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November 2014

BioMarketing Insight Newsletter

Creating Markets and Marketing Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I covered "Things to Consider When You're Planning to Outsource Work to a Consulting Firm." If you missed last month's article, click here to read it. Since news headlines continue to feature the Ebola outbreak, I will cover what you need to know about Ebola regarding your health and protection.

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on December 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
BioMarketing Insight

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Previous Newsletters

Regulatory Challenges - Rapid Response

I'm pleased to announce that my article on regulatory challenges entitled "Rapid Response" has been published in the October 2014 issue in European Biopharmaceutical Review. To read an electronic version, please click here, my article is on page 10. To learn more about EBR, click here.

ebr
European Biopharmaceutical Review

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Save the Date: Medical Informatics World Conference - May 4-5, 2015

Third Annual
Medical Informatics World Conference 2015

May 4-5, 2015
Renaissance Waterfront Hotel | Boston, MA

Transforming Care Delivery Models with IT Innovation
Presented by Cambridge Healthtech Institute and Clinical Informatics News

I will be presenting at the Medical Informatics World Conference in May. My presentation will be on "Designing Your Wearable Technology with Mobile Apps: What is Needed for Successful Product Adoption and Impact". More details to follow. For more information on the conference, click here.

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The Facts About Ebola

News of the Ebola epidemic has been talked about almost 24/7, yet many people are misinformed about the basic facts, despite that there is reliable information available on line. Both the Centers for Disease Control (CDC) and the World Health Organization (WHO) websites have posted comprehensive information and timely updates concerning Ebola. Unfortunately, misinformation and incomplete information have created much hysteria and paranoia and caused some people to over - react. So here are the facts.

Definition of the Ebola Virus

According to the CDC Ebola, or Ebola

hemorrhagic fever, is a rare and deadly disease caused by infection with one of five Ebola virus strains in the virus family Filoviridae, genus Ebolavirus.Ebola can cause disease in humans and nonhuman primates (monkeys, gorillas, and chimpanzees).

Ebola Virus
Source: Center for Disease Control.

Four of the five identified Ebola virus species are known to cause disease in humans: Ebola virus (Zaire ebolavirus); Sudan virus (Sudan ebolavirus); Taï Forest virus (Taï Forest ebolavirus, formerly Côte d'Ivoire ebolavirus); and Bundibugyo virus (Bundibugyo ebolavirus). The fifth, Reston virus (Reston ebolavirus), has caused disease in nonhuman primates, but not in humans.

Ebola is classified under Biohazard Level 4 (BL4) - Viruses and bacteria that cause severe to fatal disease in humans, and for which vaccines or other treatments are not available. So precaution is critical when treating Ebola patients and wearing a full biohazard suit is required. More important, correctly removing the biohazard suit is required, in order to avoid contact with any fluids associated with the virus.

According to the WHO, the average Ebola Virus Disease case fatality rate for the current outbreak has been around 50% . Case fatality rates have varied from 25% to 90% in past outbreaks.

Current Status of Ebola

Ebola was first discovered in 1976 near the Ebola River in what is now called the Democratic Republic of the Congo. Since then, outbreaks have appeared sporadically in Africa. The reason those outbreaks were not heavily reported in the news is because they occurred in remote and sparsely populated areas, where outbreaks could not spread as easily as they did recently in a densely populated Sierra Leone. Moreover 40 years ago, international travel between the various African countries was comparatively infrequent.

According to WHO, "The current outbreak in West Africa, (first cases notified in March 2014), is the largest and most complex Ebola outbreak since the Ebola virus was first discovered in 1976. There have been more cases and deaths in this outbreak than all others combined. It has also spread between countries starting in Guinea then spreading across land borders to Sierra Leone and Liberia, by air (1 traveler only) to Nigeria, and by land (1 traveler) to Senegal."

"The most severely affected countries, Guinea, Sierra Leone and Liberia, have very weak health systems, lacking human and infrastructural resources, having only recently emerged from long periods of conflict and instability. On August 8, the WHO Director-General declared this outbreak a Public Health Emergency of International Concern."

