Patient Safety - Medication Errors within Pharmacovigilance Centres

Concept,
Terminologies,
Methods

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Aims of the presentation

- Raising the attention of PV professionals about their ability in managing Medication Errors “ME” through reported adverse drug event;
- Describing how to undertake step-by-step detection and analysis of data relating to ME contained in Pharmacovigilance Centre “PVC” databases;
- Rising up the need of materiel on standard terminology for ME incidents, classification and strategies to manage and minimize harms from ME;
- Outline the importance of collaboration between all concerned parties involved to prevent ME.

Contents

1. Burden of ME on Public Health
2. Organizations involved in ME
3. Terminologies and definitions
4. ME Classification
5. Identifying and reporting ME
6. Analyzing ME: Root Cause Analysis
7. Strategies to manage and minimize harms from ME
8. Collaboration

Preliminary Definitions

Adverse Drug Reaction
ADR ?

Adverse Drug Reaction
ADR

"a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of a physiological function" **(WHO, 1972)**

WHO collaborating centre for International Drug Monitoring (UMC). Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre. London, UK: EQUUS; 2000.

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"noxious and unintended effect resulting not only from the authorized use of a medicinal product at normal doses, but also from **medication errors and uses outside the terms of the marketing authorization, including the misuse and abuse of the medicinal product**" Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010

See also: Importance of Pharmacovigilance WHO guideline

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Medication Error

A failure in the treatment process that leads to, or **has the potential to lead to, harm** to the patient".

http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

National Patient safety Agency – UK

1. Burden of ME on public health

- **Patient Safety Incidents and MEs**
  - Developed countries: 1/ 10 patients is harmed while receiving hospital care (Bates 2010)
  - Developing countries: probability of patients being harmed in hospitals is higher than in industrialized nations (WAPS 2010)
  - cost about between US$ 6 billion and US$ 29 billion a year *(World Alliance for Patient Safety 2010)*

- **Medication incidents**
  - First studies on ADEs (1984.Harvard Medical Practice Study 30,195 included patients) showed that in 19.4% of ADEs, 17.7% are preventable ADEs

Actions Taken by Pharmacovigilance for safety reason

(January 2005- October 2008)

		Withdrawn	Restricted	Warning	Other
Non preventable ADR	74.0%	Aprotinine Astemizole Clobutinol Ephedrine Metamizole Nitrofural Pemoline Pergolide Phenylpropanolamine Rimonabant Rofecoxib Technetium 99mTc Tegaserod Trimethobenzamide supp Valdecoxib Veralipride Ximelagatran Nasal/oropharyngeal antibiotics	Aspirine Amlodipine Cinacalcet Cisapride Desmopressine Dolasetron Gatifloxacine Interferon G-1b Natalizumab Nevirapine Nimesulide Parecoxib Piroxicam Promethazine Pseudo ephedrine Telithromycine Thioridazine Chlorproguanil and dapsone	Cabergoline Codeine Isotretinoine Ketoconazole Lamotrigine L-arginine Quinine Rosiglitazone Cyproterone Metamizole ACE ADHD Alendronic acid Antidepressants Antiretroviral agents Corticosteroids topical Cox2inhibitors NSAID Risperidone Thiazolidinedione antidiabetics	Not registered Lumiracoxib Sulfanilamide
Misuse	4.0%		ketamine	Corticosteroid Cyproheptadine	
Interaction	8.0%	Hydromorphone hydrochloride	ceftriaxone	Meloxicam Terfenadine Tizanidine Atazzzzanavir-ritonavir	
Overdose	6.5%	Buflomedil Triaminic vapor patch	Lidocaine Dextrpropoxyphene		Small pack size Venlafaxine
Dependance	1.0%	Meprobamate			
Medication error	6.5%			Flucloxacilline Azithromycine Metoclopramide BCG Vaccine Methyl ergometrine	

2. Organizations involved in ME

- **International level**
  - World Health Organization “WHO-WAPS”
  - International Medication Safety Network “IMSN”

- **National level**
  - Patient Safety Organizations “PSOs”: dedicated to this role
  - Pharmacovigilance Centres: start to be aware about their role
  - Poison Control Centres “PCCs”: not yet aware about their role

- **Local level**
  - Hospitals
  - Consumer/Patient organizations

2. Organizations involved in ME

2.1 *International level*

- **World Health Organization**
  - **May 2002:** "*Resolution WHA55-18"* of the, 55th World Health Assembly urged members' state to focus on PS
  - **October 2004:** Launch of the WHO *World Alliance for Patient Safety* confirmed and endorsed objectives resolution to focus on PS

