Plenary Session 2: Landscape
Integrated Reconstitution Devices

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Integrated reconstitution devices: Description

Technology description:
• Integrated reconstitution (IR) devices – a prefilled device designed to store, mix and deliver two or more components of a vaccine, most commonly a dry powder and diluent.

Examples include:
• Vial
  – Eulysis
• Prefilled Syringe
  – VaccJect
  – LyoGo
  – LyoTip
• Point of delivery
  – AktiVax ARCH
Overview:

- Dried vaccines requiring reconstitution place additional burden on the user in order to achieve safe delivery.
- Integrated reconstitution devices reduce the burden on the user by combining the reconstitution and often the delivery steps into a single device.
IR devices: Eulysis Single Vial System

Description:
• Glass vial system
• Cake stored in cap, diluent stored in vial
• Activated by pressing cap
• Delivery by separate needle and syringe

Status:
• E. coli vaccine tested in SVS
• Accelerated stability studies
• Available for research
IR devices: Duoject VaccJect

**Description:**
- ISO standard 1 ml glass cartridge contains powder & diluent
- Delivery using single use, retractable needle delivery device

**Status:**
- ISO facilities in France and Canada
- Seeking 510(k) approval
IR devices: LyoGo

Description:

• Glass cartridge contains powder & diluent
• Valve inside intermediate stopper activates with pressure
• Screw on plunger and needle

Status:

• Available for research
IR devices: LyoTip

**Description:**
- Lyophilized vaccine contained within screw cap
- Attached to luer-lock prefilled syringe
- Reconstitution and delivery step combined

**Status:**
- Commercially available
IR devices: AktiVax ARCH

Description:
• ARCH (Aseptic Reconstitution Package Hybrid)
• Frangible seal between compartments
• Deliver using variety of methods

Status:
• In development
• SBIR funding
IR devices: Benefits and challenges

Benefits:
• Reduced burden (and errors) associated reconstitution and delivery
• Can be used with existing or new vaccines
• Compatible for all routes of administration

Challenges:
• Complexity and cost
• Maintaining integrity of dry powder
• May require non-standard filling lines
• Cold chain volume
IR devices: Opportunities and way forward

Challenges for global public health:

• Value proposition
• Vaccine application (cost/benefit trade-off)

Technology availability:

• Most technologies are available for clinical research
• Application to additional vaccines