

## Ohio Department of Health (ODH) Vaccines for Children (VFC) Vaccine Management Plan

- All Ohio VFC providers are required to use this vaccine management plan to document vaccine handling and storage protocols.
- This document must be maintained at a location accessible to all health care personnel who handle vaccines and near the vaccine storage units at your facility.
- All health care personnel who handle vaccines at this practice must adhere to the protocols described in this document and must review the protocols at least annually.

|                         |  |
|-------------------------|--|
| Name of Office / Clinic |  |
| ODH VFC Number          |  |
| Original Plan Date      |  |

### **VACCINE STORAGE PRACTICES LISTED IN THIS DOCUMENT ARE THE PRIMARY RESPONSIBILITY OF:**

|                             |                      |                        |
|-----------------------------|----------------------|------------------------|
| Primary Vaccine Coordinator | Primary Phone Number | Secondary Phone Number |
|                             |                      |                        |
| Back-up Vaccine Coordinator | Primary Phone Number | Secondary Phone Number |
|                             |                      |                        |

### **1. RESPONSIBILITIES OF HEALTH CARE PERSONNEL WHO HANDLE VACCINES**

The responsibilities of the primary vaccine coordinator and the back-up vaccine coordinator include the following vaccine management activities:

- Adjust the temperature of the vaccine storage unit as necessary to maintain correct temperatures.
- Document temperatures on the ODH-provided temperature log or other log that contains the same necessary information.
- Provide annual training of health care personnel who are responsible for administering vaccines (or who may be required to transport vaccine in any emergency) on the vaccine management plan. A log sheet with the staff member's name and date of training is attached for use at the end of this document.
- Complete annual training and maintain certificates of completion.
- Review temperature logs weekly to ensure that vaccine temperatures are recorded properly and verify that no temperature excursions occur.
- Act as the lead and back-up vaccine contacts for the office.
- Act as the lead and back-up emergency vaccine plan coordinators.
- Manage all vaccine aspects including access to the ImpactSIIS system; order VFC vaccine using ImpactSIIS; reconcile VFC vaccine inventories in ImpactSIIS at least monthly; monitor vaccine storage conditions daily; assure vaccine loss is minimized; and assure all vaccine shipping, receiving, packaging and transportation is performed according to current policy.

## 2. **VACCINE STORAGE & HANDLING BASICS**

### A. **Vaccine Storage Units**

Providers must have appropriate equipment that can store vaccine and maintain proper conditions.

- Vaccine storage units must be able to maintain required vaccine storage temperatures.
- Vaccine storage units must be large enough to hold maximum vaccine needs.
- Vaccine storage units must be able to use the ODH-supplied digital data logger (WiFi/Cloud-based) with a glycol thermistor probe (ODH maintains the calibration certificate) or an ODH approved provider-supplied digital data logger.

The current Centers for Disease Control and Prevention (CDC) recommendation for the types of storage units includes the following:

1. Purpose-built or pharmaceutical/medical-grade units, including door-less and dispensing units.
2. Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.
3. Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines—a separate, stand-alone freezer should then be used to store frozen vaccines.

**Note: Dormitory-style refrigerators are not acceptable for storage of any vaccines.** These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.

### B. **Vaccine Handling Practices**

- Open and correctly store vaccine shipments as soon as they arrive at your health care facility.
  - Maintain proper vaccine storage temperatures:

| Refrigerator              |
|---------------------------|
| 36°F to 46°F (2°C to 8°C) |

| Freezer                        |
|--------------------------------|
| -58°F to 5°F (-50°C to -15 °C) |