The CDC has stated that the outbreaks in Sierra Leone, Liberia and Guinea have affected the entire region. Cases in other countries have been traced back to travelers or healthcare workers from these countries. The CDC has stated that travelers who go to these areas are not at risk of getting Ebola unless they are in direct contract with an Ebola patient.

Here are the latest numbers that was reported by Boston.com:

Number of cases worldwide in the current outbreak: 13,042 (as of Nov. 5)

Number of deaths: 4,818 (as of Nov. 5)

Countries currently affected by Ebola: Mali, Guinea, Liberia, Sierra Leone, Spain, and the United

States of America.

Countries where the outbreak has ended: Nigeria (Oct. 19), Senegal (Oct. 17)

And here's your daily reminder not to panic:

The likelihood of contracting Ebola in Massachusetts remains very low, according to the state's public health officials. You have to be in direct contact with an infected person's bodily fluids while they are contagious (displaying symptoms of Ebola). Even if someone has been exposed, symptoms may appear in as little as two days, and in as many as 21 days, after exposure. According to the CDC the average is 8 to 10 days.

How is Ebola Spread?

According to the CDC, Ebola is not air borne and cannot be caught through coughing or sneezing. One has to have direct contact with blood or body fluids (diarrhea, sweat, vomit, urine, semen, and breast milk); exposure to large droplets and sprays from an infected patient that penetrate through your mouth, nose, eyes or a break in your skin; or through sexual contact. It can also be transmitted by objects (like needles and syringes) that have been contaminated with the virus and from infected fruit bats or primates (apes and monkeys).

"Ebola is not spread through the air or by water, or in general, by food. However in Africa, Ebola may be spread as a result of handling bushmeat (wild animals hunted for food) and contact with infected bats. There is no evidence that mosquitos or other insects can transmit Ebola virus. Only a few species of mammals (for example, humans, bats, monkeys, and apes) have shown the ability to become infected with and spread Ebola virus."

The people at highest risk are healthcare workers caring for Ebola patients, people who handle burial services for Ebola patients and the patient's family.

Ebola can be transmitted when the person with Ebola is sick after symptoms begin. Symptoms may appear anywhere from 2 to 21 days after exposure, but the average is 8 to 10 days. The signs and symptoms of Ebola are the following:

- Fever (greater than 38.6°C or 101.5°F)
- Severe headache
- Muscle pain
- Weakness
- Fatigue
- Diarrhea
- Vomiting
- Abdominal (stomach) pain
- Unexplained hemorrhage (bleeding or bruising)

The controversy between the CDC guidelines and the governors of states that have received healthcare workers returning from Ebola-affected areas has been highlighted in the news. CDC guidelines recommend that state and local health authorities actively monitor these people daily "for the presence of symptoms and fever" and if a person has signs and symptoms of Ebola, the CDC then recommends that patients be quarantined.

However, the governors of New York, New Jersey and Maine want those who've come back from West Africa quarantined for 21 days. This drew criticism from the White House "as unnecessary and a threat to the fight against Ebola in Africa." In Maine, the case of a nurse also made the news when she refused to be quarantined in her house for 21 days, since she is symptom -free and tested negative for Ebola when she was quarantined in New Jersey.

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What is Being Done

Prevention

Healthcare workers caring for Ebola patients should wear appropriate Personal Protective Equipment (PPE) that includes masks, protective eyewear, protective apparel, and gloves. No skin should be exposed, to prevent all possible contact with blood and bodily fluids when wearing and removing PPE. Proper infection control and sterilization measures should be followed.

Those traveling to western Africa have recommendations from the CDC, which can also apply to those who interacting with someone who has recently returned from the area.

Practice careful hygiene. For example, wash your hands with soap and water or an alcohol-based hand sanitizer and avoid contact with blood and body fluids.

Do not handle items that may have come in contact with an infected person's blood or body fluids (such as clothes, bedding, needles, and medical equipment).

For more information, click here.

There is currently no FDA - approved Ebola vaccine available, but there are a number of pharma/biotech companies working on a vaccine or therapy.

The following companies are working on a vaccine.

