Adverse Drug Events/Reactions

Ewan Tommy (BPharm)

Medicines Information Centre | National HIV & TB Health Care Worker Hotline

We are available Monday to Friday 08:30 - 16:30

PHONE
0800 212 506
021 406 6782

E-MAIL
pha-mic@uct.ac.za

SMS/PLEASE CALL ME/WHATSAPP
071 840 1572

WEBSITE
www.mic.uct.ac.za

FACEBOOK
HIV & TB Health Care Worker Hotline, South Africa

FREE ANDROID & APPLE APP
SA HIV/TB Hotline

UNIVERSITY OF CAPE TOWN
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MEDICINES INFORMATION CENTRE

NATIONAL HIV & TB HEALTH CARE WORKER HOTLINE
0800 212 506

Definitions & Terminology

Pharmacovigilance:

The science and activities relating to the detection, assessment, understanding and prevention of long term and short-term adverse effects of medicines or any other medicine-related problems.

Adverse Drug Event (ADE)

Any untoward medical occurrence in a patient (or clinical trial subject) administered a medicine that may present during treatment with that medicine, but which does not necessarily have a causal relationship with this treatment.

- Any unfavourable and unintended sign, symptom or disease temporally associated with the use of a medicine, whether considered related to the medicine or not.

Adverse Drug Reaction (ADR) | Adverse Effect (AE)

Any response to a drug (medicine) which is noxious (adverse) and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or treatment of disease, or for the modification of physiological function, including lack of efficacy, and can result from overdose, misuse or abuse of any drug.

Medication Error (preventable ADE/ ADR)

Any preventable event resulting from failure in the treatment process, including prescribing, dispensing, medicine preparation, administration and monitoring errors, and which has the potential to cause or lead to inappropriate medication use and harm to the patient.

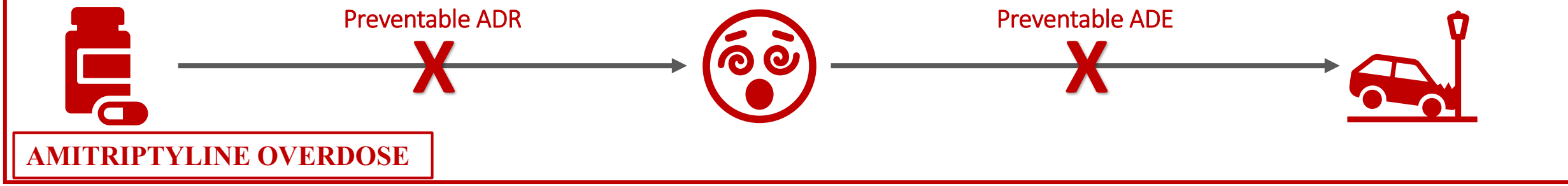
ADVERSE DRUG EVENT (ADE)

No causal relationship established between drug therapy and occurrence of the event

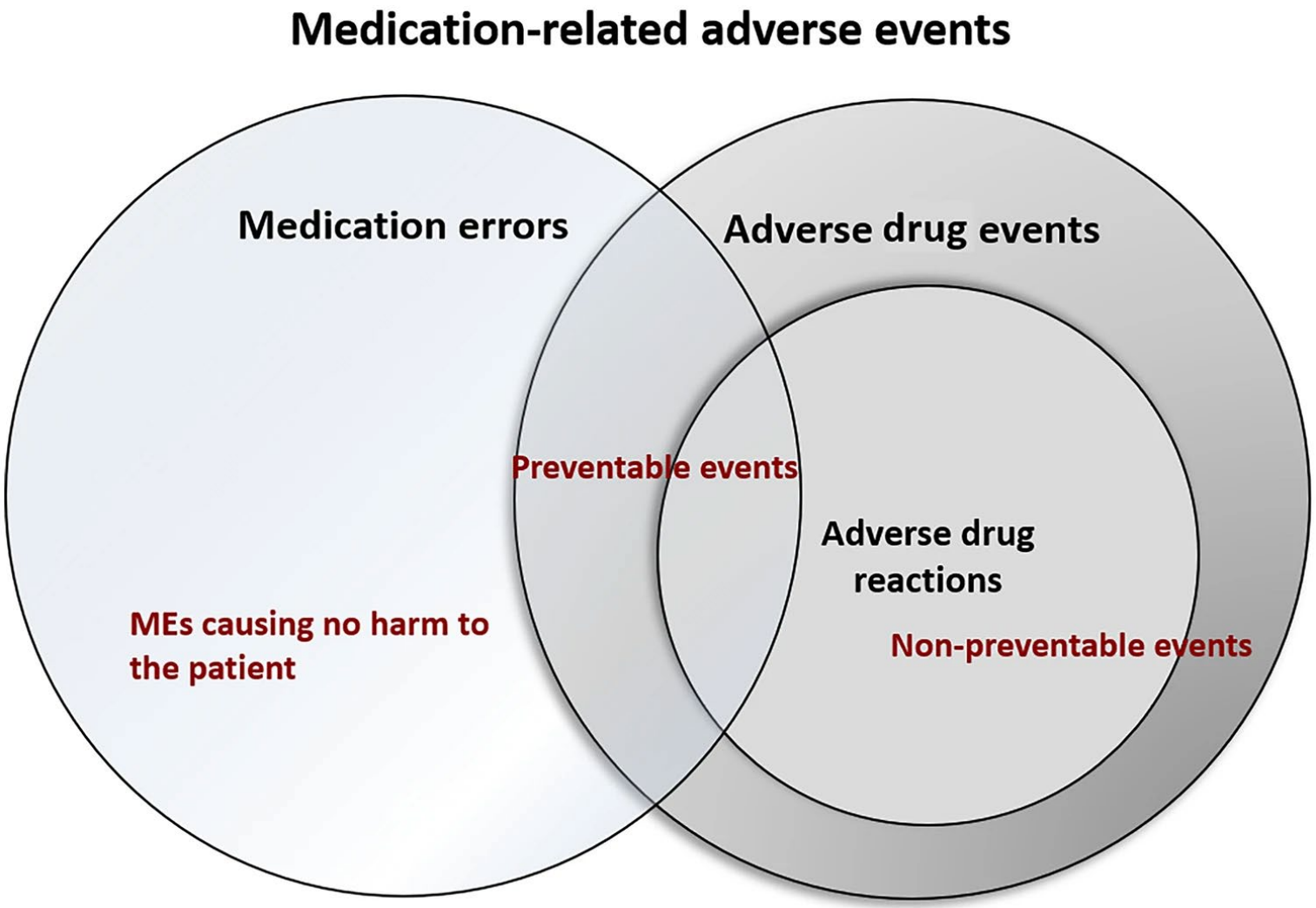
ADVERSE DRUG REACTION (ADR)

Possible causal relationship established between time of drug exposure (amitriptyline) and occurrence of the event

MEDICATION ERROR (ME)



ADE - ADR - ME Relationship



Eur J Clin Pharmacol 78, 159–170 (2022)

Many ADRs are preventable and may lead to serious health issues and even death

SOUTH AFRICA

Hospital Admissions:

- 1 in 12 admissions were due to an ADR
- **45% of ADRs were preventable**

Mouton JP et al. Medicine (Baltimore). 2016 May;95(19):e3437

Mortality following admissions:

