

# Los Angeles County Department of Public Health PUBLIC HEALTH QUARTERLY CONNECT

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# **Important Updates from Public Health**

# Measles Clinical Guidance: Identification of Suspect Measles Cases

Los Angeles County Department of Public Health (LAC DPH) has recently confirmed five cases of measles in Los Angeles County. All of the cases were adults, the majority were unvaccinated, and two had recently travelled internationally. LAC DPH is investigating multiple exposures in adults and children related to these cases. It is important to consider measles in patients who present with measles symptomatology and who have traveled outside North America despite prior measles-mumps-rubella (MMR) vaccine or exposure to measles disease. Note that a self-reported history of measles infection or immunization does not rule out a diagnosis of measles. Providers

are being asked to IMMEDIATELY institute respiratory and airborne precautions for all patients with a measles-like rash and fever. If hospitalization is required, notify the Emergency Department first and do not refer patients to ancillary services. Additionally, IMMEDIATELY report suspect cases to the LAC DPH Morbidity Central Reporting Unit by calling 888-397-3993. For after-hours, call 213-974-1234 and ask for the physician on call. For additional guidance with suspect cases, please visit:

http://publichealth.lacounty.gov/ip/providers\_resources.htm. Furthermore, LAC DPH recommends everyone who has not been immunized to receive two doses of the MMR vaccine and asks providers to advise patients on vaccination. For more vaccine information visit: https://www.cdc.gov/vaccines/vpd/measles/index.html. For the most current information, go to:

# **Hepatitis C Associated with Outpatient Clinic in LA**

LAC DPH has identified six cases of acute Hepatitis C infection among patients treated at the Westside Multispecialty Medical Group. Providers should call LAC DPH at 213-288-8787 (dedicated Hepatitis C investigation hotline) within 24 hours if they identify patients who received care at this clinic. Public Health is providing free testing for patients of the Westside Multispecialty Medical Group at the Hollywood-Wilshire Health Center (5205 Melrose Avenue, Los Angeles, CA 90038). Patients can schedule an appointment by calling the Hepatitis C investigation hotline above. Should the patient request testing at your site, please fax results (positive AND negative) to the LAC DPH-Acute Communicable Disease Control Program (ACDC) at 213-482-4856. View the LAC DPH alert at: <a href="http://publichealth.lacounty.gov/eprp/Health%20Alerts/HCV%20HAN%202.21.19%20Final.pdf">http://publichealth.lacounty.gov/eprp/Health%20Alerts/HCV%20HAN%202.21.19%20Final.pdf</a> or for more information on bloodborne pathogens, like Hepatitis C, go to: <a href="https://www.cdc.gov/niosh/topics/bbp/default.html">https://www.cdc.gov/niosh/topics/bbp/default.html</a>

# Ongoing Ebola Outbreak in the Democratic Republic of Congo

The California Department of Public Health (CDPH), in collaboration with the CDC, has been closely monitoring the Ebola Virus Disease (EVD) outbreak in the Democratic Republic of Congo (DRC). An outbreak of EVD was declared in the North Kivu Province of the DRC on August 1, 2018; as of April 22, 2019, there have been 1353 confirmed and probable EVD cases, and 880 confirmed and probable deaths. Vaccination and other disease control efforts have been hampered by armed conflict in the area, and the outbreak is ongoing. There have been no EVD cases associated with this outbreak detected outside the DRC, thus far. Healthcare and emergency medical services providers should identify suspect cases by routinely asking patients with acute and possibly infectious illness about recent travel. Healthcare providers (HCP) are encouraged to implement appropriate response procedures in all settings which include: Identifying the potential case based off of travel history and symptoms, immediate isolation of the patient, and inform the local health department. For additional guidance please visit: <a href="https://www.cdc.gov/vhf/ebola/clinicians/evd/clinicians.html">https://www.cdc.gov/vhf/ebola/clinicians/evd/clinicians.html</a>;

http://www.publichealth.lacounty.gov/acd/ebola.htm. For the latest health alert

visit: http://publichealth.lacounty.gov/eprp/Health%20Alerts/CDPHAdvisoryEbola021519.pdf; Additionally, for guidance for employers and HCP working in EVD outbreak areas refer to the LAC DPH ACDC recommendations:

http://www.publichealth.lacounty.gov/acd/docs/EbolaHCWGuide.pdf

# **Understanding Stem Cell Treatment**

## **Bloodstream Infections After Stem Cell Injections**

Stem cells have tremendous promise to help us understand and treat a range of diseases, injuries, and other health-related conditions if used as approved by the Food and Drug Administration (FDA). In 2018, a CDC investigation identified 12 bloodstream infections in patients from three different states who had received injections or infusions of non-FDA approved umbilical cord blood-derived stem cell products. The outbreak led to the voluntary recall of stem cell products used in the outbreak. Additionally, in late December 2018, LAC DPH identified two cases of *Enterobacter cloacae* bloodstream infections in individuals who had received stem cell injections. These outbreaks highlight the importance of practicing regulated stem cell treatment and educating patients. Here are key points to discuss with patients that are considering stem cell therapy.