1) GlaxoSmithKline is developing an Ebola vaccine in conjunction with the National Institute of Health's National Institute of Allergy and Infectious Disease, or NIAID unit. "Development of the vaccine candidate is progressing at an unprecedented rate, with first phase 1 safety trials with the vaccine candidate underway in the USA, UK and Mali, and further trials due to start in the coming weeks.

Initial data from the phase 1 trials are expected by the end of the year and if successful, the next phases of the clinical trial programme will begin in early 2015 which will involve the vaccination of thousands of frontline healthcare workers in the three affected countries - Sierra Leone, Guinea and Liberia. If the vaccine candidate is able to protect these healthcare workers as we hope it will, it could significantly contribute to efforts to bring this epidemic under control."

2) NewLink Genetics Corp. is working on a vaccine program with the Public Health Agency of Canada. NewLink got FDA approval to conduct Phase 1 studies of the drug in September 2014 in the U.S.

3) Inovio Pharmaceuticals announced it will advance its DNA vaccine for Ebola into a phase I clinical trial in a collaboration with GeneOne Life Science Inc. (KSE: 011000), a DNA vaccine manufacturer in which Inovio holds a minority interest. It plans to start human trials of a DNA-based vaccine in early 2015. "In published preclinical testing of its Ebola vaccine, Inovio observed that 100% of vaccinated guinea pigs and mice were protected from death after being exposed to the Ebola virus. Unlike the non-vaccinated animals, vaccinated animals were also protected from weight loss, a measure of morbidity. Researchers found significant increases in neutralizing antibody titers and strong and broad levels of vaccine-induced T-cells, including "killer" T-cells, suggesting that this product could provide both preventive and treatment benefits."

4) Johnson & Johnson (J&J) announced it will fast-track the development of a promising new combination vaccine regimen against Ebola. "The accelerated vaccine program features a prime-boost regimen, in which one vector is used to prime and the other to boost the immune response. It consists of two vaccine components that are based on AdVac® technology from Crucell N.V. (Janssen pharmaceutical companies part of J&J based in the Netherlands) and the MVA-BN® technology from Bavarian Nordic, (a biotech company, based in Denmark). The program has received direct funding and is also utilizing vaccine preclinical services from the National Institute of Allergy

and Infectious Diseases (NIAID), part of National Institutes of Health (NIH). Crucell will bring this development program forward, in close collaboration with Bavarian Nordic and the NIAID, to allow for initiation of a clinical trial of this combined regimen in humans in early 2015."

5) Profectus BioSciences recently got two government contracts worth $17m to speed up work on its vaccine. Profectus is developing vaccines for pre- and post-exposure protection against the hemorrhagic disease caused by Ebola and Marburg viruses.

Program Status:
"Multiple studies conducted by a team from the NIAID, CDC, FDA, and DoD have shown that a single dose of the Profectus VesiculoVax™ vectored Ebola and Marburg vaccines provides 100% protection of non-human primates against challenge with 1,000 times the lethal dose of both Ebola and Marburg viruses. A trivalent VesiculoVax™ vectored vaccine to protect against all filoviruses has entered non-human primate testing with financial support from the NIAID."

The following companies are working on treatment.

1) BioCryst Pharmaceuticals Inc. in collaboration with the WHO, BioCryst has furnished a one-page executive summary and a slide summary regarding BioCryst's broad spectrum antiviral BCX4430 as a drug candidate for the treatment of Ebola Virus Disease and other hemorrhagic fever virus diseases. These documents summarize: nonclinical disease model and safety research results; anticipated timelines for filing an Investigational New Drug (IND) Application with the U.S. Food and Drug Administration to commence human safely studies of BCX4430; and projections for BCX4430 drug supply. There are those who think it maybe a second-line treatment where the if the first drug fails you can use BioCryst's drug.

2) Tekmira Pharmaceuticals Corp. "In May 2014, Tekmira successfully completed the single ascending dose portion of the TKM-Ebola Phase I Clinical Trial in healthy human volunteers. The FDA granted expanded access use of TKM-Ebola under Tekmira's Investigational New Drug application (IND) and Health Canada established a similar framework. Using emergency protocols, TKM-Ebola has been administered to a small number of patients." The Company is reporting it has commenced limited GMP manufacture of a new therapeutic specifically targeting the Ebola - Guinea variant, which is the viral variant responsible for the Ebola epidemic currently prevalent in West Africa. Supply of this new product will be available in early December, 2014, for potential use by various collaborators."

