



# The World Health Organization Immunization Safety Priority Project

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# Immunization Safety

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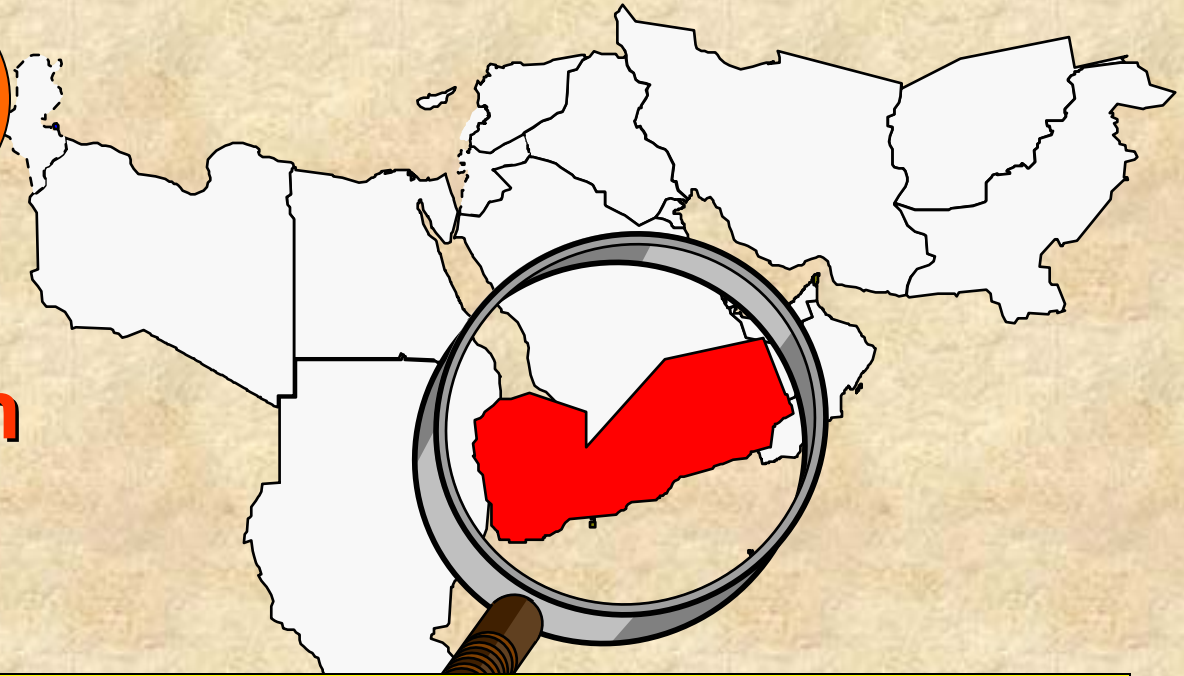
**“Ensuring and monitoring the safety of all aspects of immunization, including vaccine quality, storage and handling, vaccine administration and the disposal of sharps”**





