Rx for Prevention

Promoting health through prevention in Los Angeles County

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Alcohol Screening and Brief Intervention for Prevention

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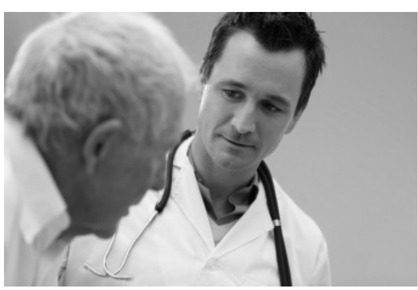
Screening for excessive alcohol use is ranked among the 5 most beneficial and cost-effective preventive services by the National Commission on Prevention Priorities (Table 1). The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen adults aged 18 years or older for alcohol misuse, then provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions. According to the Centers for Disease Control and Prevention, 38 million Americans consume alcohol at levels that increase their risk of chronic disease and acute injury. The majority of these drinkers are non-dependent binge drinkers (i.e., individuals who use risky amounts of alcohol but have not developed a physical dependence). They consume an average of 7.7 drinks per occasion and drink 4 times a month.

For non-dependent drinkers, an alcohol use screening and brief intervention (SBI) can reduce excessive alcohol consumption, emergency room visits, automobile accidents, and disease morbidity. Despite the effectiveness of SBI, only 15% of patients report having ever been asked about their alcohol use by their physician. Evidence suggests that alcohol SBI in primary care is a cost-effective, cost-saving, and easily implemented practice. Given the current emphasis on accountable care and provisions within the Patient Protection and Affordable Care Act for reimbursement, it is an opportune time to begin alcohol SBI for all adult patients.



Non-Dependent Risk Drinking

Risk drinking is defined as alcohol consumption that creates a significant increase in the probability of harm and occurs when consumption exceeds a moderate level. Guidelines for moderate drinking are shown in Figure 1.

Drinking above the recommended guidelines puts people at greater risk of chronic diseases, acute injury and disease, alcohol use disorder (AUD), and death. The relative risk of liver disease, cancer, diabetes, neuropsychiatric disease, and cardiovascular disease is positively correlated with the volume of alcohol consumed.[1] However, it is important to note that the more alcohol-attributable deaths result from acute injury, such as car accidents, poisoning, suicide, and accidental falls than from chronic disease. Moreover, the majority of alcohol-attributable injuries are not caused by people with a diagnosable AUD, but by people who are simply drinking at risky levels. This emphasizes the need to identify and counsel individuals who drink above moderate levels, regardless of the presence of any diagnosable condition.

Effectiveness of Alcohol SBI

SBI is a prevention and early intervention service that involves universal

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Table 1. Top Priorities Among Effective Clinical Preventive Services

Effective Clinical Preventive Services	Clinical Preventive Burden	Cost Effectiveness	Total
Discuss daily aspirin use—men 40+, women 50+	5	5	10
Childhood immunizations	5	5	
Smoking cessation advice and help to quit—adults	5	5	
Alcohol screening and brief counseling—adults	**4**	**5**	**9**
Colorectal cancer screening—adults 50+	4	4	8
Hypertension screening and treatment—adults 18+	5	3	
Influenza immunization—adults 50+	4	4	
Vision screening—adults 65+	3	5	
Cervical cancer screening—women	4	3	7
Cholesterol screening and treatment—men 35+, women 45+	5	2	
Pneumococcal immunizations—adults 65+	3	4	

Source: Partnership for Prevention's National Commission on Prevention Priorities

