



Iraqi Pharmacovigilance Center
المركز العراقي لليقظة الدوائية

Overview of Pharmacovigilance Plan in Iraq for COVID-19 Vaccines

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Virtual GLZ training

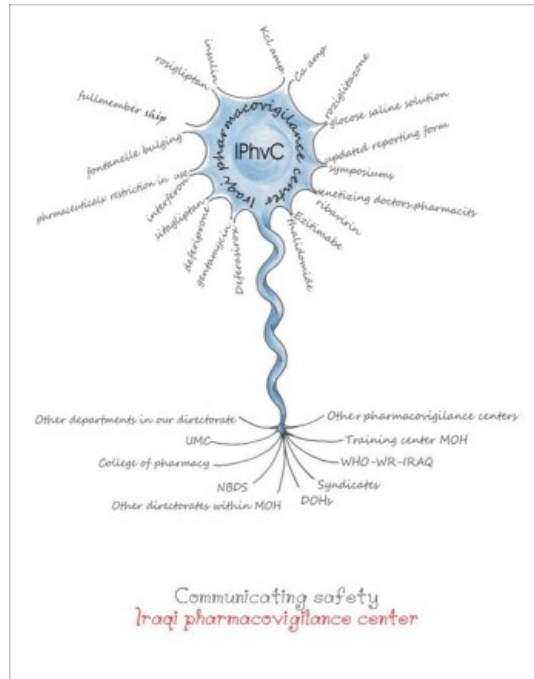
15-19 March 2021

Objectives

- Background of pharmacovigilance in Iraq
- Preparedness of the pharmacovigilance for COVID-19 vaccines
what has been done so far and/or what is planned by Iraq
- Challenges faced during the surveillance plan
During the reporting and communication process, logistics and capacities



Iraq is a full member of the WHO programme PIDM since 2010
Iraq # 102 in the PIDM



IPC Vision

Creating a safe medicinal environment

Mission

Contribute to ensuring patient safety throughout monitoring , evaluation and prevention of adverse events and medication errors.

