Vaccine safety monitoring: challenges with new vaccine introduction

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The ‘new’ challenges for immunization

Targeted development of vaccines to meet developing country requirements
  • e.g., liquid pentavalent, mening polysaccharide and conjugate, JE vaccines

Contemporary introduction of vaccines globally
  • e.g., rotavirus, HPV, pneumo conjugate vaccines

External donor support reduces traditional gap of 15-20 yrs before "new" vaccines become available to low/lower middle income countries.

Source: UNICEF Supply Division
Special safety considerations for new vaccine introduction

- **New vaccine or new manufacturer**
  - No (or limited) post-licensure safety experience
  - Sensitivity to potential safety issues heightened (providers + public)

- **New or different target populations**

- **Other pressures**
  - Programme versus political (decisions re vaccine withdrawal/suspension)
  - Donor funding (multiple stakeholders)
  - Internal and external media attention

Vaccine safety "factsheets" are an essential tool for introduction!
Example of "new vaccine" safety crisis

- Liquid pentavalent (DTwP-HepB-Hib) vaccine
  
  **Sri Lanka (April 08)**
  - Suspension 3 mths after introduction following deaths
  - concern about a "new" reaction (hypotonic-hyporesponsive episodes)

  **Pakistan (Dec 08)**
  - Temporary suspension in two health units 3 months after introduction following deaths

- No causal link to pentavalent vaccine found in either case.
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<th>Activities to address key safety challenges</th>
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<td>Global crisis management plan</td>
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<td>Global Network for Postmarketing Surveillance of PQ vaccines</td>
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Currently multiple resources for managing crises (incl. communication)
Global vaccine safety crisis management: Defining a way forward

**Objective**

By end 2009: Establish a plan/strategy for the effective management of vaccine safety crises of potential global importance.

Desired features:
- Timely response
- Proactive rather than reactive
- Effective (i.e., produce results)
- Efficient (optimum use of resources)
- Feasible, acceptable and adaptable (consultation process)
Global network for postmarketing surveillance (PMS) of PQ vaccines

- To support vaccine PQ programme with safety data in post-marketing phase

**Objectives**

- Ensure standardised approach to monitoring AEFIIs
- Identify/address safety signals (potential real safety issues) in timely manner
- Ensure adequate safety information to support vaccination policy and recommendations
  - possible need for more controlled studies
Improving vaccine safety monitoring through UMC:

- Capacity for global monitoring (global database)
- Capacity for risk assessment (signal detection + evaluation)
- Improved use of reporting standards (vaccines + AEFI)
- Increased awareness among AEFI surveillance programmes
- New vaccine safety officer as of 1 March 2009
PMS Network: Structure

Members (11)
Senegal, Uganda, Brazil
Mexico, Iran, Tunisia, Albania
Kazakhstan, India (1 State)
Sri Lanka, Vietnam

Uppsala Monitoring Centre (UMC)
WHO Collaborating Centre for International Drug Monitoring

Network Secretariat & Management Group
WHO (HQ, Regions), UMC
UNICEF + PAHO Revolving Fund
Representation of Member Countries

Technical Oversight Committee

- Funding source: Gates Foundation PQ grant (approx 3.8 million USD)
PMS Network: Key implementation steps (2009)

- Pre-implementation meetings and consultations
  2007-2008

- Finalize government agreements on membership
  Nov 08 to Q1 09 (HQ and NS) (Industry briefing?)

- Finalize management structures

- Advocacy & communication (industry etc.)

- Finalize data submission parameters + analysis framework (*Regular data to UMC from mid-09*)
  April 09 (NMG, TOC)

- Country needs assessment + support

- Network meetings (1-2 per year)
  Rolling basis NS (+ consultants)

NS: Network Secretariat, NMG: Network Management Group, TOC: Technical Oversight Cttee
PMS Network: Expected outputs

- Improved reporting and analysis of vaccine safety data at global level
  - Quality of data
  - WHO-UMC tools and resources for vaccines
  - Signal generation

- Improved assessment of causality
  - Investigation capacity
  - Individual case causality assessment
  - Assessment of signals (special studies as needed)
Defining longer-term solutions

What will it take to maintain/improve public trust?

- Openness and honesty in communication
  - attitude change

- Strategies for trust-building in immunization programmes
  - budget/resources + capacity to deliver specific services

- Global investment in the science to build evidence
  - more advanced methods of risk assessment
  - resources for research
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