Figure 1. Drinking Limits and "Standard" Drink Equivalents

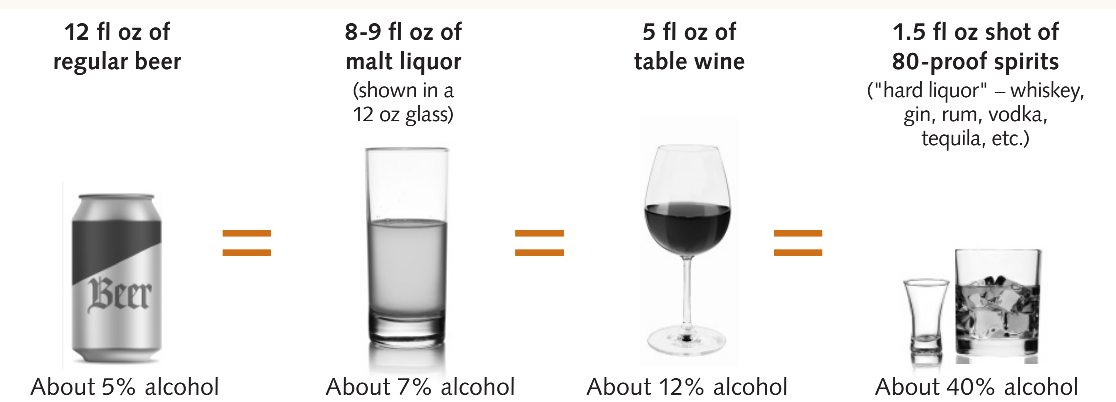
Low-Risk Drinking Limits

	Men	Women	Over 65 (Men and women)
On any single day	No more than **4** drinks on any **day**	No more than **3** drinks on any **day**	No more than **3** drinks on any **day**
		AND	
Per week	No more than **14** drinks per **week**	No more than **7** drinks per **week**	No more than **7** drinks per **week**

To stay low risk, keep within both the single-day and weekly limits

Note: Pregnant women and people under 21 should avoid alcohol completely.

One "Standard" Drink Equivalents



The percent of "pure" alcohol, expressed here as alcohol by volume (alc/vol), varies by beverage. In the U.S., one "standard" drink contains about 14 grams of pure alcohol.

Source: Adapted from National Institute on Alcohol Abuse and Alcoholism

screening of adult patients and a brief counseling session for patients who are drinking more than the recommended amount. SBI is part of a comprehensive Screening, Brief Intervention, and Referral to Treatment (SBIRT) approach, which includes a referral to specialty alcohol treatment for more severe cases. SBI can reduce alcohol consumption by 20%-30%[2] and, overall, save $254 in medical costs per patient.[3] Although the primary focus of SBI is non-dependent drinkers, the SBI may also help patients with AUD by increasing the likelihood that a patient with a severe AUD will enter treatment.[4]

Implementing SBI in Primary Care

Health care providers should inquire about risky alcohol use as a part of routine preventive care. Screening for risky alcohol use only takes a few minutes, and screening instruments accurately identify risky drinkers. It is important to screen all adult patients because risky drinking may be otherwise undetected. Further, risky drinking could be playing a role in uncontrolled chronic conditions (such as diabetes and hypertension) that are costly and life-threatening.

There are three steps to alcohol-use SBI. Many of the training resources listed on page 5 detail each step and how it may be implemented in different medical settings, although the general guidelines here still apply.

Step 1. Brief annual screen: This is typically 1-2 questions that are posed to all patients and generally completed as a paper form with the rest of the intake paperwork. This is all that will be required for the majority of patients.

Step 2. Full screen: For those patients with a "positive" response on the brief annual screen, a full alcohol screening should be completed. This screening may also be done on paper by the patient or verbally by the appropriate staff, depending on the screening tool and practice environment. Accurate screening instruments range from the single-question screener to the 10-question Alcohol Use Disorders Identification Test.

Step 3. Brief Intervention: Primary care providers should have a brief conversation with patients who score positive on the full screen. During the intervention, the provider offers feedback on the patient's level of alcohol consumption, enhances the patient's motivation to change drinking behaviors, and negotiates a plan for behavioral change with the patient. There is variation in how the brief intervention is done. However, non-confrontational, non-judgmental approaches, such as motivational interviewing, have been shown to be effective.[5] (See Table 4 for trainings and resources.)

For patients who have a moderate or severe AUD, it might be necessary to provide a referral for further assessment and/or treatment. Federal law requires health insurance plans to cover substance use disorder treatment services at parity with other medical conditions; therefore, referrals should be facilitated in the same manner as other specialty care referrals.

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Table 2. Alcohol-Use SBI: Questions for Patients at Each Step

1. Do you sometimes drink beer, wine, or other alcohol? How many drinks do you have per week? On a typical day when you drink, how many drinks do you have? *For men under age 65*: How many times in the last 6 months have you had 5 or more drinks on one occasion? *For all women and men 65+*: How many times in the last 6 months have you had 4 or more drinks on one occasion?
2. Do you mind filling out this additional form? [Provide alcohol screening form]
3. I see you completed our alcohol screening form. Do you mind if we go over your results?
    - It looks like you are drinking more than is medically recommended. Your drinking could even be part of why we can't seem to get your blood pressure under control. My medical advice is that you reduce how much you drink. Tell me what you think about this information and how you feel about reducing your alcohol consumption.
    - If you're willing to cut back, what would that look like for you?
    - That sounds great. If you don't mind, I'll check in with you at your next appointment to see how it's going.

