A Guide to the California Immunization Registry and Its Use to Enhance the Delivery of Immunization Services

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Abstract

Pharmacists in California are assuming a greater role as independent providers of immunizations for children and adults under Senate Bill 493 (SB 493). One of the requirements for pharmacists as independent providers of immunizations in California is that they must report their administered doses to the California immunization registry system (CAIR). The National Vaccine Advisory Committee Standards for Immunization Practice also supports this practice by recommending that all immunizing providers report vaccinations to their local and state immunization information systems (IIS). This document presents background and specific features of CAIR; best practice recommendations for the use of IIS lookup, forecasting, follow-up, and recall; and documentation features to enhance the delivery of immunization services.

Background

Immunization Information Systems (IIS)

Vaccinations are among the most significant public health advancement in the prevention of many communicable diseases. However, there are still gaps in care, as adult vaccination rates for routine recommended vaccines in the United States are low and well below projected Healthy People 2020 targets. It is estimated that 40,000 to 50,000 adults still die annually from vaccine-preventable disease in the United States.[1,2]

As recommended in the 2013 updated National Vaccine Advisory Committee (NVAC) Standards for Immunization Practice, one step toward improving immunization coverage in the United States is better collaboration among healthcare providers, healthcare systems and organizations, public health departments, and other stakeholders.[3] Collaboration among such a large group of providers and stakeholders to increase immunization coverage depends on the ready availability of timely, complete, and accurate patient vaccination information.

A tool that provides this information and has shown to enhance vaccine collaboration and communication among providers, facilitate public health monitoring, and increase immunization rates are immunization information systems (IISs), also known as immunization registries.[4] The Centers for Disease Control and Prevention (CDC) defines IISs as "confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area." In addition to providing clinical, decision support, an IIS consolidates a patient's immunization record from a variety of immunization providers with the goal of assembling a complete patient immunization record for continuity of care and public health assessment. Each state has its own state-based IIS program that is independent of other states but follows policies and recommendations made by the CDC, American Immunization Registry Association (AIRA), and other relevant public health agencies and organizations. Features that are available in most IISs are the ability to query patient vaccine records, receive up-to-date ACIP vaccine recommendations for specific patients, be notified of due or overdue vaccines for patients, and manage vaccine inventory.

A current limitation of IISs at this time is the variability that exists within and between states with regard to IIS reporting of administered vaccine doses. Some states require reporting, while others do not. States that require reporting vary in who is required to report, which age groups are required or even allowed to be reported, which vaccines are required to be entered, and which vaccines are allowed to be entered.

Although these limitations exist, they do not undermine the usefulness of IISs, which continue to benefit from ongoing reporting of childhood and adult doses that still add value.[5]

California Board of Pharmacy Immunization Documentation Requirements

Prior to 2013, pharmacists in California were only able to administer vaccinations under a signed protocol with a physician. With the passage of Senate Bill 493 (SB 493) in 2013, pharmacists in California are assuming a greater role as independent providers of vaccinations for children and adults. Section 4052.8 of California Business and Professions code authorizes pharmacists with specified training to initiate and administer the CDC's Advisory Committee on Immunization Practices (ACIP) routinely recommended vaccines independent of a physician signed protocol. The regulation also mandates that pharmacists in California who provide immunizations must report their administered immunizations into the California Immunization Registry (aka CAIR) and provide notification of vaccination to the patient's primary care provider (PCP), if known. Pharmacists must also notify a pregnant patient's prenatal provider in addition to their PCP. These reporting mandates must be completed within 14 days of administration of any vaccine. While the state law requirement is for pharmacists to report vaccine doses administered, it is the pharmacy that needs to be registered with CAIR. If the pharmacist wants to view immunization records or enter them manually, then they will need to be added as an individual user under the pharmacy that is registered with CAIR.

