The Science and Technology of Vaccine Delivery Systems

National Influenza Vaccine Summit
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Chris Colwell, MPP
Becton, Dickinson and Company

“Helping all people live healthy lives”

- Reduce spread of infection
- Advance global health
- Enhance therapy
- Improve disease management
Outline

- Role of vaccine delivery technologies in
  - Rational development of vaccines
  - Achieving immunization goals
  - Supporting best clinical practices

- Innovations in vaccine delivery

Vaccine Delivery Systems: Element of Rational Design

- Enhance access and improve immunization efforts
  - Resource settings
  - HCW preference & safety
  - Extend supply, increase access
  - Reduce patient hesitancy

- Promote high quality clinical practice

- Enhancing efficiency of vaccine administration
  - Routine / Mass vaccination / pandemic considerations

- Enhance immune response
Vaccine Delivery Systems: Achieving Immunization Goals

Developing world immunization strategies:
- Reuse prevention
- Healthcare worker safety
- Simplified logistics
- Economical

Global health campaigns:
- Maternal and neonatal tetanus (MNT)
- Measles Initiative (American Red Cross, CDC, Unicef)
- IAVI partnership
- Haiti earthquake response

Vaccine Delivery Systems: Achieving Immunization Goals

Domestic and global campaigns:
- Global smallpox eradication campaign
- Salk polio trials and polio eradication campaign
- 2009 H1N1 response
  - Lessons learned
  - Need for stockpiling
“5 Rights” *
1) Right vaccine
2) … patient
3) … time
4) … dose
5) …. route, site, needle

Achieved through:
• Policy
• Clinical Training
• Technology

*“Pediatric vaccination errors: Application of the ‘5 rights’ framework to a national error reporting database,” by Dr. Bundy, Andrew D. Shore, Ph.D., Laura L. Morlock, Ph.D., and Marlene R. Miller, M.D., in the June 2009 Vaccine 27(29), pp. 3890-3896.

Policy, Guidance and Regulation

• ACIP General Recommendations on Immunizations
• “The Pink Book”
• The Joint Commission (TJC)
• USP 797
Supporting Best Clinical Practices: Training

- Injection route and site
- Sterile technique
- Infection control
  - Patients
  - HCWs
- Patient records

*BD Just-In-Time Injection Training (web accessible)*

Deviations from Best Practices Observed in the Field

- Neglecting to write the date it was opened on a vial
- Not properly sterilizing the rubber stopper prior to withdrawing vaccine dose
- Trusting memory to remember the lot number when transcribing it
- Pre-drawing flu vaccine was extremely common
- Pre-drawing the day before or using leftover pre-drawn syringes from a prior day
- Syringes were often left out unrefrigerated for long periods of time and, in some cases, for a whole day
- Drawing vaccine from multiple vials, especially without checking if the lot numbers are the same

*Dr. David Bishai, JHU WVC 2010 presentation*
Supporting Best Clinical Practices: Technology Solutions

A variety of safety-engineered devices for infection control are available

- BD Integra™
- BD SafetyGlide™
- BD Eclipse™
- BD Safety-Lok™

Integrated Delivery Devices (prefilled syringes)

- Non-integrated Delivery System
  Delivery: Disposable Syringe
  Container: Vial

- Integrated Delivery System
  Delivery and Container: Manufacturer Prefilled Delivery System (MPFS)

- In the US, non-integrated delivery systems have been predominantly used for vaccine administration.
- In Europe, approximately 93% of liquid vaccines are administered using manufacturer prefilled delivery systems (in this case, primarily prefilled syringes).

1. IMS Health MIDAS 2007
Outline

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Immune Response as a Function of Route of Administration
Innovations in Vaccine Delivery

**Intradermal**

Prefill Intradermal System with specially-designed skin-contacting geometry & micro-needle

**Nasal and Pulmonary**

Prefill Intranasal System provides a non-invasive ROA to potentially impact patient compliance

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**BD Soluvia™ Microinjection System**

- Specially-designed ID skin-contacting element and microneedle
- Absence of fluid leakage from the injection site
- Safety-engineered for needle-stick prevention
- Reproducibility
- Reduced need for training
- Designed for use with stable vaccines that can be pre-filled and stored at 4°C
- Being commercialized with sanofi pasteur
Gates Grand Challenges in Global Health

• “Needle Free Vaccine Delivery”
• Funded through Gates Foundation & administered by FNIH
• Aktiv-Dry is the Principal on the Award and is developing a dry powder measles vaccine
• Serum Institute of India (SII) is the vaccine supplier and is responsible for powder vaccine production, device filling and a Phase I clinical trial in India
• BD’s role is to develop a device for respiratory delivery of measles vaccine

BD Solovent for Respiratory Delivery of Dry Powders

Pulmonary Solovent

Proprietary Container for Dry Powders

Nasal Solovent
Vaccine Delivery Systems: Summary

- Vaccine administration systems/devices have played and will continue to play an important role in successful vaccination campaigns.

- We can continue to **advance best clinical practices** and **advance immunization goals** through policy, training, and product technology.

- Continued innovations in delivery systems/devices will enhance the vaccine enterprise in local and global health vaccination initiatives.