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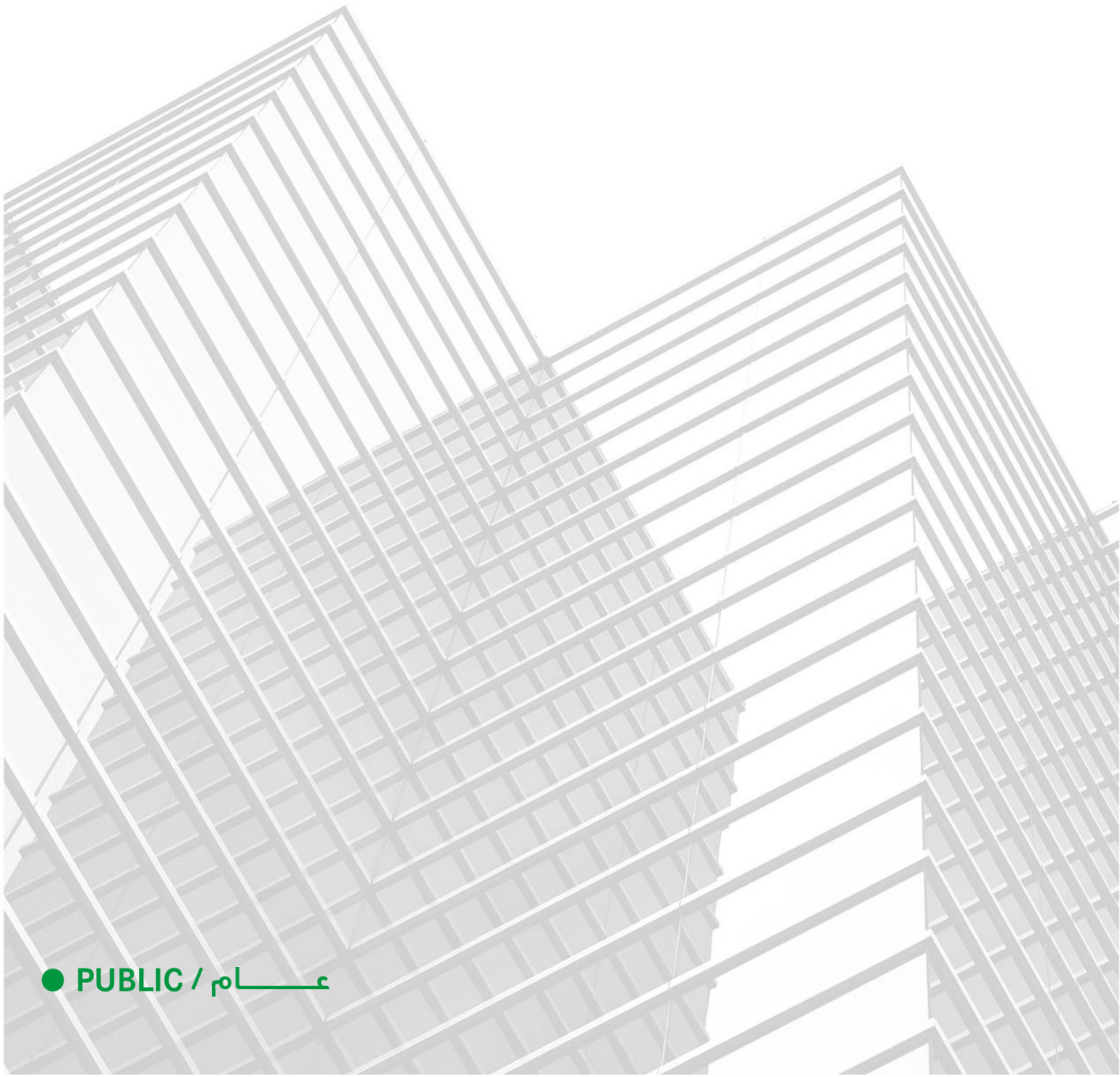
DEPARTMENT OF HEALTH

Standard on the Administration of Vaccines in Outpatient Pharmacies



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1.Standard Scope

1.1 This standard applies to all outpatient pharmacies qualified to deliver vaccinations, as well as pharmacists authorized by the Department of Health (DoH) as Pharmacist Vaccinators. It covers the administration of vaccines authorized for distribution in outpatient pharmacies in the Emirate of Abu Dhabi, specifically for population age groups 18 years and above.