- ADRs contributed to the death of 2.9% of medical admissions
- Overall mortality was 18 per 100 admissions and 16% of these deaths were ADR-related
- **43% of ADR-related deaths were preventable**

Mouton JP et al. Br J Clin Pharmacol. 2015 Oct;80(4):818-26

Classification of ADRs

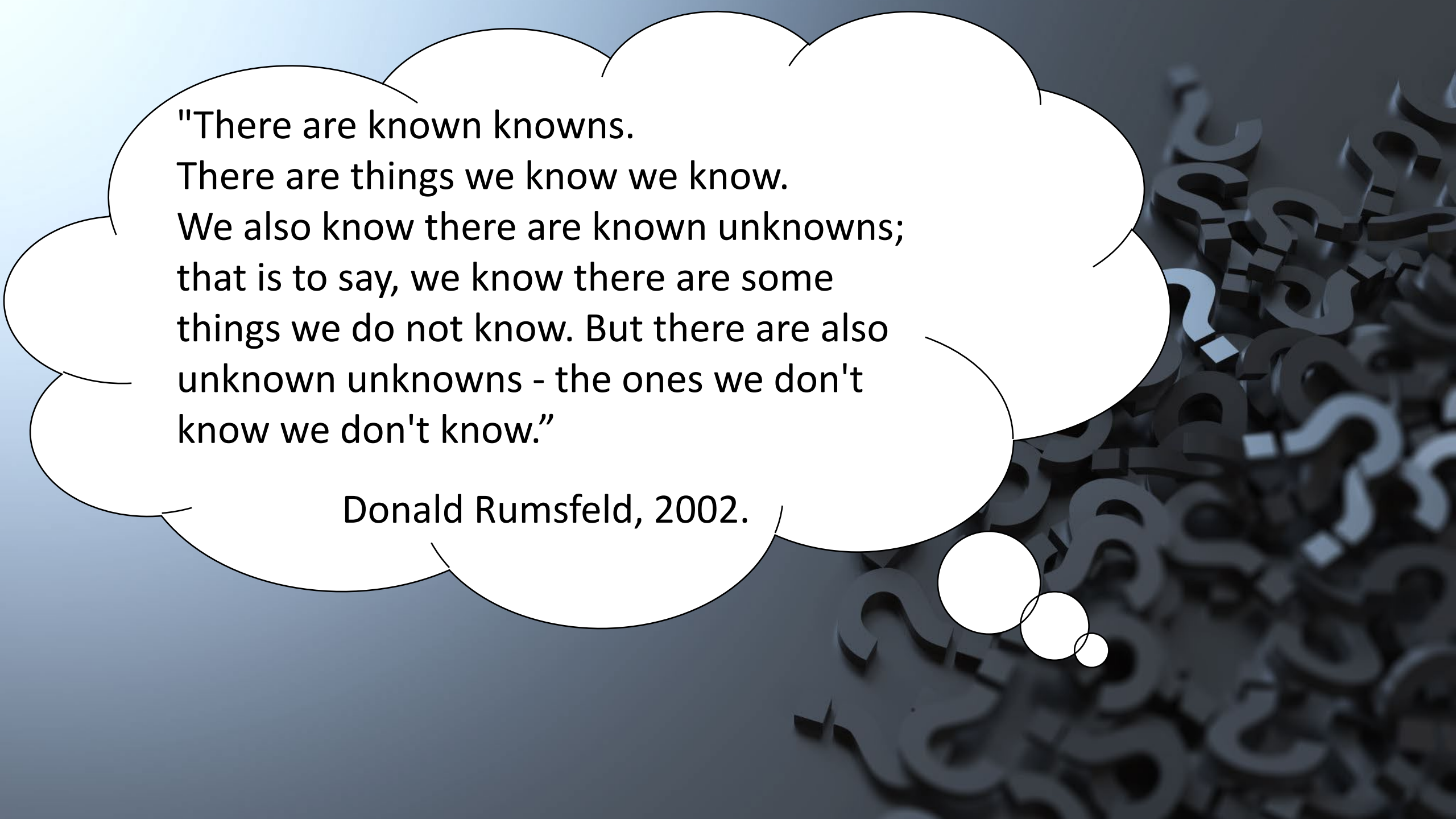
Type of reaction	Mnemonic	Features	Examples
A: Dose-related	Augmented	• Common • Related to a pharmacological action of the drug • Predictable • Low mortality	• Toxic effects: Digoxin toxicity; serotonin syndrome with SSRIs • Side effects: Anticholinergic effects of tricyclic antidepressants
B: Non-dose-related	Bizarre	• Uncommon • Not related to a pharmacological action of the drug • Unpredictable • High mortality	• Immunological reactions: Penicillin hypersensitivity • Idiosyncratic reactions: Acute porphyria Malignant hyperthermia Pseudoallergy (eg, ampicillin rash)
C: Dose-related and time-related	Chronic	• Uncommon • Related to the cumulative dose	• Hypothalamic-pituitary-adrenal axis suppression by corticosteroids
D: Time-related	Delayed	• Uncommon • Usually dose-related • Occurs or becomes apparent some time after the use of the drug	• Teratogenesis (eg, vaginal adenocarcinoma with diethylstilbestrol) • Carcinogenesis • Tardive dyskinesia
E: Withdrawal	End of use	• Uncommon • Occurs soon after withdrawal of the drug	• Opiate withdrawal syndrome • Myocardial ischaemia (β-blocker withdrawal)
F: Unexpected failure of therapy	Failure	• Common • Dose-related • Often caused by drug interactions	• Inadequate dosage of an oral contraceptive, particularly when used with specific enzyme inducers

SSRIs=serotonin-selective reuptake inhibitors.