Products covered by pharmacovigilance in Iraq



Medicines



Vaccines



Herbals



T&CM

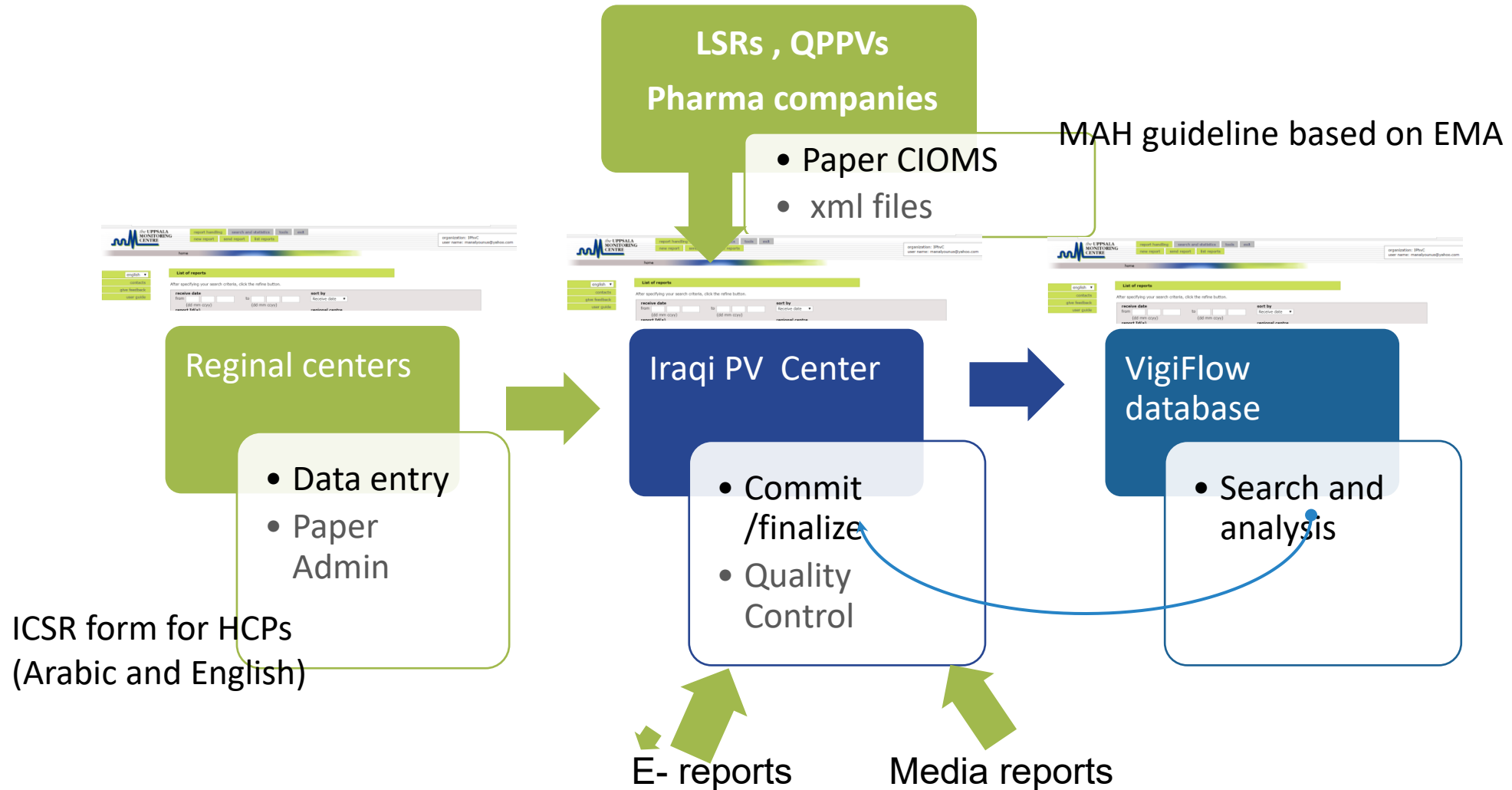


**Biological
products**



**Blood
products**

Flow of data in the national database

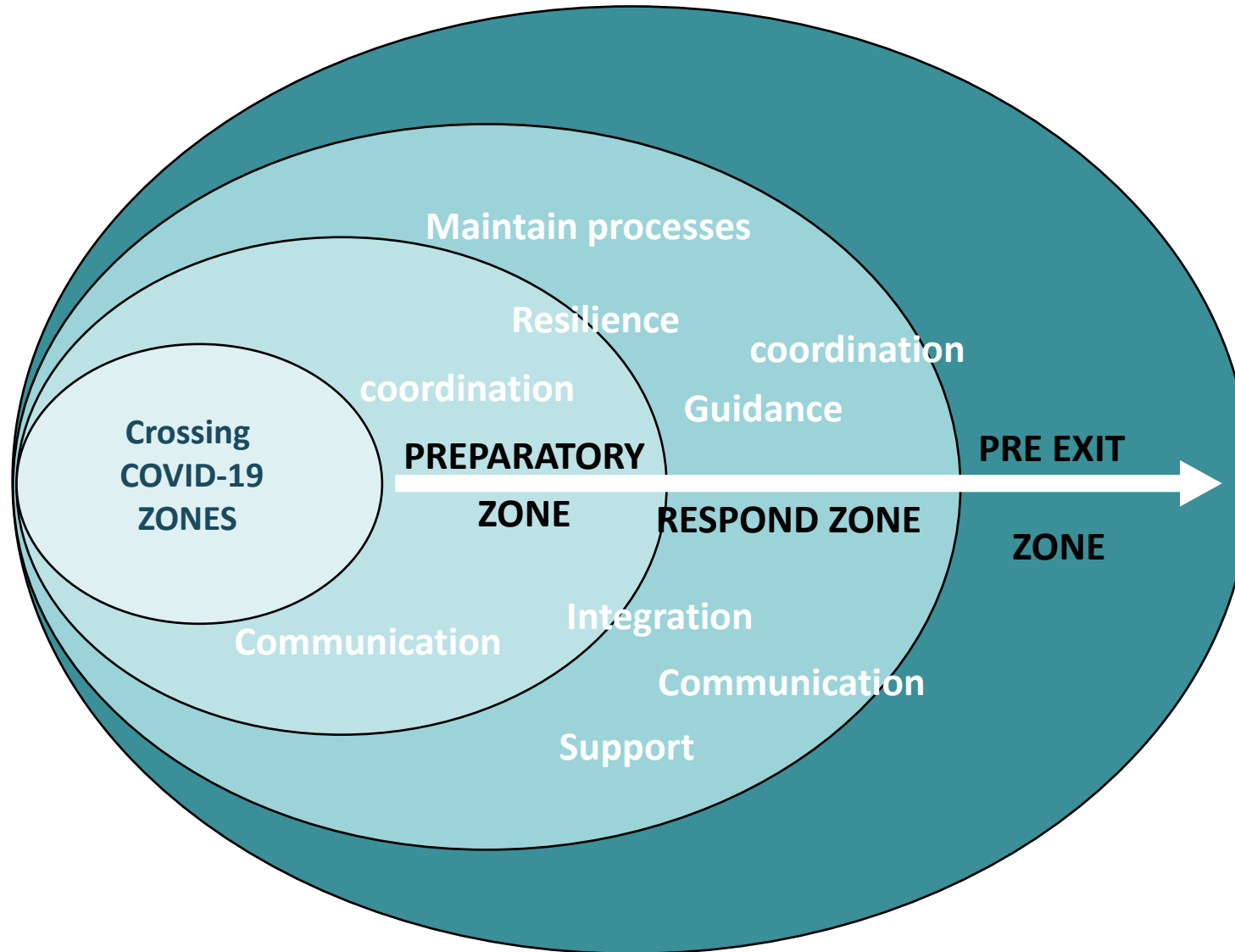




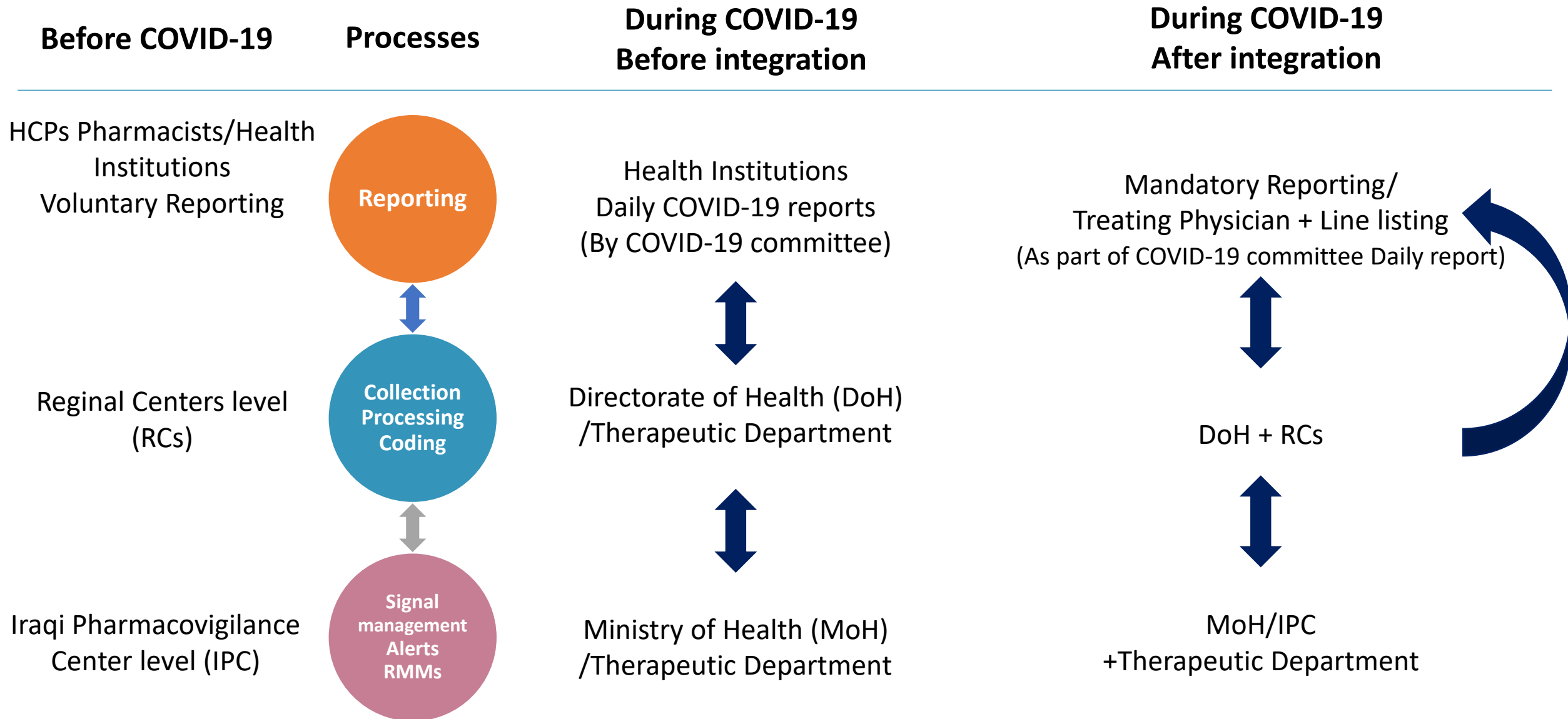
COVID-19 Era

Before vaccine introduction

During COVID-19 Era



Business Continuity; Health Institutions





Reports details



COVID-19 Era

After vaccine introduction

The COVID-19 pharmacovigilance plan levels



**The regulatory and
administrative level**



Communication



**Data
management**



Tools and support



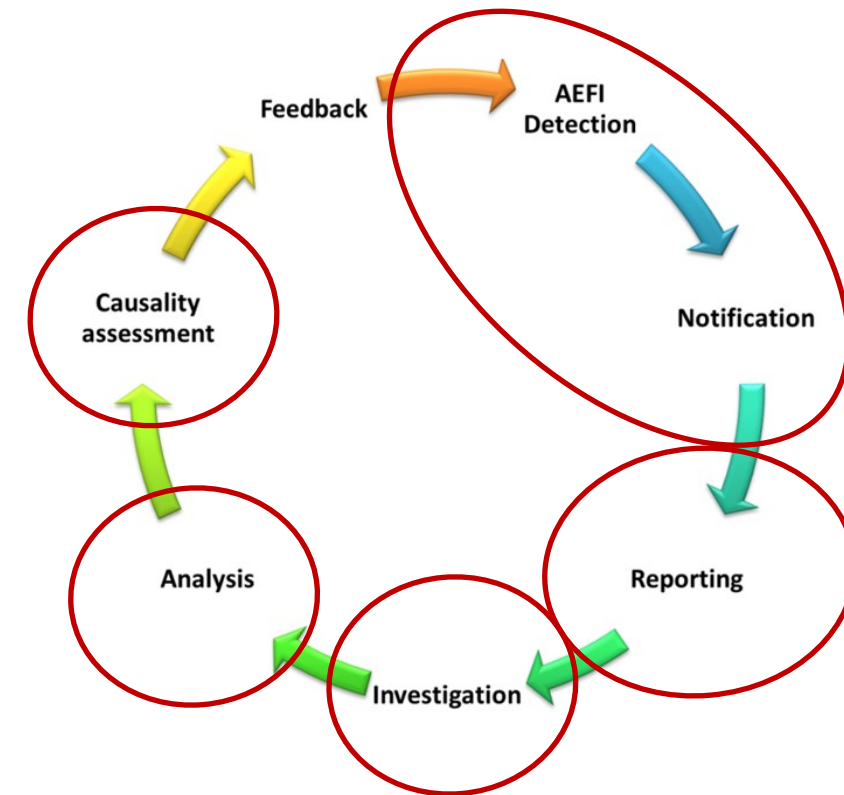
Training and capacity building

Roles & responsibilities

