

Pharmacovigilance in the time of Covid19

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practices 06 May 2021

Context

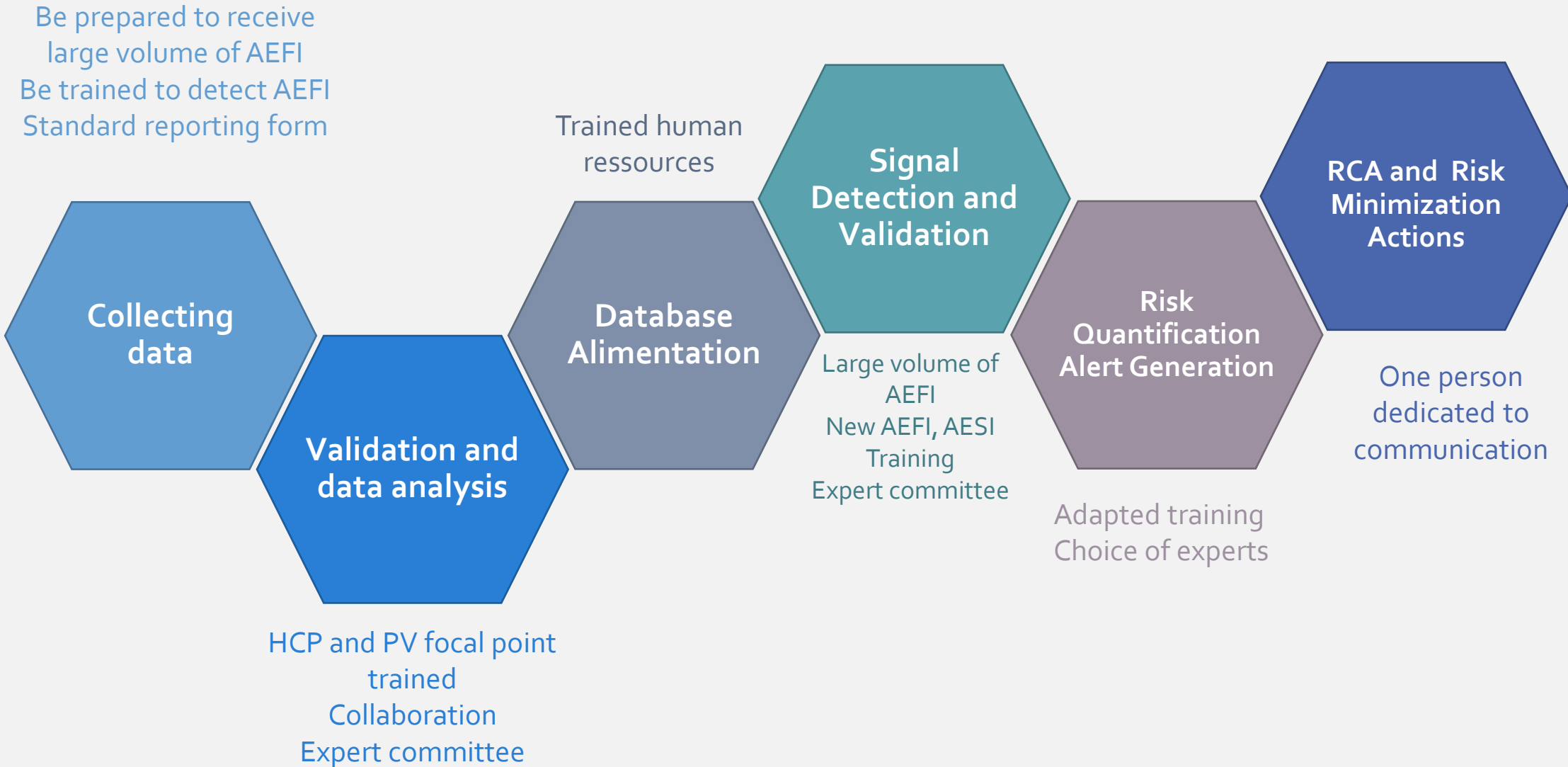
Covid 19 in Morocco

- 1st case of covid 19: March, 2nd, 2020
- Total cases: 512 285
- Deaths:9038
- Vaccination campaign started: January, 28th, 2021