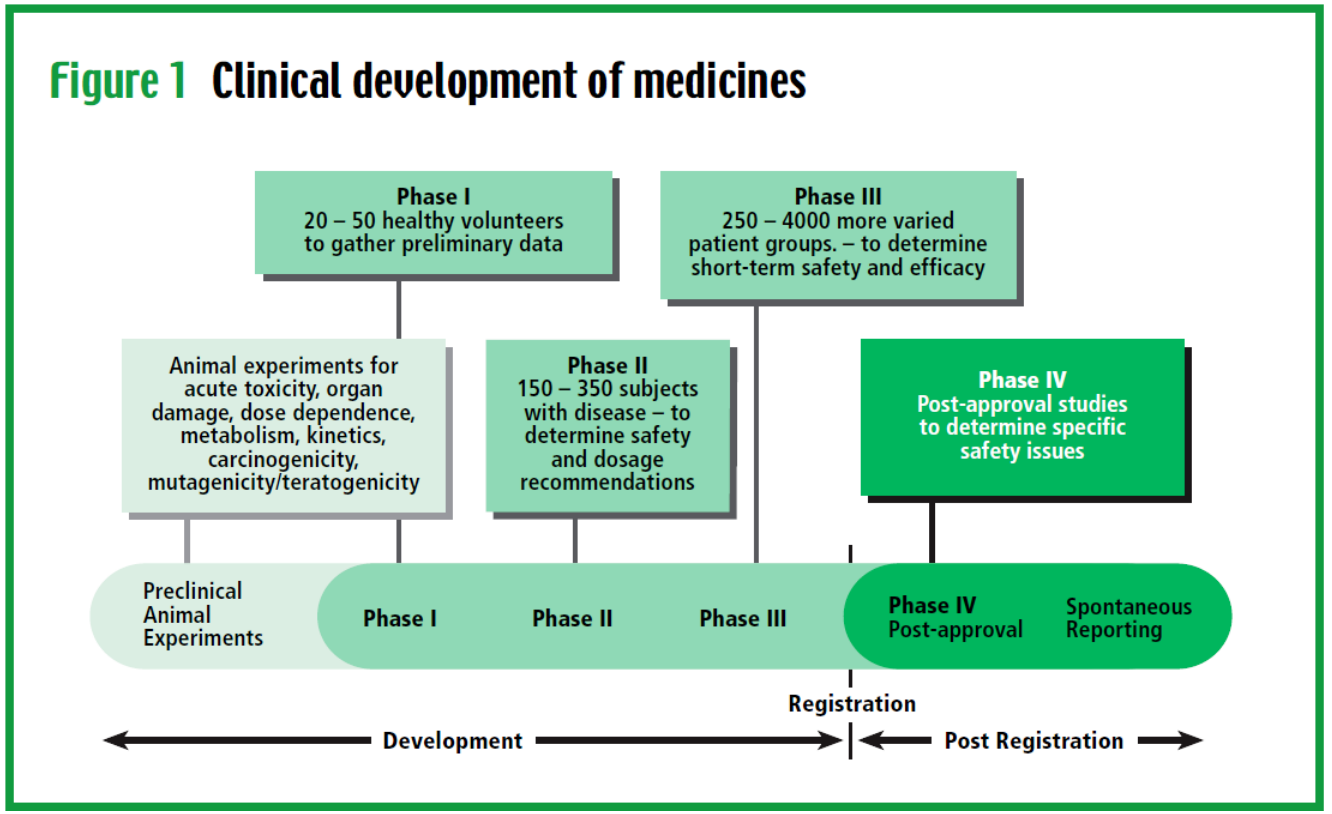
TYPE A, C, D, E, F are related to the pharmacological properties of the drug

TYPE B are **not** related to the pharmacological properties of the drug

Lancet 2000; 356: 1255–59


"There are known knowns.
There are things we know we know.
We also know there are known unknowns;
that is to say, we know there are some
things we do not know. But there are also
unknown unknowns - the ones we don't
know we don't know."
Donald Rumsfeld, 2002.

Limitations of studies during clinical development



- ❑ **Small number of patients** (< 5000 participants enrolled)
- ❑ **Limited/excluded populations** (age, gender, ethnicity, co-morbidities, pregnancy, breastfeeding)
- ❑ **Limited duration, short follow-up** – limited/unknown safety data on long-term and rare reactions
- ❑ **Conditions and indications differ** from those in clinical practice (off-label use)

Source: World Health Organization. 2004. WHO Policy Perspectives on Medicines - Pharmacovigilance : ensuring the safe use of medicines. World Health Organization. Available at: https://apps.who.int/iris/handle/10665/68782

The importance of post-marketing surveillance to identify ADRs

Registration

Development → | ← Post Registration →

Very common	Common	Uncommon	Rare	Very rare
≥ 10 %	1 – 10 %	0.1 – 1 %	0.01 – 0.1 %	< 0.01 %
≥ 1 in 100	1 – 10 in 100	1 – 10 in 1000	1 – 10 in 10 000	< 1 in 10 000
Very common / uncommon and short-term adverse effects Identified in clinical trials			Limited/lacking info on long-term and rare adverse effects	
Identified ADRs/risks Known knowns			**Unidentified ADRs/risks** Known unknowns & Unknown unknowns	

Rule of 3

95% confidence in observing 1 occurrence of an event requires exposed group 3 times the size of the event's frequency

Council for International Organizations of Medical Sciences (CIOMS)

ADE Detection Methods

Spontaneous reporting

Voluntary reporting (main method used internationally by members of WHO Programme for International Drug Monitoring)

Medical record or chart review

- Systematic method for identifying ADEs
- Pros - detects more ADEs vs spontaneous reporting and computerized surveillance
- Cons - costly and time-consuming, ADEs are not reliably recorded in the medical record due to variable standards for documentation, liability concerns, lack of clinician awareness of the ADE, and incomplete record retrieval.
- ADE trigger tools - list of clinical “clues” that an ADE may have occurred.
  - antidote medications such as naloxone for opioid-related ADEs
  - abnormal laboratory tests (i.e., renal function or transaminase elevation) that may indicate medication-related toxicity

Computerized surveillance

- Pros - detects many events not captured by voluntary reporting. Useful to monitor a large patient population continuously, requires little labour hours than chart review.
- Cons - limited access to automated surveillance systems.

Direct observation - most effective method to medication errors (especially administration errors) but expensive.

Reports by patients and family members - complements other approaches, but its performance in operational settings requires further study.

Spontaneous Reporting & Signal Detection

Spontaneous reporting - passive surveillance method of healthcare professionals and patients voluntarily reporting ADEs to detect signals of suspected ADRs .

Pros	Cons
• Most common passive surveillance method • Easy and least labour-intensive method • Covers all population and includes all medicines • Monitoring throughout life-cycle of a medicine • Detect previously unknown/rare reactions • Useful in identifying signals and trends	• Under- or incomplete reporting (quality and quantity of data) • No denominator – cannot determine incidence or risk rates • Bias and variance in voluntary reporting: – Significance - seriousness vs. severity of reactions – Time since market introduction (new vs. old medicine) – Advertising/ promotional claims – Publicity of specific ADRs and specific drug association