- **International medication Safety network**
  - **DOB 2006:** 20 different members (PVCs, PSOs, WHO, independent agencies..)
  - **Objectives:** develop a common terminology, share, exchange cases of ME and prevention strategies

2. Organisations involved in ME

2.2 National Level

- **Patient Safety Organizations**
  - In charge of medication safety incidents
  - Collect, analyze and prevent ME
- **Pharmacovigilance Centres**
  - PVCs: valuable source of detecting ME
  - Preventable ADRs = 14.4% of ADRs (Moroccan PV database)
  - International survey involving PVCs assesses the ability of PVCs to detect and analyse ME
- **Poison Control Centres**
  - PCCs: source to detect and understand ME
  - Studies show that PCCs receive ME among poisoning cases

2. Organisations involved in ME

2.3 *Local level*

- **Hospitals**

  Most commonly methods used: incident report review, chart review of patient, direct observation, interventions by pharmacists, adverse drug event trigger tools

- **Consumer / patient organisations**
  - Need to be more involved in PV networks
  - Educate patient and disseminate effective communication of drug safety and collect ADRs and ME

3. Terminologies and Definitions

Organizations with Medication Safety Related Terms and Definitions on their Website

- Adverse Drug Reaction Advisory Committee (ADRAC):Australia
- N Agency for Healthcare Research and Quality (AHRQ): USA
- N American Society of Consultant Pharmacists (ASCP): USA
- N American Society of Healthcare Risk Management (ASHRM):USA
- N American Society of Health-system Pharmacists (ASHP):USA
- N Association of Perioperative Registered Nurses (AORN):USA
- N Australian Capital Territory Health (ACT Health):
- Australia
- N Australian Council for Safety and Quality in Health Care
- (ACSQHC): Australia
- N Australian Patient Safety Foundation (APSF): Australia
- N British Medical Association (BMA): UK
- N Canadian Institute for Health Information (CIHI): Canada
- N Commission for Healthcare Improvement (CHI): UK
- N Commonwealth Department of Health and Aging:Australia
- N ECRI (formerly the Emergency Care Research Institute):USA
- Food and Drug Administration (FDA): USA
- N Health Canada: Canada
- N Institute for Healthcare Improvement (IHI): USA
- N Institute for Safe Medication Practices (ISMP): USA
- N Institute of Medicine (IOM): USA
- N Joint Commission on Accreditation of Healthcare
- Organisations (JCAHO): USA
- N National Academy for State Health Policy (NASHP): USA
- N National Association of Public Hospitals and Health
- Systems (NAPH): USA
- N National Center for Patient Safety (NCPS): USA
- N National Committee for Quality Assurance (NCQA): USA
- N National Coordinating Council for Medication Error
- Reporting and Prevention (NCCMERP): USA
- N National Patient Safety Agency (NPSA): UK
- N New South Wales Therapeutic Advisory Group (NSW
- TAG): Australia
- N Northern Sydney Health (NSH): Australia
- N Quality Interagency Coordination Task Force (QuIC): USA
- N The Royal College of Physicians and Surgeons of Canada
- (RCPSC): Canada
- N United Kingdom Department of Health: UK
- N Victorian Drug Usage and Advisory Committee (VDUAC):
- Australia
- World Health Organisation (WHO): International

160 organizations

Number of medication safety related terms and corresponding definitions term

Terms	Number of definitions (total)
Adverse drug event	10
Adverse drug reaction	11
Adverse effect	1
Adverse event	21
Adverse incident	2
Adverse medication event	1
Adverse reaction	3
Critical event	1
Critical incident	1
Error	13
Incident	8
Medical error	3
Medication error	7
Medication incident	1
Near miss	8
Potential adverse drug event	4
Potential adverse event	1
Potential error	3
Preventable adverse drug event	2
Preventable adverse event	2
Sentinel event	5
Serious adverse event	2
Side effect	6
Significant adverse event	1
Unpreventable adverse event	2

Total of 119 definitions for 25 terms

3. Terminologies & Definitions

Minimum Needs

- **Adverse Event**
- **Adverse Drug Event**
- **Adverse Drug Reaction**
- **Preventable Adverse Drug Event**
- **Preventable Adverse Drug Reaction**
- **Medication Error**
- **Potential Adverse Drug Event**