Reimbursement for Alcohol SBI

The American Medical Association and the Centers for Medicare and Medicaid Services have approved several billing codes for alcohol SBI, as shown in Table 3. The SBI must be performed by a qualified provider, be distinct from all other Evaluation and Management (E&M) services provided during the same visit, and be documented in the clinical record. Brief interventions can be billed up to 3 times within a year for Medicaid and 5 times for Medicare. Research shows that followup with patients who require a brief intervention may sustain long-term reductions of alcohol use.

SBI for Drug Use

Although the USPSTF has not found sufficient evidence to recommend screening all adults for risky drug use, there is evidence suggesting that SBI for both alcohol and other drugs may be effective in reducing drug use. Primary care systems that have implemented SBI have generally screened for both alcohol and other drugs. In that case, the annual brief screen could include 1 or 2 additional questions, such as "Have you used any drugs for non-medical reasons?" The full screen should be one that screens for both alcohol and other drug use.

Conclusion

Primary care providers who are responsible for managing a patient's health must consider a range of potential health risks. Incorporating alcohol-use SBI into your routine preventive examination is effective in reducing the alcohol consumption of risky drinkers and the risk of long-term associated health problems. Of course, appropriate training in the delivery of brief interventions and motivational interviewing will greatly improve its effectiveness. This article provides the resources to implement SBI into your practice.

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Table 3. Reimbursement CPT Codes

Payer	Code	Description	Fee Schedule
Commercial Insurance	99408	Alcohol and/or substance abuse structured screening and brief intervention services; 15 to 30min (Most commonly used for commercial insurance)	$33.41
Commercial Insurance	99409	Alcohol and/or substance abuse structured screening and brief intervention services; greater than 30min	$65.51
Medicare	G0396	Alcohol and/or substance abuse structured screening and brief intervention services; 15 to 30min	$29.42
Medicare	G0397	Alcohol and/or substance abuse structured screening and brief intervention services; greater than 30min	$57.69
Medicare	G0442	Prevention: Screening for alcohol misuse in adults including pregnant women once per year. No coinsurance; no deductible for patient https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/MPS_QuickReferenceChart_1.pdf	$17.33
Medicare	G0443	Prevention: Up to four, 15 minute, brief face-to-face behavioral counseling interventions per year for individuals, including pregnant women, who screen positive for alcohol misuse; No coinsurance; no deductible for patient http://www.cms.hhs.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=249	$25.14
Medi-Cal	H0049	Alcohol and/or drug screening. Must use AUDIT or AUDIT-C screening form. See Table 4 for a link to the AUDIT tool.	$24.00
Medi-Cal	H0050	Alcohol and/or drug service, brief intervention, per 15min, up to 3 per year.	$48.00

Table 4. Resources for Training, More Information, and Help with Alcohol and Drug Use

Resource	Link	Notes
Department of Health Care Services	http://www.dhcs.ca.gov/services/medi-cal/Pages/SBIRT.aspx	Information for providers in California, including lists of upcoming SBIRT trainings and other provider resources.
Foundations of SBIRT training	http://www.healtheknowledge.org/	SBIRT training from Pacific Southwest ATTC (https://www.thedatabank.com/dpg/423/donate.asp?formid=meetb&c=816960). 1.5 hour online course with continuing education credits available.
Alcohol Use Disorders Identification Test (AUDIT)	http://www.dhcs.ca.gov/services/medi-cal/Documents/AUDIT%20Screening%20Tool.pdf	AUDIT screening tool provided by the Department of Health Care Services.
Colorado SBIRT	http://improvinghealthcolorado.org/	Information for PCPs in the Colorado SBIRT project, including sample pain management contract and other resources for providers.
Oregon SBIRT	http://www.sbirtoregon.org/	This website provides demonstration videos, examples of clinic flows and tools, and other information for primary care clinics interested in implementing SBI.
UCLA Integrated Substance Abuse Programs	http://www.uclaisap.org/sbirt/	Provides SBIRT resources and trainings.
Substance Abuse and Mental Health Services Administration	http://www.integration.samhsa.gov/clinical-practice/SBIRT	Provides SBIRT resources.
Yale School of Medicine	http://medicine.yale.edu/sbirt/index.aspx	Online training videos for SBIRT
Screening for Alcohol Misuse and Abuse	http://publichealth.lacounty.gov/wwwfiles/ph/media/media/rxmayjune10.pdf	2010 *Rx for Prevention* article that provides detailed information on SBIRT and alcohol.
National Institute on Alcohol Abuse and Alcoholism	http://www.niaaa.nih.gov/publications/clinical-guides-and-manuals/helping-patients-who-drink-too-much-clinicians-guide	Provides information on alcohol and SBIRT.