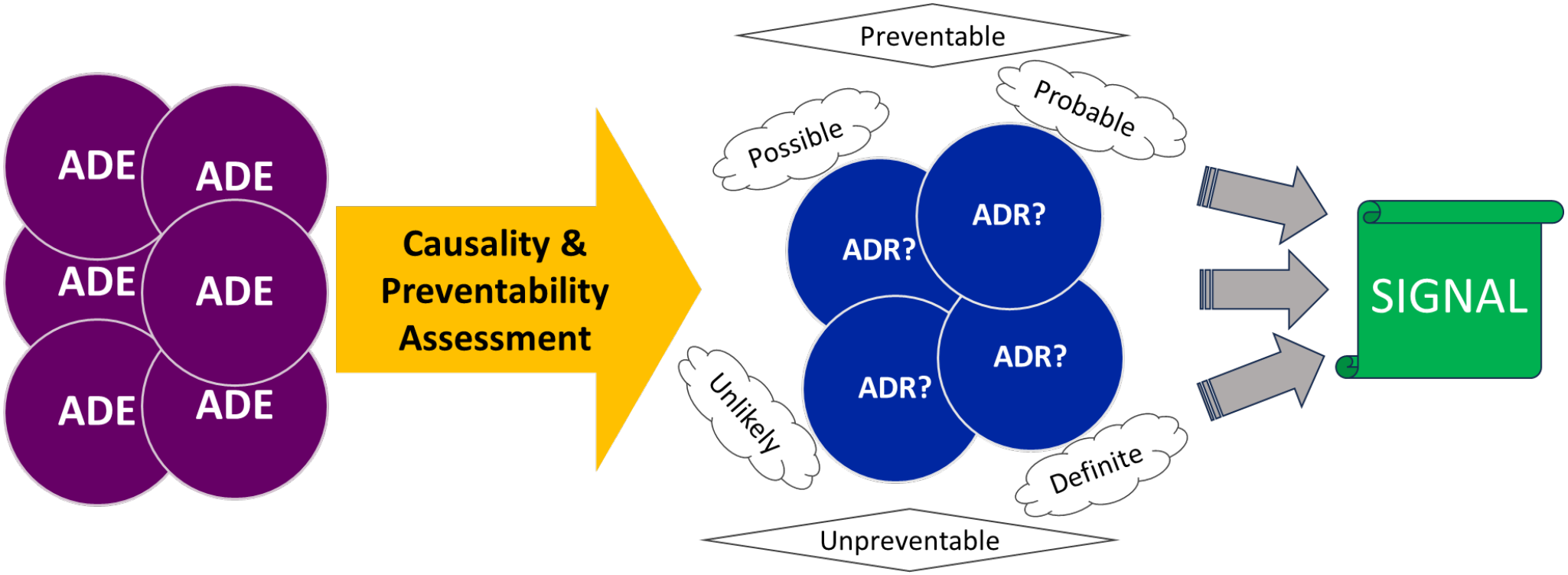
Causality Assessment & Signal Detection

Signal

Reported information on a possible causal relationship between an adverse event and drug that was previously unknown or incompletely documented.

More than one report is needed to generate a signal, depending on:

- Quality of the information provided in the report
- Seriousness of the event reported



Who Should Report ADE?

All healthcare workers - doctors, nurses, pharmacists, dentists, etc. and patients

Regulation 40: Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended:
A healthcare professional /provider, veterinarian or any other person should inform the Authority (SAHPRA), in the manner as determined by the Authority, of any suspected ADRs/AEFIs; or new or existing safety, quality or effectiveness concerns, occurring as a result of the use of any medicine or scheduled substance.

Profession	Role/Function
Nurse	• Initial contact for complaint and observation/description of suspected ADR • Referral for evaluation and management of suspected ADR
Pharmacist	• Check and complete relevant medication history relative to the onset and duration of the suspected ADR • Rational medicine use evaluation - identify any actual or potential medicine-related problems which may cause or contribute to ADRs
Medical officer and allied HCPs	• Evaluation of signs, symptoms or other abnormal clinical and laboratory findings • Diagnosis of suspected ADR – differential diagnosis (disease vs disorder vs drug) • Intervention and follow-up to resolve/prevent harm – severity of symptoms and seriousness of harm outcomes • Check all relevant clinical information is provided when reporting suspected ADR

Pharmacy role in Pharmacovigilance and reporting ADE/ADR

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES

DOMAIN 2: SAFE AND RATIONAL USE OF MEDICINES AND MEDICAL DEVICES				
COMPETENCIES	BEHAVIOURAL STATEMENTS			
	Item no.	Entry Level into Practice	Intermediate Practice	Advanced Practice
2.7 Pharmacovigilance	2.7.1	2.7.1.1 Monitor, receive, record and report quality defects, adverse drug reactions and events.	2.7.1.2 Manage pharmacovigilance activities and classify the events accordingly.	2.7.1.3 Design and implement interventions to prevent and minimise adverse drug events.
	2.7.2	2.7.2.1 Perform post marketing surveillance studies.	2.7.2.2 Compile reports of the post marketing surveillance studies.	2.7.2.3 Review pharmacovigilance reports and report to regulatory authority.

66 No. 41621 GOVERNMENT GAZETTE, 11 MAY 2018

✓Right patient ✓Right drug ✓Right dose ✓Right route ✓Right time

National Drug Policy for South Africa

7.6 The role of pharmacists

Although all health care providers and the public are involved in the rational use of drugs, WHO has recommended a special role for pharmacists, particularly in quality assurance and in the safe and effective administration of drugs. Pharmacists will be in a strong position to promote the rational use of drugs through their extensive knowledge.

Detecting suspected ADEs/ADRs

- Listen carefully to client's complaints of symptoms suggestive of an ADR (subjective
- Check for any signs as objective evidence to suggest an ADR
  - New or unusual signs or symptoms
  - Abnormal laboratory test finding
  - Abnormality detected on imaging or diagnostics (CT scan, MRI, X-ray)
  - Abnormal clinical measurements (temperature, pulse, BP, blood glucose, body weight).
- Ask the client questions related to their treatment and how they feel
- Assess adherence (non-adherence may be due to intolerance to ADRs)
- Obtain a complete medication history
- Verify that the suspected medicine and other medicines were administered/taken prior to onset of the ADR
- Verify that the onset of the suspected ADE/ADR was after the medicine was administered/taken
- Consider whether the event is pharmacologically plausible

Detecting suspected ADRs

- Check for any medicine-related problems
  - Contraindications - age, gender, weight, comorbidities, pregnancy, breastfeeding
  - Dosing is appropriate for indication, age, weight, renal/hepatic impairment
  - Drug interactions - food, disease, other medicines (polypharmacy)
- Check if there have been any recent therapy adjustments - dose changes, addition of therapy, discontinuation of therapy
- Check for any follow-up on outcomes of the suspected ADR following any interventions to resolve/prevent harm
- Consider alternative factors causing or contributing - comorbidities, other medicines incl. OTC & CATM
- Check relevant up-to-date literature - summary of product characteristic (SmPC), professional information (PI), guidelines, medical databases, journals

Not all ADRs may be adequately reflected in the SmPC/PI/PIL

Report What?

All adverse events with:

- All registered and unregistered medicines, including:
- Medical devices | In-vitro diagnostics
- Vaccines | Biologicals
- Complementary | Alternative | Traditional | Herbal | Natural products

