



# AEFI Surveillance Workshop

for Medical Officers



# Objective

1

Role of  
Medical  
Officers in  
AEFI  
surveillance

2

Define and  
identify  
various type  
of AEFI

3

Manage,  
record &  
report AEFI  
cases as per  
categories  
(exercise)

4

Fill the CRF,  
collect  
requisite  
documents  
(exercise)

5

Review  
Block/PHC  
AEFI register  
(exercise)

6

Train and  
communicate  
with front line  
health  
workers and  
other  
stakeholders  
(training film)



# Activities related to Universal Immunization Program

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1. Training of the frontline health workers
2. House to house surveys
3. Micro planning
4. Ensuring availability of all vaccine and logistics
5. Cold chain management and maintenance
6. Bio medical Waste management
7. Ensure good monitoring and supervision of activity
8. Prevention, management & reporting of AEFI cases



## Need for AEFI surveillance

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- To ensure vaccine safety and **build vaccine confidence**.
- To **capture rare, serious AEFI** undetectable during clinical trials.
- To **recognise, correct and prevent immunization programme errors** and take corrective action.
- To **investigate known coincidental events** causing concern and prevent false blame.
- **Document and convey** the cause to parents/community.
- **Estimate rates of occurrence** of AEFI in the local population.



## What is an AEFI?

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An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine

The adverse event may be any unfavorable or unintended sign (e.g. Abscess following vaccination), abnormal laboratory finding (e.g. Thrombocytopenia following measles vaccination) symptom or disease (e.g. Disseminated BCG infection following BCG vaccination).

# Types of AEFI



## Minor

Usually occur within a few hours of injection.

Resolve after short period of time and pose little danger.



## Severe

Can be disabling and, rarely life threatening

Most do not lead to long-term problems

Must be reported



## Serious

Death.

Inpatient hospitalization

Results in persistent or significant disability.

AEFI cluster

Parent/Community / media concern

**All categories of AEFI are to be recorded in PHC/block AEFI register**

**Report all serious and severe AEFIs immediately in Case Reporting Formats (CRFs)!**





# Vaccine Adverse Events

## MINOR REACTIONS

- ✦ Usually occur within a few hours of injection and resolve after short period of time and pose little danger.
- ✦ Minor vaccine reactions are part of the body's immune system reaction and is generally self-limiting.
- ✦ Treat symptomatically – paracetamol, cold sponging, others.



### Examples-

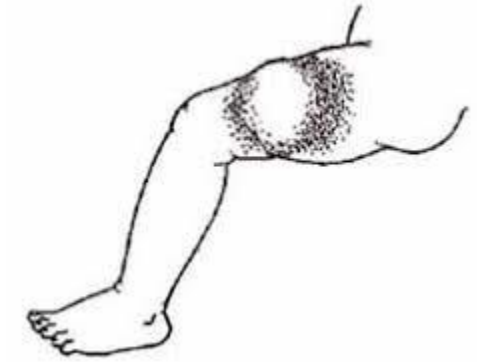
Pain, swelling &/or redness at injection site with or without fever	DPT containing vaccine (pentavalent), Tetanus
Papule (lump) which becomes ulcerated & heals leaving a scar	BCG vaccination
Fever, rash, &/or conjunctivitis	Measles/MR vaccine



# Vaccine Adverse Events

## SEVERE REACTIONS

- ✦ Progression of minor AEFI results in severe.
- ✦ Can be disabling and rarely life threatening.
- ✦ Examples **INCLUDE NON- HOSPITALIZED CASES** of :
  1. Seizures may or may not recovered
  2. Allergic reactions and anaphylaxis that has recovered,
  3. High fever( >102-degree F),
  4. Severe local reaction (swelling extending beyond nearest joint)
  5. Injection site abscess
  6. Persistent crying more than 3 hours, etc.