# **9 Things to Know About Stem Cells**



## 1. Currently, very few stem cell treatments have been proven safe and effective

Beware of stem cell treatments offered without regulatory approval or outside the confines of a legitimate and registered clinical trial. The only FDA approved treatment is hematopoietic (or blood) stem cell transplantation to treat certain blood and immune system disorders or to rebuild the blood system after treatments for some kinds of cancer. These procedures are widely accepted as safe and effective by the medical community. All other applications of stem cells are yet to be proven and should be considered highly experimental.

#### 2. There is something to lose when you try unproven treatment

Unproven treatments present serious health, personal, and financial considerations for patients. Complications may create new short- and long-term health problems, and/or may make patient's condition or symptoms more difficult to manage. Receipt of one unproven or experimental treatment may make the patient ineligible for future clinical trials or treatment options and create unnecessary out-of-pocket expenses among other hardships.

#### 3. Different types of stem cells serve different purposes in the body

Be wary of offering treatments with stem cells originating from a part of the body unrelated to the disease or condition being treated. Scientists are exploring the different roles tissue-specific stem cells might play in healing, with the understanding that these stem cells have specific and limited capabilities.

#### 4. The same stem cell treatment is unlikely to work for different diseases or conditions

Exercise caution with clinics that offer the same cell treatment for a wide variety of conditions or diseases. Be wary of claims that stem cells will somehow just know where to go and what to do to treat a specific condition. If not properly directed, some stem cells may overgrow and cause tumors when injected into the patient.

#### 5. The science behind the disease should match the science behind the treatment

The more the patient is educated regarding the science behind their disease the more empowered they are to identify their treatment options. For instance, if the patient is diabetic, receiving a blood-forming stem cell treatment does not make sense, because the problem is in the pancreas rather than in the blood itself.

#### 6. Cells from the patient's own body are not automatically safe when used in treatment

The processes by which the cells of a patient's own body (autologous cells) were acquired, grown, and then reintroduced into the body carries risks. A few known risks of autologous stem cell treatments include: contamination with viruses, bacteria or other pathogens that could cause disease when reintroduced, interference with the cells' normal function, and the risk of placing the cells back where they do not belong.

#### 7. Patient testimonials and other marketing provided by clinics may be misleading

Most specialized doctors receive patient referrals, while clinics selling stem cell treatments tend to market directly to patients, often through persuasive language on the Internet, Facebook, and in newspaper advertisements. Clinics peddling unproven stem cell treatments frequently overstate the benefits of their offerings and use patient testimonials to support their claims. These testimonials can be intentionally or unintentionally misleading.

#### 8. An experimental treatment offered for sale is not the same as a clinical trial

Responsible clinical trials share several important features some of which include:

- Lab-based research on cells, tissues and animals, that indicates the treatment being tested is likely to be safe and effective
- Oversight by an independent medical ethics committee to protect participant's rights
- Conformity to regulatory requirements, including a listing in a recognized clinical trial registry
- Results are usually compared with a control group of patients who do not receive the experimental treatment
- The cost of the new treatment and monitoring is not covered by the participant
- A clinical trial is studied under an Investigational New Drug Application (IND), which is a clinical investigation plan submitted and allowed to proceed by the FDA

#### 9. The process by which science becomes medicine is designed to minimize harm and maximize effectiveness

There is a lengthy, multi-step process involved in responsibly translating science into safe and effective medical treatments. This process is often long, but it is designed to minimize patient harm and to maximize the likelihood of effectiveness.

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# Potential risks related to unproven stem cell treatments

- Injection site reaction
- Failure of the cells to work as expected
- Growth of tumors
- Infections
- Potential for contamination of the product
- The ability of cells to move from placement sites and multiply or change into inappropriate cell type

# **Support Safe Stem Cell Treatment**



Despite effort from the FDA to regulate stem cell treatment, some companies, clinics, and clinicians continue to use and market unapproved products. Some providers claim to treat diseases including orthopedic, neurologic, and rheumatologic conditions. Some clinics may advertise stem cell clinical trials without submitting an IND and others may falsely advertise that FDA reviewed and approved their clinical trial. A potential risk of unapproved stem cell treatment is the risk of infection. For example, bloodstream infections (BSI), pneumonia, and diarrhea are commonly seen among the Hematopoietic Stem Cell Transplantation (HSCT) population. Notable organisms include methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* (VRE), multi-drug resistant gram-negative bacilli (MDR-GNB), and *Clostridium difficile* (C. Diff). The risk of infection is even greater if the process is not approved. Therefore, as a healthcare provider, it is important to know how you can play a roll in safe stem cell therapy practice.

