BP 605 T. Pharmaceutical Biotechnology (Theory)

Storage conditions and stability of official vaccines

Dr Chandresh Sharma

Assistant Professor

Department of Biotechnology

Chhatrapati Shahu Ji Maharaj University, Kanpur

Overview

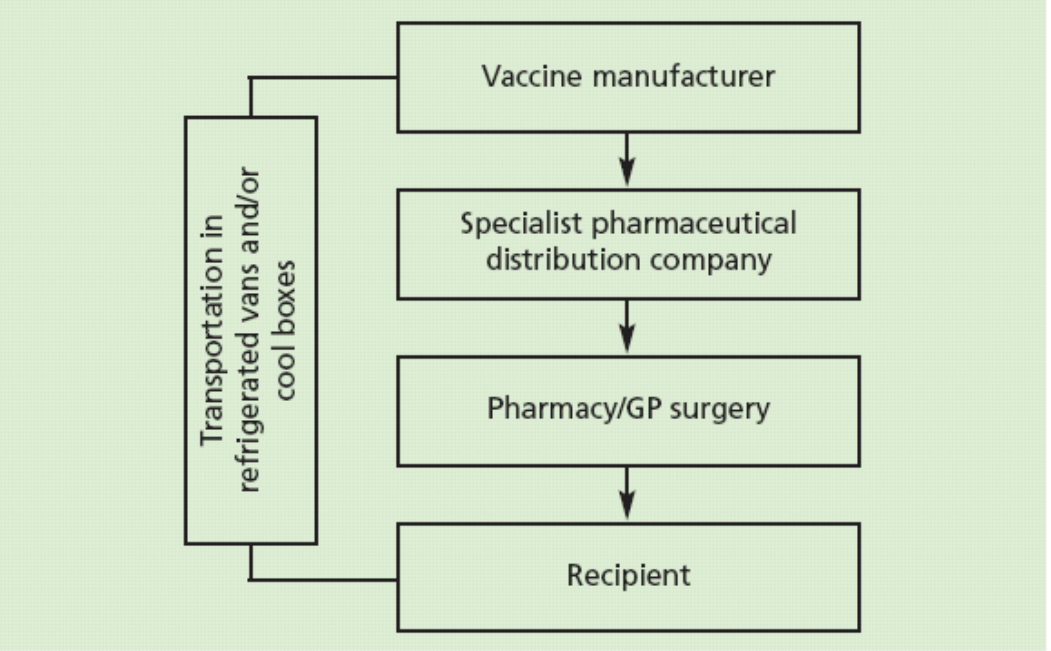
- Storage
- Cold chain or temperature management
- Distribution, Usage and Disposal.

The Cold Chain

Definition: Maintaining vaccines within the manufacturer's recommended storage temperature during transport and storage until the point of administration

Why is the "Cold chain" so important?

- ✓ Efficacy depends on correct storage conditions +2°C to + 8°C
- ✓ Compliance with Specific Product Characteristics and marketing authorisation
- ✓ Assurance and confidence in a potent product
- ✓ Ensuring maximum benefit from immunisation



Effect of Temperature on Vaccines

- ✓ Live vaccines
- ✓ tolerate freezing
- ✓ deteriorate rapidly after removal from freezer
- ✓ Inactivated vaccines
- ✓ damaged by exposure to freezing temperatures
- ✓ tolerate short time out of refrigeration

Storage

Storage of vaccines outside recommended storage temperatures can lead to:

- ✓ Deterioration in the vaccine and failure to produce a satisfactory level of immunity
  - **Heat speeds up decline in potency - ↓shelf life**
  - **Freezing causes**
    - **Increased reactogenicity & loss of potency**
    - **can lead to hair line cracks in ampoules, vials or pre-filled syringes causing contamination of contents**

Vaccine Stability

Temperature Sensitivity

- Sensitive to Cold and Heat

Light Sensitivity

- Sensitive to strong light, sunlight, ultraviolet and fluorescent light (neon)

- All vaccines should be stored in their original packaging until they are administered

Storage and Management of Vaccines

- ✓ Receipt and Transport
- ✓ Storage
- ✓ Temperature monitoring
- ✓ Use in vaccination sessions
- ✓ Disposal and spillage
- ✓ Disruption of the cold chain

Receipt of Vaccines

- ✓ Checked against order for discrepancies
  - Have vaccines been stored between 2°C – 8°C ?
- ✓ Inspect for leakage and damage
- ✓ Signed for and *refrigerated* immediately
- ✓ Record vaccine type, brand, quantity and batch numbers (date and time)