Vaccination campaign preparation: August 2020

- Vaccine vigilance assessment
- Identification of the needs
- Actions

Maturity and strenghtening AEFI surveillance system





National vaccination strategy involving PV

- 24h/24h 7 days: free PV phone on duty
- Designation of couple: SOC / pharmacovigilant
 - Analysis
 - Investigation: discussion with reporter, clinicians, and expert committee when needed
 - Follow up
 - Weekly report

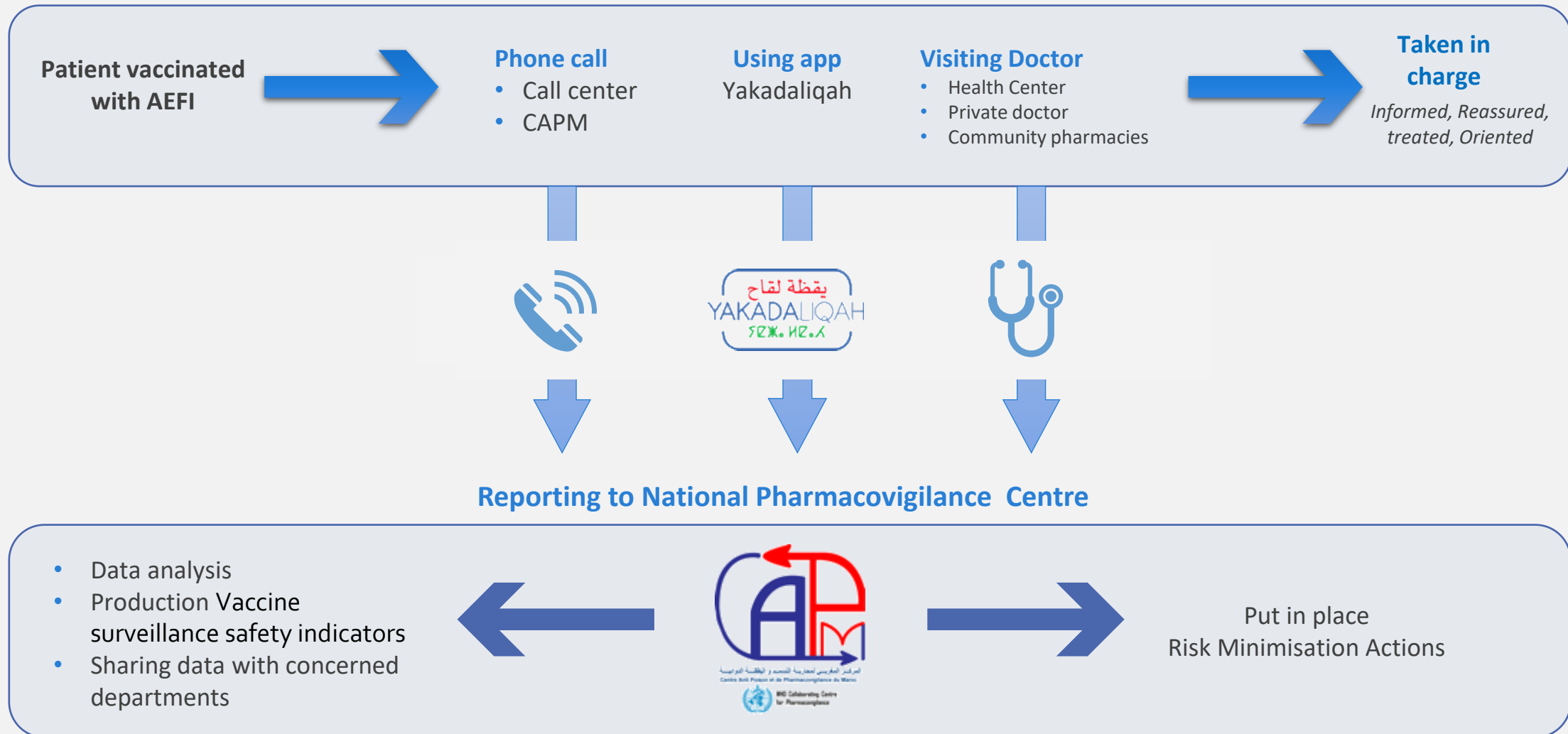
- ❖ Obligation to report AEs following Covid-19 vaccine
- ❖ Designation of PV focal point at regional levels
- ❖ Role of doctors in vaccination centers
- ❖ Designation of expert groups in each hospital
- ❖ Organization of the monitoring of AEFI at regional and national level