- Place the digital data logger glycol in the middle of each vaccine storage unit away from the coils, walls, floor, and cold air vent.
- Use the temperature log to record the following information:
  - Time of each temperature check.
  - Min/Max temperature using the digital data logger display (only in the a.m.).
  - Vaccine storage unit temperature (do this twice each day: a.m. and p.m.).
  - If temperatures are out-of-range, unit is audibly alarming, or if the red LED is flashing on the data logger, immediately place a “DO NOT USE” sign on the vaccines, maintain the vaccine in the storage unit, and call the ODH Immunization Program. ODH personnel will discuss the situation and determine the next steps of action. If an excursion occurs on the weekend or after business hours, the provider should take the same actions upon discovering the excursion, Staff from the ODH Immunization Program will respond the next business day.
- Retain the temperature logs in your practice for at least three years.
- Store vaccines in the middle of the refrigerator or freezer compartment away from the coils, walls, floor, and cold air vent.
  - **Do not** store vaccines against the walls (or sides), in the doors, in the vegetable bin, or in the bottom of the refrigerator / freezer unit.
- Ensure stored vaccines have space around their containers for cold air circulation.
- Store extra ice packs in the door of the freezer.
- Place water bottles labeled “DO NOT DRINK” in the refrigerator door to stabilize temperatures.
- Label “VFC” vaccines and “private stock” vaccines and physically separate VFC vaccines from private stock vaccines in separate containers in the refrigerator and freezer unit(s) so that inventories are separately

identifiable.

- Check the refrigerator/freezer doors to ensure they are closed at the end of each day.
- Place “**Do Not Unplug**” signs near the vaccine storage units’ electrical outlets and circuit breakers.
- Store and rotate vaccines according to expiration dates. Use vaccines with the shortest expiration dates first.
- If vaccines will not be used and they are within 90 days of the expiration date, contact your VFC Immunization Consultant for instructions.
- Conduct an inventory of your VFC vaccines at least once each month (this will prevent running out of vaccine and the need to borrow vaccine).
- **Do not** store food in the vaccine storage units.

### **3. DATA LOGGER PROCEDURES**

- A. VFC provider locations must use a digital data logger (DDL) with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing VFC vaccines.
- DDLs must be used during routine, on-site vaccine storage, vaccine transport, and temporary, mobile, off-site, satellite, and community vaccination clinics. In Ohio, VFC providers have the option of using ODH-supplied WiFi DDLs or their own provider supplied DDLs, once vetted and approved by the ODH Immunization Program.
  - To meet VFC program requirements, the DDL must be equipped with:
    - A temperature probe or sensor (a buffered probe is required for awardee-provided probes and is optional, but recommended, for provider-purchased probes or sensors).
    - An active temperature display outside the unit that can be easily read without opening the storage unit’s door.
    - Continuous temperature monitoring and recording capabilities and the capacity to routinely download data.
- Additional DDL features must include:
- Alarm for out-of-range temperatures.
  - Temperature display showing current, minimum, and maximum temperatures.
  - Low battery indicator.
  - Accuracy of +/-1°F (0.5°C).
  - User-programmable logging interval (or reading rate) recommended at a maximum time interval of no less frequently than every 30 minutes.

Each DDL must have a current certificate of calibration testing.

#### **Temperature Monitoring and Documentation:**

The CDC and ODH require providers to perform the following actions to ensure the proper storage and handling of VFC vaccine:

- Twice each day, view and document temperatures from each storage unit containing VFC vaccine (e.g. a.m./p.m. each day that the office is open) to include time, date, and initials of staff person recording temperatures. The temperatures are to be recorded on the ODH-provided temperature log or other log that contains the same necessary information.
- **During the a.m. temp check, document the minimum (lowest/coldest) and maximum (highest/warmest) temperatures from the digital data logger. Clear out the DDL values from the previous day.**
- **If the DDL is alarming, quarantine the vaccine and immediately contact the ODH VFC program** during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546.
- Ensure the glycol probe is standing upright and located in the center of the storage unit and not directly under the cold air return in the unit.

