Vaccine Manufacturing Industry

South African Health Products Regulatory Authority (SAHPRA)

National Department of Health (NDoH)

World Health Organization (WHO)

Ministerial Advisory Committees on Vaccines and Immunisation

Consistent with causal association to immunisation

Vaccine product-related reaction

Caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product

Implications for COVID-19

- Identification of rare and very rare adverse events is not sufficient at the time of COVID-19 vaccine registration
- More information will be needed for which AEFI surveillance has to be strengthened

Vaccine quality defect-related reaction

Caused/precipitated by a vaccine, due to one/ more quality defects of the product

Implications for COVID-19

- Knowledge of potential vaccine quality defects might not be sufficient for new vaccine platforms at time of registration
- Rapid scaling up of vaccine production poses additional potential risks
- Identification of exact substance causing event is needed

Immunisation error-related reaction

Caused by inappropriate vaccine handling, prescribing or administration

Implications for COVID-19

- Vaccines will be administered on massive scale within short time interval; larger number of immunization error-related reactions are anticipated if preparation is insufficient
- Staff who are not familiar with immunisation might assist
- Multiple vaccines with different specifications for administration, dose and storage, may in be in use

Immunisation anxiety-related reaction

Arising from anxiety about the immunisation and fear of injection

Implications for COVID-19

- Larger number of immunisation anxiety-related reactions are anticipated due to numerous factors including
  - older age groups
  - different vaccinating environments
  - novelty of the vaccines and their administration modalities
- Example: Vasovagal syncope following vaccination