- ❖ Training and capacity building for vaccine vigilance
- ❖ Reorganization of the national PV work

- ❖ Set up of national AEFI reporting app: yakadaliqah.ma

To ensure vaccine safety:
Exhaustive collection of AEFI, data analysis to react early

Strengthening reporting means

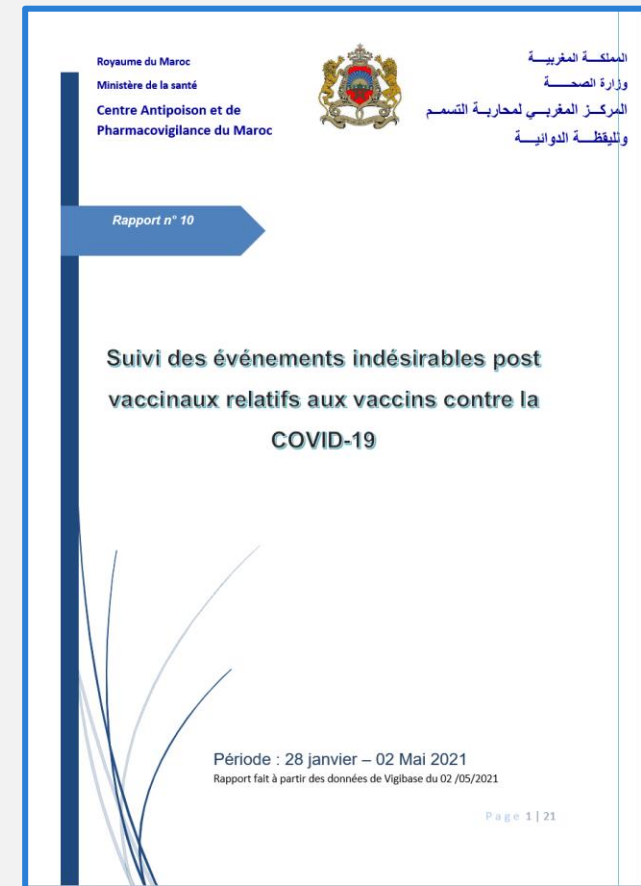


Reports

A report is shared on a weekly basis with

- The health Minister
- The immunization Programme
- The Drug Regulatory Authority
- The WHO Office – Morocco
- The WHO at EMRO

Discussed in a weekly meeting with the Central committee of Immunization



Vaccination plan

Vaccines available: Astrazeneca Covishield (India) and Sinopharm verocel inactivated (China)

- Started on January, 28th, 2021.
 - Elderly 75 and +
 - HCP 40 years and +
 - Teachers:45 years and +
 - Police, firemen...40 years and +
- Then:
 - HCP: 18 years and +
 - People 70 and +, 65 and +, 60 and +
- Everyone from 17 and more is eligible to vaccination except :
- Contraindications:
 - Pregnant women and breastfeeding
 - People who have had previously an anaphylactic chock or angioedema
 - People who have had an allergic reaction to the 1st dose of vaccine
 - People with active ongoing disease