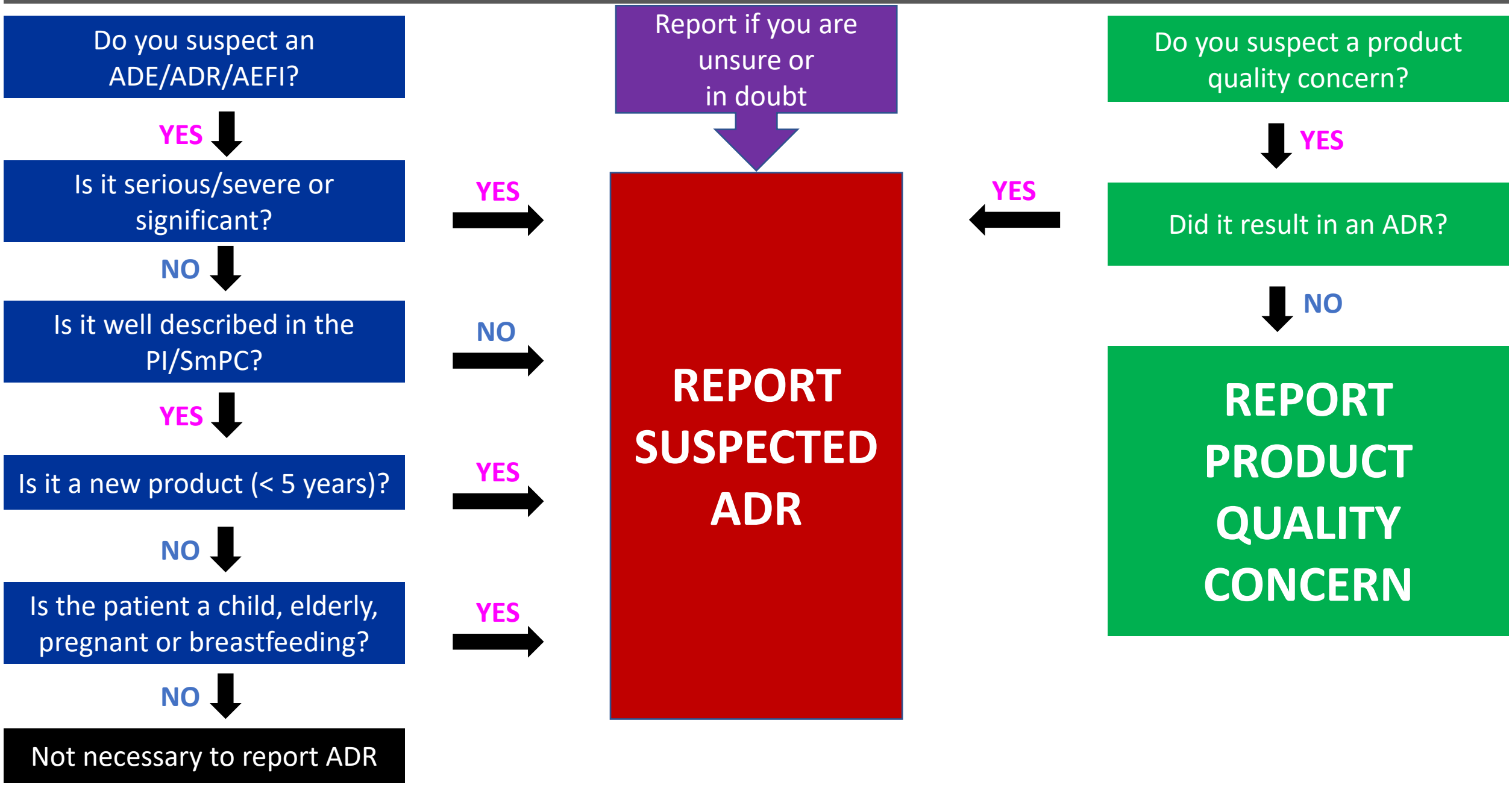
Serious/severe events resulting in:

- Any intervention to resolve/prevent any harm
- Hospitalisation (initial/prolonged)
- Disability/impairment (temporary/permanent)
- Congenital anomaly/ birth defect
- Life-threatening
- Death

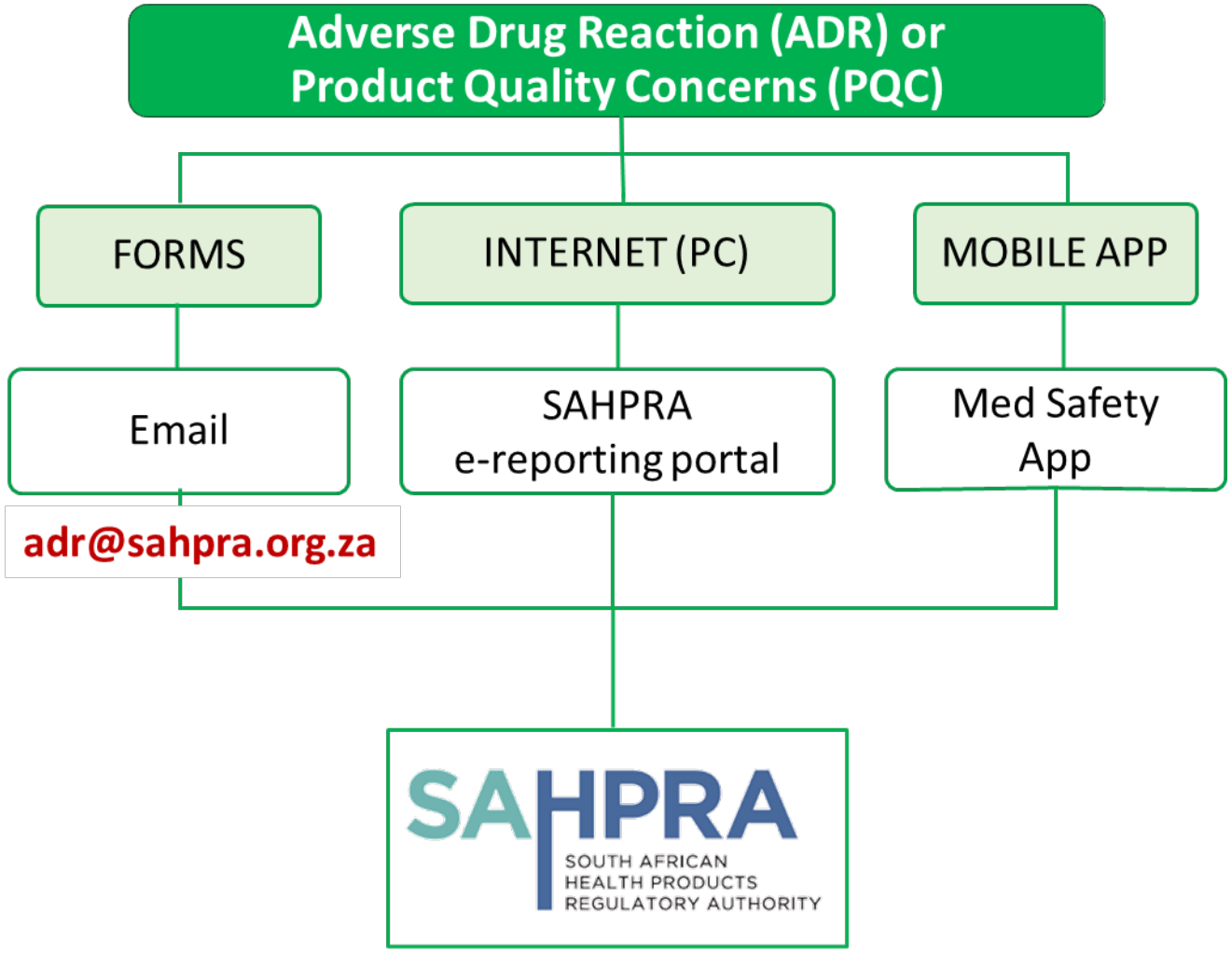
Significant events:

