COVID19 Vaccine Safety: Challenges and Opportunities

Dr Shanthi Pal
Team Lead (a.i)
Pharmacovigilance
Department of Regulation and Prequalification
COVID19 Vaccines: unprecedented x 4

- Development - 6-12 months
- Deployment - Billions of doses over 12-18 months
- New technologies- never approved in vaccines for human use
- Potentially many different vaccines
More than ever a need for

- systems to rapidly detect and minimise serious risks to patients
- near real-time data
- proactive vigilance: hot pursuit of safety concerns of special interest
- collaboration, to come together, to share knowledge, experience and information
- stemming unfounded safety concerns
But, we are not starting from scratch

We have leverage

• Platforms
• Partners
• Presence
• Precedence
WHO Global Adverse Events database has
• 23+ million reports
• 1,528,421 AEFI reports

100+ Member States supported with a national database, VigiFlow

Reporting tools available: paper-based, e-Reporting, App-based, web-based....

As on 26 August 2020: 170 Member States of the WHO PIDM have PV systems

Global Vaccine Safety Blueprint

Developed with and for low- and middle-countries

8 Implementation Objectives of the Global Vaccine Safety Blueprint 1.0

- **AEFI Detection:** To strengthen vaccine safety monitoring in all countries
- **Investigation of Safety Signals:** To strengthen the ability of countries to investigate vaccine safety signals
- **Vaccine Safety Communication:** To develop vaccine safety communication plans at country level
- **Tools and Methods:** To develop internationally harmonized tools and methods to support country vaccine safety activities
- **Regulatory Framework:** To promote a legal, regulatory and administrative framework for the safety of vaccines at national, regional and international levels
- **Technical Support and Trainings:** To strengthen regional and global technical-support platforms that meet countries’ expressed needs
- **Global Analysis and Response:** To provide expert advice on vaccine safety issues at national, regional and international level
- **Public-Private Information Exchange:** To put in place systems for appropriate interaction between national govts, multilateral agencies and manufacturers

A capacity-building model towards, at least, a **minimal capacity** for vaccine pharmacovigilance.

Solutions for **enhanced** vaccine pharmacovigilance capacity to adequately monitor newly available vaccine products.

Access to **technical support** from institutions with adequate expertise, cultural and geographical proximity through an integrated **network**.

GVS blueprint implemented through a large collaborative partnership: Global Vaccine Safety Initiative
% and number of countries reporting* at least 10 per 100000 AEFI cases by WHO Region 2010, 2016, 2017 and 2018
GVSI - Measuring progress
AEFI reports 2010 & 2018

Countries meeting GVAP indicator
2010

Countries meeting GVAP indicator
2018

GVAP indicator: a country is said to have minimal capacity if it reports at least 10 (AEFI) cases per 100,000 surviving infants per year
Utility of the Blueprint and GVI

Utility of Support

- PPI Exchange
- Global Analysis and Response
- Technical Support and Trainings
- Regulatory Framework
- Tools and Methods
- Vaccine Safety Communication
- Investigation of Safety Signals
- AEFI Detection

Legend:
- Green: Extremely Useful
- Teal: Somewhat Useful
- Orange: Not Useful
- Red: Not Applicable

https://www.who.int/vaccine_safety/publications/2019_Landscape_Analysis.pdf?ua=1
Global Vaccine Safety Blueprint 2.0 – What is different?

Moving from minimal/enhanced capacity to a maturity level concept

- Aligns with the WHO NRA benchmarking tool
- Aligns with the Immunization Agenda 2030
Global Advisory Committee on Vaccine safety (GACVS)

Background and mandate

- Established in 1999
- Provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short or long term national immunization programmes:

GACVS

- Risk Assessment of vaccines and provides recommendations to the SAGE* that makes policy decisions
- Advices on vaccine safety monitoring systems, tools and studies
- Significant role in composing scientific messages for use by risk communicators

*SAGE: Strategic Advisory Group of Experts on Immunization. SAGE is the principal advisory group to WHO for vaccines and immunization [https://www.who.int/immunization/policy/sage/en/]
Global Advisory Committee on Vaccine Safety (GACVS)

Standing committee:

- 15 global experts
- Meets twice a year
- Regular consultation and interaction between members during the year (working groups)
- GACVS alert

Agenda developed/proposed by:

- The secretariat and current/former members
- Strategic Advisory Group of Experts (SAGE) on Immunization

Recommendations

- Published in the Weekly epidemiological record and disseminated through WHO website and electronic newsletter

https://www.who.int/vaccine_safety/committee/en/
Extraordinary meeting of GACVS on COVID19 Vaccine Safety, May 2020

The COVID-19 vaccines in the pipeline and current lead candidates under consideration

Potential adverse events of special interest (AESI) with COVID vaccines

Regulatory perspectives and approaches in the context of COVID-19 vaccine introduction

The application of standardized templates for risk/benefit assessment of vaccines


GACVS Recommendations published

https://www.who.int/wer/2020/wer9528/en/
To conclude

- Introducing, on a very large scale, different COVID-19 vaccines with new technologies will create new challenges
- WHO has a network of AEFI reporting countries and a Global Advisory Committee; these should be leveraged to meet COVID19 Vx safety challenges
- Pharmacovigilance methods, tools and databases exist; these should be adapted to meet COVID19 AE issues (collecting, reporting, analysis, data management..)
- Collaboration between different actors is key (regulators, public health authorities, vaccine manufacturers, international organisations, others)

Thank you