Vaccine surveillance safety indicators

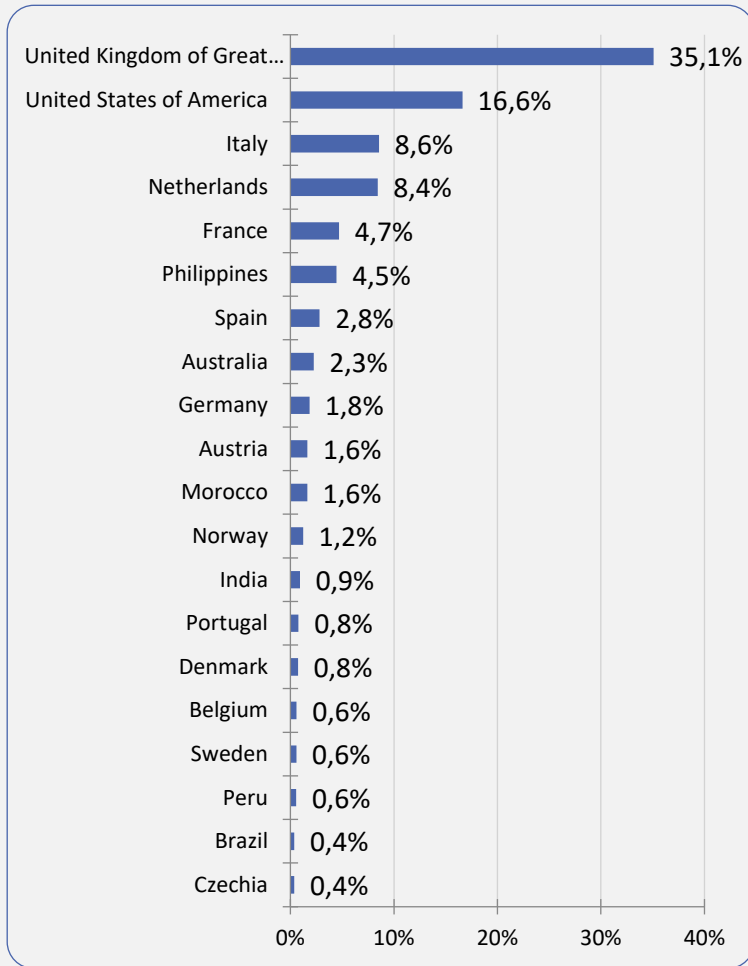
Vaccines

Vaccines	Number of Doses administered	Number of Cases of AEFIs	Reporting rate/1000 doses administered
AstraZeneca	7 205 724	9318	1,12
Sinopharm	1 601 903	1034	0,69
Both vaccines	9 447 627	10 682	1,14

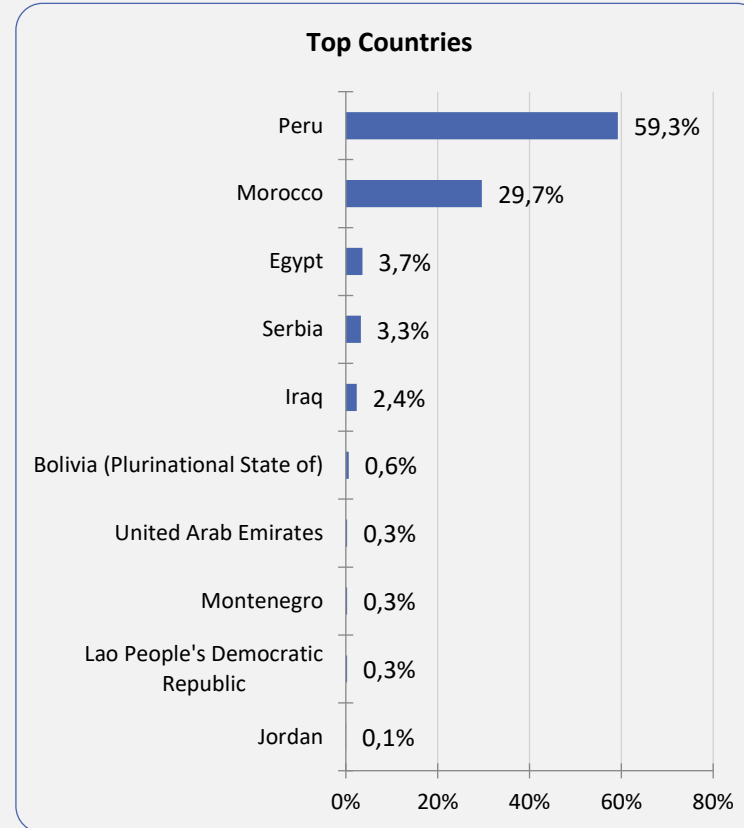
Total Number of vaccinees (D1, D2): 4 303 826