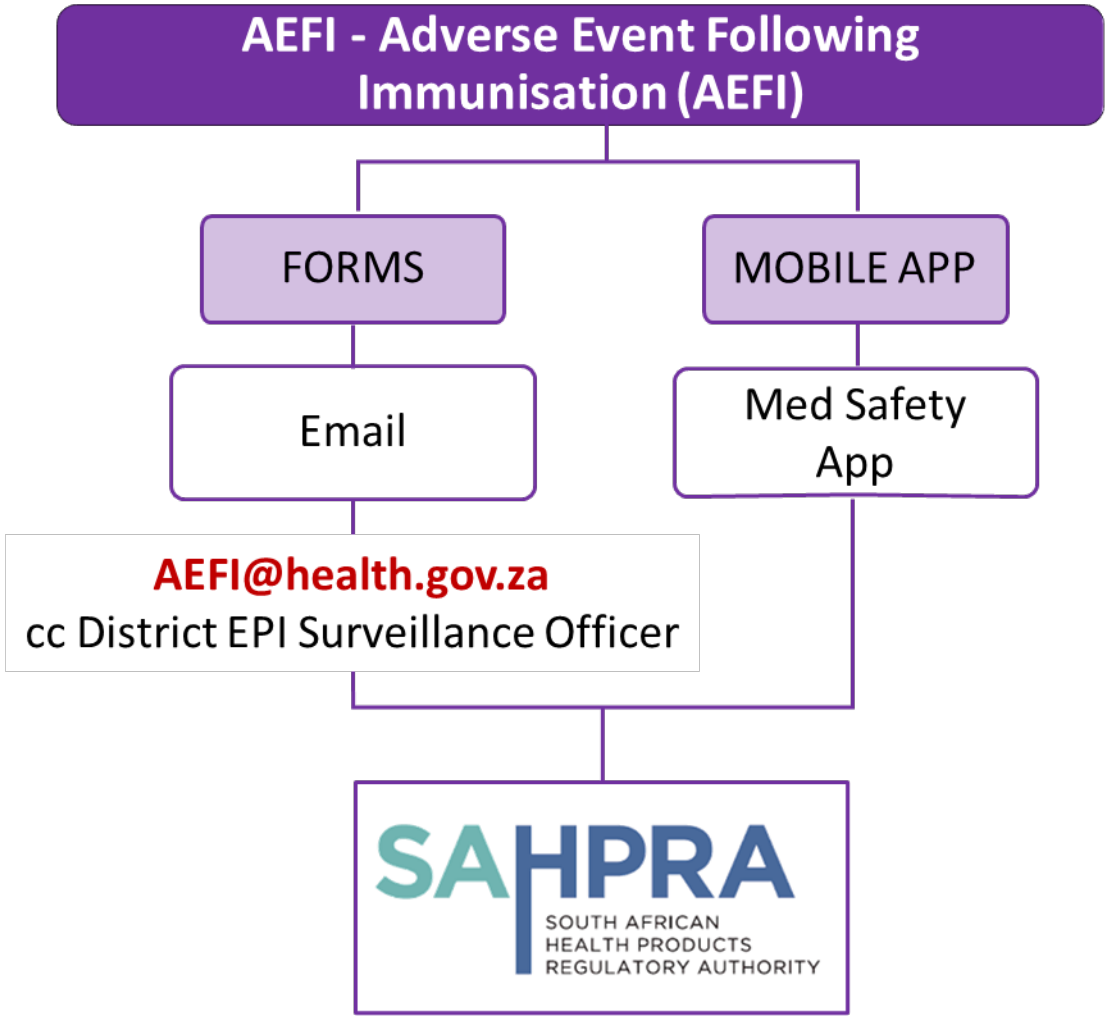
- In children, elderly, during pregnancy or breastfeeding
- Foetal or infant exposures during pregnancy/breastfeeding
- Newly marketed products (< 5 years)
- Not clearly stated in package inserts
- Occurring more frequently than previously reported
- Resulting from interactions (drug, food, disease)
- Therapeutic failures

Should I report all ADEs?



Reporting to SAHPRA





Pharmacovigilance related queries: pvqueries@sahpra.org.za

ADR Reporting Form

Doc Number: GLF-CEM-PV-06A *[Old Doc no. 6.04]*	**ADVERSE DRUG REACTION (ADR)/ PRODUCT QUALITY PROBLEM REPORT FORM** (PUBLIC AND PRIVATE SECTOR) (Including Herbal Products)	SAHPRA South African Health Products Regulatory Authority
Revision: 5.0		Effective date: 21 August 2023

See Page 2 for CONSENT CLAUSE, more information regarding reporting of PRODUCT QUALITY PROBLEMS and ADVERSE EVENTS FOR VACCINES

Reporting Health Care Facility/Practice

Building A, Loftus Park 402 Kirkness Street, Arcadia, Pretoria Tel: (012) 501 0311 E-mail: adr@sahpra.org.za	Facility/Practice			
	District		Tel	
	Province		Fax	

Patient Details

Patient Initials		File/Reference Number				Date of Birth/Age			
Sex	☐M ☐F ☐Unk	Race		Weight (kg)		Height (cm)		Pregnant?	☐N ☐Y
Allergies				Estimated gestational age at time of reaction					

Suspect Medicine(s) [Medicines suspected to have caused the ADR], Concomitant [Other medicines taken together with the suspect medicine(s)] OR Interacting [Other medicines taken together with the suspect medicine(s)] [Including over-the-counter and herbal products].

Trade Name [Active Ingredient if Trade Name is unknown]	Medicine role (Please tick the applicable box)	Route	Dose (mg) and Interval	Date Started/ Given	Date Stopped	Reason for use	Batch Number	Expiry Date
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							
	☐ Suspect ☐ Concomitant ☐ Interacting							

Adverse Drug Reaction/Product Quality Problem

Date and time of onset of reaction		Date reaction resolved	

Please describe Adverse Event/Product Quality Problem: (kindly add as much clinical information as possible)

Intervention (Tick all that apply)	**Patient Outcomes** (Tick all that apply)	**ADR seriousness criteria** (Tick all that apply)
☐ No intervention. ☐ Intervention unknown. ☐ Patient counselled/non-medical treatment. ☐ Discontinued suspect drug; **Replaced with**: _____ ☐ Decreased suspect drug dosage; **New Dose**: _____ ☐ Treated ADR – with: _____ ☐ Referred to hospital: **Hospital name**_____ ☐ Other intervention (e.g., dialysis): _____	☐ ADR recovered/resolved. ☐ Recovering/resolving. ☐ Not recovered/not resolved. ☐ Recovered with sequelae. ☐ ADR resolved after suspect medicine was stopped: ☐N ☐Y. ☐ ADR reappeared after restarting suspect drug/similar drug (rechallenge): ☐N ☐Y ☐ Not done ☐ Unknown	☐ Resulted in death. Date of death: _____ ☐ Patient hospitalised or hospitalisation prolonged. ☐ Life threatening. ☐ Impairment/disability. ☐ Congenital anomaly/ birth defect. ☐ Other medically important condition.

Laboratory Results			**Additional Laboratory Results**		
Lab Test	**Test Result**	**Test Date**	**Lab Test**	**Test Result**	**Test Date**

Co-morbidities/Other Medical Condition(s)

Reported by			
Name		E-mail	
Designation	☐Nurse ☐Pharmacist ☐Doctor ☐Other:	Telephone	
Date reported:		Signature	

THIS ADR REPORT IS NOT A CONFIRMATION THAT THE REPORTER OR THE SUSPECT MEDICINE(S) CAUSED THE ADR

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
- medications (medicines and biologicals),
- complementary / alternative medicines (including traditional, herbal remedies, etc).

Report even if:
- you're not certain the product caused the event,
- you don't have all the details.

Please report especially:
- adverse drug reactions to newly marketed products,
- serious reactions and interactions with all products,
- adverse drug reactions which are not clearly reflected in the package insert.

