available tools, anticipated users, description/when to use, and location on share drives. Its purpose is to provide easy access to all of the departmental development resources.

Promotion of Tools and Programs
The Development Newsletter is distributed quarterly and shows how the development program and its tools can “facilitate growth and careers.” It provides links to resources; introduces new development opportunities, tools, and programs as they become available; offers recommended trainings and advice for how to fit professional development into “busy work schedules”; and announces new hires, promotions, and group and individual achievements. The Development Newsletter is helpful in keeping everyone apprised of new information while also building team morale.

Metrics
The medical writing management team gathers metrics to measure the success of the programs and find areas for improvement. For example, management measures participation in the writer mentoring program by gathering the number of mentor/mentee pairs, the types of projects, and the time spent on activities. They have also been gathering feedback from surveys completed by mentors and mentees, which are submitted at the end of the mentoring relationship.

The company started this initiative 3 years ago, and Yih stated that some aspects of the program are very popular and that others are gaining traction.

Lessons Learned
1. Ensure senior management buy-in on employee development plans. Time and effort need to be invested and supported to implement long-term development plans.
2. Work closely with your HR representative to ensure your department plans align with company policies and plans.
3. Think big picture and long term; consider long-term goals planned for your team and how your development plan will support these goals.
4. When drafting guides, programs, or tools, circulate for global review so they are applicable across a global team.
5. Pilot projects within a region or small groups to see what works and what needs adjustment; feedback via focus groups is useful.

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ZIKA—THE BITE HEARD ROUND THE WORLD

Speakers
Larry Lynam
Principal, The Lynam Group, LLC, Coral Springs, FL
R Michelle Sauer, PhD, ELS, CRA
Director of Office of Sponsored Programs, Prairie View A&M University, Prairie View, TX

By Rebecca Mueller, PA-C, MSc
This open session sought to update professionals in the medical writing industry on the history, science, and current state of the public health situation surrounding the Zika virus and the mosquito vector, Aedes aegypti.

The Virus
Mosquitoes, the deadliest animals in the world, are linked to 475,000 human deaths annually. Both Florida and Texas have had hot spot zones that were monitored by the Centers for Disease Control and Prevention (CDC), though most recently, Texas has been removed as a hot spot. Texas and Florida have over 80 species of mosquitos; however, only 1 has been confirmed as a transmitter of the Zika virus—A. aegypti.

The Zika virus is part of a unique group of viruses known as the Flaviviridae. Viruses of the flavivirus family are most often transmitted through vectors, most commonly mosquitos and ticks. Some members of the flavivirus family, including Zika, have been associated with sexual transmission and blood-borne transmission. Cross-reactivity has been a problem in diagnosing the specific flavivirus, but the cross-reactivity of the antibodies has not proven to be protective between species of virus. Zika appears to be unique in the flavivirus family in that it has proven both competent at crossing the placental barrier during pregnancy and capable of causing congenital abnormalities.

The Zika virus was first identified in 1947 in primates of Uganda. The vector for these primates was a mosquito in the Ugandan forest that was active at night and fed off primates, not humans. The virus has now jumped vectors to a human-biting mosquito, Aedes aegypti, that feeds during dawn and dusk. The first serious Zika outbreak was in Yap, a Micronesian island, in 2007. The virus has continued to spread east throughout the years, complicating the 2014 Olympics in Brazil. Climate change has allowed A. aegypti to live farther north, aiding the spread of the virus farther into the United States, giving rise to the title of this talk: “Zika—The Bite Heard Round the World.”

Researchers from the Chinese Academy of Science in Beijing have linked a single gene mutation, S139N, to the virus’ ability to cause microcephaly in utero and Guillain-Barré syndrome. The switch of serine to glutamine at the 139th posi-
tion in the Zika genome occurred in 2013 and makes the virus deadlier to neuron precursor cells, disrupting fetal development and causing congenital Zika syndrome. This same mutation has also been linked to Guillain-Barré complications in adult Zika infections, particularly in the elderly.