WHAT	HOW	WHO
Reporting tools	Paper AEFI form & phone no	DPH
Documentation tools	Electronic database (vigiflow)	DTA
Investigation tools	Investigation form	DPH
Data analysis tools	vigilyze	DTA
Causality assessment tools	Causality assessment committee and form	WHO
feedback	Communication plan	All

Reporting timelines were also identified

Safety responsible roles & responsibilities at the vaccination center were also identified.



Electronic Data Management System 3 levels (Vigiflow)

Ministry level
EPI & IPC data access

level 1



Directorates of Health
EPI & RC data access

level 2



Public Health Districts

Hospitals

level 3



AEFI form for HCPs
Arabic version

Public Health Center
AEFI form for HCPs

Challenges

- Possibility of increasing number of AEFI reports
- Missing information within AEFI reports.
- Workload because of coincidental AEFIs.
- Understaff at all levels.
- Only passive reporting system is implemented.
- Increasing the awareness regarding the importance of pharmacovigilance among public health centres and districts is crucial.
- Logistics related to internet, laptop for data management.
- Logistics related to mobile phone number availability to help in implementation of stimulated passive surveillance.
- No list for AESI, no decision whether to go for sentinel surveillance or not
- Lack of well trained staff to do investigation, analysis and causality assessment (started a training program to cover all AEFI cycle)

Thank you