# Vaccine Adverse Events

## SERIOUS REACTIONS

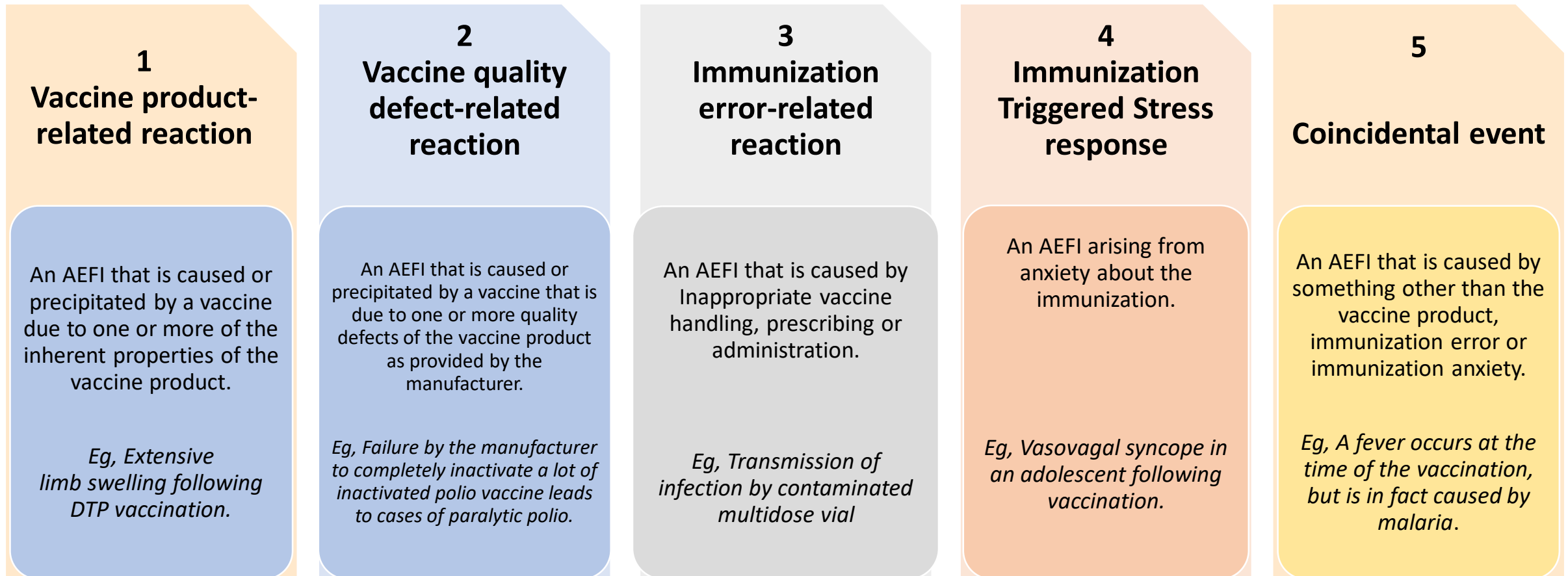
- \* Results in death.
- \* Requires inpatient hospitalization.
- \* Results in persistent or significant disability.
- \* AEFI cluster
- \* Parental/ Community / media concern

## Examples:

Vaccine	Reaction	Onset interval
BCG	Fatal dissemination of BCG infection	1 – 12 months
OPV	Vaccine associated paralytic poliomyelitis (VAPP)	4 – 30 days
DTwP (Pentavalent)	Prolonged crying and seizures	0 – 24 hours
	HHE	0 – 24 hours
Measles/MR	Febrile seizures	6 – 12 days
	Thrombocytopenia	15 – 35 days
	Anaphylaxis	1 hour



# WHO cause specific definition of AEFIs



This is utilized for causality Assessment by State and National AEFI Committees



# Immunization errors related reactions

Non stérile injection

Reconstitution error

Injection at incorrect site

Vaccine transported/  
stored incorrectly

Contraindication ignored



Local injection site reactions.

Toxic shock syndrome.

Blood-borne transmission of disease

Local abscess.

Vaccine ineffective.\*

Effect of drug (e.g., insulin, oxytocin, muscle relaxants).

Toxic shock syndrome

Local reaction or abscess or other local reaction.

Local reaction or abscess or other local reaction.

Sciatic nerve damage

Increased local reaction from frozen vaccine.