Report Product Quality Problems via:
- phone: 0800 204 307
  SAHPRA portal: https://www.sahpra.org.za/complaints-relating-to-medicine-and-medical-devices/

Report Product Quality Problems such as:
- suspected contamination,
- questionable stability,
- defective components,
- poor packaging or labelling,
- therapeutic failures.

Report Adverse Events Following Immunisation (AEFI) experienced with vaccines on:
- the dedicated Case Reporting Form accessed from SAHPRA portal: https://www.sahpra.org.za/health-products-vigilance/
- forward the dedicated form to AEFI@health.gov.za
- phone: 0800 02 9999.

Other reporting tools available at SAHPRA include:

Med Safety Application

The Med Safety Application is a mobile application designed for the public and healthcare professionals to report suspected ADRs/adverse event following immunisations (AEFIs). It is the preferred reporting tool by SAHPRA and allows for a seamless electronic submission of ADR/AEFI reports directly from the source into SAHPRA's reporting systems. The app can be downloaded onto a smart mobile phone directly from the SAHPRA website, https://medsafety.sahpra.org.za.
For more reporting channels please visit SAHPRA website, https://www.sahpra.org.za

CONSENT CLAUSE

By the signature above, the reporter hereby provides consent to the processing of personal information provided for the purpose of reporting a suspected adverse reaction. The reporter acknowledges that this information may be used a) to access all medical and clinical records for the purpose of gathering additional information for a clinical meaningful data, when required; b) in the generation of statistics; and c) to make policy decisions relating to safe use of medicines.

SAHPRA Vigilance unit undertakes to collate the personal information contained in this form and collected during the process of reporting of suspected adverse drug reaction in a manner that adheres to the Protection of Personal Information Act, so that your personal data is processed fairly, lawfully and transparently, adequate, relevant, and limited to what is necessary, processed for specific and legitimate purposes, accurate and kept up to date where necessary, kept in an identifiable form no longer than necessary for the purpose, processed securely . SAHPRA has put appropriate technical and organisational measures to safeguard your information. The information will not be stored for any longer than is necessary to achieve the purpose for which it was collected, unless SAHPRA Vigilance unit has a lawful basis to do so. If the reporter wishes to access and/or rectify their personal information, they may do so by contacting SAHPRA Vigilance unit at 012 501 0311 or via email: adr@sahpra.org.za.

Confidentiality:

Identities of the reporter and patient will remain strictly confidential.

Your support of the South African Health Products Regulatory Authority's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of medicine safety and therapy in South Africa.

CONSENT FORM | CASE REPORTING FORM (CRF) | CASE INVESTIGATION FORM (CIF)

Patient name & surname: _____ EPID Number: _____

CONSENT CLAUSE FOR COLLECTION AND PROCESSING OF PERSONAL INFORMATION

By their signature below, the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) hereby provides consent to the collection and processing of their personal information (as set out in this Case Reporting Form) by the National Department of Health and third parties appointed by it (the "Department") for the purposes of investigating and assessing potential adverse events related to a vaccine/s received. The vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) acknowledges that this information may be used i) to access all medical and clinical records for the purpose of case investigation, when required; ii) in the generation of statistics; and iii) to make policy decisions relating to vaccine safety and efficacy. This consent may be withdrawn at any time, and the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) may, at any time, object to the collection and processing of their personal information, by contacting the Department (AEFI@heath.gov.za) and the South African Health Products Regulatory Authority (adr@sahpra.org.za).

The Department undertakes to process the personal information contained in this Case Reporting Form, and collected during the process of case investigation in a manner that adheres to the Protection of Personal Information Act. The information will not be stored (in a manner that identifies the vaccine recipient) for any longer than is necessary to achieve the purpose for which the information was collected, unless the Department has a lawful basis to do so. If the vaccine recipient or relative (in the event of the vaccine recipient being unresponsive or has demised) or caregiver (in the case of a child) wishes to access and/or rectify their personal information, they may do so by contacting the Department (AEFI@heath.gov.za).

Vaccine recipient: _____ (Name and Surname)

Signed by the vaccine recipient / relative / caregiver*

_____ _____ _____

Name and Surname Signature Date

*Delete what is not applicable

health

ALL VACCINES including COVID-19

CASE REPORTING FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

EPID Number: S O A - - - - - - - - - - - -
Country - Province - District - Year - Case no

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

Today's date: D D / M M / Y Y Y Y

All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

SECTION A: IDENTIFYING INFORMATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____

If child: Caregiver's name & surname: _____

Vaccine recipient's residential address: _____

Mobile no: _____ Telephone no: _____

Email: _____

Sex: ☐ M ☐ F ☐ Other *If applicable*: ☐ Pregnant ☐ Breastfeeding

Date of birth: D D / M M / Y Y Y Y

OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

If applicable: Gestation: ☐ Full-term ☐ Premature

Reporter's name & surname: _____

Designation/Position: _____

Institution & Department: _____

Telephone no: _____

Mobile no: _____

E-mail: _____

Date patient notified event to health system: D D / M M / Y Y Y Y

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Health Booklet OR Vaccination Card)

NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Health facility / vaccination center name: _____ ☐ DoH ☐ Private ☐ NGO

Address / location: _____

Vaccine administered								Diluent (*if applicable*)		
Vaccine/s given (Use trade name)	Date vaccinated	Time vaccinated	Dose number (1st, 2nd)	Batch/ Lot number	Expiry date / Manufacture date (COVID-19)	VVM Stage (if applies)	Manufacturer	Batch/ Lot number	Expiry date	Date & time of reconstitution

Consumables used (unless pre-filled)		
	Needles	Size: _____ Batch: _____ Expiry date: _____
	Syringes	Size: _____ Batch: _____ Expiry date: _____

SECTION C: TRIGGER EVENTS

Date & time AEFI started: D D / M M / Y Y Y Y ☐☐ Hr ☐☐ Min *Adverse event (s): (Tick (✓) all boxes that apply)*

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ Other (specify): _____

health

ALL VACCINES including COVID-19: CASE INVESTIGATION FORM (CIF)

Adverse Events Following Immunisation (AEFI) AND Adverse Events of Special Interest (AESI)

ONLY for Serious and Severe Adverse Events Following Immunisation, Clusters and Adverse Events of Special Interest

SECTION A: BASIC DETAILS

Province: _____ EPID No: S O A - - - - - - - - - - - -
District: _____ Country - Province - District - Year - Case no.

