Prospective Models of Vaccine Security Collaborations in National Immunization Programme (NIP)

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Vaccine Supply and Quality
Vaccine as public good

Which benefit is Non-excludable and Non-rivalry in consumption. Prevention of communicable diseases is non-excludable; that is, all people will benefit from this prevention. Also there is non-rivalry in consumption; that is, one person who benefits does not stop another from benefiting.

Prevention of communicable diseases that can spread from one population to another on a global scale is thus a global public good. It follows then that access to specific vaccines is an international, and not strictly a national, issue, requiring international coordination and co-operation.

It also follows that monopolization of access to limited vaccine supplies by any one country or region in the event of an outbreak will represent failure to attain this global public good.

“Julie Milstien & Al. Emergency response vaccines - a challenge for the public sector and the vaccine industry”
WHO PQ Vaccine Supply

- In 2001, 9 WHO PQ vaccines available through UNICEF from 13 Manufacturers.
- 2014, 36 WHO PQ vaccines from 28 manufacturers from 21 countries.
- The number of vaccine producers in LMIC increased from 15% in 2001 to 35% in 2014.

![Bar chart showing number of vaccine and number of producers in 2001 and 2014.]

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PQ vaccine availability much better than in 2001 however, some vaccines are still in short supply.

2001
- DTP-HepB and DTP-HepB-Hib vaccines 1 manufacturer
- MMR and MR no PQ manufacturer

2014
- DTP-HepB and DTP-HepB-Hib vaccines 6 manufacturers
- MMR 4 manufacturers
- MR, Rubella, Typhoid, Meningo A, DTPa have one manufacturer.
Concerns of vaccine security in SEA countries

- Several SEAR countries are graduating countries under the GAVI Alliance eligibility criteria.
- Countries in SEARO e.g. Myanmar, Thailand, Timor Leste experienced shortages of EPI vaccines.
- MoH Sri Lanka, Bhutan and Maldives requested IVD to explore options for cost-effective mechanisms to procure vaccines post-GAVI support.
- Out of the 11 SEAR Member States, 4 have significant manufacturing capacity (India, Indonesia and Thailand) or are in the process of building it (Bangladesh).
National Vaccine procurement policy for the NIP in SEARO

• IN SEA region 5 out of 11 procure traditional EPI vaccine through national procurement agency
• 8 countries out of 11 are self-financing for traditional EPI vaccines
• Out of 8 countries with no production of EPI vaccine 3 are using UNICEF procurement services
• All countries using GAVI funds to supply new vaccines are procured through UNICEF.
Vaccine different than other medicines

- stringent regulatory requirements
- complex to manufacture,
- requires a lot by lot release
- there are Temperature Time Sensitive Pharmaceutical Products (TTSPP) with short expiry dates.
- Safety, quality and efficacy to be monitored in post-marketing phase
- Very few producers of vaccine compared to medicines
Challenges and opportunities

Vaccines require expertise for the procurement, regulatory requirements, storage, and distribution. Trained staff is required to:

- understand vaccine market to identify appropriate procurement strategy,
- review vaccine dossier for MA, to assess production process, to understand the WHO PQ scheme, to license the vaccine and monitor safety quality and efficacy of the products,
- store and distribute vaccine under a control cold chain infrastructure to ensure that the vaccine is potent until it is administered.

Coordinated collaboration among countries to share vaccine suppliers information - WHO V3P project

Standardization of regulatory procedures and mutual recognition to assist licensing procedures in LIC with limited expertise

Active collaboration with medical institutes and faculties of public health to conduct operational and other post-marketing vaccine safety studies.

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Challenges and opportunities

- Involve private/public partners to make informed decision for vaccine R&D at national and regional levels.
- Exchange suppliers information and established multi-year Long Term Agreement with manufacturers for vaccine procurement.
- Share AEFI reports with manufacturers and regulators not only at the time of the market authorization but also during the post-marketing phase once the vaccine is used in the NIP.

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Vaccine supply forecast

• Vaccine requirements can be classified into 3 categories:
  
  – Vaccine for NIP e.g.: BCG, Measles and/or MCV, DTP-HepB-Hib, Td, DT and where disease epidemiology supports them e.g. JE, HPV, Thypoid, Rubella
  
  – Vaccine for SIA e.g. polio eradication and measles elimination that are part of global initiatives and vaccines that are recommended by WHO
  
  – Vaccine for outbreak response i.e. Influenza pandemic
Vaccine pool procurement

Pooled procurement is a generic term encompassing different forms of group activities within defined parameters established to improve the outcomes of procurement for the individual members of the group.

Pooled Procurement ranges from group learning activities through to distinct and structured legal arrangements and delegation of procurement activities to a central authority.
Group procurement models

1. Informed buying
   - Member Countries share information about suppliers and products
   - Member Countries conduct procurement individually

2. Coordinated informed buying
   - Member Countries undertake joint market research, share supplier performance info and monitor prices
   - Member Countries conduct procurement individually
Group procurement models

3. Group Contracting

- Member Countries jointly negotiate prices and select suppliers.
- Member countries agree to purchase from selected suppliers.
- Member Countries conduct procurement individually.

4. Central Contracting

- Member Countries jointly conduct tenders and award contracts through an organization acting on their behalf.
- The central buying unit manages the purchases on behalf of Member Countries.
- Tender preparation committee
- Tender Opening Committee
- Tender Award Committee
- An Executive Board
- Etc...

All require long term political commitments and long negotiations toward agreed procedures for the management and standards to be applied.
To establish pool procurement mechanisms

• Pooled procurement mechanisms require a great deal of negotiations and preparations to be successful
• It requires compliance at national level with internationally recognized regulatory procedures and Good Procurement Practices for public sector
• A gradual approach is recommended starting with informed buying mechanisms to acquire product knowledge, vaccine market understanding and to have better analysis of demand and supply forecasts
Way forward

• MLIC in SEA procuring vaccine through UNICEF need to better understand vaccine market to be able once donor support will end to make informed decision about vaccine procurement policy

• Countries which procure vaccine directly should explore possibility to establish multi-year LTA to improve predictability of demand

• All countries would benefit from informed buying and coordinated buying pool procurement mechanisms and as the system become mature to move into more complex Group contracting and central contracting with countries in the region interested to get together to procure vaccine of assured quality at affordable price.
Thank you