**The VFC program encourages each provider to review temperature data at least monthly.**

#### **4. VACCINE SHIPPING, RECEIVING, AND COLD CHAIN FAILURES**

- A. Staff accepting vaccine deliveries must be aware of the importance of maintaining the cold chain and the need to notify appropriate staff of vaccine delivery. At practices, the Vaccine Coordinator and the Back-up Vaccine Coordinator are responsible for the following procedures:
- Upon receipt of a vaccine shipment, examine the container and contents for physical damage.
  - Verify that the shipping time is less than 48 hours or that the shipment is received by the specified date documented by the manufacturer on the packing slip (e.g. direct shipments from Merck).
  - Check the temperature monitors in the vaccine container(s) to see if temperatures were out of the recommended range.
  - Cross-check the contents and expiration dates with the packing slip.
  - Check to make sure that refrigerated vaccines and the diluents are cold or room temperature, but not frozen.
  - Check to make sure that frozen vaccines (Varicella or ProQuad) are 5°F or below (-15°C or below).
  - Check for the correct type and quantity of diluents.
- B. If there are any discrepancies with the packing slip, concerns about the viability of the vaccine, or possible cold chain failures with the vaccine shipment, immediately notify your practice's Vaccine Coordinator and take action.
- If you suspect the vaccines may not be viable
    - Mark the vaccine or diluents as "DO NOT USE;"
    - Store the vaccine under proper conditions; and
    - Contact the ODH Immunization Program during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546.
  - ODH personnel will review the vaccine temperatures and determine what further action is necessary.
  - If the vaccine shipment was incorrect, contact the ODH Immunization Program at 1(800) 282-0546.

These actions must occur on the same day the shipment is received.

#### **5. EMERGENCY PLAN (For Vaccine Relocation)**

##### **A. Responsible Personnel**

In the event the refrigerator or freezer malfunctions, the facility has a power failure, a natural disaster occurs, or some other emergency compromises appropriate vaccine storage conditions, vaccines may need to be transported to another location. The Vaccine Coordinator or the Back-up Vaccine Coordinator will be responsible for making decisions about relocating the vaccines during normal and after business hours including these actions:

- Open the provider office after regular business hours to get to the vaccine;
- Alert the emergency relocation site about the need to relocate vaccine (during regular or after hours);
- Pack the vaccines for shipment (during regular office hours or after regular hours);
- Transport the vaccines to the emergency relocation site (during regular or after hours).

| Vaccine Coordinator         | Primary Phone Number | Secondary Phone Number |
|-----------------------------|----------------------|------------------------|
|                             |                      |                        |
| Back-up Vaccine Coordinator | Primary Phone Number | Secondary Phone Number |
|                             |                      |                        |

If the Vaccine Coordinator and Back-up Vaccine Coordinator are not available, the person(s) listed below will relocate the vaccine:

| Alternate Emergency Contact Name | Primary Phone Number | Secondary Phone Number |
|----------------------------------|----------------------|------------------------|
|                                  |                      |                        |

## B. Procedures for Emergency Transport of Vaccine

Vaccine potency must be protected by maintaining the cold chain at all times during relocation and transport. Always inform ODH at 1 (800) 282-0546 or (614) 466-4643 during weekday business hours from 8 a.m. – 5 p.m. about your intention to transport VFC vaccines, the location where the vaccines will be transferred to, and the number of vaccine doses to be transferred. If it is necessary to move the vaccine outside normal business hours, please proceed and contact the ODH Immunization Program the following business day.

**Please note that a residence is not a sufficient first option for an emergency relocation site but may be a viable last resort.**

| Emergency Relocation Site Name | Emergency Relocation Address:    |
|--------------------------------|----------------------------------|
|                                |                                  |
| Relocation Contact Name(s):    | Relocation Contact Phone Number: |
|                                |                                  |
|                                |                                  |

During vaccine transport, the following guidelines must be followed:

- An ODH-supplied or provider-supplied digital data logger must be placed in the vaccine transport container with the vaccine.
- If vaccines are maintained in an insulated cooler, the temperatures must be checked and recorded hourly.
- The vaccines should not be left unattended. Always stay with the vaccines during transport and promptly place into appropriate storage units upon arrival.
- When transporting vaccines in vehicles, use the passenger compartment - not the trunk.
- **For additional guidelines, see [Clinical Resources: Storage and Handling on Immunize.org](#).**

## Emergency Transport and Short-Term Storage Guidelines for Refrigerated Vaccines

Use the following procedures for packing vaccine when refrigerated vaccines need to be transported. These procedures should keep all vaccines (except Varicella vaccine) within recommended temperatures for 12 hours during transport and/or temporary storage.

