

---

# Roadmap toward an International Standard for Prefillable, Disposable Jet Injection Cartridges

Martin Friede Ph.D.

Initiative For Vaccine Research

World Health Organization



---

Need for  
~~Roadmap toward~~ an International  
Standard for Prefillable,  
Disposable Jet Injection  
Cartridges

Martin Friede Ph.D.

Initiative For Vaccine Research

World Health Organization



# Disposable cartridge jet injectors

---

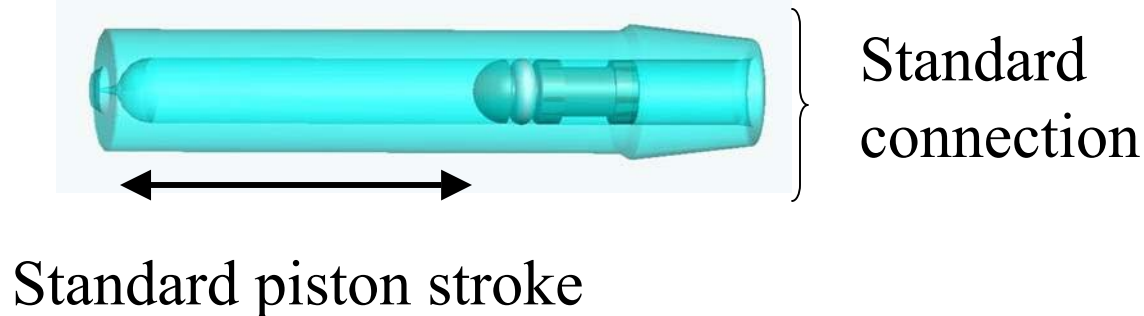
- Advantages:
  - needle-free
  - no risk of blood transmission
  - No fluid-path issues
  - no need to reformulate vaccine
- Issues:
  - lyophilised vaccines: need to fill in field (device)
  - field fill : potential contamination, logistics
  - pre-fill : vaccine manufacturer, cost, cold-chain space
  - need device (injector) to administer vaccine
  - **incompatible models** → **Logistic nightmare !!**



# Standardization for Immunization

---

- There is only room for ONE standard immunization cartridge format
  - Fits all immunization jet injector devices
  - Injectors use standardized socket



# How to Standardize ?

---

- Option 1: Don't.
  - Let market forces select the device and cartridge.
- Disadvantage:
  - may finish up with multiple standards
  - lack of standard may prevent investment in field
  - standard implemented may be controlled by a single industry/manufacturer not interested in public sector concerns.



# How to Standardize ?

---

- Option 2: Choose an existing format based on:
  - design advantages
  - willingness of manufacturer to offer non-exclusive licenses on cartridge (and on injector head)
- Disadvantage:
  - Good design ideas from other manufacturers excluded



# How to Standardize ?

---

- Option 3: Develop a list of desired specifications. Put out design tender.
- Disadvantage
  - May need to negotiate IP on some aspects
  - Existing development 'lost'
  - Cost of developing new design



# Selection Criteria

---

- Perspectives from
  - Device manufacturer
  - Cartridge manufacturer
  - Vaccine manufacturer
  - Users





# Device/cartridge manufacturer perspective

---

- Potential market is 1,500,000,000 cartridges per year.
- What is effective market ?
- Require exclusive / monopoly to justify risk ?
- Require Guaranteed market ?



# Vaccine Manufacturer perspective

---

- Pre-filling liquid vaccines at manufacturer
  - Cartridge material compatible with vaccines
  - Adaptable to high-speed filling line
  - Reliable supplier(s) of cartridges
  - Regulatory issues
- Market
  - Industrialised: perceived added value (cf pre-filled syringes) ?
  - Developing: guaranteed purchase ?



# User perspective

---

- Cost
  - Purchase cost
  - Recurrent costs
- Safety
- Device supply and maintenance
- Cartridge supply
- Option for field-fill
- Disposal method
- Package volume
- ...



# Proposed path

---

- Meeting of Interested Parties: May 2004 ?
  - Vaccine manufacturers
  - Jet Injector manufacturers
  - Cartridge manufacturers
  - Users: WHO, UNICEF, GAVI, CDC, FDA...etc.
- Objectives
  - Determine interest from industry
  - Feasibility / challenges to pre-filling
  - Criteria for a standardised cartridge



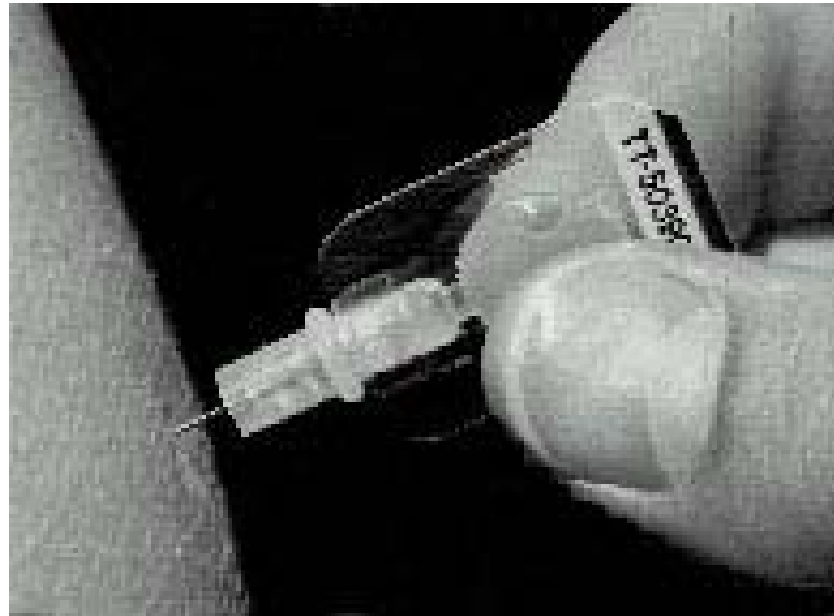
# Challenges to implementing new technologies

---

- Making a technology is not enough

eg. Uniject

- great idea
- poor uptake



# Requirement for implementing new immunization technologies

---

- Need
- Impact
- Cost effectiveness
- Buy-in (marketing) from :
  - vaccine manufacturer (formulation, fill, label)
  - purchaser / distributor /user
  - Unicef, EPI, Governments,...
- Policy, training, logistics,.....

