WHO Programme for International Drug Monitoring

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Covid-19 Vaccine Safety Interest Group (CVSIG) Meeting

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Content

Principles COVID-19 vaccines

WHO Global database of Individual Case Safety Reports, VigiBase

Signal detection at UMC

COVID-19 vaccines focus on Medication errors

- *What have we been reported so far?*

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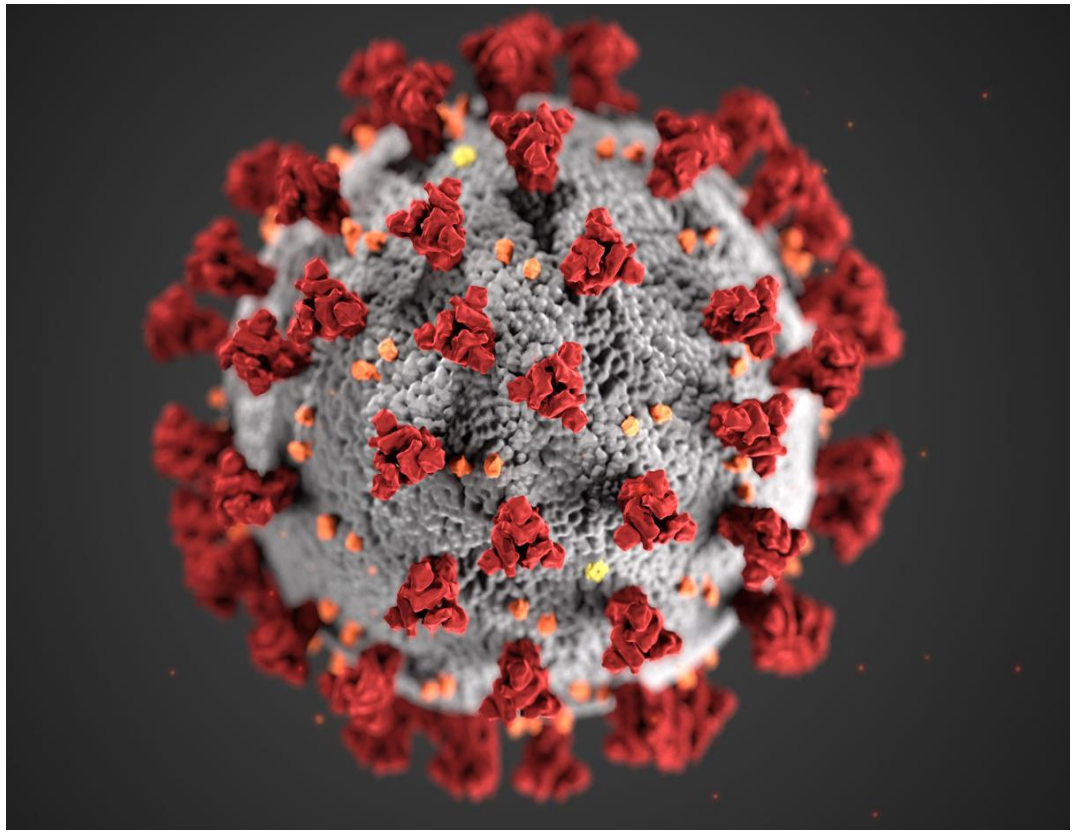
COVID-19 vaccine surveillance

- **Timely detection** and **reporting** of Adverse Events Following Immunization (AEFIs) ensuring the continued vaccine safety, surveillance and response
- COVID-19 vaccine surveillance includes:
  - AEFIs
  - Adverse events of special interest (AESIs)
  - Other safety events: Substandard and counterfeit vaccines, medication errors etc.