Programmatic  
error

Yemen  
1997



Insulin given to **70 infants** instead of  
DPT vaccine with **21 deaths**



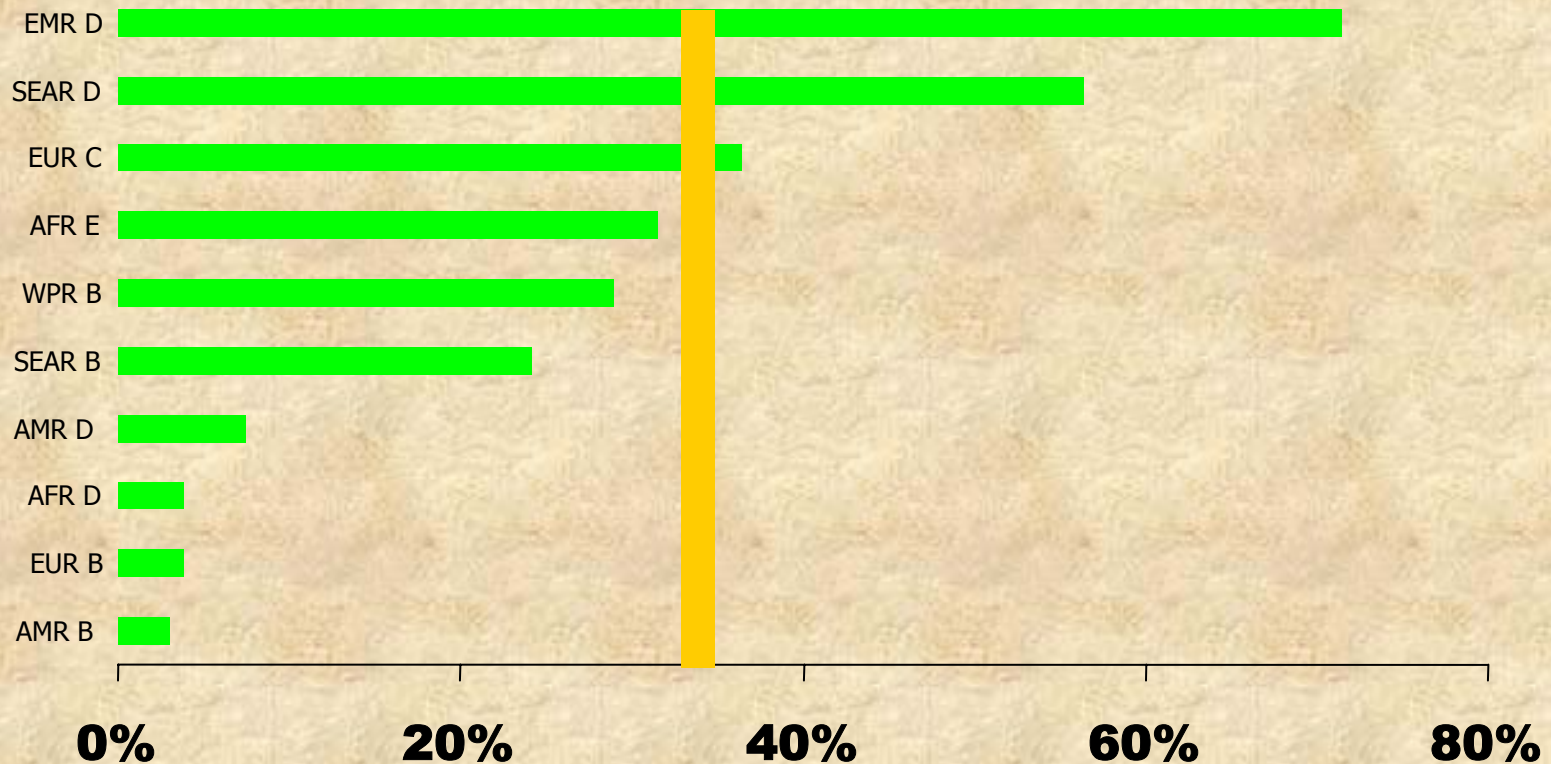
Insulin vial

Vaccine vials



# Proportion of New Hepatitis B Infections Attributable to Unsafe Injections, 2000

World: 35%, N= 22.5 million



Global Burden of Disease, 2000





# WHO's Immunization Safety Priority Project: a Growing Partnership to Support Countries (Capacity Building)

## Target:

Strengthen countries' capacity to ensure the safety of immunizations through country support to improve all programme components relevant to immunization safety

## Strategy:

Bring an *overall culture of safety* to allow for the:

*prevention;*

*early detection;*

*quick response to adverse events*



# Immunization Safety

## 1. Ensuring safety of vaccines

- ☑ Use only vaccines of demonstrated quality, safety and efficacy
- ☑ Strengthen National Regulatory Authorities