3. Terminologies & Definitions

PV Terminology

Adverse Event

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Adverse Event

Any Untoward medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related

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Causality

evaluation of the likelihood that a particular treatment is the cause of an observed adverse event

Assessment

If Reasonable link between the Event and the drug

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Causality Assessment

evaluation of the likelihood that a particular treatment is the cause of an observed adverse event

If Reasonable link between the Event and the drug

Adverse Drug Reaction

Noxious and unintended effect resulting not only from the authorized use of a medicinal product at normal doses, but also from **medication errors and uses outside the terms of the marketing authorization, including the misuse and abuse of the medicinal product**"

Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010

3. Terminologies & Definitions

PV Terminology

Adverse Event

Causality Assessment

Adverse Drug Reaction

Preventability Method

Yes
Preventable ADR
=
Medication Error

NO
Non Preventable ADR

3. Terminologies & Definitions

PS Terminology

Adverse Event

An injury related to medical management, in contrast to complications of disease

Robin E. Ferner, Jeffrey K. Aronso. Clarification of Terminology in Medication Errors :Definitions and Classification. Drug Safety 2006; 29 (11): 1011-1022

3. Terminologies & Definitions

PS Terminology

Adverse Event

An injury related to medical management, in contrast to complications of disease

Adverse Drug Event

any injury resulting from medical interventions related to a drug "

Linked to drug + NO harm
=
Potential ADE

Event linked to drug + harm
=
ADE

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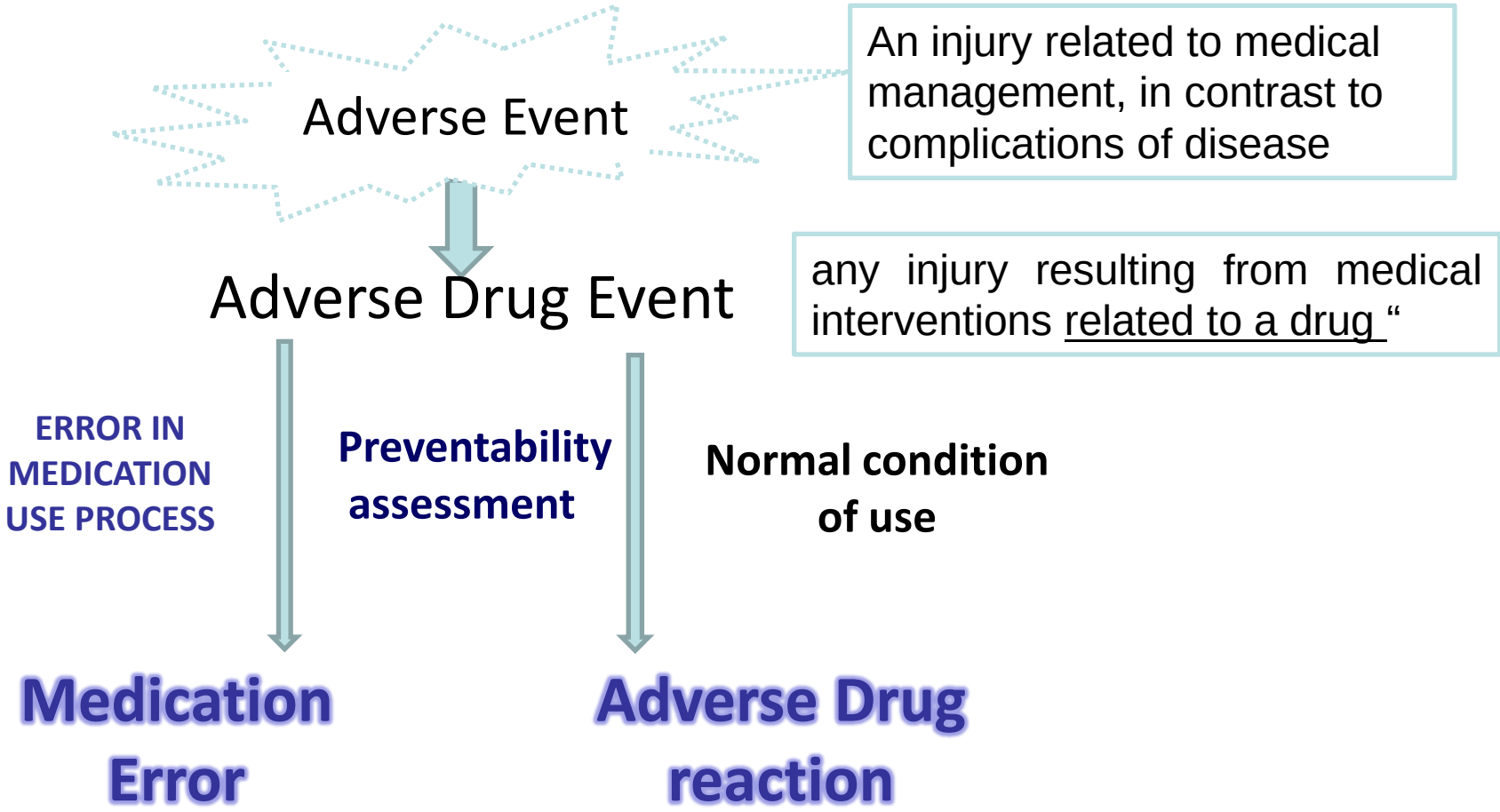
3. Terminologies & Definitions