1.2 Governed by this standard, DoH will announce the vaccines permitted to be provided in Outpatient Pharmacies in the Emirate of Abu Dhabi through quarterly or ad-hoc circulars issued to all licensed facilities in Abu Dhabi.

1.3 Compliance will be monitored through periodic DoH audits, staff competency reviews and adverse event reporting.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Outpatient pharmacy	A facility licensed by DoH to store, dispense, sell and display medical products directly to the public.
2.2	Cold Chain	A network of cold/freezer rooms, refrigerators, freezers & cold boxes that is organized and maintained by teams of people to ensure vaccine is kept at the right temperature to retain its potency, from the moment it leaves the vaccine manufacturer, through shipping and storage, until the moment it is administered.
2.3	Vaccination Qualified Pharmacy (VQPh)	Outpatient Pharmacy licensed by DoH to provide vaccination services in the Emirate of Abu Dhabi.
2.4	Pharmacist Vaccinator	DoH licensed Pharmacist to administer vaccines in the Vaccine Qualified Pharmacy (VQPh).
2.5	Vaccine coordinator	Pharmacist Vaccinator nominated by the facility to be responsible for cold chain, reporting and other vaccination activities.
2.6	Cold chain breach	An event that has led to vaccines being stored or transported in temperatures outside the required temperature range.
2.7	Datalogger	An electronic device that measures the current temperature 24/7 at preset intervals and records information that can then be downloaded/ accessed and reviewed.
2.8	Validation	The act of checking or proving the validity or accuracy of temperature monitoring equipment, to confirm that a sensor is recording accurately.
2.9	Patient	The vaccinated person or the person who visits the facility to be vaccinated.
2.10	Basic Life Support (BLS)	Freeze Sensitive Indicator.

2.11	Department of Health (DoH)	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi, Established based on law No. (10) of 2018
2.12	ADPHC	Abu Dhabi Public Health Center
2.13	AEFI	Adverse Events Following Immunization
2.14	ME	Medication Error
2.15	IIS	Immunization Information System

3.Standard Requirements and Specifications

All DoH licensed Vaccination Qualified Pharmacy (VQPh) should have the following in place:

3.1 A designated physical space within the outpatient pharmacy that meets the DoH's minimum requirements for administering vaccines, as detailed in Appendix 1.

3.2 A DoH licensed, trained, and certified Pharmacist Vaccinator

3.2.1 Pharmacist should be certified to be a vaccinator after attending a training course that is approved by the DoH for Administration of Vaccines by Pharmacists. (See Appendix 1)

3.3 Arrangements to ensure the availability of uninterrupted and continuous vaccination services throughout their facilities, including:

3.3.1 Maintaining an adequate supply of vaccines at all times by securing stock from the local agent or the DoH, in the case of national immunization vaccinations, based on the vaccine types approved by the DoH for administration in outpatient pharmacies.

3.3.2 Ensuring that resources (both equipment and personnel) are available to support the continuity of services.

3.4 Arrangements to determine when vaccine administration should occur based on a physician's order, standing orders, or protocols.

3.5 Written standard operating procedures and protocols compliant with DoH standards and guidelines to ensure:

3.5.1 Appropriate vaccine storage and handling:

3.5.1.1 Facilities must use continuous digital data loggers (DDLs) with automated alerts and 30-day storage memory to monitor refrigerator temperatures for vaccines. Temperature logs should be reviewed daily and retained for a minimum of 5 years.