3) Sarepta Therapeutics is working on a Marburg (AVI-7288) and Ebola virus (AVI-7537) therapy. Both cause hemorrhagic fever and are a severe and often fatal disease endemic to Africa. AVI-7288 is designed to bind to viral RNA and inhibit the synthesis of the nucleocapsid protein (NP). NP supports the replication of the viral genetic material in an infected cell, and is also involved in the assembly of mature viruses. Inhibition of NP is intended to interrupt the viral lifecycle and stop or slow the spread of the disease to other cells in the body. Both are in Phase 1 according to the company website.

4)) Mapp Biopharmaceutical: Mapp's therapy for Ebola, known as ZMapp, MB-003 is comprised of three monoclonal antibodies. " According to lead investigator Gene Olinger, Ph.D., a virologist at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), this consortium of investigators has taken very distinct technologies and combined them to develop a cutting-edge medical countermeasure against a lethal viral disease.

"It is rare that an antiviral compound prevents Ebola virus infection with limited to no morbidity in treated animals at any point of treatment following infection by this lethal virus," said Olinger. "Until recently, attempts to utilize antibodies to provide protection against Ebola virus have been met with failure. The level of protection against disease that we saw with MB-003 was impressive," according to the company's website.

5) Chimerix received fast-track federal approval to start testing brincidofovir, an experimental antiviral drug on people infected with the Ebola virus disease. "The Chimerix drug was previously available to individual Ebola patients whose doctors submitted emergency requests to the U.S. Food and Drug Administration. To date, the drug has been released under the emergency protocol to only two known patients, including Thomas Eric Duncan, the Liberian national who died of Ebola last week.

6) ExThera Medical is developing a whole blood sorption hemoperfusion device that should quickly

reduce the circulating concentration of Ebola virus in blood during a short dialysis - like extracorporeal treatment.

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Closing Thoughts

The spreading of deadly diseases continues to be the biggest downside of globalization. Returning Crusaders kicked off the European plague epidemics of the Middle Ages. Colonizers brought smallpox to the Americas in the 1500s and severely decimated the population of two continents. The 21st century has brought Ebola to the world.

The US is on a sharp learning curve as officials grapple with how to prevent Ebola from entering the country and spreading within its borders. Currently, the US is restricting people who are traveling from affected areas to land at five designated airports (New York/Kennedy, Chicago/ O'Hare, Newark, Atlanta and Washington/Dulles), where trained personnel will monitor anyone who could be affected by taking their temperature, quarantining and testing for Ebola if there is evidence of fever or any other symptoms. Only those who are symptomatic with the Ebola virus are contagious.

Healthcare professionals who treat Ebola patients know to wear the complete personal protective equipment and to incorporate a buddy system, where each person checks the other to make sure that no skin is exposed.

"There are more than 30 steps involved in putting on and taking off the protective equipment. The most difficult part is taking the equipment off without contaminating yourself," said Dr. Lauge Sokol-Hessner, a hospitalist at Beth Israel Deaconess Medical Center and a physicians on a short list of those volunteering to care for Ebola patients in Boston.

The US is taking precautions to prevent the entrance and spread of Ebola in the US, but people who are either uninformed or misinformed tend to blow things out of proportion and create hysteria and paranoia. The example of the nurse in Maine who was quarantined for 21 days despite the fact that she was symptom - free and tested negative for Ebola stands as evidence.

I agree with the Obama administration that these healthcare workers should be treated with respect because they are trying to contain the outbreak in West Africa before it becomes more wide spread. They are healthcare professionals who study Ebola and are knowledgeable as to what needs to be done and the precautions to take. These healthcare professionals are volunteering at their own risk to help.

In an effort to contain any panic, Massachusetts health officials stated that "while the risk of Ebola remains very low in the state, six hospitals are prepared to handle one patient each, meaning the state could treat six patients at any given time." The announcement and plan eliminates confusion as to which hospitals are ready to care for an Ebola patient if there is a confirmed case in Massachusetts. These hospitals are not expecting to take patients who reside outside of MA because each state needs to have its own plan and protocols.