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California Children's Services:
A Resource for California's Children

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Mary L. Doyle, MD, FAAP

About 1 million children in California have one or more physical, behavioral, mental, or emotional conditions that can affect their ability to develop, function, and live long, healthy lives. California Children's Services (CCS) is a joint state and county program providing crucial medical case management and authorization of services for Children and Youth with Special Health Care Needs (CYSHCN) who meet specific medical, residential, and financial eligibility requirements. In Los Angeles County, CCS is administered as a partnership between the California Department of Health Care Services (DHCS) and the Children's Medical Services (CMS) division of the Los Angeles County Department of Public Health.

There are two major components to CCS: the General Program and the Medical Therapy Program. The General Program provides case management and authorizations of services, including both diagnostic services (Newborn Hearing Screening Program; High-Risk Infant Follow-Up) and treatment services (including emergency room care, hospital stays, surgery, medication, and special equipment). The Medical Therapy Program provides direct occupational and physical therapy services for children at 23 therapy units housed in public schools and an additional 9 satellite locations throughout LA County. It also provides home or school visits to assess specific equipment needs, participates in Individual Educational Planning (IEP) meetings, and provides Medical Therapy Conferences (MTC) to assess a full and comprehensive care plan for clients.

Eligibility

Although CCS' medical and financial eligibility requirements are specific, they cover children of many complex health conditions and family income levels.

CCS covers conditions that are complex, chronic, catastrophic, congenital, or functionally disabling and that need to be treated with medication, surgery, or rehabilitation (Figure 1). Medical eligibility is determined through review of the medical documentation submitted for each child. Consider CCS for patients with severe, chronic, or life-threatening conditions.

To be financially eligible for the General Program, families must have either:

- An adjusted gross income of less than $40,000
- Out-of-pocket medical expenses for the child that are expected to be more than 20% of family income, regardless of whether they are uninsured or have private insurance.

Functions of California Children's Services

- Diagnostic services and case finding
- Case management
- Certification of providers, hospitals, and special care centers
- Direct rehabilitation services through a Medical Therapy Unit.

Family income is not a factor for children who need diagnostic services to confirm a CCS-eligible medical condition, or who are full-scope Medi-Cal beneficiaries.

The Medical Therapy Program has no income requirement. As such, CCS plays a crucial role in ensuring that all children, regardless of family income level, have access to essential health care.

Los Angeles County CCS

Currently, CCS offers services for more than 150,000 children statewide and over 46,000 children in Los Angeles County alone. Among the county's children, about 45%, or close to 21,000, of these cases are considered "complex," meaning their condition requires a multidisciplinary care team (including the use of specialized durable medical equipment) and is not likely to be resolved within 12 months. Of these cases, more than 10% of the children have multiple conditions that affect the complexity and intensity of care.

To serve these clients and their families, LA County employs 198 nurses, 8 on-site physicians, and 38 Nurse Case Managers, Nurse Instructors, Assistant Nurses, and Nursing Supervisors to coordinate and authorize care for these children. Additionally, CCS employs dentists, audiologists, nutritionists, social workers, physical and occupational therapists, and therapy technicians to serve its clients. In total, CMS employs 683 positions (including those in administration, financing, contracting, and technology) to support CCS. These numbers do not reflect the number of physicians, nurses, caregivers, vendors, social workers, and external staff CMS may authorize to provide pertinent medical care for these children.

Quality Assurance

CCS sets the state standard for what services and therapies should be available for CYSHCN. It works to ensure that such services are provided at the appropriate time and place by the necessary specialists. CCS limits authorization to state CCS-paneled health care providers who have documented training

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Figure 1. CCS-Eligible Medical Conditions