NB: The EPID number must be IDENTICAL to the number on the CASE REPORTING FORM

PATIENT IDENTIFICATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____ Note: Use a separate form for each case in a cluster

Sex: ☐ M ☐ F ☐ Other

Date of birth: D D / M M / Y Y Y Y OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

Patient's full residential address with landmarks (Street name, house number, locality, etc.):

_____

_____

Telephone no: _____ Mobile no: _____ E-mail: _____

INVESTIGATOR'S DETAILS

Name & surname of reporting officer: _____

Designation / Position: _____ E-mail: _____

Telephone: _____ Mobile: _____

Date of filling this form: D D / M M / Y Y Y Y

Date of investigation: D D / M M / Y Y Y Y This report is: ☐ First ☐ Interim ☐ Final

DETAILS OF THE EVENT

Date of onset of event: D D / M M / Y Y Y Y Time of first symptom: ☐☐ Hr ☐☐ Min

Date first reported to the health authority: D D / M M / Y Y Y Y

Date of hospitalization (if applicable): D D / M M / Y Y Y Y Status on the date of investigation: ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely ☐ Recovered with complications ☐ Unknown

If died, date of death: D D / M M / Y Y Y Y Time of death: ☐☐ Hr ☐☐ Min

Autopsy done: ☐ Yes ☐ No If YES, date of autopsy: D D / M M / Y Y Y Y Attach report (if available)

If NO, autopsy planned: Date: D D / M M / Y Y Y Y Time ☐☐ Hr ☐☐ Min

Autopsy NOT done nor planned. Provide reasons: _____

IMMUNISATION HISTORY

Name of vaccinator: _____ Designation: _____

Name of vaccination site: _____

Address of vaccination site: _____

Place of vaccination: ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____

Type of site: ☐ Fixed ☐ Mobile ☐ Outreach

Vaccination in: ☐ Campaign ☐ Routine ☐ Other (specify): _____

TRIGGER EVENTS

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ Other (specify): _____

SAHPRA's response to safety concerns

Changes to product labelling which can be addition of warnings, precautions or adverse effect in the Professional Information and Patient Information Leaflet.

Distribute Dear Healthcare Professional Letters (DHCPL) or publish medicine safety alerts (MSA) in medical journals to inform healthcare professionals.

Issue press releases to inform consumers.

Limit/restrict access to the health product by either up-scheduling, limiting prescribing indication and population, etc.

Recall, suspend or cancel the registration of a product.

Undertake post-marketing studies to investigate the safety concern if more information is needed.

PHARMACOVIGILANCE CYCLE

PREVENTION

Inform + Prevent
Guidelines
Policies & Protocols
Restriction
Medicine alerts/ recalls
Withdrawal/suspension
Media statements
Training & education

PATIENT
Complaint/concern
Adverse drug event

DETECTION

HEALTHCARE
Manage & Report
Suspected ADRs

REGULATOR & POLICY MAKERS
Estimate + Understand
Further studies
Seriousness and severity
Trends, risk factors
Incidence and prevalence

Review + Update
Rescheduling/restrictions
Labelling/packaging
PIL, PI updates

PHARMACEUTICAL
Collect + Research
Pre- & post-marketing
safety information

PHARMACOVIGILANCE CENTRE
Collect + Assess + Research
Causality & Preventability
Signal detection, trends, risk factors

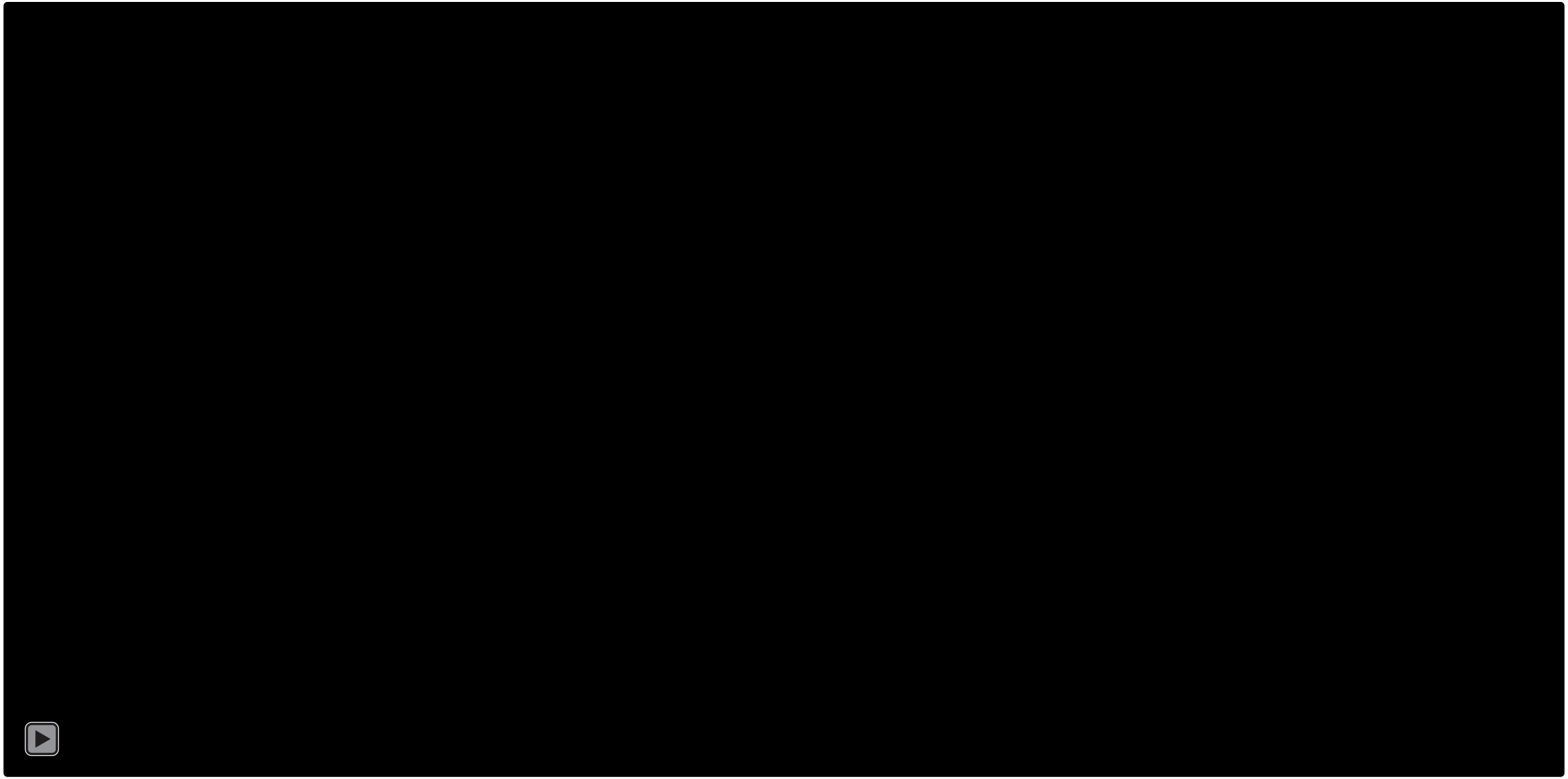
Train + Educate
Pharmacovigilance & ADE reporting

UNDERSTANDING

ASSESSMENT

SAHPRA Health Products Vigilance Portal:

www.sahpra.org.za/health-products-vigilance



Reporting Tools

FORMS

Reporting Form
ADR | PQC
Submit by e-mail: adr@sahpra.org

Case Reporting Form
AEFI (all)

Case Reporting Form
AESI incl COVID-19

Case Investigation Form
Serious or severe AEFI + AESI

Submit by e-mail: AEFI@health.gov.za + District EPI Surveillance officer

ONLINE

E-reporting (online)
ADR | PQC
http://primaryreporting.who-umc.org/ZA

Med Safety App
ADR | AEFI

Link to Guidelines

ADR - adverse drug reaction; AEFI - adverse event following immunisation
PQC - product quality concerns

THANK YOU