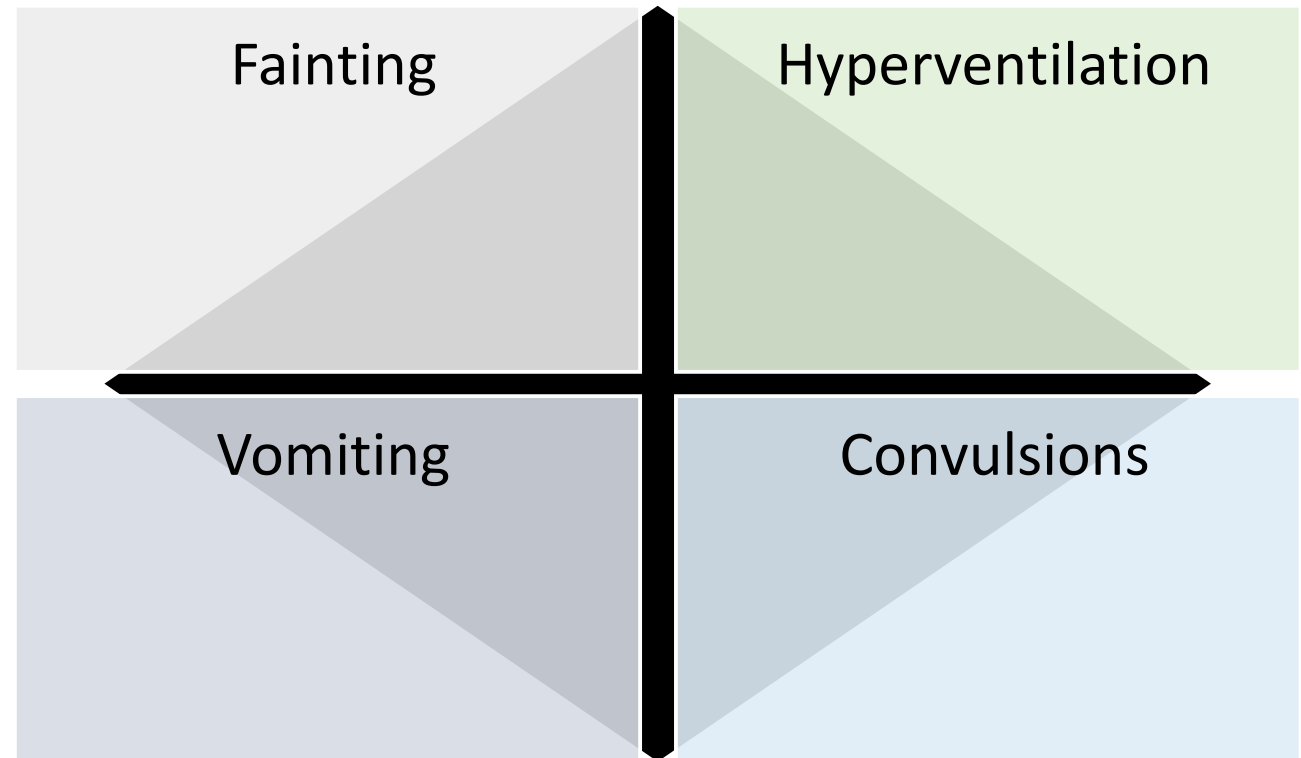
Ineffective vaccine.

Avoidable severe reaction



# Anxiety-related reactions

- Especially common in mass vaccination campaign due to fear or pain of injection
- Not related to the contents of the Vaccine
- Can be minimized with clear explanation regarding vaccination, shorter waiting times, privacy during procedure.
  
- Anxiety related reactions could present as
  - Fainting
  - Hyperventilation
  - Vomiting
  - Convulsions





## Coincidental events

- An event happening after immunization is falsely considered to be caused by immunization.
- Vaccinations are normally scheduled in infancy and early childhood, when illnesses are common and congenital or early neurological conditions become apparent. Therefore coincidental events are inevitable.
- **Encourage the ANM/Health workers to report such events even if unrelated to immunization.**
- Immediate investigation is critical to:
  - Respond to community's concern about vaccine safety
  - Maintain public confidence in immunization
  - To collect all relevant documents for establishing causality of the event.
- Malaria, Dengue or Measles after Pentavalent vaccination, Death of a child due administered with BCG with congenital ailments, etc. are some of the examples.