Vaccine surveillance safety indicators

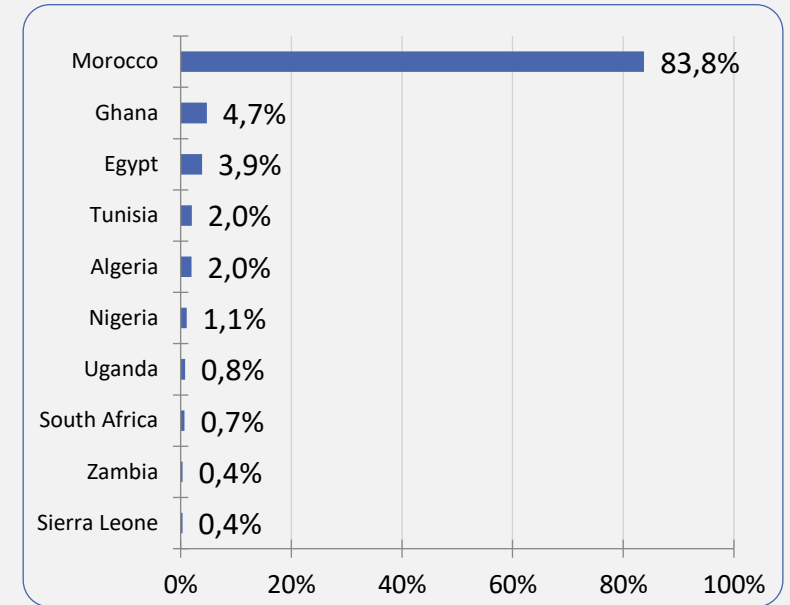
Top countries reporters



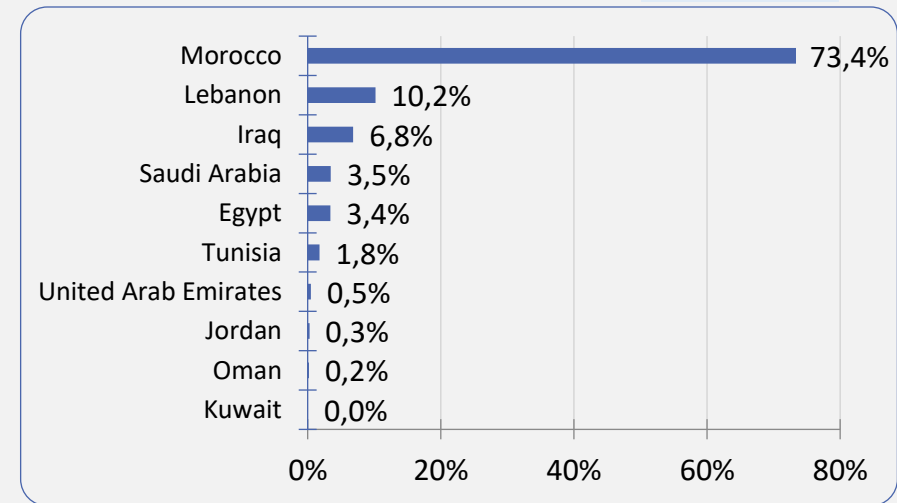
Worldwilde/Astrazeneca



Worldwilde/Sinopharm



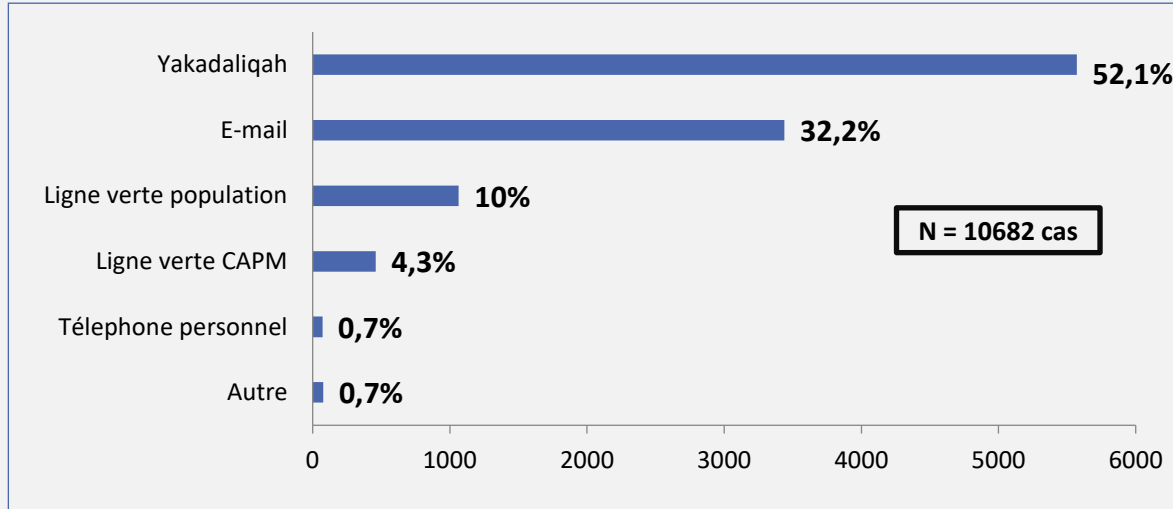
Africa



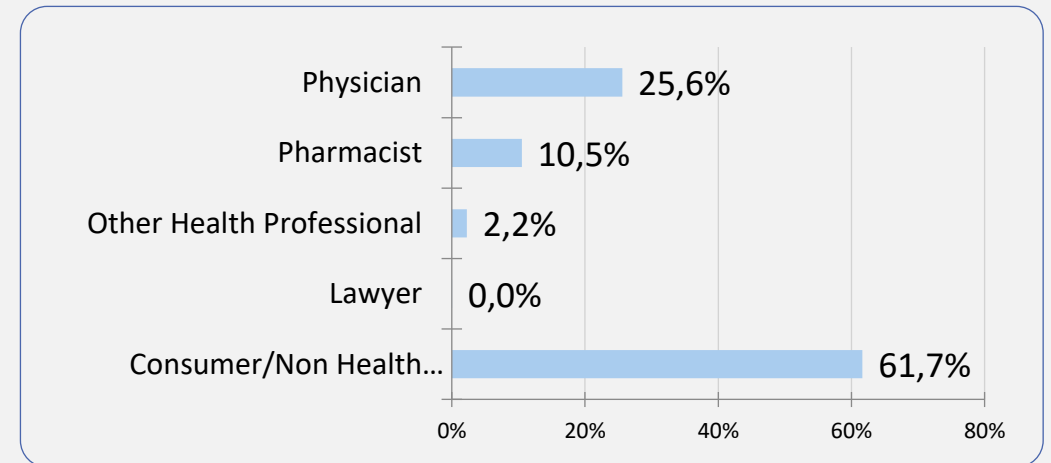
Eastern Mediterranean Regions

Vaccine surveillance safety indicators

Reporting profile



Reporter qualification



Means of reporting

Vaccine surveillance safety indicators

Demographics

Variables	Both vaccines (N= 10682)	AstraZeneca (n= 9318)	Sinopharm (n= 1042)	Non specified (n= 322)
Range of age				
18 - 44	2986 (28%)	2699	268	29
45- 64	3958 (37,1%)	3526	365	66
65 -74	1807 (16,9%)	1505	195	105
75 and more	863 (8,1%)	704	108	48
Non specified	1046 (9,8%)	872	98	74
Gender				
Female	5883(55,1%)	4812	647	179
Male	4698(44%)	3909	379	140
Non specified	101 (0,9%)	89	8	3