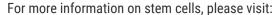




Inquire about stem cell therapy in patients presenting with bacterial infections such as acute discitis, joint, bone, or bloodstream infections as well as cellulitis and abscesses



- Report suspected infections to LAC DPH immediately by calling 888-397-3993
- Be aware of the unapproved therapies that are being marketed and the associated risks, including infection
- Ask your laboratory to save clinical isolates and any stem cell product for further testing, if infection is identified along with stem cell treatment
- Report adverse events associated with stem cell therapies to FDA's MedWatch Safety Information and Adverse Event Reporting Program
- Counsel patients on the risks of unapproved stem cell therapies. Warnings and advice for consumers
  who are considering obtaining stem cell therapy in the US and overseas, is available from the FDA
- Ensure you practice under guidance of California Senate Bill No. 512 Chapter 428, which requires the
  licensed healthcare practitioner who is practicing unapproved stem cell therapy to post the following
  notice: "THIS NOTICE MUST BE PROVIDED TO YOU UNDER CALIFORNIA LAW. This health care
  practitioner performs one or more stem cell therapies that have not yet been approved by the United
  States Food and Drug Administration. You are encouraged to consult with your primary care physician
  prior to undergoing a stem cell therapy."



### **SPOTLIGHT**

In this issue we highlight the work being done by the California Ambulatory Surgery Association

# California Ambulatory Surgery Association: Advocating for and Measuring Safe, Outstanding Patient Care in Outpatient Settings

The California Ambulatory Surgery Association (CASA) helps to advance communication and education regarding trends, outcomes and opportunities within the ambulatory surgery center (ASC) industry.

#### **Ensuring Patient Safety**

There are more than 750 ASCs in California – they offer safe, well-equipped facilities for specific surgical procedures by highly trained, specialized physicians. These facilities create significant cost savings for patients and the healthcare system while producing outstanding health outcomes, high patient satisfaction, and low infection rates. California ASCs are regulated by several rigorous processes including Medicare certification, California state licensure, and accreditation.

ASCs have an excellent track record of patient safety – in the past five years alone, more than 100 million Americans have had successful outpatient surgery in an ASC. Comparative data from over 1 million surgeries performed in ASCs between 2015 – 2016 indicate an ASC post-operative surgical site infection rate to be extremely low (or rare) and comparable if not better than hospital outpatient surgery departments.\* CASA has also been devoted to providing education on infection prevention for ASCs for the past 11 years.

#### Offering Transparent Data and Reporting

CASA members participate in a voluntary benchmarking program that aggregates and reports outcomes for a variety of indicators at ASCs, which provides patients, payors, accrediting agencies, and regulators with helpful data on Quality Indicators and Adverse Risk Events (burns, falls, medication errors, surgical-site infections, and post-operative complications). The CASA benchmarking data can be a helpful tool for marketing an ASC and highlighting its individual outcomes. Overall data and quality reporting show that incidences of unplanned or adverse events that occur in ASCs is extremely low. ASCs also report quality metrics equal to or better than other sites of care, including hospitals.

\*Infection prevention measures are based on protocols established by the Centers for Disease Control and Prevention (CDC) and recommendations by the Centers for Medicare & Medicaid Services (CMS). Source: Wilson, T. (2017, August 24). Benchmarking study of 1,000,000 surgeries in ASCs demonstrates minimal surgical site infections, emergency department visits and readmission rates. Retrieved from https://www.beckersasc.com.

# **About the Outpatient Care Team**

The Outpatient Care Team at LAC DPH is under the Healthcare Outreach Unit within the Acute Communicable Disease Control Program. The team's mission is to enhance infection prevention and control in outpatient settings in Los Angeles County through strengthened communications and collaboration. Given the rapid growth and complexity of procedures performed in outpatient settings, enhancing patient safety and minimizing risk are critical. Since 2014 the Outpatient Care Team has focused on patient safety by adapting successful infection prevention strategies for use in outpatient settings, reviewing infection control protocols, supporting set up and analysis using the National Healthcare Safety Network, investigating outpatient outbreaks, and serving as a resource for healthcare-associated infection reporting, prevention, and control. To learn more about the Outpatient Care Team or to access information about past and current projects, past and most recent outpatient quarterly connect issues, and other resources please visit <a href="http://publichealth.lacounty.gov/acd/Outpatient.htm">http://publichealth.lacounty.gov/acd/Outpatient.htm</a>. If you have a question related to outpatient infection control or would like to be added to the outpatient emailing list, please email <a href="https://publichealth.lacounty.gov/acd/Outpatient.htm">outpatient@ph.lacounty.gov/acd/Outpatient.htm</a>. If you have a question related to outpatient infection control or





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