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COVID-19

- New infectious disease and new vaccine platforms
- Several vaccines – different mechanism of actions, manufactures etc.
- Different implementation strategies adopted by different countries
- Broad target populations
- Limited safety profile (risk of rare serious reactions)

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- 143 Full members
- 28 Associate members
- Covers > 95% of World population

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Characteristics and Limitations

Type of report

Primarily Post-marketing spontaneous cases

Also accepted Clinical trial reports, Literature reports

Case Seriousness

Serious

Non-serious

Level of suspicion

Adverse events

Possible causality

Type of reporter

Physicians

Pharmacists

Patients

…

Type of drug

Allopathic (incl. OTC), Traditional, Biologicals (incl. Vaccines)

Counterfeit drugs, Medication errors, Therapeutic failure

Not: Veterinary medicines, Cosmetics and Medical devices

Transmission frequency > 1 month

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VigiBase – unique and heterogenous

- >25 million case reports
  - > 1.7 million for vaccines in total
  - > 440 000 for Covid-19 vaccines

- Aim: Detect saftey problems not seen during development, adverse event characterisation

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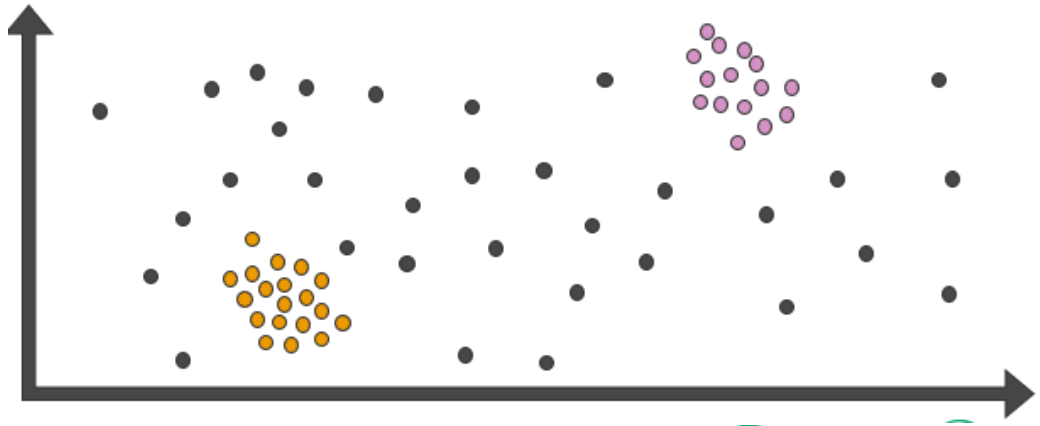
Signal detection at Uppsala Monitoring Centres (UMC)

“Traditional” signal detection

- Disproportionality Analysis (IC)
- Looks on the level of **terms**

Syndrome detection (cluster)

