts, Michigan, and Texas, and the program begins in Illinois on August 1. The project requires that once physicians order home health services for Medicare beneficiaries, the home health services may begin, but the home health agency must submit supporting written evidence of medical necessity earlier than they normally would. Medicare will review the evidence and issue a pre-claim review decision within 10 days if all coverage requirements are met. The demonstration project was instituted because of improper payment of home health services in 2015 that exceeded $9 million. CMS estimates that the costs for industry will be $21.6 million for the first 3 years and $300 million for the federal government. ■

CMS Aims to Prevent Discrimination With a New Proposed Rule

Hospitals participating in Medicare and Medicaid must abide by antidiscrimination policies and inform patients in writing about these policies, according to a Proposed Rule published this month in the Federal Register. The rules cover discrimination based on sexual orientation, race, color, national origin, sex, gender identity, age, and disability. Failure to follow the provisions will cost hospital $773 to $1.1 billion. ■

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on bones including reduced bone mineral content and density, physeal hypertrophy, and decreased cortical bone also occurred at all dose levels. Recovery was not assessed at the 2 mg/kg dose level (approximately 0.32 times the clinical dose of 60 mg based on body surface area) due to high levels of mortality. At the low dose level, effects on bone parameters were partially resolved but effects on the kidney and epididymis/testis persisted after treatment ceased.

Geriatric Use

In the Phase 3 study, 41% of RCC patients treated with Cabometyx were age 65 years and older, and 8% were age 75 and older. No differences in safety or efficacy were observed between older and younger patients.

Hepatic Impairment

Increased exposure to cabozantinib has been observed in patients with mild to moderate hepatic impairment. Reduce the Cabometyx dose in patients with mild (Child-Pugh score (C-P) A) or moderate (C-P B) hepatic impairment. Cabometyx is not recommended for use in patients with severe hepatic impairment

Renal Impairment

Dosage adjustment is not required in patients with mild or moderate renal impairment. There is no experience with Cabometyx in patients with severe renal impairment.

Clinical Studies

Study 1 was a randomized (1:1), open-label, multicenter study of Cabometyx versus everolimus conducted in patients with advanced RCC who had received at least 1 prior anti-angiogenic therapy. Patients had to have a Karnofsky Performance Score (KPS) ≥ 70%. Patients were stratified by the number of prior VEGFR tyrosine kinase inhibitors and Memorial Sloan Kettering Cancer Center (MSKCC) Risk Group.

Patients (N = 658) were randomized to receive Cabometyx (n = 330) administered orally at 60 mg daily or everolimus (n = 328) administered orally at 10 mg daily. The majority of the patients were male (75%), with a median age of 62 years. Sixty-nine percent (69%) received only one prior anti-angiogenic therapy. Patient distribution by MSKCC risk groups was 46% favorable (0 risk factors), 42% intermediate (1 risk factor), and 13% poor (2 or 3 risk factors). Fifty-four percent (54%) of patients had 3 or more organs with metastatic disease, including lung (63%), lymph nodes (62%), liver (29%), and bone (22%).

The main efficacy outcome measure was progression-free survival (PFS) assessed by a blinded independent radiology review committee among the first 375 subjects randomized. Other efficacy endpoints were objective response rate (ORR) and overall survival (OS) in the Intent-to- Treat (ITT) population. Tumor assessments were conducted every 8 weeks for the first 12 months, then every 12 weeks thereafter. Patients received treatment until disease progression or experiencing unacceptable toxicity. Patients on both arms who had disease progression could continue treatment at the discretion of the investigator.

Statistically significant improvements in PFS, OS, and ORR were demonstrated for Cabometyx compared to everolimus.

How Supplied and Storage

Cabometyxtablets are supplied as follows:

- 60-mg tablets are yellow film-coated, oval shaped with no score, debossed with "XL" on one side and "60" on the other side of the tablet; available in bottles of 30 tablets.
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Store Cabometyx at 20C°–25°C (68°F–77°F); excursions are permitted from 15°C–30°C (59°F–86°F).

Motivating the Unmotivated Client *continued from page 12*

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Updated Guidance from the CDC on Zika Virus *continued from page 21*

Registry to monitor pregnancy and infant outcomes to learn more about the timing, absolute risk, and spectrum of outcomes associated with Zika virus infection during pregnancy to help inform clinical guidance and direct public health action.