Inconsistent with causal association to immunisation

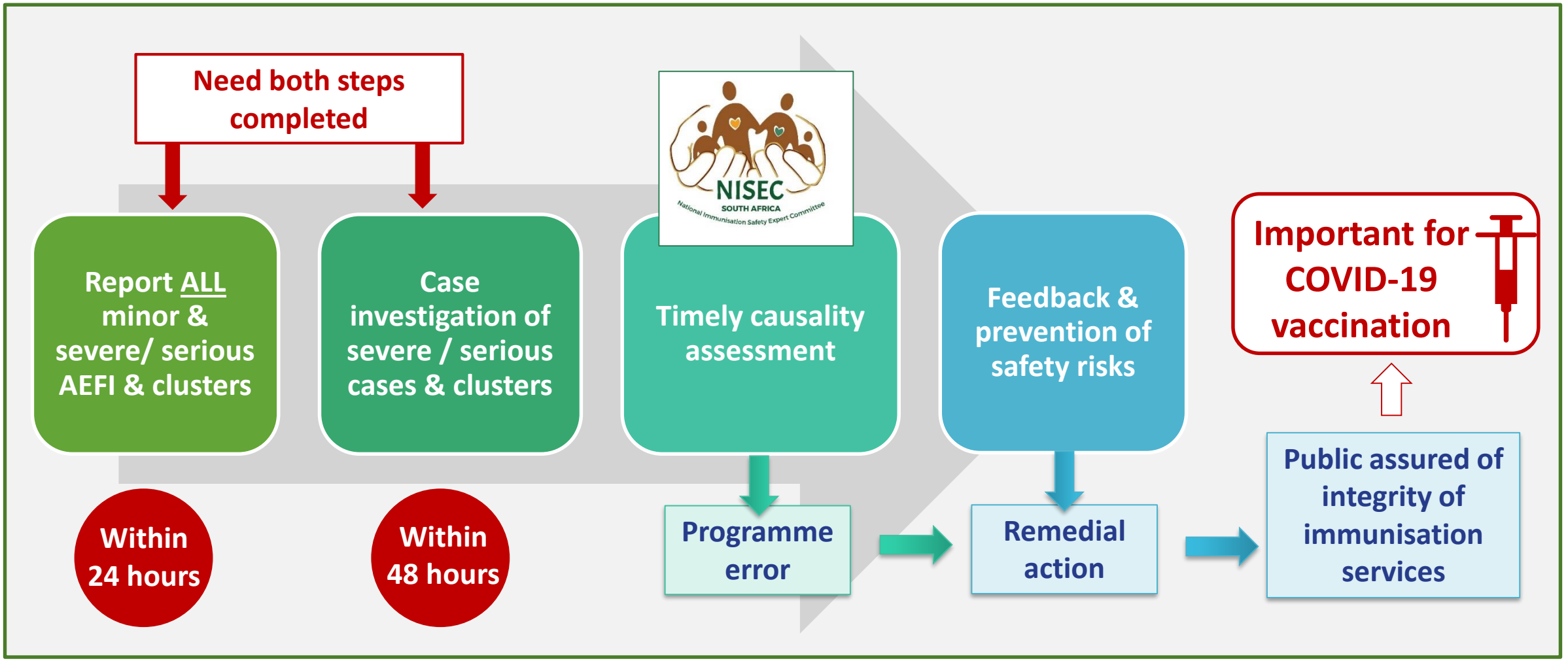
Coincidental event

An event that happens after vaccination but is not caused by the vaccine or vaccination process

Implications for COVID-19

- Coincidental events will be of utmost importance for COVID-19 vaccination and one of the reasons for active surveillance of AESI
- Because of potential comorbidities in vaccine recipients, it will be challenging to differentiate true coincidental events from COVID-19 vaccine product-related reactions or drug reactions or interactions
- Coincidental events can occur in healthy individuals without comorbidities
- Knowing population-based incidence (background rates) of pre-specified AESI helps to anticipate and respond to such events

- Screen for **contraindications** to vaccination e.g. previous anaphylaxis
  If any contraindication → do NOT vaccinate
- Screen for **precautions** and determine if the benefits of the vaccine outweigh the risks. If any precautions → vaccinate with CAUTION
- **Do not store** and/or pack **other diluents** or **medicines** together with any COVID-19 vaccines to avoid reconstitution errors
- Always check the labels of **vaccines and diluents** before reconstitution – use the diluent recommended by the manufacturer
- Follow manufacturer's recommendations on vaccine **preparation, route & technique of administration**.
- Check **expiry-** or **manufacturing date** of vaccine and diluent. Check for signs of **freezing**. Do NOT use beyond specifications
- **Draw the vaccine into the syringe** just before vaccination and **do not touch** the **needle** to avoid contamination of the vaccine and/or the syringe
- **Do not touch** the **rubber cap** of the vaccine vial to avoid contamination of the vial. If reconstituted, discard open vaccine vial at end of immunisation session
- Do not cover the **vaccine carrier** with the lid while the reconstituted vaccine vial is in the foam pad
- **Discard** vaccine if **reconstituted** or **opened** after 6 hours or at end of session, whichever comes first
- When in doubt, **contact** your supervisor for clarification. Do not hesitate to **report** issues or **concerns** when identified


Need both steps completed
Report ALL minor & severe/ serious AEFI & clusters
Case investigation of severe / serious cases & clusters
NISEC
SOUTH AFRICA
National Immunisation Safety Expert Committee
Timely causality assessment
Feedback & prevention of safety risks
Important for COVID-19 vaccination
Within 24 hours
Within 48 hours
Programme error
Remedial action
Public assured of integrity of immunisation services

Med Safety App

Reporting AEFI

1

- Complete case report form (CRF) for **ALL** detected AEFI and AESI cases
- Submit CRF within **24 hours** of detection or notification
- Complete line list

ALL cases of AEFI and AESI: Complete and submit CRF within 24 hours

AEFI and AESI Serious or severe cases and clusters

2

- Manage AEFI/AESI
- Arrange for case investigation by multi-disciplinary team, to be completed **within 48 hours**
- In case of a death, immediately inform District surveillance Officer via phone

3

- Case investigation by multi-disciplinary healthcare team in the district
- Submit completed CIF and documentation to District Surveillance Officer within **48 hours**

Conduct case investigation within 48 hours including the completed CIF

Line list Submit weekly

4

- Provincial AEFI Coordinators to submit updated line list on a weekly basis to the National AEFI Coordinator

5

- Follow-up on any outstanding documentation from the case investigation
- Submit for causality assessment by NISEC

Causality assessment completed by NISEC

Feedback and Prevention

6

- Follow-up on feedback from NISEC
- Communicate outcome of causality assessment with vaccine recipient
- Implement corrective measures in the case of programmatic errors