## 2. Securing safety of injections

- ☑ One syringe, one needle (auto-disable syringes)
- ☑ No recapping



## 3. Controlling safety of disposal

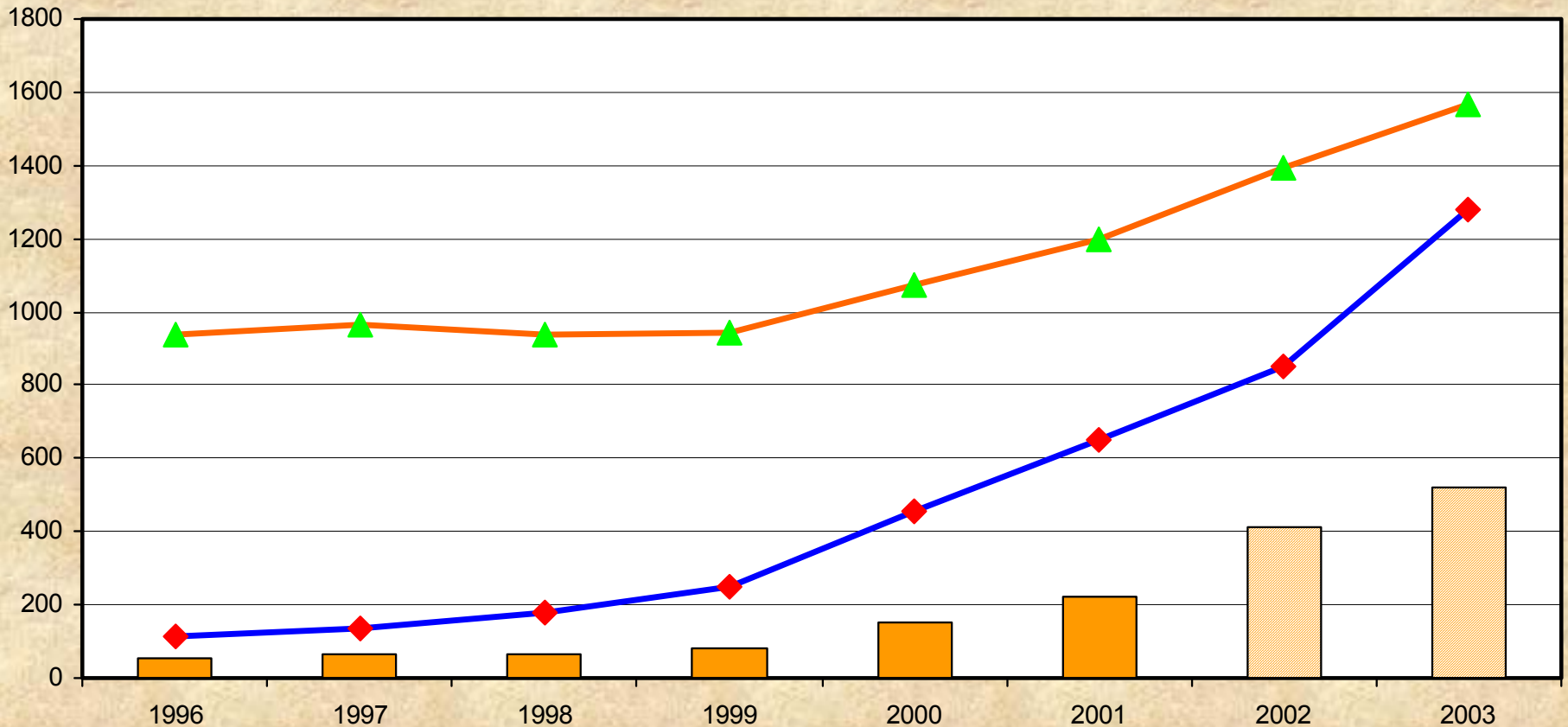




# Past and Projected Distribution of Auto-Disable Syringes

*millions*

AD supply (unicef only)    Manufg Cap    Global needs



# Vaccine Safety Issues

## WHO perspective

- Global issues with some regional differences
- Implicate active ingredients or non specific substances and diseases of unknown etiology
- “Amalgamation”
- Potential of signal generation and systematic search to identify spurious associations and generate false hypothesis
- Can generate huge amount of work and undue fear
- Need for quick hypothesis testing and international collaboration
- Science compounded by legal issues
- Global supply of quality vaccines and global perspective
- Misperception that vaccines from developing countries and WHO standards sub-optimal





# Examples of Programmatic Errors and Other Incidents Wrongly Attributed to the Vaccine

- ⌘ Egypt: 3 deaths labelled post DPT encephalopathy due to methanol impregnated compresses, 1999
- ⌘ India: outbreak of acute renal failure with neurological involvement actually due to other paramyxovirus (Nipah-Hendra type), 1998-2001
- ⌘ Algeria: 7 infants died following measles vaccination. Use of selenium vials instead of proper diluent, 2001
- ⌘ Zimbabwe: 1 infant died after measles vaccination. Review indicates toxic shock and not anaphylaxis, 2001
- ⌘ Guinea: 2 adults died after yellow-fever vaccination. Investigation points to contamination of vial, 2002