Registry is a supplemental surveillance effort coordinated by the CDC and is dependent on the voluntary collaborations of clinicians and state tribal, local, and territorial health departments. The registry will include pregnant women that have laboratory evidence of Zika virus infection and exposed infants born to these women. If infants with previously unrecognized congenital Zika virus infection are identified their mothers will be included in the registry retroactively. It is worth noting that the Zika Pregnancy Registry inclusion criteria are broader than the current counsel of states and territorial epidemiologist's interim case definition. The registry includes pregnant women with positive or inconclusive Zika test results regardless of whether symptoms are present.

It also includes all children born to these women, not only those with identified congenital infection. You can support the registry by spreading the word about its importance and working with your health department to report cases and collect clinical and follow-up information.

If you'd like more information about the US Zika Pregnancy Registry please feel free to call the Zika Pregnancy Hotline or email us at zikapregnancy@cdc.gov. CE II

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Hospital Case Management: Patient-Centered, Team-Based *continued from page 5*

of entry." Professional case managers work with clinicians, other staff, and patients to ensure that the individual is at "the right place at the right time, all the time."[1]

Looking ahead, changes in demographics, the regulatory environment, and a focus on team-based patient-centered care drive the need for case management services. Board-certified case managers will play a crucial role. These case management professionals understand better than anyone the complexities of the health care continuum, and they know how to integrate all members of the care team. Board-certification demonstrates their competence and also attests to their peer-recognized capabilities in the team-based health care environment—in the hospital and across the full health care continuum. CM

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LITSCAN FOR CASE MANAGERS

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710 cases of colorectal cancer (478 for colon, 152 for rectum, and 80 unknown site) developed. Significantly increased risks associated with frontal-only baldness and frontal-plus-mild-vertex baldness relative to no baldness were observed for colon cancer with respective HR being 1.29 (95% CI, 1.03-1.62) and 1.31 (95% CI, 1.01-1.70). Over the 19-year study period, 3526 cases of colorectal adenoma were detected. Evidence for an increased risk of colorectal adenoma relative to no baldness was significant with frontal-only baldness (OR, 1.16; 95% CI, 1.06-1.26) and borderline insignificant with frontal-plus-severe-vertex baldness (OR, 1.14; 95% CI, 0.98-1.33). CONCLUSIONS: Subtypes of male pattern baldness at age 45 years were positively associated with colorectal neoplasia. Future studies are warranted to confirm our results and to determine the predictive value of male pattern baldness to identify those at high risk for colorectal neoplasia.

PLoS One. 2016 May 19;11(5):e0155608. doi: 10.1371/journal.pone.0155608. eCollection 2016.

The evaluation of more lymph nodes in colon cancer is associated with improved survival in patients of all ages.

Aan de Stegge WB, van Leeuwen BL, Elferink MA, de Bock GH. BACKGROUND: Improvement in survival of patients with colon cancer is reduced in elderly patients compared to younger patients. The aim of this study was to investigate whether the removal of ≥ 12 lymph nodes can explain differences in survival rates between elderly and younger patients diagnosed with colon cancer. METHODS: In a population-based cohort study, all patients (N = 41,074) diagnosed with colon cancer stage I to III from 2003 through 2010 from the Netherlands Cancer Registry were included. Age groups were defined as < 66, 66-75 and > 75 years of age. Main outcome measures were overall and relative survival, the latter as a proxy for disease specific survival. RESULTS: Over an eight years' time period there was a 41.2% increase in patients with ≥ 12 lymph nodes removed, whereas the percentage of patients with the presence of lymph node metastases remained stable (35.7% to 37.5%). After adjustment for patient and tumour characteristics and adjuvant chemotherapy, it was found that for patients in which ≥ 12 lymph nodes were removed compared to patients with < 12 lymph nodes removed, there was a statistically significant higher overall survival (< 66: HR: 0.858 (95% CI, 0.789-0.933); 66-75: HR: 0.763 (95% CI, 0.714-0.814); > 75: HR: 0.734 (95% CI, 0.700-0.771)) and relative survival (< 66: RER: 0.783 (95% CI, 0.708-0.865); 66-75: RER: 0.672 (95% CI, 0.611-0.739); > 75: RER: 0.621 (95% CI, 0.567-0.681)) in all three age groups. CONCLUSIONS: The removal of ≥ 12 lymph nodes is associated with an improvement in both overall and relative survival in all patients. This association was stronger in the elderly patient. The biology of this association needs further clarification.

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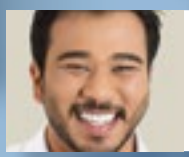

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