

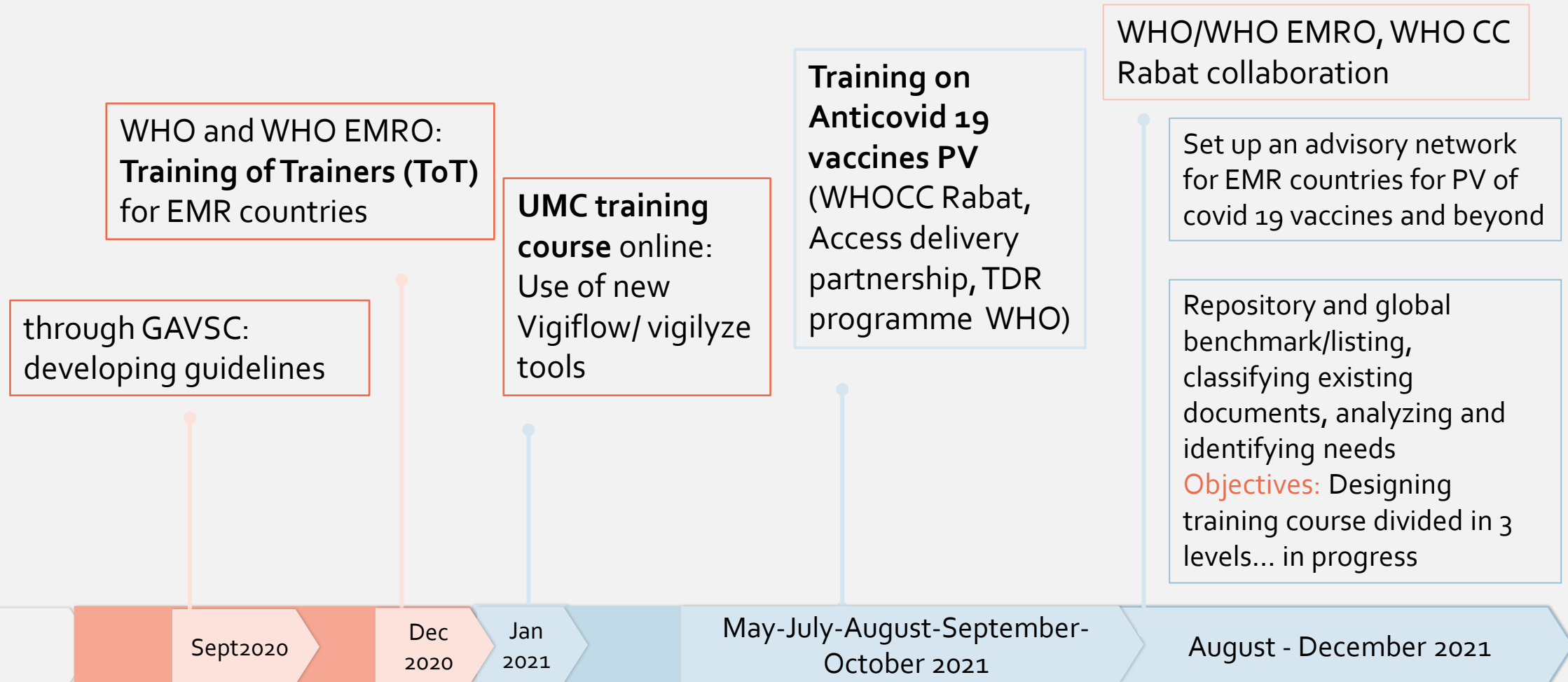
PV update

Ghita Benabdallah
CAPM, WHO CC for Strengthening PV practices

17th Annual IMSN Virtual Meeting
November, 14-15, 2022



Moroccan experience in the time of covid 19 collaboration



Aim of PV training and capacity building

- Building a PV system is intimately linked to skills development
- PV is a very precise field with specific tools and methods that need to be mastered
- The initial and continuous training of the people in charge of the discipline is crucial as well as their day-to-day practice and experience
- PV cannot be performed by PV professionals only and needs the involvement of many other stakeholders
- These stakeholders should also be sensitized and trained in order to collaborate with PV professionals but also increase patient safety at their level