The Vector: *Aedes Aegypti*

There are roughly 80 species of mosquitoes throughout Florida, only one of which has been a confirmed transmitter of the Zika virus—*A. aegypti*. The mosquito has distinctive black and white markings and can transmit Zika, dengue fever, and chikungunya individually or can co-infect a victim with multiple viruses. There have been suspicions that a concurrent infection of Zika with another vector-born virus (dengue fever or chikungunya) could result in a worse outcome; however, recent studies have not demonstrated a link.

The Victims: Health Presentation, Diagnosis, and Congenital Zika Syndrome

Approximately 1 in 5 people infected with the Zika virus will develop symptoms, which are generally mild and last 2 to 7 days. The disease presentation includes common symptoms that include headache, fever, conjunctivitis, joint pain, diffuse itchy and blanching rash, and muscle pain (see Box). As these are very common and general symptoms of a myriad of diagnoses, it is difficult to determine a specific diagnosis without specific testing. There are no standard-of-care guidelines for practitioners at this time, further presenting a challenge when tracking the virus. As of October 2017, there have been 254 confirmed symptomatic Zika cases in the United States, 3 of which were transmitted through sexual contact and the remainder presumed through a mosquito vector while traveling in an endemic area; 554 cases have been confirmed in US territories.

<table>
<thead>
<tr>
<th>Zika Symptoms</th>
<th>Congenital Zika Syndrome</th>
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<tbody>
<tr>
<td>Headache</td>
<td>Microcephaly</td>
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<tr>
<td>Fever</td>
<td>Encephalitis</td>
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<tr>
<td>Conjunctivitis</td>
<td>Vision/hearing loss</td>
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<td>Joint pain</td>
<td>Arthrogryposis</td>
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<tr>
<td>Itchy rash</td>
<td>Fetal demise</td>
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<tr>
<td>Muscle pain</td>
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<tr>
<td>Guillain-Barré syndrome</td>
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The risk for developing congenital Zika syndrome is approximately 4%; this is higher than the occurrence of congenital abnormalities in the United States, which is only 3%. This is an alarming number considering the relatively high rate of occurrence and the high cost associated with its treatment (estimated $4,000,000 per child). Congenital Zika Syndrome includes microcephaly, encephalitis, vision and hearing loss, arthrogryposis, fetal demise, and possible long-term behavioral changes.

Prevention

Currently, prevention is the best approach to tackling the Zika problem in the United States, as the understanding of the disease process and treatment is still in its infancy.

In order to prevent sexual transmission, condoms, among other deterrents, are recommended for 3 weeks. There is controversy surrounding this recommendation; the challenge of recommendations to prevent sexual transmission is that it is unknown how long the virus is transmittable. Although the virus has been detected up to a year post infection, transmission risk at this time is uncertain.

There are some easy changes people can make to protect themselves from mosquitoes, including insect repellent and eliminating standing water around or near their home.

In Florida, recent measures to control the *A. aegypti* mosquitoes include the use of a biological pesticide containing the organism *Bacillus thuringiensis* (BT) to kill the larvae and a chemical pesticide, Naled, to kill the adult mosquito. The use of both of these products has raised environmental protests in the public.

There are 2 other very promising methods of decreasing the transmission of Zika through *A. aegypti*: (1) male mosquitoes that are infected with *Wolbachia* bacteria, which can only infect insects, and (2) Oxitec genetically modified male mosquitoes, both of which have been approved for release. *Wolbachia* is a Gram-negative parasitic bacteria, and the World Mosquito Program has found the when *A. aegypti* is infected with *Wolbachia*, it reduces the transmission of the Zika virus to other people bitten by the mosquito. When male *A. aegypti* infected with *Wolbachia* breed with infected females, the eggs remain unhatched. This somewhat lowers the *A. aegypti* mosquito population. However, *Wolbachia* will become established in the population, and when female mosquitoes have *Wolbachia* infections, their offspring will be born with the *Wolbachia* infection. Although females with *Wolbachia* will live, they will be unable to transmit viruses. So as a population of mosquitoes becomes more infected with Wolbachia, the transmission of dengue and Zika will be reduced.

