PHYSICIAN PRACTICE ENHANCEMENT PROGRAM

Assessment Standards

Safety: Vaccine and Medication

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Assessment Standards 2016

Safety

VACCINE AND MEDICATION

Vaccine and medication administration is a common practice in most physician clinical offices. Best practices related to the safe storage, handling and administration of vaccines and medications including medication that is available in single-dose vials and multi-dose vials, and narcotics, ensure that patients receive safe, uncontaminated and effective agents.

This standard describes required and recommended best practices for safe storage, handling and administration of vaccines and medications, including single-dose and multi-dose vials and narcotics.

The medical director maintains oversight of and responsibility for all operational and administrative components. In a clinical office, where the care of patients is shared by a number of physicians (i.e. walk-in clinic, urgent care or multi-physician clinic), a single physician must be designated as the medical director. In a solo physician clinic, the physician is the medical director.

For detailed information on the roles and responsibilities of the medical director refer to the College standard on *Walk-in, Urgent Care and Multi-physician Clinics*.

UNDERSTANDING THE ASSESSMENT STANDARD

An assessment standard consists of three components:

1. **Standard** – a goal statement of achievable levels of performance. An assessment standard is identified by a first level whole number ending in ".0" such as 1.0, 2.0, 3.0 etc.
2. **Criterion** – activities or components of the standards that once implemented lead to the overall attainment of the standard. A criterion is identified by the first level number indicating the standard to which it is associated, and a second level number such as X.1, X.2, X.3, etc.
3. **Criterion Descriptors** – specific actions for each criterion. Criterion descriptors are identified by the first level standards number, the second level criterion number and a third level criterion number such as X.Y.1, X.Y.2, etc.

   A criterion marked by an **M** indicates that the criterion is mandatory and must be met. If the registrant is assessed by PPEP, the expectation is that the registrant has met this criterion.

Criterion that is not marked by an M is based on best practices using current provincial, national and international standards and guidelines. A non-M criterion should be met, but is not required. A registrant should use their best judgement to determine whether or not the unique circumstances of their practice necessitate meeting each non-M criteria.

No.	Standard Criterion		Reference
VM 1.0	**VACCINE STORAGE, HANDLING AND ADMINISTRATION**		
VM 1.1	**Facility has processes to ensure that vaccines are safely stored, handled and administered.**		
VM 1.1.1	**M**	Manufacturer's instructions are followed for storing, handling, and administering vaccines.	2,3,5
VM 1.1.2	**M**	Vaccine doses are not prepared in advance of seeing the patient by prefilling syringes or leaving syringes ready on the counter.	3,5
VM 1.1.3	**M**	There is a process in place to check vaccine expiry dates regularly.	2,3,5
VM 1.1.4	**M**	Expiry date of the vaccine to be used is checked before preparation of the dose.	3,5
VM 1.1.5	**M**	Expired vaccines are returned to the vaccine-ordering source.	2,3
VM 1.1.6	**M**	The local public health department or the vaccine's manufacturer is contacted for advice if there is reason to suspect that the vaccine may be spoiled, and whether it is to be used.	2,3
VM 1.1.7	**M**	Date multi-dose vaccine is opened is clearly printed on the label of the vial.	3,5
VM 1.2	**Vaccines and other temperature sensitive drugs are safely and appropriately stored in a designated refrigerator.**		
VM 1.2.1	**M**	Vaccines and other temperature-sensitive drugs are stored in an **appropriate**, designated refrigerator. • Appropriate refrigerator is referred to as a purpose-built refrigerator; also called a pharmacy, vaccine, biologicals, laboratory or industrial grade refrigerator. • Domestic frost-free refrigerators can be used; however, temperatures may fluctuate in different compartments of the refrigerator, and vaccines can only be stored in certain areas. • Pharmacy-grade under-the-counter units are acceptable for vaccine storage. • Standard "bar" fridges (small volume combination fridge/freezer with one exterior door) are not adequate because they do not maintain even temperatures.	2,3
VM 1.2.3	**M**	Only vaccines and other temperature sensitive drugs are stored in the vaccine refrigerator. (It is preferable to store laboratory specimens in a refrigerator other than the one dedicated to vaccine storage. If laboratory specimens must be stored in a vaccine refrigerator, these specimens should be stored in a separate, clearly marked container.)	2,3
VM 1.2.4	**M**	Vaccine refrigerator is equipped with a maximum-minimum thermometer.	2,3
VM 1.2.5	**M**	Vaccine refrigerator temperature is maintained between 2.0 C and 8.0 C.	2,3
VM 1.2.6	**M**	Vaccines are refrigerated within the temperature range recommended by the vaccine's manufacturer.	2,3
VM 1.2.7	**M**	Vaccine refrigerator temperature is checked twice a day.	2,3

No.	Standard Criterion		Reference
VM 1.2.8	**M**	Vaccines are stored on the middle shelf of the vaccine refrigerator, never on the doors or in the crispers.	2,3
VM 1.2.9	**M**	No food or beverage is stored in the designated refrigerator.	2,3
VM 1.2.10		A separate tray is used in the vaccine refrigerator for opened vaccine.	2,3
VM 1.2.11		Vaccines are kept in their original packaging.	2,3
VM 1.2.12		Opened vaccine vials are used prior to opening new vials/packages.	2,3