### Assemble Packing Supplies

1. It is best to use qualified containers specifically designed for vaccine transport. Containers are qualified through laboratory testing under controlled conditions. If you do not have qualified containers, it is acceptable to use hard plastic Igloo-type coolers or a Styrofoam™ cooler from a previous vaccine shipment. Attach a “Vaccines: Do Not Freeze” label to the cooler.
2. Use “conditioned” frozen water bottles. Condition frozen water bottles by holding them under running tap water or submerging them in a sink filled with tap water until the block of ice can spin freely when the bottle is rotated. Phase change material (PCMs) can also be used to transport vaccines.
3. Use the ODH-supplied digital data logger or provider-supplied digital data logger.
4. Use two(2) pieces of corrugated cardboard.
5. Use two 1-inch layers of bubble wrap. Insufficient bubble wrap can cause the vaccine to freeze.

### Pack the Vaccine

1. Spread conditioned water bottles or PCMs to cover the bottom of the cooler.
2. Place a piece of cardboard over the water bottles.
3. Place a 1-inch layer of bubble wrap on top of the cardboard. The bubble wrap is to be placed above the cardboard and below the vaccine.
4. Stack layers of vaccine boxes on the bubble wrap.
5. Place the glycol for the data logger in with the boxes of vaccine on the layers of bubble wrap. Assure that it is connected to the data logger.
6. Completely cover the vaccine with a 1-inch layer of bubble wrap.
7. Place another piece of cardboard on top of the bubble wrap to completely cover the bubble wrap.
8. Spread “conditioned” water bottles or PCMs on top of the cardboard.
9. Fill the cooler to the top with bubble wrap. Place the Vaccine Transfer Form on top of the bubble wrap. (Note: temperatures may go above 46°F for a short time while packing – this is acceptable.)
10. The data logger should be placed on the outside of the cooler with a temperature log. Assure that it is attached to the probe in glycol.
11. The lid on the cooler should be attached securely (tape may be needed).

As soon as you reach the destination site, check the vaccine temperature using the data logger.

- If the temperature is between 36°F and 46°F (2°C-8°C), put it in the refrigerator.
- If the temperature is below 36°F or above 46°F, place the vaccine in a refrigerator with temperatures between 36°F and 46°F (2°C-8°C), quarantine the vaccine and label the vaccine “DO NOT USE.” Be sure to keep the data logger with the vaccine. Contact the ODH VFC program during regular business hours at 1 (800) 282-0546.

### **Transport and Short-Term Guidelines for Freezer Vaccines**

The vaccine manufacturer does not recommend transporting Varicella-containing vaccines (MMRV, VAR, and VZV). If these vaccines must be transported (e.g., during an emergency) CDC recommends transport in a portable freezer unit that maintains the temperature between -58°F and 5°F (-50°C and -15°C). Portable freezers may be available for purchase or rent.

If Varicella-containing vaccines must be transported and a portable freezer unit is not available, you should use the process for transporting refrigerated vaccine outlined above. Varicella-containing vaccines may be transported at refrigerated temperatures between 36°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution (refer to Varicella-containing vaccines in CDC’s [Vaccine Storage and Handling Toolkit](#)).

According to the vaccine manufacturer, immediately upon arrival at the alternate storage facility:

- a. Place the vaccines in the freezer 5°F or below (-15°C or below) and label “DO NOT USE.” Any stand-alone freezer that reliably maintains a temperature 5°F or below (-15°C or below) is acceptable for storage of Varicella-containing vaccines.
- b. Document the time the vaccines are removed from the container and placed in the alternate storage unit.
- c. Note that transporting frozen vaccines in a cooler with conditioned water bottles is considered a temperature excursion, so contact ODH during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546 for further guidance.

## **6. VACCINE ORDERING BASICS**

- A. Order VFC vaccine in accordance with the actual vaccine need. Avoid stockpiling or a build-up of excess vaccine inventory. For sites ordering quarterly, the site should typically have a three to four (3-4) week supply of on-hand vaccine inventory when placing a new order.
- B. Vaccine orders must be submitted through the Vaccine Ordering Management System (VOMS) software application on-line. A vaccine reconciliation process (inventory count) must be completed at least five (5)

days prior to any VFC vaccine order using VOMS.