# AEFI Clusters

**Clusters of events** is two or more cases of the same adverse event related in time, place or vaccine administered.

**Clusters are serious AEFI** and are to be thoroughly investigated, even if the event related is a minor reaction.

**Clusters can be usually associated with:**

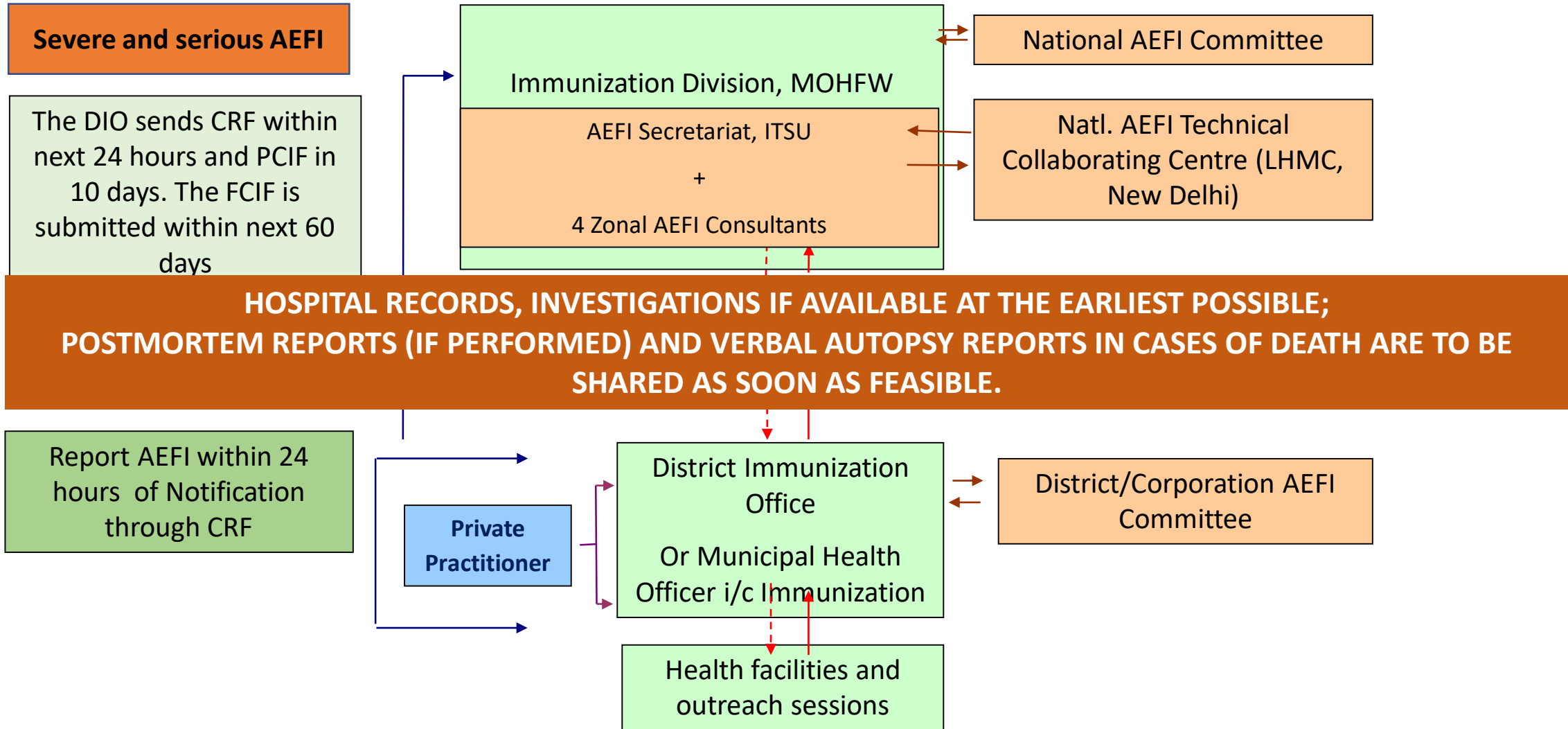
- A particular provider or health facility or site of vaccination &/or in particular village/place of residence

**Some of the examples of AEFI clusters are-**

- **Anxiety related clusters** are common, especially in mass immunization campaigns, such as Headache, Nausea, Vomiting, Giddiness. Recover with reassurance and rest.
- **Immunization error related clusters** can occur when a vial/vials of vaccine that has/have been :
  - Inappropriately prepared
  - Contaminated
  - Inappropriately stored (e.g. freezing vaccine during transport).
- **Coincidental AEFI** can also result in clusters :
  - Measles outbreak in a geographical area unrelated to vaccination but coinciding with Vaccination session
  - Scabies outbreak in children of a residential school vaccinated with MR