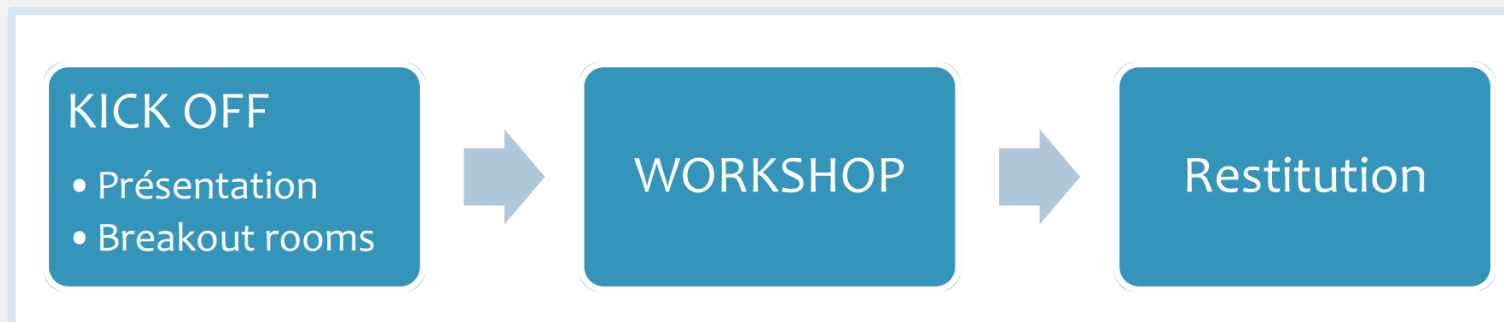
Training overview

	Basic	Intermediate	Advanced
Target audience	HCPs at vaccination sites	HCPs responsible for implementing the vaccine strategy (<i>immunization program, regulatory body, national and regional pharmacovigilance centers, vaccination committees</i>)	Pharmaceutical professional teams
Prerequisites	Basic health science knowledge		
Skills taught	Identify an AEFI Manage a patient Notify an AEFI Communicate Communicate		

The image shows a Zoom meeting interface with a poll active. The poll question is: "S8: Did you find a mechanism of action to explain the occurrence of these inflammatory neurologic disorders in children?". The poll results show "yes, antegen mimicry" and "yes" as the top responses. A WhatsApp chat overlay is visible on the right side of the screen, showing a message about a "Covid-19 vaccine PV ADVANCED" meeting. The Zoom interface also shows a list of poll questions on the left and a "Words moderation" section at the bottom.

Curriculum Basic level/Train of Trainers

Module	Courses
I. Generalities on PV	<ol style="list-style-type: none">1. Basics of Pharmacovigilance2. Adverse reaction definition and classification3. Overview of concepts, tools and technics
II. Vaccines and vaccine safety	<ol style="list-style-type: none">1. Importance of vaccination and overview of the different types of vaccines2. Adverse Event Following Immunization (AEFI)
IV. Anti-covid-19 vaccines and AEFIs	<ol style="list-style-type: none">1. Different types of anti-Covid-19 vaccines2. Adverse Event of Special Interest (AESI) management3. Case studies



Curriculum Intermediate level

Modules	Courses
I. Generalities on PV	<ol style="list-style-type: none">1. Extent of the problem and contributing factors2. Pharmacovigilance globally3. National Pharmacovigilance centers and systems4. Adverse reaction definition and classification5. Concept, tools and technics used in pharmacovigilance
II. Vaccines and vaccine safety	<ol style="list-style-type: none">1. Importance of vaccination and overview of the different types of vaccines2. Adverse Event Following Immunization (AEFI)3. Vaccine safety institutions and mechanisms4. Basics of active surveillance
III. Vaccine-vigilance processes	<ol style="list-style-type: none">1. Reporting forms, means of reporting and reporting flow2. Causality assessment3. Databases and signal detection4. Communication and crisis management
IV. Anti-covid-19 vaccines and AEFIs	<ol style="list-style-type: none">1. Different types of anti-Covid-19 vaccines2. Specificities of anti-covid-19 vaccines vigilance3. Strategies implemented in response to the immunization campaign
V. Case studies	<ol style="list-style-type: none">1. AESI : Adverse Event of Special Interest2. Anaphylactic reactions3. Declaration of death case4. Immunization errors

