SAN FRANCISCO HEALTH PLAN
Here for you

October 3rd, 2022

UPDATES INCLUDE:

- Medication-Related Quality Improvement
- FSR Provider Pearl: Vaccine Storage

Medication-Related Quality Improvement

SFHP has an interdisciplinary Quality Improvement (QI) workgroup that focuses on appropriate testing, medication regimen, and adherence for patients with diabetes, asthma, schizophrenia or schizoaffective disorder on antipsychotics, and major depression on antidepressants. A few preliminary findings are outlined below.

Antipsychotic Medication Adherence
Adherence to antipsychotic medications for members with schizophrenia or schizoaffective disorder is measured using Proportion of Days Covered (PDC). With this measurement, members are considered adherent to their medications if they have their medications for 80% of the coverage period. Preliminary data gathered by SFHP indicates that members with multiple emergency department visits in a year are less likely to be adherent to antipsychotic medications. Of the members with four or five ED visits in a year, 39.5% of members are adherent and 44.9% of members with six or more ED visits are adherent. Conversely, members with more PCP visits are more likely to be adherent to their antipsychotic medications. A majority (72.8%) of those members with a PCP/non-PCP visit ratio of 6 or higher were adherent. These trends emphasize the importance of establishing care to effectively treat schizophrenia and schizoaffective disorder.

Antidepressant Adherence
Antidepressant adherence is measured by the number percentage of members 18 years or age or older with a diagnosis of major depression who remain on an antidepressant medication. There are two points at which this is measured – 12 weeks and 6 months. Members who identified their preferred language as Spanish had the lowest rate of adherence at 6 months (47%) as did those members who identified as Black (38.8%) or Hispanic (49%). These low adherence rates highlight a potential need for increased access to culturally competent care. SFHP intends to work with our provider groups and with Beacon Health Options to identify strategies for addressing these populations.

FSR Provider Pearl: Vaccine Storage

This article will provide an overview of the FSR vaccine storage practices criteria evaluated in the onsite review process. The California Department of Health Care Services (DHCS) 2022 Facility Site Review (FSR) updated Standards includes more detailed criteria to evaluate clinic vaccine storage and handling, which are critical to vaccine potency for adequate immune responses in patients and protection from disease, avoids the need to revaccinate patients and potentially cause them to lose trust in their provider and his/her staff, and prevents lost revenue when vaccines must be wasted.

For a comprehensive tool to align your clinic practices, the Centers for Disease Control and Prevention (CDC) has a detailed Vaccine Storage and Handling Toolkit (Addendum added April 12, 2022) that provides the recommendations on storage, handling, and transport of vaccines and diluents. The FSR Team encourages providers and staff to review this toolkit to ensure compliance with the nuances of this site review criteria.

Vaccine Storage and Handling Guidance:
1. Review and follow practice standards in the CDC Vaccine Storage and Handling Toolkit
2. Review and learn the specific requirements in the new 2022 DHCS FSR Standards regarding vaccine handling and storage

(Full *specifications also provided at the end of this article) with key points summarized as follows:*
Drugs are prepared in a clean area or "designated clean" area if prepared in a multi-purpose room.
Drugs for external use are stored separately from drugs for internal use.

Room temperature where drugs are stored does not exceed 30ºC (86ºF).

Routinely checking for expiration dates for all drugs kept onsite.

Keep log of sample medications to include the name of the patient to whom a drug given, the name and strength of the medication, instructions for use, and the quantity or duration of therapy is documented in the patient's chart.

There is a written site-specific policy and procedure (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers' representatives and language in P&P for the safe and effective distribution, control, storage, use and disposition of drugs.

There is written Vaccine Management Plan for routine and emergency vaccine management (required for Vaccines for Children (VFC) providers).

Vaccines are kept in a refrigerator maintained at 2-8ºC or 36-46ºF.

Freezer thermometer temperature is 5º Fahrenheit or –15º Centigrade, or lower.

**Site utilizes drugs/vaccine storage units that are able to maintain required temperature ranges.*

Site does not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

Refrigerator and freezer temperatures are documented at least once a day (required twice daily for VFC providers). CDC recommends use of a continuous temperature monitoring device (digital data loggers or DDL).

Site must demonstrate capacity for continuous monitoring and recording of vaccine storage conditions where the data can be routinely downloaded

At least one back-up device should be readily available for emergency vaccine transport or when primary DDL is sent in for calibration.

There is a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer.

Site personnel must be able to verbalize the procedures in the plan used to promptly respond to OUT OF RANGE TEMPERATURES.

For VFC providers, follow program requirements for documentation and reporting.