3.5.1.2 Facilities must have a documented power outage protocol, including immediate actions, transfer procedures, and designated cold chain equipment.

3.5.1.3 Each facility must maintain access to backup cold storage units (e.g., portable vaccine-grade refrigerators or coolers with gel packs) for emergency use, validated for appropriate temperature ranges.

3.5.1.4 All staff involved in vaccine storage and handling must undergo initial and annual refresher training on cold chain principles, equipment use, and response to temperature excursions.

3.5.1.5 Temperature Disruption Response Protocol; to ensure vaccine integrity and patient safety in the event of a temperature excursion:

3.5.1.5.1 Document the date, time, and duration of the temperature excursion.

3.5.1.5.2 Check and record the minimum and maximum temperatures reached.

3.5.1.5.3 Visually inspect vaccines for any signs of damage (e.g., thawing).

3.5.1.5.4 Move vaccines to a designated quarantine storage unit.

3.5.1.5.5 Immediately notify the designated vaccine coordinator or supervisor.

3.5.1.5.6 Report the incident to the relevant DoH department or vaccine manufacturer.

3.5.1.5.7 Document all actions taken.

3.5.1.5.8 Training: All staff must be trained on this protocol annually.

3.5.1.6 Vaccine Transfer Stability Protocol; to maintain vaccine temperature stability during transfers between outpatient pharmacy branches, ensuring vaccine efficacy and safety:

3.5.1.6.1 Use validated insulated containers and pre-conditioned ice packs or coolant packs.

3.5.1.6.2 Ensure a functional Datalogger is available to monitor temperature.

3.5.1.6.3 Document the starting temperature of the vaccines.

3.5.1.6.4 Place vaccines in the insulated container, ensuring they do not directly contact the ice packs.

3.5.1.6.5 Use dividers or padding to prevent movement and damage.

3.5.1.6.6 Transport vaccines in a temperature-controlled vehicle.

3.5.1.6.7 Monitor the temperature inside the container throughout the transfer.

3.5.1.6.8 Upon arrival, immediately check and record the temperature inside the container.

3.5.1.6.9 Inspect vaccines for any signs of damage.

3.5.1.6.10 Document the receiving temperature and condition of the vaccines.

3.5.1.6.11 Store vaccines in the designated refrigerator or freezer promptly.

3.5.1.6.12 Maintain a log of all vaccine transfers, including date, time, origin, destination, vaccine types, quantities, temperatures, and personnel involved.

3.5.1.6.13 Training: All staff involved in vaccine transfer must be trained on this protocol.

3.5.2 Compliance with Occupational Safety and Health Administration (OSHA) requirements; Vaccination areas must adhere to infection control protocols including hand hygiene, PPE use, and spill response procedures. Regular safety drills should be conducted quarterly.

3.5.3 Safe administration of vaccinations; Pharmacists must follow a DoH-approved checklist during vaccine administration, including verification of patient eligibility, allergy screening, correct vaccine/dose, and 15-minute observation period.

3.5.4 Appropriate patient clinical needs assessment, screening and patient education. Pharmacy Vaccinators must document clinical history, prior immunizations, and contraindications in the patient's electronic medical record or DoH-approved registry prior to administration. (See Appendix 2)

3.5.5 Uphold confidentiality and patient privacy requirements.

3.5.6 Assessment of individual vaccination status; through vaccination card and records in IIS prior to administering a vaccine;

3.5.7 Post-immunization care

3.5.8 Appropriate vaccination documentation, management and recording of patient consent;

3.5.8.1 Documenting all vaccinations given through online e-notification system.

3.5.8.2 Submitting all incidents of suspected vaccine adverse events through the e-notification system: Adverse Event Following Immunization (AEFI).