Curriculum Advanced level « A la carte »

Modules	Courses
I. Investigation	<ol style="list-style-type: none">1. Theoretical content2. Investigation simulation
II. Causality assessment	<ol style="list-style-type: none">1. Theoretical content2. Case studies
III. Vigiflow data & signal detection	<ol style="list-style-type: none">1. Theoretical content2. Personal project
IV. AEFI comittee	<ol style="list-style-type: none">1. Theoretical content2. AEFI committee simulation
V. Active surveillance	<ol style="list-style-type: none">1. Theoretical content2. Working groups
VI. Communication	<ol style="list-style-type: none">1. Theoretical content2. Role play

Advanced courses

5 days Training course – Pool of experts



Safety of medicinal products during pregnancy: Scope of the problem
R. Soulaymani
TERATOVIGILANCE

250 participants

3 days Training course – Pool of experts



Introduction to RMP and the place of active surveillance and proactive pharmacovigilance
Ghita Benabdallah
Active Safety Surveillance

270 participants

Going beyond strengthening PV of covid 19 vaccines

University Hospital PV: Assessment Building/Strengthening

- Hospitalization of polymedicated patients (multiple and serious pathologies)
- Most serious AE are in universitarian hospitals
- More complex and numerous treatments
- Different stakeholders at each stage of the drug circuit
- In huge settings, the risk of AE, medication errors, misuse, etc is higher
- Clinical trials, off-label prescription, etc.

Medication errors examples

Confusion of name - Fatal case

- Poison Control Center: Call from Gastro-enterology specialist
- Question: Ibuprofene and hepatitis toxicity???? For a patient taking Ibuprofen from USA
- Case of patient treated for hepatic failure – Paracetamol Contraindicated
- For a flu, patient was taking 2 tab 3x/day Ibuprofen.
- Blood analysis: increased level of transaminases (GPT, GOT)
- Doctor asked the patient if she was not taking Paracetamol, and the **patient said no**

Medication errors exemples

Confusion of name - Fatal case

- 3 days later: hospitalized for acute hepatitis, coma and died

PCC medical doctor asked for the brand name of medicine: **Acetaminophen**

Acetaminophen instead of Ibuprofene

Confusion: Acetaminofen et Ibuprofen



Paracetamol

Contributing factors identified: look alike drug name and 2 INN for the same medicine

Actions need to be done

- In contact with the INN and classification of medicinal products department



Medication errors examples

Administration route error

- **Atrovent®** (Ipratropium): Bronchodilator indicated in treatment of asthma crisis and chronic obstructive pulmonary disease
 - Solution for inhalation
- Patient, 28, at ER at 11.00 am.
- Staff: medical doctor, head nurse and and recruited nurse.
- In ER: 5 people
- Patient put in condition: a venous line
- Start of the nebulization
- Indication was done to the new nurse.
- Nurse took bottle of Atrovent and administered by IV



Medication errors examples

Administration route error

- Immediately (few min): discomfort and tachycardia **up to 200 BPM**
- Cardiologist and PCC contacted for the taken in charge:
- The patient had a panic, did a hysterical crisis that worsened the situation.
- Problem of management: **Pilocarpine** which is the antidote to atrovent (anticholinergic) is contraindicated in asthma.
- Since she was in hospital, the PCC recommended 1 tab of B-blocker to stabilize her by keeping her under surveillance but the cardio refused.
- Patient kept in ICU for surveillance 24 hours and BPM downed to 120. Outcome : favorable
- Contributing factors identified: **lack of training and problem of look alike drug bottles**
- Actions needed: **Training of newly recruited staff**

