

Next Generation Vaccine Delivery Technologies Meeting

Considerations from Day 1

Technologies Reviewed

- AD Syringes
- Jet injectors
- Uniject
- Aerosols
- Dry powder inhalation
- Vaccine vial monitors
- i.d. devices
- Microneedle patches
- Mucosal immunization
- Electroporation

Technologies/Issues Reviewed

- Primary container design
- Reconstitution devices
- Thermostability
 - Freeze stability
 - Heat stability
- Value Proposition for increasing thermostability of vaccines

Getting Traction

- Ensure that technology is addressing an essential problem and is not a solution looking for a problem ('nice to have')
- Public sector needs to agree on what it wants, avoid confusing signals.
- Impact quantification needed in terms of lives and costs saved, not just acceptance of a new delivery technology.
- Better definition of improvement of a new product over what exists:
 - efficacy (how much is significant?);
 - financial (how measured?);
 - health care worker time (is it valued?)
- Global leadership is key factor for success: Groups of stakeholders and individual champions that believe in and push for change (i.e. VVMs, AD syringes)

Getting Traction

- Simplicity is key given concerns about complexity of separate delivery technologies for different antigens (e.g. aerosol, jets, patches, uniject).
- Large purchasing agreements (e.g. GAVI, UNICEF SD) were critical to widespread adoption of technologies (e.g. AD syringes, VVMs).
- Need for 'pull mechanisms' for influencing vaccine delivery technology development for developing country markets?
- Parallel streams of investment are possible (short, medium, long-term), e.g. continuation of cold chain strengthening and vaccine thermostability research.
- Late stage, prequalified technologies need boost to get to market (to avoid developers' frustration).

Regulatory Issues

- Regulations today are tighter—more rigor but also better monitoring of safety.
- Call for improved guidance on regulatory pathways.
- Critical to set a standard and stick to it – constant changes (even improvements) – may lead in partners losing interest
- Early discussions with regulators for new categories of products are critical.
- Acceptance of ‘game changer’ technologies take more time and require more effort.
- New vaccine delivery devices/primary containers require approval of device and re-labelling of the vaccine -> Partnering with vaccine manufacturer who may or may not be willing to take an early stage risk.
- Each device may need to be licensed/ approved in each country of use. For small companies, this can be particularly challenging.

Purchasing Decisions

- Cost often trumps value. Current vaccine purchasing decisions do not look at which product has the lowest cost per dose administered (systems cost); instead focus on cost per dose purchased.
- Cost-benefit analysis does not necessarily reflect who pays and who benefits.
- For lower cost vaccines, new delivery technologies are harder to justify given significant cost implication relative to the (low) price. Changing price of vaccines leads to changes in value proposition for delivery devices
- Safety issues are often undervalued, but can also be detrimentally overemphasised as part of purchasing decisions.

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