3.5.9 Protocols for identification and management of adverse events following immunization;

3.5.10 Protocols for managing any emergency adverse or immediate reactions with access to Basic Life

Support (BLS)

3.5.11 Immunization reporting and management;

3.5.12 The medical management of vaccine reactions in adults in an outpatient setting;

3.5.13 Reporting adverse events following immunizations;

3.5.14 Reporting medication errors;

3.5.15 Support monitoring and auditing of immunization services by DoH;

3.5.16 Identify referral cases for vaccination to medical centers / hospitals; follow up to complete the immunization schedule for previously vaccinated within the pharmacy or high-risk population.

3.5.17 Having in place bloodborne pathogen exposure and needlestick protocol.

4.Key stakeholder Roles and Responsibilities

All DoH licensed Vaccination Qualified Pharmacy (VQPh) should fulfill the requirements for:

4.1 Adverse Events Following Immunization (AEFI)

4.1.1 All Vaccination Qualified Pharmacy (VQPh) must have readily available access to medications needed to handle any anaphylactic reaction.

4.1.2 The pharmacist vaccinator must be competent to manage anaphylaxis post vaccination, in accordance with the DoH Standard for Minimum Preparedness for Emergency Response in the Ambulatory Setting including identification of roles for staff working in the immediate area where vaccines will be administered.

4.1.3 The pharmacist vaccinator must ensure an ambulance is called to attend a person who experiences anaphylaxis post vaccination.

4.2 Payment Mechanism

4.2.1 Payment mechanism for Vaccination services shall be in accordance with Standard Provider Contract, DoH Mandatory Tariff, associated Claims and Adjudication Rules and related coverage regulations; all documents are available on https://www.DoH.gov.ae/en/Shafafiya ;

4.2.2 Coverage of vaccinations shall be in accordance with the health Insurance policy approved by DoH and provider network agreements.

5.Monitoring and Evaluation

5.1 Data Reporting:

All DoH licensed Pharmacist Vaccinators should:

5.1.1 Report and submit immunization data in a timely, accurate and complete manner to DoH using the DoH electronic Immunization in accordance to DoH data standards Information System (IIS). Submit reports when and as directed by DoH/ADPHC.

5.1.2 Reporting AEFI using electronic reporting system available at DoH website.

5.1.3 In the case of medication errors that directly involve the vaccine recipient, i.e., wrong medication/dose/route being administered or another medication error, the incident must also be reported to DoH within timeframe in line with Doh Policy on Reporting Medication Errors.

6.Enforcement and Sanctions

6.1 DoH may impose sanctions in relation to any breach of requirements under this Standard in accordance with the Disciplinary Regulations of the Healthcare Sector.

7.Exempted from Scope

N/A.

8. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	2016	Federal Decree-Law No. (4) of 2016 Concerning Medical Liability	https://uaelegislation.gov.ae/en/legislations/1192/download
2	2011	Standard for Safe Vaccine Handling and Cold Chain maintenance in the Emirate	https://www.doh.gov.ae/en/resources/standards
3	2008	Policy on Patient Rights and Responsibilities	https://www.doh.gov.ae/en/resources/policies
4	2024	Patient Consent Standard	https://www.doh.gov.ae/en/resources/standards
5	2015	Standard for Medical Record Health Information Retention and Disposal	https://www.doh.gov.ae/en/resources/standards
6	2024	Abu Dhabi Healthcare Information and Cyber Security Standard.	https://www.doh.gov.ae/en/resources/standards
7	2020	Policy on Health Information Exchange.	https://www.doh.gov.ae/en/resources/policies
8	2020	Digital Health Policy	https://www.doh.gov.ae/en/resources/policies
9	2012	Standard on Reporting Suspected Adverse Drug Reactions and Adverse Events Following Immunization	https://www.doh.gov.ae/en/resources/standards
10	2023	Standard on Reporting Medication Errors & Suspected Quality Problems Related to Medicinal Products and	https://www.doh.gov.ae/en/resources/standards
11	2024	Standard for Childhood and Young adult Immunization	https://www.doh.gov.ae/en/resources/standards
12	2025	Policy on Medical Waste Management in HCFs	https://www.doh.gov.ae/en/resources/policies
13	2007	Policy for Infection Control in the HCFs	https://www.doh.gov.ae/en/resources/policies
14	2019	EHSMS Standards	https://www.doh.gov.ae/en/resources/standards
15	2024	Pharmacist and Pharmacy Technician Scope of Practice	https://www.doh.gov.ae/en/resources/scope-of-practice