- Pattern recognition
- Looks on the level of **reports**



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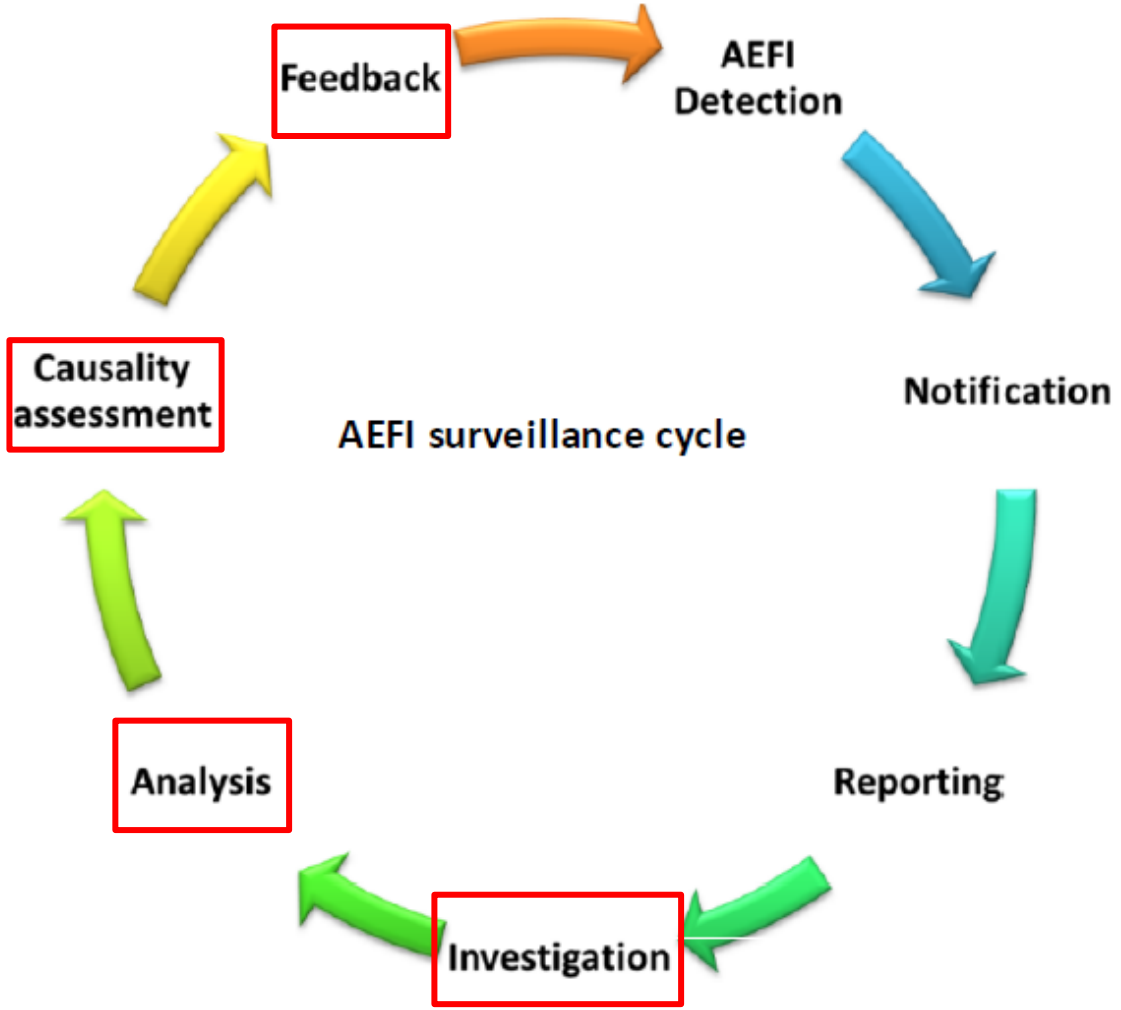
UMC's role

The role of UMC



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What are we doing?

- We receive updates to VigiBase twice a week
- Run the clustering algorithm weekly
  - Pfizer-BioNTech
  - Moderna
  - Astra-Zeneca
  - Sinovac
  - Vaccines grouped by platform (mRNA, vector, inactivated)
- Team members with clinical expertise review the clusters
- Disproportionality

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Reported medication errors 1(2)

- 1697 cases (MedDRA-SMQ Narrow)
- Age distribution
  - >16y
  - 18-44y largest group (367 cases)
- Female: 1021 cases (60.2%), Male: 663 cases (39.1%)
- United States, United Kingdom, Germany, France and Poland

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Reported medication errors 2(2)

- Vaccines
  - Moderna – 903 reports (53.2%)
  - Pfizer-BionTech – 571 reports (33.6%)
  - Astra Zeneca – 113 (6.7%)

- **Serious**: 237 cases (14%) → 34 life threatening/Death

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Top-10 reported terms

Reaction (MedDRA)	Count	Percentage
PT: Inappropriate schedule of product administration	294	17.3
PT: Product administered to patient of inappropriate age	223	13.1
PT: Incorrect dose administered	184	10.8
PT: Wrong product administered	177	10.4
PT: Product administered at inappropriate site	136	8.0
PT: Incorrect route of product administration	125	7.4
PT: Product storage error	117	6.9
PT: Extra dose administered	74	4.4
PT: Exposure via skin contact	57	3.4
PT: Product label confusion	46	2.7

- 1697 reports
- Vaccines

  Pfizer-BioNTech

  Moderna

  Astra-Zeneca

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What have been seen so far?

- Incorrect schedule of product administration – received second dose within a short period of time
- Under/overdose – dilution, syringe problem
- Incorrect route of product administration – given subcutaneous
- Product label confusion

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Conclusion

- VigiBase reflects what have been seen so far
- Spontaneous reports contains limited information of **why** the error happened
- Challenging opportunities to apply risk minimization actions to prevent unnecessary patient harm

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Making medicines **safer for patients**

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