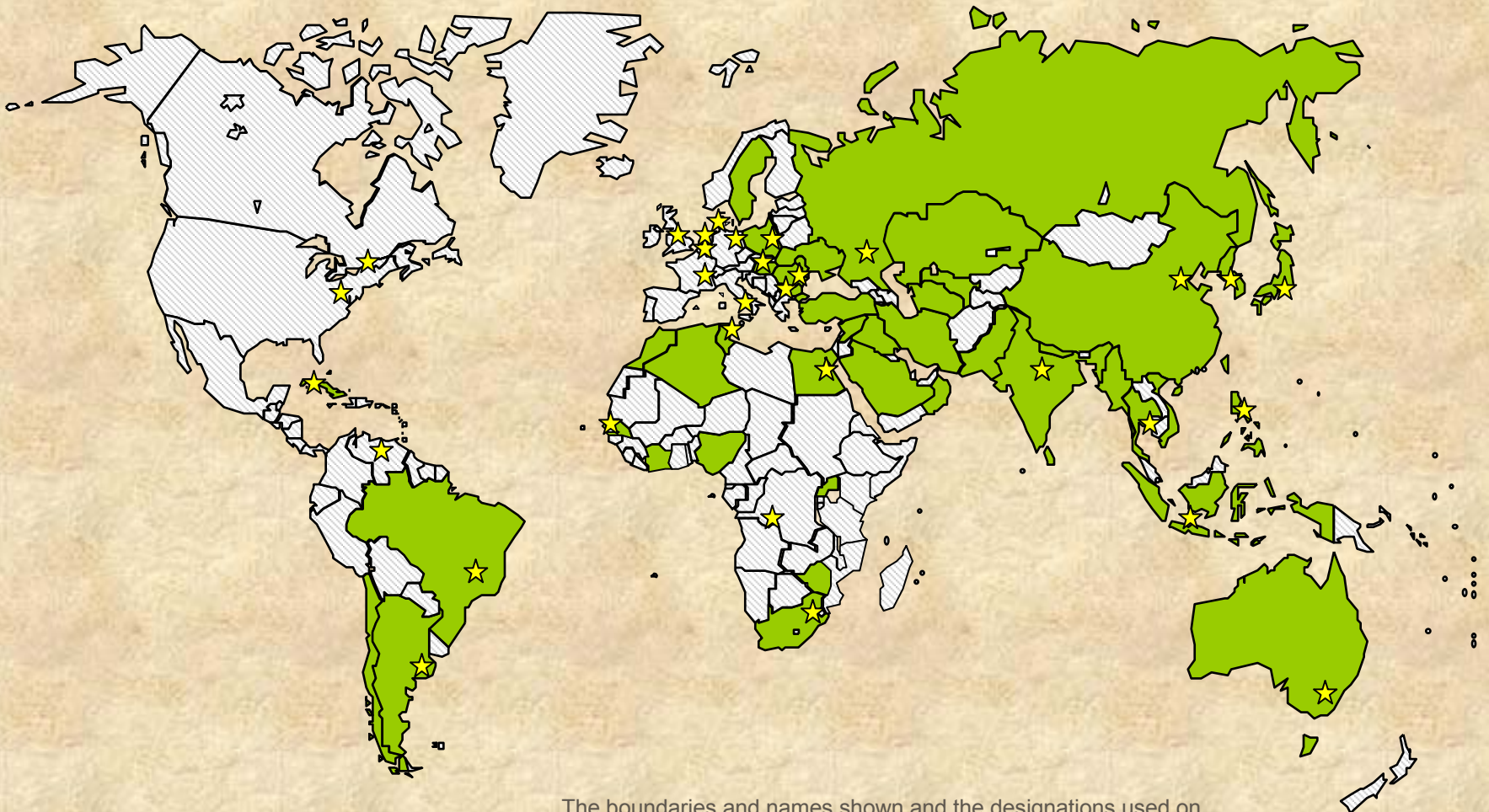


# Mechanisms to Respond to Safety Concerns: WHO's Support



- 📄 **Technical documents (multiple languages)**
- 📄 **Technical assistance for investigation of serious AEFI**
- 📄 **Assistance with implementation or strengthening of AEFI surveillance**
- 📄 **Strengthening of National Regulatory Authority functions (NRA assessments)**
- 📄 **Training for AEFI monitoring and management (including dealing with media) - Global Training Network**
- 📄 **Brighton Collaboration**



# National Regulatory Assessments Conducted (October 1998- June 2002) and experts available as of June 2002



## Country status of NRA assessment

-  Conducted
-  Not yet conducted

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.





# Global Advisory Committee on Vaccine Safety

- ⌘ To respond promptly, efficiently, independently and with scientific rigor to vaccine safety issues of global importance
- ⌘ Review of latest knowledge in collaboration with all parties involved
- ⌘ Determination of causal relationships
- ⌘ Multidisciplinary, global, and under strict conflict of interest and confidentiality rules
- ⌘ Ad hoc specialists teams and mandate to commission research
- ⌘ Decides which issue should be reviewed