- Conditions involving the heart (congenital heart disease, rheumatic heart disease)
- Neoplasms (cancers, tumors)
- Diseases of the blood (hemophilia, sickle cell anemia)
- Diseases of the respiratory system (cystic fibrosis, chronic lung disease)
- Endocrine, nutritional, and metabolic diseases (thyroid problems, PKU, or diabetes that is hard to control)
- Diseases of the genito-urinary system (serious kidney problems)
- Diseases of the gastrointestinal system (liver problems such as biliary atresia)
- Serious birth defects (cleft lip/palate, spina bifida)
- Diseases of the sense organs (eye problems leading to loss of vision, such as glaucoma and cataracts, or hearing loss)
- Diseases of the nervous system (cerebral palsy, uncontrolled epilepsy/seizures)
- Diseases of the musculoskeletal system and connective tissue (rheumatoid arthritis, muscular dystrophy)
- Severe disorders of the immune system (HIV infection)
- Disabling injuries and poisonings requiring intensive care or rehabilitation (severe head, brain, or spinal cord injuries, and severe burns)
- Complications of premature birth requiring an intensive level of care
- Diseases of the skin and subcutaneous tissue (severe hemangioma)
- Medically handicapping malocclusion (severely crooked teeth)

Figure 2. CCS Eligibility Requirements

	General Program	Medical Therapy Program
Age	Under 21 years	Under 21 years
Residency	LA County	LA County
Diagnosis	Diagnosis or high suspicion of congenital, chronic, catastrophic and/or disabling condition	Restricted to brain, neuromuscular or musculoskeletal disorders
Financial	Income less than $40,000 or medical expenses that will exceed 20% of family's adjusted gross income	No requirement applies; open to all children who meet the above 3 criteria

Physicians Needed for CCS Medical Therapy Program

California Children's Services (CCS) is California's Title V program for children with special health care needs. The Los Angeles County CCS Program provides case management and medical benefits for infants, children, and youth (up to age 21) who meet all the necessary eligibility criteria. More information about the program may be found at www.publichealth.lacounty.gov/cms/index.htm.

An important part of the CCS program is the Medical Therapy Program (MTP). This program is devoted to providing physical and occupational therapy to children with certain chronic neuromuscular and orthopedic disabilities. In LA County, children in the MTP receive their therapies at Medical Therapy Units (MTUs) located within public schools throughout the county. There are cooperative agreements between local school districts and the MTP to help meet the therapy needs of these young people. Most MTP-eligible children are evaluated at regular intervals by pediatricians and orthopedists at multidisciplinary team conferences. These Medical Therapy Conferences are held at each MTU.

The pediatrician's dual role is 1) to provide oversight of MTU-based therapy and 2) to serve as a care coordinator, ensuring that all medical needs related to each child's CCS-eligible conditions are met through the CCS program. For example, the pediatrician will ensure that appropriate subspecialty medical providers are authorized by CCS, while also addressing psychosocial needs and assuring that a medical home/primary care foundation is in place in the community.

The orthopedist primarily oversees the medical management of the physically disabling medical condition. This oversight frequently includes referrals for interventions (such as surgery or Botox injections) provided under CCS authorizations to the appropriate subspecialists.

Medical Consultative Positions

The LA County California Children's Services is currently seeking well-qualified orthopedists and pediatricians to serve as MTC physicians at one or more of our county's numerous MTU sites. Experience in the medical management of children with special health care needs (especially children with physical rehabilitative needs) is preferred.

For further information, please contact Los Angeles County California Children's Services

- **Dr. Stephen Melli**, Assistant Medical Director
  smelli@ph.lacounty.gov, (626) 569-6463

- **Dr. Edward Bloch**, Medical Director
  ebloch@ph.lacounty.gov, (626) 569-6013

and experience in pediatrics and/or one of its subspecialties. The state CCS program assesses the qualification of each provider on its panel and updates its list of specialists. It also maintains a list of hospitals that have been reviewed and are found to meet program standards. As such, it elevates the standard of care across the "CCS-approved" facilities and through the physicians recognized as "CCS-paneled." The impact of such CCS standards is far-reaching as all children who go to those providers will benefit from the elevated quality of care standardized by CCS.

To become a CCS paneled provider, submit a CCS panel application online at https://cmsprovider.cahwnet.gov/PANEL/index.jsp.

Making Referrals to CCS

Many potentially eligible children may be identified by their primary care physicians. However, a referral may originate from any source, including other health care providers, parents, legal guardians, school nurses, regional center counselors, or other interested parties. Thus, it is important that all persons who interact with CYSHCN are aware that CCS exists as a key resource for children and their families.

Program referrals must be submitted on the appropriate "Service Authorization Request (SAR)" form (http://www.dhcs.ca.gov/formsandpubs/forms/Forms/ChildMedSvcForms/dhcs4488.pdf) and faxed to the LA County CCS Office at 1-855-481-6821. To expedite the process, providers should also attach supporting documentations to support the service request, such as medical reports documenting the suspicion or confirmation of a CCS-eligible medical condition, prescriptions, clinic visit reports, and/or evaluation reports.