**Excellent detailed information in the CDC Vaccine Storage and Handling Toolkit*

Sites still using dorm-style refrigerators for the storage of vaccines should consider this additional information. DHCS and CDC state clearly not to store vaccines in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances. Dorm-style refrigerator is acceptable for basic home storage purposes, but it is not suitable for maintaining the conditions needed for more sensitive medical materials, such as vaccines due to variations in temperature. The CDC does state that in some circumstances a household-grade unit can be an acceptable alternative to pharmaceutical-grade vaccine storage units. But note the difference, this is a full-sized unit and not a dorm-style or mini-sized unit. If a full-sized household-grade unit is used, the freezer compartment of this type of unit is still not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well such as the door compartments. If using a household-grade unit and your facility provides frozen-stored vaccines, a separate freezer unit is necessary.

While dorm-style refrigerators are less expensive than medical refrigerators, there is no big-picture cost savings when compared to accrued expenses from disposing of and replacing vaccines, not to mention the risk you take of administering damaged vaccines to your patients. Recommended by the CDC and proved experimentally by Felix Storch, Inc., a dedicated refrigerator specifically designed for medical storage is the only viable option for maintaining the safety and potency of vaccines.

Dorm-Style Refrigerators: Frequently Asked Questions

Q: I've had this refrigerator a long time, why haven't prior reviewers identified it as inadequate?
A: DHCS updated the FSR Standards in 2022 and the CDC has clear guidelines about proper storage and monitoring of equipment.

Q: What if the medical grade vaccine storage refrigerator is too expensive?
A: Disposing of and replacing vaccines or administering compromised vaccines can drive up practice costs due to revaccinating patients, replacing expensive vaccines, and losing patient confidence in your practice. The SFHP team is researching opportunities for small clinic assistance. Any updated findings will be shared when available.

Q: What if there is no room for a medical grade refrigerator in our small clinic (or small space)?
A: Depending on the model, a medical grade refrigerator size that is comparable to a dorm or mini refrigerator can be found with the following sample measurements: 23.44 x 19.44 x 33.38 inches

Q: If I get the medical grade refrigerator, do I still need to buy a temperature monitoring device (TMD)?
A: Yes, this is a requirement in the new 2022 FSR Standards.

Q: What if I don't have enough time to keep track of all these vaccine storage and handling specifications?
A: Designate a primary vaccine coordinator. This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling standard operating procedures. See CDC Vaccine Storage and Handling Toolkit (Addendum added April 12, 2022) for details how to do this.

Consider printing this article and working with your staff to check your practice's Vaccine Storage and Handling processes.
If you have any questions, your FSR team is here to help.

California Department of Health Care Services Managed Care Quality and Monitoring Division Facility Site Review Standards (July 2022)

Section IV. Clinical Services – Pharmaceutical Standards (Consultation with CDC is available when necessary: www.cdc.gov)

B. Drugs are handled safely and stored appropriately.

distribution, etc.) must be addressed in a corrective action plan (CAP).

IV.B.1) Drugs are prepared in a clean area or "designated clean" area if prepared in a multi-purpose room.
Drug Preparation: Drugs shall be drawn up in a designated clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. The drug preparation area should be cleaned and disinfected on a regular basis: CDC guidelines for drug preparation and safety.

IV.B.2) Drugs for external use are stored separately from drugs for internal use. Storage:
- Drugs shall be separated by route of administration, especially ophthalmic and optic preparations.
- Vaccines and other drugs should be stored separately from food, lab specimens, human specimens, cleaning supplies, and other items that may potentially cause contamination.
- The Center for Disease Control (CDC) recommends avoiding storing other medications and biological products such as lab specimens/human specimens in a vaccine storage unit.

IV.B.3) Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.
- Storing food, other medications, and biological products with vaccines put vaccines at risk for temperature fluctuation, excessive light exposure, administration errors, and contamination.
- If food, other medications, and biological products must be stored in the same refrigerator with vaccines, they must be in the sealed containers and stored below vaccines on the different shelves.
- Drugs are stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug product are not affected.
- Room temperature where drugs are stored does not exceed 30ºC (86ºF).
- A drug or device is considered "adulterated" if it contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed or held under unsanitary conditions.
- A drug is considered contaminated if it has been held under unsanitary conditions that may have been contaminated with filth or rendered injurious to health.
- Drugs that are unused are considered by the Environmental Protection Agency (EPA) to be toxic wastes and must be disposed in accordance with 40 CFR, part 261.