- C. Depending on the volume of patients reported to the ODH Immunization Program and order history, practices are typically requested to order VFC vaccine quarterly. A practice should contact the ODH Immunization Program during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546 or (614) 466-4643 for more information on ordering cycles.

After the VFC vaccine order is delivered to the provider, the vaccine order must be received electronically, “e-received” in VOMS for the vaccine inventory to be added correctly to the inventory count.

## 7. **INVENTORY CONTROL GUIDELINES**

The vaccine storage and inventory practices listed below are the responsibility of the following staff member(s):

| Staff Name | Note:   |
|------------|---|
|            | The vaccine coordinator may delegate this duty to another staff member, however the vaccine coordinator must still oversee this activity. |
|            |   |

- At least five (5) days prior to each vaccine order (and preferably once each month) conduct a physical count of VFC vaccines and record the vaccine inventory in VOMS using the reconciliation process.
- Always place vaccines with shorter expiration dates in front of those with later expiration dates so that they can be used first (“first-in, first-out”). Short-dated vaccines should be checked at least every four weeks in case the expiration date order gets out of sequence.
- Vaccines are checked for expiration dates every \_\_\_\_\_ week(s).
- Vaccines are rotated every \_\_\_\_\_ week(s).
- Notify your assigned ODH VFC Consultant of vaccines that are within 90 days of expiration and will not be used. They will facilitate potential transfer of these vaccines to another VFC provider.
- Develop and maintain complete, accurate, and separate stock records for both public and private stock vaccines.
- VFC providers are not required to have separate storage units for the public and private sector vaccines, but vaccine stock supplies must be clearly labeled and separated between the public and private vaccine supplies.
- This practice differentiates public vaccine stock from private vaccine stock by (check each that applies).  
☐ Labeled Baskets   ☐ Labeled Shelves   ☐ Separate Storage Units   ☐ Other: \_\_\_\_\_

## 8. **VACCINE EXPIRATION AND SPOILAGE GUIDELINES**

- A. If vaccine becomes spoiled or expired, the Vaccine Coordinator or the Back-up Vaccine Coordinator will be responsible for reporting these vaccines to the ODH VFC Consultant. Assigned health care personnel must:
- Quarantine the suspected spoiled vaccine in the storage unit until the vaccine manufacturers and ODH determine the vaccine to be either viable or non-viable.
  - Do not administer the suspected spoiled vaccine. Post a “DO NOT USE” sign on the vaccine storage unit indicating that the vaccine must not be used until viability is determined.
  - Call ODH at 1 (800) 282-0546 during weekday business hours from 8 a.m. – 5 p.m. to report the suspected spoilage.
    - Share temperature data from the vaccine storage unit with ODH to review.
    - Email a summary of the suspected vaccine spoilage to the ODH VFC staff.
    - If the vaccine is determined to be spoiled or expired, complete a [VFC Vaccine Transfer Form](#) with the spoiled or expired vaccine listed.
  - Review and confirm the spoiled or expired VFC vaccine information with the ODH VFC Consultant.

**B. Spoiled and Expired VFC Vaccine Return Process:**

- CDC requires spoiled/expired VFC vaccine to be returned to McKesson.
- If your site has expired and/or spoiled vaccines, make sure the ODH Immunization Program has been contacted and notified (i.e. reporting a temperature excursion, contacting the assigned VFC consultant regarding expiring doses).
- Email the vaccine transfer form to [vaccine@odh.ohio.gov](mailto:vaccine@odh.ohio.gov) with the subject: “Return Label Request”.
- ODH will process the request for a return label from McKesson Specialty Shipping.
- Labels are sent to providers via email and come directly from a UPS email address.
- Upon receipt of the return shipment label, package the vaccine in one of the original vaccine shipping containers, apply the return label to the box, tape and seal the box, and present the package to the package courier service listed on the return label the next time a delivery is made to your site.
- **Do not** call McKesson Specialty Shipping directly to arrange a pickup or you will be charged for the pickup.
- For any questions, please call the ODH Immunization Program during weekday business hours from 8 a.m. –5 p.m. at 1 (800) 282-0546.