Oxitec GMO mosquitoes are another line of defense in which sterile male mosquitoes are released, thereby contributing to a population decrease. When males are so altered, they breed and transmit the defective gene to their offspring. The defective gene means that the offspring larvae will not develop into adults. This methodology has been approved and some male mosquitoes have already been released.
The benefit to both of the Wolbachia and Oxitec methods is that they will decrease the A. aegypti mosquito population and, subsequently, the Zika virus prevalence without negatively affecting other ecosystems, though we should keep in mind that these methods involve the release of male mosquitoes and that only female mosquitoes are the ones that bite.

In Closing
Zika is a virus with potentially dire consequences to infected individuals and their babies while also potentiating high medical costs. Stay up to date on the numbers infected and the research by following the CDC.

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MEDICAL WRITER’S GUIDE TO CLINICALTRIALS. GOV RESULT POSTINGS IN THE EVOLVING REGULATORY LANDSCAPE

Speaker
Roshawn Watson, PharmD, PhD
Associate Director, Clinical Scientist, Vertex Pharmaceuticals Incorporated, Boston, MA

ClinicalTrials.gov is both a clinical trial registry and results database that is run by the United States (US) National Library of Medicine at the National Institutes of Health (NIH). Both publicly and privately funded clinical studies conducted in all 50 US states and around the world are included. Registration occurs at study initiation, and the registry/database summarizes information from the study protocol (eg, brief title, study design, study type, study phase, primary outcome measure information, and eligibility criteria) and recruitment information (eg, enrollment start and completion dates, eligibility location, and overall recruitment status). Study results are submitted either after the primary completion date (if partial results are submitted) or after study completion.

There are several reasons to post to ClinicalTrials.gov. Posting to ClinicalTrials.gov is a statutory mandate for sponsors and others (ie, principal investigators) responsible for certain clinical trials of US Food and Drug Administration–regulated drug, biologic, and device products. Posting to ClinicalTrials.gov also increases public awareness for a study and may assist with recruitment. Posting additionally provides an avenue to share the study results with both participants and the broader scientific community. The posting requirement is independent of decisions related to manuscript publishing. In fact, as of 2005, journals adhering to the International Committee of Medical Journal Editors guidance will not accept a manuscript of an applicable clinical study for publication unless the study was registered in a study repository such as ClinicalTrials.gov. Additional consequences for not posting to ClinicalTrials.gov include the following: responsible parties, including the grantee institution, could be held accountable for noncompliance; grant funding from Health and Human Services agencies could be withheld; substantial civil monetary penalties could be levied; and criminal proceedings could be launched.

On January 18, 2017, the Final Rule for the US Food and Drug Administration Amendments Act 801 became effective, providing much-needed clarity about which studies were required to post to ClinicalTrials.gov. It also expanded the transparency requirements of posting beyond the basic statutory requirements and necessitated that the National Institutes of Health post submitted records within specified time frames.

Medical writers are uniquely situated to facilitate ClinicalTrials.gov results postings. First, entering results is analogous to manuscript writing. Additionally, the data provider must comprehend the study design; appreciate the data analysis, nuances, and limitations; and provide thoughtful interpretation. In addition, these postings often require involvement of other team members, with whom medical writers often have already worked during the authoring of the clinical study report. Last, medical writers tend to be very detail oriented, which is required to author or oversee these postings.

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INTERMEDIATE HEALTH ECONOMICS AND OUTCOMES RESEARCH & REAL-WORLD EVIDENCE: ELEMENTS, CONCEPTS, AND WRITING CONSTRUCTS

Speakers
Patti Peeples, RPh, PhD
Founder, CEO, and Principal Researcher of HealthEconomics.com, Ponte Vedra Beach, FL
Tom Drake, MA
Founder and Director of Global Outcomes Group, Reston, VA

By Denise Galipeau, MSc

Rising health care costs are driving many organizations toward value-based decision-making methods to decide which health care interventions are worth paying for and for how much. The aims of this open session were to explain how payers determine value, what types of tools or studies are available to characterize value, and what types of medical writing opportunities there are in this fast-growing area of health economics and outcomes research (HEOR) and real-world evidence (RWE).