9. Appendices

APPENDIX 1: Licensing Requirements, Minimum Service Specifications for Pharmacist Vaccinators & Vaccination Site Auditing Requirements:

LICENSING REQUIREMENTS	DETAILS
1. Facility Licensing	A. Outpatient pharmacies can apply to provide this service through the e-licensing system "Add Service" by visiting: (Service Card-eligibility- Custom Components - TAMM - Manage the Details of the Healthcare Facility's License) I. Meet the minimum requirements of two (2) pharmacists with approved privilege from DoH. B. Meet the minimum pharmacy premise infrastructure requirements: i. Have a dedicated, clean, well-lit room for administration of the vaccine, with the minimum size of 5 square meters to be added within the pharmacy layout of (30 square meter) to have sufficient floor area for equipment and furniture and to allow the Pharmacist Vaccinator adequate space to maneuver. ii. Have a private and quiet space for consultation within 5 square meters (including pre-screening, answering client questions and assessment of any conditions that may preclude vaccination or require referral). iii. Have safe and directed access in pharmacy areas to allow movement of staff between areas while minimizing the risk of workplace incidents (e.g. moving doses from preparation area to client administration area, accessing refrigerators or cool boxes etc.). iv. Ensure client privacy and cultural sensitivity is adhered to in the vaccination room. v. Adequate handwashing facilities for staff, and antimicrobial hand sanitizers available. vi. Have visual reminders and cues in place to reduce the risk of errors. vii. Ensure compliance with the DoH waste management regulation. viii. Have adequate sharps disposal bins, appropriate for the number of clients served, and securely placed and spaced to mitigate the risk of needle stick injuries. ix. Appropriate security provisions to ensure no unauthorized access to vaccine doses. x. The observation area must be close enough to the immunization service provider, so that the individual can be observed and medical treatment rapidly provided if needed. xi. Have ready access to appropriate emergency equipment for managing anaphylaxis.
2. DOH licensed pharmacist	Vaccination services provided in outpatient pharmacies must be administered by a clinical pharmacist or a pharmacist licensed by DoH. Both must fulfill the following training requirements: i. Training Requirements for Vaccinator Pharmacists/Clinical Pharmacists: • Vaccination-related training • Must complete an accredited competency-based training program on vaccination, the training must include both didactic and hands-on experiential learning. This training should cover the necessary knowledge, skills, and competencies for the safe administration of vaccines by injection, as well as the management of adverse drug reactions and anaphylaxis. • Must undertake a refresher training every two years