The CCS program then notifies the potential applicant of a CCS referral and provides the applicant with the opportunity to complete an Application to Determine CCS Program Eligibility (http://www.dhcs.ca.gov/formsandpubs/forms/Forms/ChildMedSvcForms/dhcs4480.pdf). Once the family applies, CCS determines whether the child meets the medical, residential, and financial eligibility requirements.

Referrals should be made to CCS as early as possible because CCS does not pay for any medical care that is provided before the date of referral.

LA County's CCS program is a vital resource for children with special health care needs and their families. Furthermore, CCS' standards and assessments promote quality services for all children regardless of their participation in CCS.

Health care practitioners play an integral role in continuing to improve the quality of care, educating and connecting families to CCS, and ensuring that potentially eligible children do not go without the care and health services they need. ℞

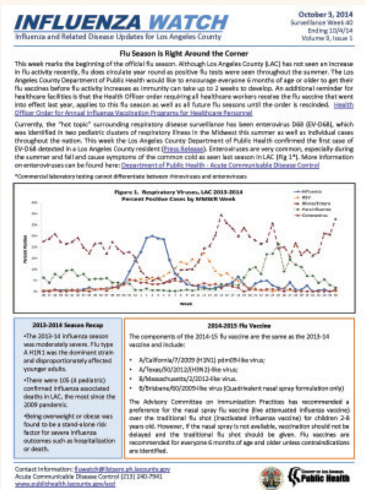
Referral Information

- Fax number: 1-855-481-6821
- Include:
  - Service Authorization Request (SAR) form: http://www.dhcs.ca.gov/formsandpubs/forms/Forms/ChildMedSvcForms/dhcs4488.pdf
  - Fax Cover Sheet for each patient: http://publichealth.lacounty.gov/cms/docs/CCSCSP.pdf
  - Supporting Documentation: Medical reports; prescriptions; clinic visit reports; evaluation reports

Register for *Influenza Watch* for Updates on Flu Activity

Influenza Watch is a biweekly e-newsletter that is published during the influenza surveillance season (traditionally ending in mid-May). It offers the latest flu surveillance and related disease updates for Los Angeles County. It provides statistics on influenza activity in Los Angeles, including the number of positive flu tests and the percentage of emergency department visits for influenza-like illness. It also offers more global information, reporting on influenza in California and the nation.

To read the latest issue, log on to www.publichealth.lacounty.gov/acd/FluSurveillance.htm. If you would like to receive this free newsletter by e-mail, sign up on the ListServ at www.publichealth.lacounty.gov/listserv (enter your e-mail address and subscribe to "FLUWATCH").



INFLUENZA WATCH
Influenza and Related Disease Updates for Los Angeles County

October 3, 2014
Surveillance Week 40
Ending 10/4/14
Volume 9, Issue 1

Flu Season is Right Around the Corner

This week marks the beginning of the official flu season. Although Los Angeles County (LAC) has not seen an increase in flu activity recently, flu does circulate year round as positive flu tests were seen throughout the summer. The Los Angeles County Department of Public Health would like to encourage everyone 6 months of age or older to get their flu vaccines before flu activity increases as immunity can take up to 2 weeks to develop. An additional reminder for healthcare facilities is that the Health Officer order requiring all healthcare workers receive the flu vaccine that went into effect last year, applies to this flu season as well as all future flu seasons until the order is rescinded. Health Officer Order for Annual Influenza Vaccination Programs for Healthcare Personnel

Currently, the "hot topic" surrounding respiratory disease surveillance has been enterovirus D68 (EV-D68), which was identified in two pediatric clusters of respiratory illness in the Midwest this summer as well as individual cases throughout the nation. This week the Los Angeles County Department of Public Health confirmed the first case of EV-D68 detected in a Los Angeles County resident (Press Release). Enteroviruses are very common, especially during the summer and fall and cause symptoms of the common cold as seen last season in LAC (Fig 1*). More information on enteroviruses can be found here: Department of Public Health - Acute Communicable Disease Control

*Commercial laboratory testing cannot differentiate between rhinoviruses and enteroviruses

Figure 1. Respiratory Viruses, LAC 2013-2014
Percent Positive Cases by MMWR Week

2013-2014 Season Recap

- The 2013-14 influenza season was moderately severe. Flu type A H1N1 was the dominant strain and disproportionately affected younger adults.
- There were 105 (4 pediatric) confirmed influenza associated deaths in LAC, the most since the 2009 pandemic.
- Being overweight or obese was found to be a stand-alone risk factor for severe influenza outcomes such as hospitalization or death.

