The Science and Technology of Vaccine Delivery Systems

National Influenza Vaccine Summit
May 2010

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Becton, Dickinson and Company

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"Helping all people live healthy lives"

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

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Outline

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

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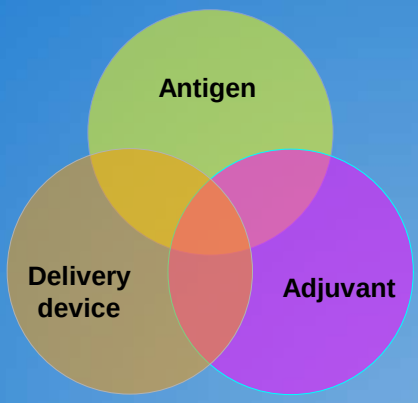
Vaccine Delivery Systems: Element of Rational Design

- **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**



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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

BD Uniject™ Prefill Injection Device

BD SoloShot™ Auto-Disable Syringe

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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

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Vaccine Delivery Systems: Supporting Best Clinical Practices

"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.

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Policy, Guidance and Regulation

- **ACIP General Recommendations on Immunizations**
- **"The Pink Book"**
- **The Joint Commission (TJC)**
- **USP 797**

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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)

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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

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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™

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Supporting Best Clinical Practices: *Technology Solutions*

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]

[1] IMS Health MIDAS 2007

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Immune Response as a Function of Route of Administration

Dose Sparing with Intradermal Injection of Influenza Vaccine

Richard T. Kenney, M.D., Sarah A. Frech, D.V.M., Larry R. Muenz, Ph.D., Christina P. Villar, M.P.H., and Gregory M. Glenn, M.D.

Preclinical Evaluation of Microneedle Technology for Intradermal Delivery of Influenza Vaccines

Jason B. Alarcon, Andrea Waterston Hartley, Noel G. Harvey, and John A. Mikszta*

BD Technologies, Research Triangle Park, North Carolina 27709

Received 17 October 2006/Returned for modification 12 December 2006/Accepted 16 February 2007

Multigene/Multisubtype HIV-1 Vaccine Induces Potent Cellular and Humoral Immune Responses by Needle-Free Intradermal Delivery

Andreas Bråve, Karl Ljungberg, Andreas Boberg, Erik Rollman, Maria Isaguliants, Björn Lundgren, Pontus Blomberg, Jorma Hinkula, and Britta Wahren

A novel dry powder influenza vaccine and intranasal delivery technology: induction of systemic and mucosal immune responses in rats

Juan Huang, Robert J. Garmise, Timothy M. Crowder, Kevin Mar, C. Robin Hwang, Anthony J. Hickey, John A. Mikszta, Vincent J. Sullivan

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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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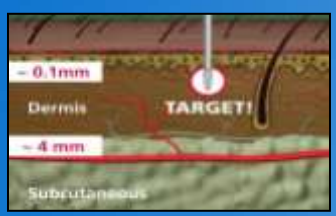
BD Soluvia™ Microinjection System



- 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 4C
- Being commercialized with sanofi pasteur

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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

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BD Solovent for Respiratory Delivery of Dry Powders

Proprietary Container for Dry Powders

Pulmonary Solovent

Nasal Solovent

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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 goal***s through policy, training, and product technology
- Continued innovations in delivery systems/devices will enhance the vaccine enterprise in local and global health vaccination initiatives