The six hospitals collaborating to provide care are Bay State Medical Center in Springfield and five Boston facilities: Boston Medical Center, Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Tufts New England Medical Center and Massachusetts General Hospital. Boston Children's Hospital and UMass Memorial Medical Center in Worcester are also expected to join the list.

It is apparent that despite the abundance of good information available about Ebola, neither the federal government nor the CDC have done a good job at making the public aware of what Ebola is and quelling rumors and misperceptions. Even though the CDC has excellent information posted on its

website, a public service campaign to guide and reassure the citizens would be so useful.

As of Monday, November 10, 2014, the Boston.com online news source reported that "There are no more Ebola patients in the United States." *The New York Times* reported that Dr. Craig Spencer, a New York City-based doctor with Doctors Without Borders and the first person to test positive for Ebola after treating patients in Sierra Leone, will be released from Bellevue Hospital. Dr. Spencer was diagnosed with Ebola on Oct. 23 at Bellevue after 10 days of self-monitoring.

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Developing a Product ?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product, contact me for an appointment.

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New Technology - Potential Diagnostic and Therapeutic for Alzheimer's Disease

There are two new technologies for Alzheimer's. One is a potential diagnostic to detect Alzheimer's years in advance and the other is a potential therapy for treatment.

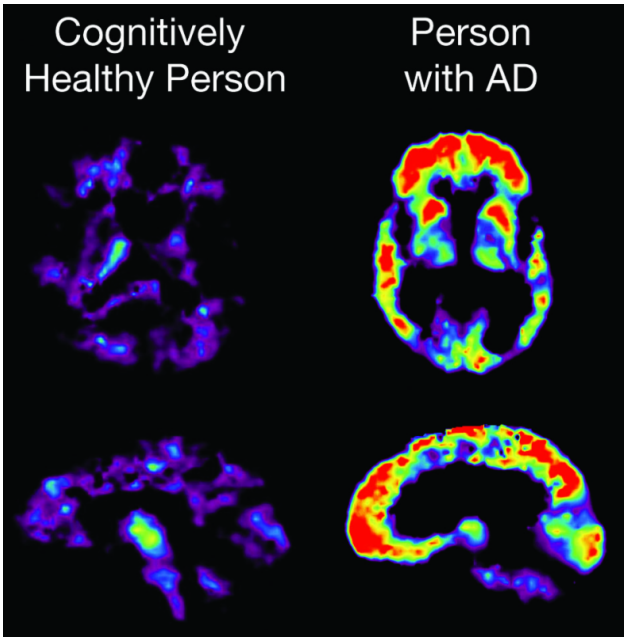
Researchers at Melbourne University have developed a blood test that has the potential to detect Alzheimer's disease five years before patients in the study were officially diagnosed according to Dr. Lesley Cheng, from the University's biochemistry and molecular biology department. The researchers are testing for microRNA genetic signatures. They tested 100 elderly people and one in five people tested positive for this genetic signature. Brain imaging was conducted and these patients showed signs of brain degeneration. The result were published in the October issue of Molecular Psychiatry.

To read the full article in *The Age* online, click here.

Tufts University professor Philip Haydon is developing a "small molecule drug to target a specific receptor on microglia, one of the types of glial cells that that serve at least two purposes. They are the "glue" in the brain that holds neurons in place and connects them to one another as they fire the electrical and chemical signals responsible for our actions and feelings."

Microglia also plays a part of the brain's specialized immune system. When inflammation occurs in the brain, such as with Alzheimer's, microglia can't clear the amyloid-beta plaques.

"Haydon believes his drug might not only stimulate the microglia's natural plaque clearing ability, but also cool off the inflammation that might be getting in their way." He believes this is what sets his company GliaCure apart from what others have tried. Their drug GC021109, began their first clinical trial.



PET Scans of healthy person and person with Alzheimer's.
Image courtesy of the National Institute on Aging/National Institutes of Health

To read the full article in *Xconomy*, click here.

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About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

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