2014-2015 Flu Vaccine

The components of the 2014-15 flu vaccine are the same as the 2013-14 vaccine and include:

- A/California/7/2009 (H1N1) pdm09-like virus;
- A/Texas/50/2012/(H3N2)-like virus;
- B/Massachusetts/2/2012-like virus.
- B/Brisbane/60/2008-like virus (Quadrivalent nasal spray formulation only)

The Advisory Committee on Immunization Practices has recommended a preference for the nasal spray flu vaccine (live attenuated influenza vaccine) over the traditional flu shot (inactivated influenza vaccine) for children 2-8 years old. However, if the nasal spray is not available, vaccination should not be delayed and the traditional flu shot should be given. Flu vaccines are recommended for everyone 6 months of age and older unless contraindications are identified.

Contact Information: fluwatch@listserv.ph.lacounty.gov
Acute Communicable Disease Control (213) 240-7941
www.publichealth.lacounty.gov/acd

Public Health

Update: Vaccine Temperature Monitoring Recommendations and Requirements

Wendi Cate, MA

The proper storage and handling of vaccines is crucial for many reasons: It maintains their stability, prevents inadvertent administration of improperly stored vaccines, and reduces vaccine wastage. Vaccine potency and effectiveness are diminished when exposed to temperatures outside the manufacturers' recommended ranges. All inactivated liquid vaccines are irreversibly damaged when exposed to freezing temperatures, and live vaccines can be compromised by sustained temperatures that are above the ranges recommended by the manufacturer.

The California Vaccines for Children (VFC) Program has implemented storage and handling requirements for all providers participating in the VFC program. In 2009, as a first step toward improving the storage and handling of vaccines, the California VFC Program developed specifications for the types of equipment that are acceptable for the storage of vaccines. Refrigerator-only units and stand-alone freezer units are required for storage of all vaccines distributed through the VFC Program. In October 2013, the VFC Program took the next step in the proper storage and handling of vaccines with the introduction of new temperature monitoring requirements, which are described in this article. Although these requirements only apply to VFC providers, they represent best practices that should be adopted by all vaccine providers to assure vaccine potency and effectiveness.

Thermometers

VFC providers must have a primary thermometer centrally located in each vaccine storage unit at all times and a minimum of one back-up thermometer.

The requirements for the thermometers (primary and back-up) are as follows:

- Be accurate within ±0.5°C (±1°F)
- Have a digital display
- Have a biosafe glycol (or similar buffered solution) encased probe
- Display the current, minimum, and maximum temperatures
- Have an audible alarm for out-of-range temperatures.

The primary thermometer is used for monitoring and documenting storage unit temperatures twice daily on a VFC Temperature Log.

The back-up thermometer is used when the primary thermometer is sent for calibration or otherwise fails.

Thermometer Calibration and Certification

Primary and back-up thermometers must be calibrated annually (or every other year at the most if recommended by the manufacturer), and each device must be covered by a Certificate of Traceability and Calibration Testing, also known as a Report of Calibration.

Calibration should be conducted by an ILAC/MRA[1] accredited laboratory and the calibration certificate must include:

- Name and address of laboratory conducting the test
- Name of device (optional)
- Model number (enables product identification)
- Serial number (enables product identification)
- Date of calibration (report or issue date)
- Measurement results for the device
  - Instrument pass or in tolerance testing result
  - Documented uncertainty (must be within ±0.5°C [±1°F)]).

If calibration is conducted by a non-accredited laboratory, the calibration certificate must also include a statement that calibration testing conforms to ISO/IEC[2] 17025 standards.

A valid Certification of Calibration must be kept on file with other VFC-required documents for at least 3 years.

Temperature Monitoring

Temperatures for each vaccine storage unit must be read and documented twice each workday, at the beginning of the day and before closing. Additionally, minimum and maximum temperatures must be read and documented at the beginning and end of each business day.

About the Vaccines for Children Program

The VFC Program, established by an act of Congress in 1993, helps families by providing free vaccines to doctors who serve eligible children 0 through 18 years of age. The VFC program is administered at the national level by the CDC through the National Center for Immunization and Respiratory Diseases. The CDC contracts with vaccine manufacturers to buy vaccines at reduced rates. Enrolled VFC providers are able to order vaccine through their state VFC Program and receive routine vaccines at no cost. This allows them to provide routine immunizations to eligible children without high out-of-pocket costs. The California VFC Program is managed by the California Department of Public Health, Immunization Branch.