Pharmacies are also required to electronically or manually document and retain vaccine administration records for each vaccine administered in the pharmacy. This is often achieved by entering the vaccine like any other prescription medication, making sure to include all federally required elements. Vaccine administration records should include patient information, name of vaccine, vaccine manufacturer name and lot number, date of edition of the VIS and date the VIS was provided to the patient, office address and name and title of the person who administered the vaccine, and date of administration for each vaccine given.

Information on legislation regarding pharmacist-provided immunization and mandated reporting of immunizations to local/state IISs varies by state laws and is updated regularly on the APhA's Immunization Center webpage (http://www.pharmacist.com/immunization-center) and on the CDC website (https://www2a.cdc.gov/vaccines/iis/iissurvey/legislation-survey.asp), respectively.

CALIFORNIA IMMUNIZATION REGISTRY (CAIR)

The IIS system in California is known as the California Immunization Registry (CAIR) System. The centralized CAIR2 registry includes patient data from the former Northern California, Greater Sacramento, Bay Area, Central Valley, Central Coast, LA-Orange, and Inland Empire regional registries and is managed by the California Department of Public Health (CDPH). California also has three non-CDPH CAIR regions (San Diego, Imperial County, and San Joaquin) that will begin sharing data with CAIR2 in the 2018. At that point, any CAIR user will be able to access statewide patient data.

CAIR Enrollment & Training

Instructions for enrolling in CAIR are provided on its website (cairweb.org). To enroll in CAIR2, the pharmacy facility (or any facility that needs access to CAIR2) is actually enrolled, and then individual users are assigned access through their enrolled facility. Information needed for enrolling in CAIR2 are name, address, city, zip code, phone, email, and fax number of the facility and the name and contact information for a main contact at the facility. The CAIR2 enrollment form also asks for a "CA Medical License," but pharmacists should enter their Registered Pharmacist License number instead (of the PIC or the main contact, if they are a registered pharmacist). When registering in CAIR2, facilities and organizations are given the option of selecting CAIR Access Levels for their facility. These access levels are data exchange, clinical, limited clinical, and read-only. If not enrolling in data exchange (electronic submission), pharmacies should choose the "clinical" access level. This will allow them to manually create new patients, enter vaccine doses, and look up patient records. For pharmacies that would like to sign up for data exchange, they should consult with their pharmacy computer system vendor to see if their system has the capability to send immunization records to CAIR2 in HL7 format. If a pharmacy computer system does not have the capability to send records directly to CAIR2 in HL7 format, there are some health information exchanges and vendors that, for a subscription fee, are able to convert data from most pharmacy computer systems to HL7 so that it can be submitted electronically to CAIR2.

When adding users to a facility, the facility administrator can also assign user levels for each user. These user levels are "Power," "Regular," and "Read-Only." Differences between these three user levels is shown in Table 1 below. Pharmacies that are manually submitting doses to CAIR2 should choose the "Regular" user type if they do not plan

to manage inventory in CAIR or the "Power" user type if they would like to use the inventory feature.

Pharmacists at sites that are enrolled in data exchange do not need to manually add/edit new doses or add/edit new patients, but they should enroll their vaccinating pharmacists as "Read-Only" so they can at least search patient records and run reports or as "Regular" users so they can search records, run reports, and enter historical vaccine doses. We will discuss the importance of pharmacists having access to these features later in this document.

After enrolling the pharmacy and users within the pharmacy, each user is emailed instructions to schedule and complete online training before they are granted access to CAIR2. "Power" users will be required to complete a 2-hour live training webinar, and "Regular" users will be required to complete a 1-1/2-hour live training webinar. "Read-Only" users are not required to complete training but will be referred to videos and quick guides for self-review.

Pharmacies in the San Joaquin, San Diego, or Imperial County have different enrollment procedures and should contact their local CAIR Representative listed on this page: http://cairweb.org/cair-regions/.