VM 2.0 MEDICATION SAFETY

VM 2.1	**Medication is safely prepared, stored and administered.**		
VM 2.1.1	**M**	Manufacturer's instructions are followed for storing, preparing and administering medication.	5
VM 2.1.2	**M**	Medication (including sample drugs) is stored in area not accessible to patients and non-authorized personnel.	5
VM 2.1.3	**M**	Medication is stored and prepared in a designated clean area on a clean surface.	5
VM 2.1.4	**M**	Hand hygiene is available in the area where medication is prepared.	5
VM 2.1.5	**M**	Medication doses are never prepared in advance of seeing the patient by pre-dispensing, prefilling syringes or leaving syringes ready on the counter.	5
VM 2.1.6	**M**	All needles are **single-patient use only.**	5
VM 2.1.7	**M**	All syringes are **single-patient use only.**	5
VM 2.1.8	**M**	A vial is **never** re-entered with a used needle or used syringe.	5
VM 2.1.9	**M**	Once medication is drawn up, the needle is immediately withdrawn from the vial. A needle should **never** be left in a vial to be attached to a new syringe.	5
VM 2.1.10	**M**	There is a process in place to check medication expiry dates regularly.	5
VM 2.1.11	**M**	Expiry date on medication is checked prior to use.	5
VM 2.1.12	**M**	Expiration dates are routinely checked and expired medications are discarded.	5
VM 2.1.13	**M**	Opened containers of sterile solutions are clearly dated with date of first use and discarded every 24 hours and/or according to manufacturer's instructions.	5

No.	Standard Criterion		Reference

VM 3.0 SINGLE-DOSE VIALS

VM 3.1	**Single-dose vials are safely and appropriately handled, stored and accessed.**		
VM 3.1.1	**M**	Single-dose vials are never reused. The vial is entered once and then immediately discarded.	5
VM 3.1.2	**M**	Always use a sterile syringe and needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been used on a patient.	5
VM 3.1.3	**M**	Never combine or pool the leftover contents of single-dose vials.	5

VM 4.0 MULTI-DOSE VIALS

VM 4.1	**Multi-dose vials are safely and appropriately handled, stored and accessed.** **Note:** Multi-dose vials should be avoided as much as possible; however, if they are used, the facility must practice safe handling and administration.		
VM 4.1.1	**M**	When accessing a multi-dose vial, the access diaphragm is scrubbed using friction and 70% alcohol and allowed to dry before inserting a new needle and new syringe into the vial.	5
VM 4.1.2	**M**	Use multi-dose vial for a single patient whenever possible and mark the vial with the patient's name.	5
VM 4.1.3	**M**	Multi-dose vials are marked with first entry date and always discarded prior to expiration date.	5
VM 4.1.4	**M**	Multi-dose vials are discarded immediately if sterility is questioned or compromised or if the vial is not marked with the patient's name and original entry date.	5
VM 4.1.5	**M**	Multi-dose vials are discarded according to manufacturer's instructions or within 28 days, whichever is shorter. Exceptions can be considered for multi-dose vials used for a single patient (e.g. allergy shots) if the manufacturer's instructions state that the vial can be used for longer than 28 days.	5

VM 5.0 EYE OINTMENTS AND DROPS

VM 5.1	**Eye ointments and drops are handled, stored and administered safely and appropriately.**		
VM 5.1.1	**M**	Multi-use eye drops and ointments are discarded according to the manufacturer's instructions.	5
VM 5.1.2	**M**	Tops/caps of eye ointments and drops are replaced immediately after use to minimize contamination.	5

No.	Standard Criterion		Reference
VM 5.1.3	**M**	Eye medication that may have been contaminated is discarded immediately and not used on a patient (e.g. if the tip of dispense comes into contact with patient's conjunctiva or tears).	5
VM 5.1.4		Single-use eye ointments and drops are preferred.	5

VM 6.0 OPIOIDS AND CONTROLLED DRUGS

VM 6.1	Opioids and other controlled drugs are safely handled stored and administered.		
VM 6.1.1	**M**	Opioids and other controlled drugs are stored separately in a secure locked location, substantially constructed cabinet (e.g. double-locked cupboard or password-protected automated cabinet).	7,10
VM 6.1.2	**M**	Opioids are only accessed by regulated health-care providers.	
VM 6.1.3	**M**	Prescription pads are secured and away from patient access.	
VM 6.1.4		The facility has policies and practices in place process if diversion is suspected or confirmed.	
VM 6.1.5	**M**	The facility has a process in place in the event of discovering that there is loss or theft of targeted substance. *Mandatory reporting within 10 days of knowledge of loss/theft to Health Canada, Office of Controlled Substances, Compliance, Monitoring and Liaison Division (613 954-1541).*	6,9
VM 6.1.6	**M**	Records of acquisition, dispensing, administration and authorized disposal of controlled drugs and substances are current, complete, accurate and meet legal requirements: http://www.bcpharmacists.org/library/K-Forms/K-7_Others/9060-Narcotics_Inventory_Form_Sample.pdf	7,10
VM 6.1.7	**M**	Receipt records of all controlled drugs and substances (CDS) include the medication name and quantity, the date received and the supplier name and address.	11
VM 6.1.8	**M**	Dispensing/administration of controlled drugs and substances records include: • heading: name of facility, page number, medication name(s) and strength, unit of issue • main body: date, time, patient's name, medication name, quantity and form, the name of the practitioner who issued the order, the date the CDS was provided and the name/initials of the nurse/physician who provided the CDS	11
VM 6.1.9	**M**	Controlled drug and substance counts and reconciliation are documented and signed by a regulated health professional; the second regulated health professional (or designate) co-signs the record.	11
VM 6.1.10	**M**	Wastage is witnessed and co-signed by a regulated health professional (or designate).	11
VM 6.1.11	**M**	Explanation of all wastage or count deviations is recorded.	11

No.	Standard Criterion		Reference
VM 6.1.12	**M**	Records are retained for at least three years from the day of the last transaction in the log (College of Pharmacists of BC) (Health Canada requirement is two years).	11

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