Any California-licensed MD, DO, or health care organization serving VFC-eligible children can become a VFC provider. Enrollment in Medi-Cal or the Child Health and Disability Program is not required. Providers are not required to accept children solely because the children are eligible for the VFC Program.

- Thermometer temperatures must be cleared after each reading of minimum and maximum temperatures (MIN/MAX).
- Temperatures must be recorded on VFC Temperature Logs, even if using a continuous temperature-recording device or digital data logger.
- Temperature logs must be posted in a visible location and maintained for 3 years.

If out-of-range temperatures are identified, immediate action should be taken to prevent spoilage of the vaccines. Improper vaccine storage conditions should be corrected. The VFC Program requires that enrolled providers identify an on-site vaccine coordinator and back-up vaccine coordinator who are responsible for performing these actions.

Trainings, Tools, and Resources

The VFC Program website (www.eziz.org) provides resources for any practice in need of additional information on vaccine storage and handling. It offers training for staff on storage and handling, vaccine inventory management, and vaccine administration. There are also storage and handling resources on temperature monitoring and calibration, and tools that can be easily downloaded. You do not have to be a VFC provider to access any of the information on this website.

Conclusion

Routine temperature monitoring is essential to the management of vaccines, and equally important is the use of precise monitoring equipment. VFC providers are now required to use calibrated thermometers to ensure accurate temperature readings, and all providers are strongly encouraged to implement the best practices discussed in this article to ensure they are administering effective vaccines to their patients. Rx

Wendi Cate, MA, is Director of Field Services, Immunization Program, Los Angeles County Department of Public Health.

FOOTNOTES

1. International Laboratory Accreditation Cooperation Mutual Recognition Arrangement

2 International Organization for Standardization/International Electrotechnical Commission

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Rx for Prevention

Promoting health through prevention in Los Angeles County

Upcoming Training

Immunization Skills Training for Medical Assistants

The Immunization Skills Institute is a 4-hour course that trains medical assistants on safe, effective, and caring immunization skills.
Topics include
- Proper vaccine administration techniques
- Immunization documentation
- Effective communication
- Proper vaccine storage and handling.

To register or learn more about other trainings sponsored by the Immunization Program, visit www.publichealth.lacounty.gov/ip/trainconf.htm or call (213) 351-7800.

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Comments or Suggestions? If so, or if you would like to suggest a topic for a future issue, e-mail Dr. Jeffrey Gunzenhauser, editor, at jgunzenhauser@ph.lacounty.gov.

Index of Disease Reporting Forms

All case reporting forms from the LA County Department of Public Health are available by telephone or Internet.

Reportable Diseases & Conditions Confidential Morbidity Report
Morbidity Unit **(888) 397-3993**
Acute Communicable Disease Control
(213) 240-7941
www.publichealth.lacounty.gov/acd/reports/CMR-H-794.pdf

Sexually Transmitted Disease Confidential Morbidity Report
(213) 744-3070
www.publichealth.lacounty.gov/dhsp/ReportCase.htm (web page)
www.publichealth.lacounty.gov/dhsp/ReportCase/STD_CMR.pdf (form)

Adult HIV/AIDS Case Report Form
For patients over 13 years of age at time of diagnosis
Division of HIV and STD Programs
(213) 351-8196
www.publichealth.lacounty.gov/dhsp/ReportCase.htm

Pediatric HIV/AIDS Case Report Form
For patients less than 13 years of age at time of diagnosis
Pediatric AIDS Surveillance Program
(213) 351-8153
Must first call program before reporting
www.publichealth.lacounty.gov/dhsp/ReportCase.htm

Tuberculosis Suspects & Cases Confidential Morbidity Report
Tuberculosis Control **(213) 745-0800**
www.publichealth.lacounty.gov/tb/forms/cmr.pdf

Lead Reporting
No reporting form. Reports are taken over the phone.
Lead Program **(323) 869-7195**

Animal Bite Report Form
Veterinary Public Health **(877) 747-2243**
www.publichealth.lacounty.gov/vet/biteintro.htm

Animal Diseases and Syndrome Report Form
Veterinary Public Health **(877) 747-2243**
www.publichealth.lacounty.gov/vet/disintro.htm

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