Top 20 most frequently reported System organ Class

System Organ Class-MedDRA	AstraZeneca		Sinopharm	
	Number AEFI	%	Number AEFI	%
Median number of AEFI per case (Q1-Q3) **	3 (2 – 5)		2 (1 – 3)	
General disorders and administration site conditions	6 348	68,1	555	53,4
Musculoskeletal and connective tissue disorders	3 169	34,0	259	25,0
Nervous system disorders	2 871	30,8	293	28,3
Ear and labyrinth disorders	2 137	22,9	277	26,8
Gastrointestinal disorders	1 672	17,9	166	16,1
Respiratory, thoracic and mediastinal disorders	1 095	11,8	157	15,2
Psychiatric disorders	864	9,3	66	6,4
Skin and subcutaneous tissue disorders	755	8,1	80	7,7
Metabolism and nutrition disorders	642	6,9	48	4,6
Vascular disorders	426	4,6	74	7,2
Eye disorders	293	3,1	26	2,5
Cardiac disorders	149	1,6	30	2,9
Infections and infestations	150	1,6	8	0,8
Blood and lymphatic system disorders	44	0,5	1	0,1
Injury, poisoning and procedural complications	14	0,2	3	0,3
Immune system disorders	33	0,4	7	0,7
Reproductive system and breast disorders	21	0,2	2	0,2
Investigations	11	0,1	4	0,3

Top 20 most frequently reported clinical signs

ICSRs of AEFIs

10682

Clinical signs

34 659 (3,3 per patient)

Clinical signs (Top 20)	Astra Zeneca		Sinopharm	
	N= 31 106		2977	
	Number	%	Effectif	%
Asthenia	2374	7,6	215	7,2
Headache	2265	7,3	209	7,
fatigue	2171	7,0	160	5,4
Pain at injection site	1941	6,2	102	3,4
Vertigo	1883	6,1	254	8,5
Fever	1775	5,7	129	4,3
Chills	1581	5,1	115	3,9
Pain in extremities	1484	4,8	65	2,2
Arthralgia	1217	3,9	107	3,6
Myalgia	1312	4,2	137	4,6
faint	897	2,9	77	2,6
Dereased appetite	622	2,0	45	1,5
Nausea	586	1,9	54	1,8
Chest pain	519	1,7	40	1,3
Insomnia	455	1,5	37	1,2
Diarrhea	451	1,5	53	1,8
Tingling	484	1,6	43	1,4
Anxiety	409	1,3	29	1,0
Dyspnea	407	1,3	54	1,8

Serious cases

Serious cases:
152/10 682 (1,18%)

Astrazeneca: 130

Sinopharm: 20

SOC (MedDRA)	Nb cases	AZ	Sinoph	AEFI	Outcome	Link to VITT/ AZ, Thrombopenia, D-D↑, Low Fibrinogen
Immune system disorders	22	16 (72,7%)	6 (27,3%)	Anaphylatic reactions (15) Cardiovascular, respiratory, dermatologic symptoms 2 immunization error (CI)	favourable	
Nervous system disorders	67	58		Cerebrovascular Ischemia (30) Meningitis aseptic (2)		NO
Cardiovascular disorders	29	21	7	HTA, myocardial infarction (3)		NO
Respiratory, thoracic and mediastinal disorders	24	9		Thrombo-embolic events (9) Dyspnea		NO
Skin and subcutaneous tissue disorders	5	5		Lyell, DRESS, purpura, polymorphic erythema	Favourable One death	

VITT: Vaccine induced immune thrombotic Thrombocytopenia

Astra Zeneca/Thromboembolic event

- 9 cases reported/9 Millions of delivered doses
- Investigation
 - **Age > 67 with risk factors (Diabetes , HTA..)**
 - The number of thromboembolic events in vaccinated people is no higher (Lower) than the number seen in the general population
 - **No one of them presented thrombopenia nor low fibrinogene**
 - 1 presented only Increase level of Ddimeres. Favourable outcome
- PV Technical committee : 16 experts
- PV national Commission
- Central committee for vaccination
- Shared with GACVS

Immunization errors

Astrazeneca : 18 cases

Type of errors	Symptomatic errors (4)	Asymptomatic errors
Indication error		
Administration to pregnant women		3
Administration to Breastfeeding Women		2
Wrong schedule of administration		
2 doses at the same time	Palpitations (1)	5
Non-observance of the interval between doses	Tachycardia (1), Dyspnea	4
Manipulation error	Pain in the eye Keratitis (1) Inflammation in the eye (1)	

Sinopharm: 4 cases

Type of errors	Symptomatic errors	Asymptomatic errors (4)
Indication error		
Administration to pregnant women		1
Administration to Breastfeeding Women		1
Wrong schedule of administration		
2 doses at the same time		1
Non-observance of the interval between doses		1 (after 3 days)
Manipulation error		