American College of Physician guidelines state sound management procedures include:
- Routinely checking for expiration dates.
- Keeping medicines off the floor.
- Labeling the sample medicines or writing prescribing information directly on the sample package.
- Keeping a log of sample medicines given. In case of a recall, keeping a log allows to track down a patient to whom the recalled drug had been prescribed.
- When a medication sample is given to a patient, the name and strength of the medication, instructions for use and the quantity or duration of therapy is always documented in the patient's chart.

ASHP guidelines for minimum standard for pharmaceutical services in ambulatory care:
- Site should have written site-specific policies and procedures (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers' representatives.
- Each clinic, which provides drug distribution services, shall have written policy and procedures for the safe and effective distribution, control, storage, use and disposition of drugs.

Immunobiologics:
- Sites should have a written Vaccine Management Plan for routine and emergency vaccine management (required for Vaccines for Children (VFC) providers).
- Vaccines are refrigerated immediately upon receipt on site and stored according to specific instructions on the package insert for each vaccine.
- Diluent does not need refrigeration if vaccine is administered right after diluent is added.
- Vaccines are not stored in the doors, floors, vegetable bins, or under or near cooling vents of a refrigerator or freezer.

IV.B.4) Refrigerator thermometer temperature is 36º-46º Fahrenheit or 2º-8º Centigrade (at time of site visit).
Refrigerator: Vaccines are kept in a refrigerator maintained at 2-8ºC or 36-46ºF, and include, but are not limited to, DTaP, Td, Tdap, Hepatitis A, Hepatitis B, IPV, Pneumococcal, Rotavirus, Hib, Influenza (inactivated and FluMist), MCV, HPV, recombinant Zoster, or any combinations of these listed vaccines.

IV.B. 5) Freezer thermometer temperature is 5º Fahrenheit or –15º Centigrade, or lower (at time of site visit). Freezer: Varicella and MMRV vaccines are stored in the freezer at -15ºC or 5ºF, or lower, and are always protected from light.
- MMR may be stored in a refrigerator or freezer; VFC recommends MMR be stored in the freezer with MMRV.
- Never freeze vaccine diluents.

IV.B. 6) Site utilizes drugs/vaccine storage units that are able to maintain required temperature. **CDC recommends for both temporary and long-term storage refrigerators and freezers using:**
- Purpose-built units designed to either refrigerate or freeze (can be compact, under-the counter style or large units).
- Stand-alone household units.
- Units dedicated to storage of biologics.

Measures should be in place to ensure that vaccine storage units are not accidentally physically disconnected from the power supply, such as "Do Not Disconnect" labels and not plugging units into surge protectors with an on/off switch. **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.**

IV.B. 7) Daily temperature readings of drugs/vaccines refrigerator and freezer are documented. Refrigerator and freezer temperatures are documented at least once a day (required twice daily for VFC providers). CDC recommends use of a continuous temperature monitoring device (digital data loggers).
- Digital data loggers (DDL) should have a minimum accuracy of +/- 1°F (0.5°C)
- Equipped with buffered probe
- Active temperature display outside of the unit
- Capacity for continuous monitoring and recording where the data can be routinely downloaded
- Calibrated at least every 2 years, to monitor vaccine storage unit temperatures

DDL is sent in for calibration.

IV.B. 8) Has a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer.

- A written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer is required. www.cdc.gov
  https://www.cdc.gov/disasters/poweroutage/vaccinestorage.html
- Site personnel must be able to verbalize the procedures in the plan used to promptly respond to OUT OF RANGE TEMPERATURES.
- Quarantine vaccines until guidance is obtained.
- Action is taken when temperatures are identified to be outside of the recommended range.
- Contacting VFC (http://eziz.org/vfc/overview/) or manufacturer are acceptable procedures.
- For VFC providers, follow program requirements for documentation and reporting.

“Provider Pearls” are monthly articles written to help you prepare for the California Department of Health Care Services (DHCS) FSR review processes. If a clinic manager, office manager, nurse manager, or operations person, can take the time to independently self-monitor clinic practices with the aid of SFHP checklists and DHCS guidelines at least annually, we can all work together to strive toward improved quality standards in office practice operations.

For any questions about the Facility Site Review or Medical Record Review processes or tools, please contact Jackie at jhagg@sfhp.org or by her direct line at 1(415) 615-5637.

[1] Felix Storch, Inc. Understanding Medical & Laboratory Refrigeration." AccuCold by Summit Appliance. 5 July 2016
Centers for Disease Control and Prevention. Vaccine Storage & Handling Toolkit updated April 2022
CDC Impact of Power Outages on Vaccine Storage:
https://www.cdc.gov/disasters/poweroutage/vaccinestorage.html

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