CAIR Disclosure/Sharing Policy

Before pharmacists can enter and submit patient information to CAIR, they are required per California law (Health and Safety Code, Section 120440) to provide patients/parents with a proper disclosure notice. Pharmacists must use the CAIR "Immunization Registry Notice to Patients and Parents" to provide disclosure; this CAIR Notice is available on the CAIR Forms webpage (http://cairweb.org/forms/) in multiple languages. Pharmacists must give a copy of the CAIR Notice or post it and point it out to each patient/parent whose information will be entered into CAIR to read. If the patient is under the age of 18, the disclosure notice must be given to the parent or guardian. Patients or parents do not need to sign the disclosure. So as long as a patient/parent is given proper disclosure, the data can be shared with CAIR and the date of disclosure is documented in the patient's profile in CAIR. This disclosure process only needs to be done once. Once disclosure is performed, patient information that is entered into or shared with CAIR can include any and all vaccine doses or tuberculosis (Tb) testing results received by the patient, regardless of when those doses or Tb tests occurred relative to the date of disclosure.

If a patient or parent wishes to limit access to their immunization record in CAIR, they must complete and submit to the CAIR Help Desk a "Decline or Start Sharing Immunization Information Request Form," which can also be found in multiple languages on the CAIR Forms webpage. Upon receipt of this form as a fax or email, CAIR Help desk staff will "lock" the record so it cannot be access by other CAIR users.

BEYOND REPORTING: USE OF CAIR TO ENHANCE THE DELIVERY OF IMMUNIZATION SERVICES

While the California Board of Pharmacy regulation currently only mandates reporting of vaccine doses administered to the IIS, CAIR offers many other features that can enhance and improve the delivery of immunization services. CAIR and many other state IISs have the feature to look up patient immunizations, provide patient-specific vaccine recommendations, run patient follow-up reports, and provide immunization record documentation. Pharmacists with access to CAIR are encouraged to incorporate these CAIR tools and features into their immunization practice and the Pharmacist's Patient Care Process for immunization services.[6,7]

Lookup

Prior to providing immunizations, pharmacists should collect patient information to screen for vaccine precautions or contraindications as well as indications for other vaccines. Information needed to screen for indications and precautions/contraindications are gathered from multiple sources, including a patient's personal immunization record, pharmacy dispensing system records, primary care providers, and patients' verbal history. Access to CAIR provides another useful and reliable source of immunization information that can be used to determine vaccine status and needs. Pharmacists with access to their state immunization registry are encouraged to query and look up patients in the registry before vaccinating. This process also ensures that patients are not receiving duplicate vaccinations, spacing and sequencing of vaccines is appropriate, and due or overdue vaccines for the patient are identified and recommended during the encounter. CAIR also has the ability to document and record notes from other CAIR providers about previous vaccine reactions and adverse events to determine if it is appropriate for the patient to receive subsequent doses of a vaccine or a particular type of vaccine.

Currently, CAIR and many other IISs are not able to access IIS data from other states; users will not be able to see vaccine records that were administered and entered in another state's IIS. This limitation is not unique to IISs but related to the absence of a centralized data and electronic health record system.

Vaccine Schedule & Forecasting

When conducting a patient search and lookup in CAIR2 prior to vaccination, providers should view the "Vaccines Recommended by Selected Tracking Schedule" section listed in the patient's "History/Recommend" page. This section notifies the user of overdue, due, and future vaccine dates to keep patients up-to-date and on schedule with current ACIP recommendations. Providers can use this registry-generated assessment section to determine if the next dose in a vaccine series is appropriate to be given, and, if not, when is the recommended date to give the dose. The schedule tool in CAIR2 is also able to inform the provider if a certain vaccine that was previously administered was considered an invalid dose if its administration did not follow ACIP recommendations. Clicking on the name of a vaccine listed under "Vaccines Recommended by Selected Tracking Schedule" for the patient will present the user with an explanation for the current status as well as what the recommended interval and age recommendations are for that vaccine. Similar to the benefits of a lookup, the vaccine schedule and forecasting tools in the CAIR IISs allows for determination of appropriate spacing and sequencing of vaccines and to identify due or overdue vaccines for the patient. The schedule and forecast tool in CAIR IISs can also save the pharmacist time by providing timely access to immunization records and recommendations without having to collect and review information from multiple sources. As more adult providers begin to document in CAIR the vaccines they administered, CAIR will become a complete immunization record.