	• Must hold current certificates in BLS. ii. Pharmacist mut be privileged by the Facility Clinical Privileging Committee to undertake the vaccination responsibility. (refer to DoH Standards for Healthcare workforce Clinical Privileging). iii. Pharmacists must be trained and oriented to the outpatient pharmacy standard operating procedures for vaccine and cold-chain management including but not limited to vaccine / cold-chain storage, temperature-monitoring device (operating data-logger), administration of vaccines, management of adverse reactions, etc. iv. Pharmacy technicians who are assigned responsibilities related to the supply-chain of vaccines and cold chain medicines management, including receiving, storage, and monitoring of temperature monitoring devices, must be trained on safe vaccine handling and cold chain management. v. Obtain DoH permission to be a Pharmacist Vaccinator by submitting a request to DoH through the TAMM portal vi. Review all relevant training modules when notifications of updates to current practices are received.
3. Vaccination Site Auditing Requirements	I. Vaccine inventory log (vaccine stock record) is maintained and current II. There is cold chain emergency backup plan and emergency staff contact list is current III. There is ''DO NOT UNPLUG'' sign next to the refrigerator electrical socket IV. Current list with the names of the vaccines and their expiry dates displayed outside the refrigerator door V. The refrigerator is dedicated for vaccines only, NO food, drinks, medicine or other items VI. Vaccines arranged inside refrigerator in accordance with the standard VII. First In First Out rule is applied and the vaccines stocked and rotated so that the newest vaccine of each type is placed behind or left the oldest vaccine VIII. The freezer compartment arranged with icepacks as advised IX. Vaccine carrier/cold box are prepared in accordance with the standard X. Opened multi-dose vials are labeled with date and time of opening XI. Vaccine vials remain from the vaccination session returned to the refrigerator and kept in specified container and not mixed with other vaccines XII. Vaccines vials remaining from the previous session are used first in the next session XIII. In the event of power or refrigerator failure, the person responsible will: • Inform the relevant person/s • Follow the emergency plan • Take immediate actions to keep the vaccine in the safe temperature zone Complete the cold chain failure form, send copy to DoH, keep the original copy at the health care facility.

APPENDIX 2: PRE-VACCINATION SCREENING[a]

Key Interview Questions for All Vaccines: The vaccinator screens for the following to identify contraindications and precautions and refers the client to the doctor if required for further advice

1. Is the client sick today[b]?
2. Does the client have any allergies to medications, food, or any vaccines?
3. Has the client had a serious reaction to a vaccine in the past[c]?
4. Has the client had a seizure or a brain (neurological) problem[d]?
5. Does the client have cancer, leukemia, AIDS, or any other immune system problem[e]?
6. Has the client taken cortisone, prednisone, other steroids, or anticancer drugs, like chemotherapy or radiotherapy in the past 3 months[e]?
7. Has the client received a transfusion of blood or blood products, or been given a medicine called immune (gamma) globulin in the past year[e]?
8. Is the female client pregnant or is there a chance she could become pregnant during the next month[e]?
2. Has the client received any vaccinations in the past 4 weeks[e]?
3. Does the client have a past history of Guillain-Barre syndrome/ has a chronic illness/ has a bleeding disorder?

a. As a precaution with moderate or severe acute illness, all vaccines must be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination.

b. If a person experiences anaphylaxis after eating eggs, do not administer influenza vaccine, or if a person has anaphylaxis after eating gelatin, do not administer MMR or varicella vaccine. Local reactions (e.g., a red eye following instillation of ophthalmic solution) are not contraindications.

c. History of anaphylactic reaction such as hives (urticaria), wheezing or difficulty breathing, or circulatory collapse or shock (not fainting) from a previous dose of vaccine or vaccine component is a contraindication for further doses.

d. History of encephalopathy within 7 days following DTP/DTaP/Td/Tdap or pertussis containing vaccine is a contraindication for further doses of pertussis-containing vaccine. Precautions to pertussis-containing vaccines include the following:

   i. Seizure within 3 days of a dose,

   ii. Pale or limp episode or collapse within 48 hours of a dose,

   iii. Fever of 40°C within 48 hours of a previous dose.
   Vaccinate as usual client with stable neurologic disorders (including seizures) unrelated to vaccination, or client with a family history of seizure, but consider the use of paracetamol or ibuprofen to minimize fever.

e. Live virus vaccines (e.g., MMR, Rubella, Varicella):

   i. Usually contraindicated in immunocompromised person, refer to specialist for advice.

   ii. Must be postponed until after chemotherapy or long-term high-dose steroid therapy has ended.

   iii. Contraindicated prior to and during pregnancy because of the theoretical risk of virus transmission to the fetus.

   iv. iv. If live injectable vaccines are not given on the same day, the doses must be separated by at least 4 weeks. Inactivated vaccines may be given at the same time or at any spacing interval.