**Best judgement in front of uncertainty**



# **Global Advisory Committee on Vaccine Safety (GACVS) : Examples of Issues 2001-2002**

- ⌘ **Macrophagic myofasciitis**
- ⌘ **Immunization and autoimmune diseases**
- ⌘ **Safety of thiomersal**
- ⌘ **Multiple sclerosis and hepatitis B vaccination**
- ⌘ **Leukemia following hepatitis vaccination**
- ⌘ **Yellow fever vaccine-related deaths**
- ⌘ **Child survival following immunization**
- ⌘ **MMR and autism**
- ⌘ **Bell's Palsy following intranasal vaccination**





# Occurrence of Bell's Palsy following Vaccination with a New Intranasal Vaccine

- ⌘ Results from 2 epidemiological studies indicate a significant increased risk of Bell's Palsy following intranasal vaccination with new inactivated influenza vaccine in a virosomal formulation with E. coli-derived LT adjuvant
- ⌘ **Manufacturer stopped distribution in May 2002**
- ⌘ **Review by the GACVS, June 2002 :**
  - ⊞ Any novel vaccine for nasal administration would need to be tested on a sufficiently large number of subjects prior to licensing and submitted to active post-marketing surveillance studies
  - ⊞ *Follow-up period in the context of clinical trials should be routinely extended to 3 months for intranasal vaccines*



# Global Advisory Committee on Vaccine Safety: Current Communications

2002, 77, 393-404

## Weekly epidemiological record Relevé épidémiologique hebdomadaire

22 NOVEMBER 2002, 77th YEAR / 22 NOVEMBRE 2002, 77<sup>e</sup> ANNÉE  
No. 47, 2002, 77, 393-404  
<http://www.who.int/wer>

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### Global Advisory Committee on Vaccine Safety, 20-21 June 2002

The Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 by WHO to respond promptly, efficiently, and independently (of WHO), and with scientific rigour to vaccine safety issues of potential global importance. The Committee meets twice a year on a regular basis.

GACVS is a scientific and clinical advisory body that aims to provide a reliable and independent assessment of vaccine safety issues through:

- Review of the latest knowledge in all fields, from basic science to epidemiology, of any aspect of vaccine safety of global or national interest, in close collaboration with all parties involved, including experts from national administrations, academia, and industry.
- Determination of causal relationships between vaccines and/or their components and adverse events attributed to them.
- Creation, where necessary, of ad hoc specialist teams with a mandate to monitor and evaluate any major concerns regarding a suggested association of vaccines and adverse events and to commission appropriate research on purported associations.

Membership of GACVS includes experts from around the world in the fields of epidemiology, internal medicine, paediatrics,

### Comité consultatif mondial sur la Sécurité des Vaccins 20-21 juin 2002

L'OMS a créé le Comité consultatif la Sécurité des Vaccins (GACVS) répondre rapidement, efficacement et indépendamment (vis-à-vis de l'OMS) et rigueur scientifique voulue aux sécurité vaccinale pouvant concevoir du monde. Le Comité se réunit deux fois par an.

Compétent dans les domaines scientifique, le GACVS est un organe indépendant à l'étude des problèmes des vaccins par:

- L'examen, à la lumière des dernières avancées dans tous les domaines fondamentaux à l'épidémiologie, de tout aspect de la sécurité vaccinale d'intérêt mondial ou national, en étroite collaboration avec l'ensemble des parties concernées, notamment des spécialistes appartenant aux administrations nationales, aux milieux universitaires et à l'industrie.
- La détermination des relations de causalité entre les vaccins ou leurs composants et les effets indésirables qui leur sont imputés.
- La création, le cas échéant, d'équipes spécialisées chargées d'étudier toute hypothèse sérieuse de lien entre des vaccins et des événements indésirables et de faire procéder aux recherches nécessaires sur l'association présumée.

Les membres du GACVS sont des spécialistes du monde entier dont la compétence est reconnue dans les domaines de l'épidémiologie, de la médecine interne, de la pédiatrie,

Targeted basis

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# **Global Advisory Committee on Vaccine Safety : Expanding Communications**

- ⌘ **February 26th partners meeting**
- ⌘ **Supported key role of GACVS and expanding communications around GACVS**
- ⌘ **Encouraged links between “qualified” sites**
- ⌘ **Shared responsibility network could undermine impact and independence of GACVS and WHO**
- ⌘ **Important considerations**
  - ⊞ **Communication about facts not advocacy**
  - ⊞ **All safety facts good or bad!**
  - ⊞ **Focus on internet**



# Conclusion

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- ⌘ Broad spectrum of immunization and vaccine safety issues
- ⌘ Different priorities in different countries
- ⌘ Limited resources
- ⌘ Need for global collaboration
- ⌘ Importance of communications and perceptions
- ⌘ Needs more attention