A caveat to mention for the schedule and forecast tool is that CAIR only provides recommendations for routine ACIP recommended vaccines; therefore, travel vaccines or elective vaccines will not be included in the list of recommended vaccines for the patient. While such vaccinations will not show up in the recommendations section, all FDA-approved vaccines can be documented in CAIR. As with many clinical support tools, there may be a lag time in which new ACIP recommendations may appear in CAIR's schedule and forecasting feature. The forecast tool is not able to make recommendations that are based off of the ACIP recommended immunizations by health condition. For example, pneumococcal recommendations in CAIR are currently only based on the patient's age and do not take into account high-risk conditions that may require a patient to receive pneumococcal vaccination before 65 years of age. Pharmacists must assess and use their clinical judgment to determine if vaccination is needed in these patient populations. Also, a listed recommendation in CAIR does not mean that the patient is medically clear to receive that vaccine—pharmacists should still conduct a thorough screening for precautions and contraindications to receiving vaccines before providing the recommended vaccine.

Follow-up & Recall Reminders

Pharmacists should have a plan to follow up with patients to provide additional doses needed to complete a vaccines series and/or booster doses. Follow-up ensures continuity of care, increases rates of immunizations and completion rates, and increases vaccine volume for your practice. Immunization registry reminder and recall systems have shown to boost immunization rates by up to 20%.[8,9] CAIR has a patient "Reminder/Recall" report feature that can identify your pharmacy's CAIR patients who are due for vaccines. Providers can run these reports to obtain a list of patients who they have provided vaccines for in CAIR and who have due or overdue vaccines and should be contacted for follow-up.

Documentation

In addition to documenting vaccines administered by the pharmacy as required by law, pharmacists are also encouraged to update the patient's historical records in CAIR. Situations that may require updating information in CAIR include the patient presenting with record of having received vaccine(s) that is not found in CAIR, a new Tb test or chest X-ray results, or a change in the patient's information/demographics. CAIR users are able to enter historical doses into the patient's record for vaccines that were administered by another healthcare provider. Entering historical doses will help complete the patient's record, make that information available to all users of CAIR, and allow CAIR's recommendation and forecasting tool to make more accurate recommendations for the patient that can avoid duplication and inappropriate spacing of vaccines. Pharmacists are only required to notify the primary care provider when they administer a vaccine but not when they update CAIR with historical immunization data. CAIR is also able to produce and print a copy of the patient's records in the "Immunization Yellow Card" format, which can be given to the patient as documentation for them to carry and share with other members of their healthcare team.

Conclusion

As California pharmacists independently initiate and administer more immunizations in the pharmacy setting, it is increasingly important for pharmacists to share those records with other healthcare providers in the "Immunization Neighborhood," such as through IIS reporting. Reporting to the IIS assists in the public

health efforts to improve immunization rates and reduce vaccine-preventable diseases. Access to an IIS like CAIR also provides the pharmacists with an additional clinical decision support tool that can reduce missed immunization opportunities by conducting vaccine assessment for patients based on their immunization record/history in accordance with ACIP recommendations. In addition to complying with Board of Pharmacy regulations for reporting to the IIS, pharmacists are encouraged to incorporate and utilize the lookup, forecasting, and recall reminder features within an IIS to enhance their delivery of immunization services.

Table 1. Comparison of the three different access levels within CAIR.

User Type	Search Records	Run Reports	Add Transcribed Doses	Add / Edit New Doses	Add / Edit New Patients	Add / Edit Inventory
Power	X	X	X	X	X	X
Regular	X	X	X	X	X	
Read Only	X	X				

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