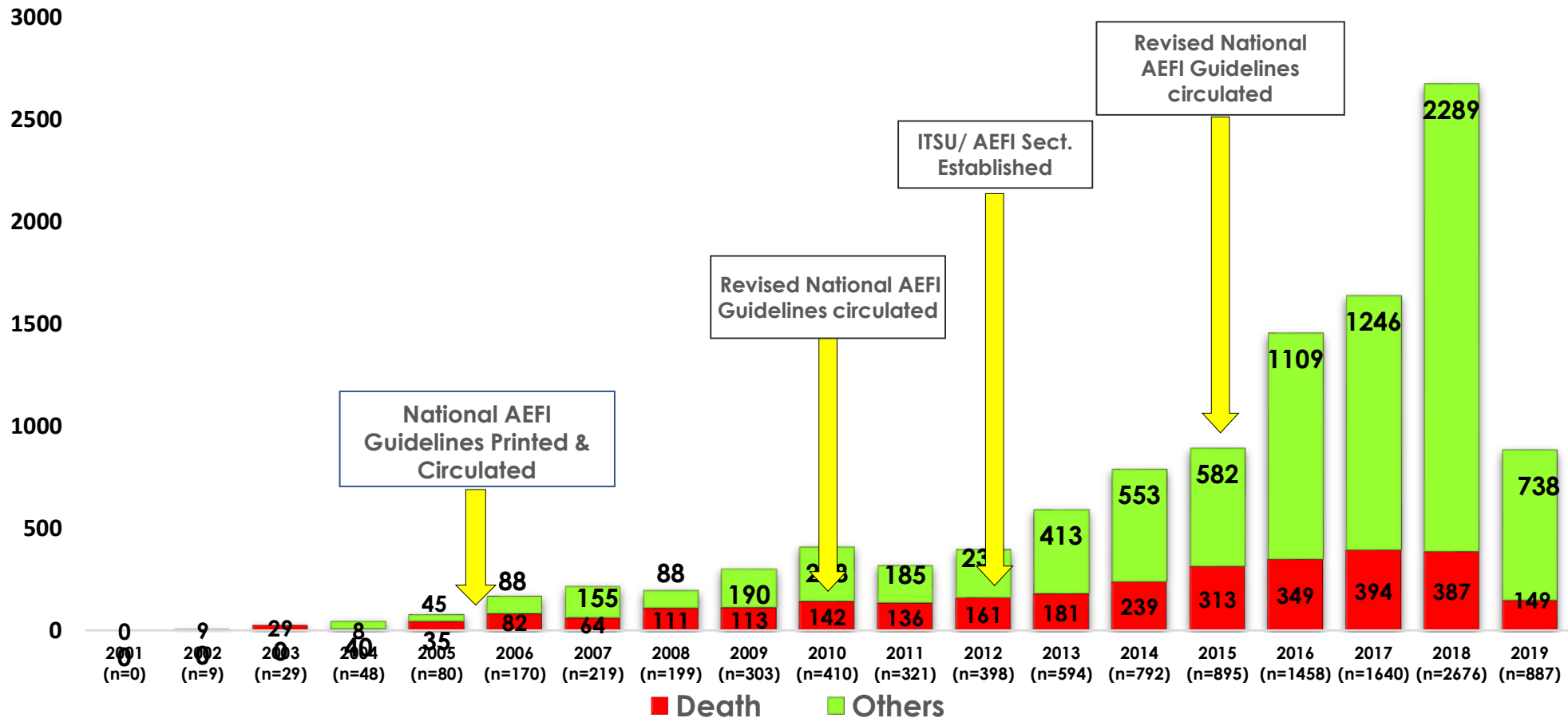
# AEFI Organizational Structure





# Trends of reporting in India (2001-2019)

## Reported severe and serious AEFI Cases





# Summary

- Identification, reporting and investigation of AEFI cases is important to-
  - **Capture rare, serious AEFI** undetectable during clinical trials.
  - **Recognise and prevent immunization programme errors**
  - **Investigate known coincidental events**
  - Document and convey the cause to parents/community **to build vaccine confidence in community**
- Recording and reporting of AEFI cases based on severity and cause specific (WHO)-
  - Minor, severe and serious AEFI cases
  - 5 categories- Vaccine product related, vaccine quality related, immunization error related, immunization anxiety related, coincidental events
- AEFI organizational structure in India
  - District level, state level and national level
- Trend of AEFI cases reporting in India and Odisha



**Thank you**