Transport of Vaccines

- ✓ Insulated validated cool boxes
- ✓ Cool boxes
  - Fridge packs
  - Frozen packs
- ✓ Spaces in cool box filled with insulating material
- ✓ Vaccines should not be in direct contact with cool packs

Transport of Vaccines

- ✓ Vaccines taken to schools or outside clinics must be transported so that the cold chain is maintained using validated insulated cool boxes
- ✓ Then transferred to a fridge if available or left in a validated cool box
- ✓ Unused vaccine transported in a validated cool box for a morning or afternoon session may be returned to the fridge with a note attached to use first
- ✓ Vaccines stored for 8 hours or more in a validated cool box should be disposed of and not returned to the fridge

Storage of Vaccines

- ✓ Within recommended storage temperatures between 2°C – 8°C

- ✓ Refrigerator Specifications:
  - Designed for storing medicines- Lockable
    - Minimal opening to maintain constant temperature
    - Ice build up *reduces* effectiveness
  - No items other than medicines stored in fridge (*e.g. food, drink, clinical specimens*)
  - Should *not* be over full
  - Ensure can not be accidentally switched off

Storage of Vaccines

- ✓ Vaccines
  - must not be removed from packaging during storage
  - Stocks stored tidily
  - Not stored on shelves in fridge doors or bottom drawers
  - Not stored next to freezing compartments
  - Patients/Parents should not be requested to store vaccines in a domestic fridge.
  - Fridges should be cleaned on a regular basis
  - Emergency storage available if fridge fails

Temperature Monitoring

- ✓ Fridges must have a reliable maximum/minimum thermometer (in addition to any integral thermometer)
  - Calibrate annually to ensure correct functioning
- ✓ Designated person responsible for vaccine storage and fridge monitoring
  - Trained to read and record current temperature, maximum and minimum temperatures correctly
- ✓ Readings should be taken daily
- ✓ Keep record chart on or near the fridge
- ✓ Retain records until next audit
- ✓ If the recorded temperature goes outside the range, contact community services pharmacy and or the manufacturer's for advice

Vaccination Sessions

- ✓ Use vaccines with shortest expiry first
- ✓ Vaccines should only be removed at the beginning of session for the shortest possible time
- ✓ Only remove the required number of doses for the session
- ✓ Prior to administration check the identity of the vaccine, its appearance and expiry date
- ✓ Record date, brand name, manufacturer, batch number and details of any diluent used in patients' notes
- ✓ Freeze dried vaccines should be reconstituted immediately prior to use and used within the recommended period
- ✓ Any remaining vaccine in vials should be drawn into a syringe and disposed of
    - Part vials, prepared unused vaccines and out of date vaccines should be placed in a sharps box labelled "Vaccine waste". The box should be sealed when two thirds full

Disposal of Vaccines

- ✓ In Health Centres the box will then be either collected by pharmacy technicians or returned to community services pharmacy on secure transport

- ✓ GP Practices should make arrangements for disposal of vaccine waste through their waste contractor

Acknowledgement

Pharmaceutical Biotechnology

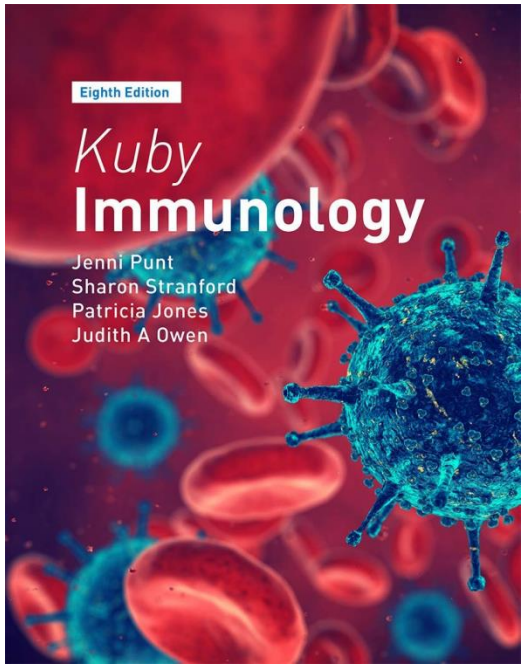
Concepts and Applications

Gary Walsh

University of Limerick, Republic of Ireland

Pearson Education Inc.

John Wiley & Sons, Ltd



For Query

chandreshsharma@csjmu.ac.in; sharmac3001@gmail.com