**C. NEVER return the following:**

- Vaccines drawn-up into the syringes but not administered.
- Broken vials.
- Used syringes with or without needles.
- Multi-dose vials that have been partially used (some vaccine has already been withdrawn).

**The items listed in section C above should be reported as “Wastage” and must be properly disposed of in office as medical waste.**

**9. TEMPORARY MOBILE UNIT (VANS, RV’S, MOBILE HEALTH CENTERS)**

Mobile clinics are movable units (i.e., trailers, buses, etc.) associated as extensions of existing providers. They allow access to health care services (e.g., immunizations) and offer flexible and viable options for treating isolated and vulnerable groups as well as displaced populations. These temporary mobile clinics are not the primary site for vaccine storage and administration—they are not to be confused with mobile providers who exclusively store and administer vaccines out of a mobile facility.

- A. These mobile clinics are not considered the primary site for vaccine storage. Staff should ensure that the proper vaccine cold-chain has been maintained during off-site clinics.
- B. Upon initial arrival at the off-site clinic location, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- C. All procedures for vaccine storage and handling are the same as outlined in Section 2: Vaccine Storage and Handling Basics above, which include the use of an approved digital data logger and recording temperatures on paper temperature logs. When storing vaccine in temporary units, temperature data must be reviewed and documented **every hour** during the clinic.
- D. Special considerations for mobile units:
  - The number of VFC vaccines transported to a temporary, mobile, off-site, or satellite clinic should be based on anticipated number of VFC-eligible children to be served.
  - Vaccines may be transported—not shipped—to a clinic site using vaccine transportation procedures outlined in CDC’s [Vaccine Storage and Handling Toolkit](#). This includes transporting vaccines to and from the site at appropriate temperatures and using appropriate equipment, as well as monitoring and documenting temperatures using a DDL with a probe in buffered material.
  - Do not draw up vaccines before arriving at the clinic site. Drawing up doses days or even hours before a clinic is not acceptable. CDC strongly recommends not pre-drawing doses before they are needed.
  - Use manufacturer-filled syringes, if possible, as an alternative to pre-drawing vaccines.
  - Each person administering vaccines should pre-draw no more than one multidose vial (MDV) at one time.



- Monitor patient flow to avoid drawing up unnecessary doses.
  - Discard any remaining vaccine in pre-drawn syringes at the end of the workday.
- E. At the end of the clinic day after vaccine is transported back to a primary/permanent storage location, temperature data must be assessed prior to placing vaccines back into the permanent storage units to prevent administration of vaccines that may have been compromised.
- F. If at any time, vaccines are exposed to temperature excursions, they must be labeled “DO NOT USE” until further information can be gathered on usability. The provider must contact the ODH Immunization Program at 1(800) 282-0546 to report the excursion.
- G. Staff should utilize the CDC [Vaccine Storage and Handling Toolkit](#) to ensure all proper procedures are being maintained.

## 10. REVIEW AND UPDATE VACCINE MANAGEMENT PLAN

At a minimum, the entire vaccine management plan must be reviewed and updated annually. If there are no staffing changes, please document the review in the table below. The plan must also be reviewed and updated when there is a change in personnel who have responsibilities specified in the plan. A new plan should be completed if there are staffing changes that directly affect the vaccine management plan.

| Date Vaccine Management Plan Reviewed | Reviewed By: (Print) | Reviewed By: (Signature) |
|---------------------------------------|----------------------|--------------------------|
|                                       |                      |                          |
|                                       |                      |                          |
|                                       |                      |                          |

## 11. DOCUMENT STAFF TRAINING ON VACCINE MANAGEMENT (INCLUDING STORAGE AND HANDLING)

Document when staff have completed the CDC You Call the Shots Modules, when they participated in a VFC Compliance Site Visit, or list other training completed by staff.

| Date | Trainee | You Call the Shots Modules<br>(write date completed) |            | Other VFC Training<br>(Site visit, MOBI, etc.)<br>Enter Training Type and Date |
|------|---------|--|------------|--|
|      |         | VFC Module   | S/H Module |  |
|      |         |  |            |  |
|      |         |  |            |  |
|      |         |  |            |  |
|      |         |  |            |  |
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