PS Terminology



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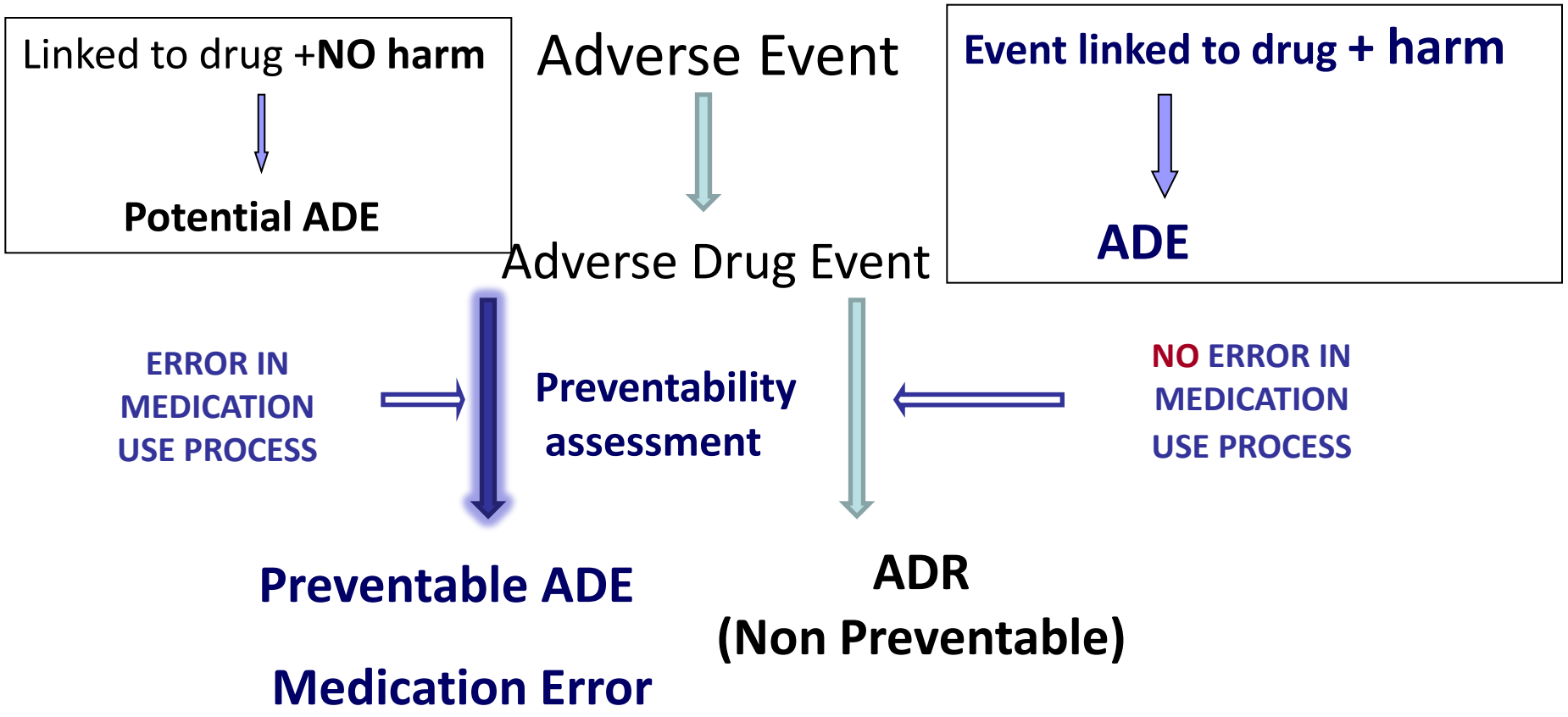
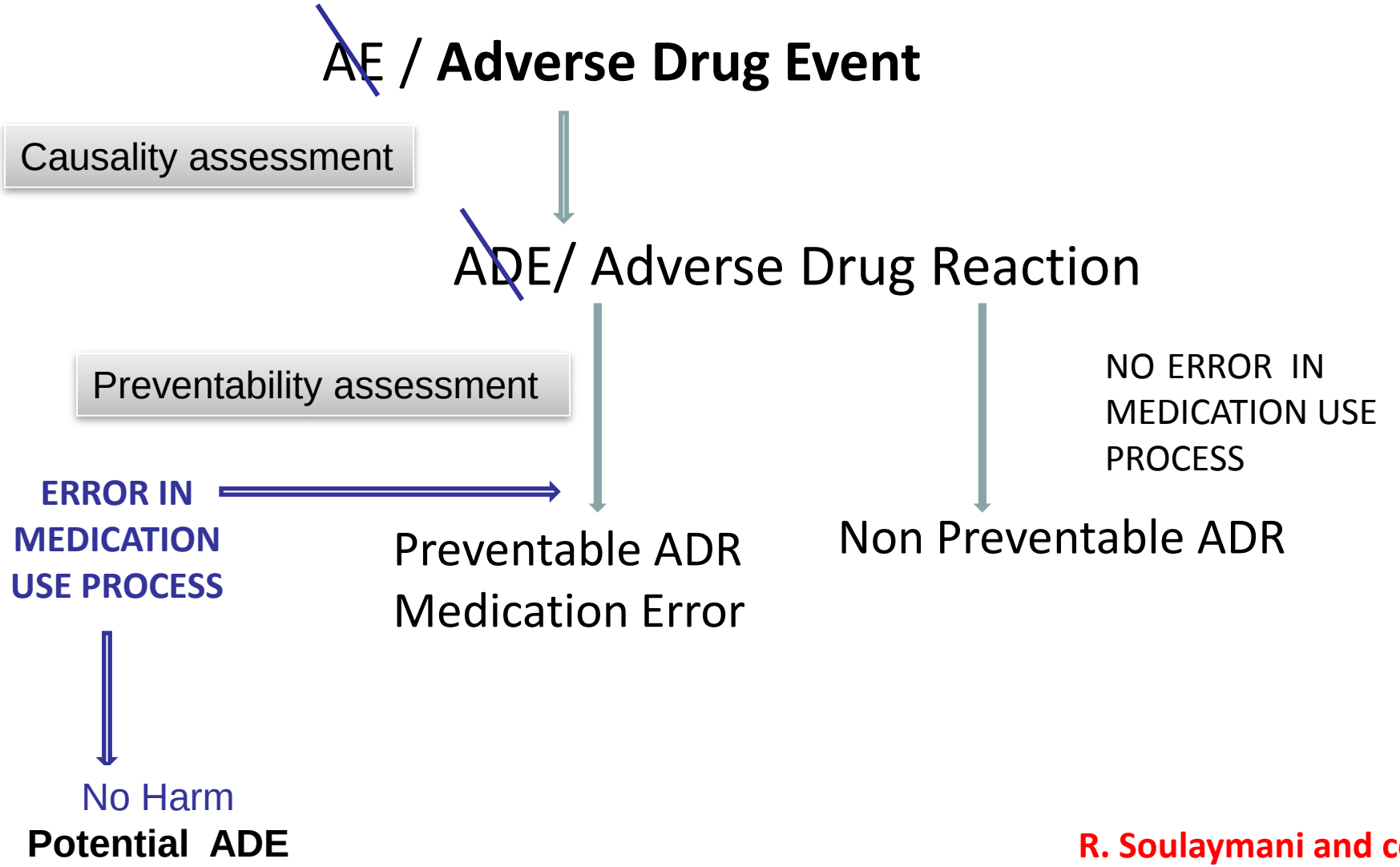
3. Terminologies & Definitions

PS Terminology



3. Terminologies & Definitions

Differences/similarities between PVCs and PSOs



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4. ME Classification

4. ME Classification

Stage of ME in medication use system

- **Prescription**
- **Administration**
- **Transcription**
- **Dispensing**
- **Monitoring**
- **Delivery**
- **Preparation**
- **Verifying and reviewing medicine orders**
- **Autoprescribing listed medicines**

4. ME Classification

Types of ME

- **Wrong/improper drug**

- **Inappropriate drug selection**
  - Previous history of allergy
  - Medication inappropriate for the patient due to his age, clinical status or underlying pathology

- **Unnecessary medication**

- **Wrong/Improper dose**

- **Insufficient monitoring of treatment**
  - **Lack of analytic Controls**
  - **Drug-drug interaction**
  - **Drug-food interactions**

- **Wrong duration of treatment**
- **Deteriorated drug error**
- **Wrong administration timing**
- **Wrong rate of administration**
- **Wrong dosage form**
- **Wrong frequency of administration**
- **Wrong administration technique**
- **Wrong preparation, manipulation**

4. ME Classification

Seriousness *(From A to I)*

No error	**Category A** Circumstances or events that have the capacity to cause error
Error, death	**Category I** An error occurred may have contributed to or resulted in patient's death

National Coordinating centre for Medication Errors Reporting and Prevention

4. ME Classification

Seriousness *(From A to I)*

No error	**Category A** Circumstances or events that have the capacity to cause error
Error, no harm	**Category B** An error occurred but the error did not reach the patient
	Category C An error occurred that reached the patient, but did not cause patient harm
	Category D An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude it
Error, death	**Category I** An error occurred may have contributed to or resulted in patient's death

National Coordinating centre for Medication Errors Reporting and Prevention

4. ME Classification

Seriousness *(From A to I)*

No error	**Category A** Circumstances or events that have the capacity to cause error
Error, no harm	**Category B** An error occurred but the error did not reach the patient
	Category C An error occurred that reached the patient, but did not cause patient harm
	Category D An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude it
Error, harm	**Category E** An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
	Category F An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged Hospitalisation
	Category G An error occurred that may have contributed to or resulted in permanent patient harm
	Category H An error occurred that required intervention necessary to sustain life
Error, death	**Category I** An error occurred may have contributed to or resulted in patient's death

National Coordinating centre for Medication Errors Reporting and Prevention

5. Identifying and reporting ME

5.1: Identifying ME through ADRs reporting

5.2: Reporting Medication Errors

5. Identifying and reporting ME

5.1: Identifying ME through ADRs reporting

5.1.1: The yellow Card (YC)

- Basis for PVC to establish causality assessment
- to optimize detection of ME,YC should be improved
- **Proposed Items to be added in YC form:**
  - Patient weight,
  - relevant medical history,
  - suspected and concomitant drug,
  - narrative case,
  - relevant laboratory test,
  - Information about the process of prescription and dispensation
  - Suspicion or not medication error

5.0 Identifying and reporting ME

5.1: Identifying ME through reporting ADRs

5.1.2: P Method

- Systematic way used to detect ME among ADRs reported to PVCs
- Not intended to classify ME nor to perform RCA
- Based on identification of 20 defined preventability criteria
- Issue of the method assessment:
  - **Preventable**: at least one preventability criteria is identified
  - **Non preventable**: none of the preventability criteria is identified
  - **Not assessable**: there is insufficient data for preventability assessment

Table 1 : the criteria for ADRs preventability assessment					
Factors related to	**Preventability Criteria**	**Yes**	**No**	**UN**	**NA**
Professional practice "Pr "	1. Incorrect ***dose***?				
	2. Incorrect ***drug administration route***?				
	3. Incorrect ***drug administration duration***?				
	4. Incorrect ***drug dosage formulation administered***?				
	5. ***Expired drug*** administered?				
	6. ***Incorrect storage*** of drug?				
	7. ***Drug administration error*** (timing, rate, frequency, Technique, Preparation, manipulation, mixing)?				
	8. ***Wrong indication***?				
	9. Inappropriate prescription according to ***characteristics of the patient*** (age, Sex, pregnancy, other)?				
	10. Inappropriate prescription for ***patient's clinical condition*** (renal failure, hepatic failure …), ***or underlying pathology?***				
	11. ***Documented hypersensitivity*** to administered drug or drug class?				
	12. **Labeled *drug-drug interaction*?**				
	13. ***Therapeutic duplication***? *(prescription of 2 medicines or more with similar ingredient)*				
	14. ***Necessary medication not given***?				
	15. ***Withdrawal Syndrome***? (due to abrupt discontinuation of treatment)				
	16. Incorrect ***laboratory or clinical monitoring of medicine***?				
Product /Drug "Pd"	17. ***Poor quality drug*** administered?				
	18. ***Counterfeit drug*** administered?				
Patient "Pa"	19. Non Compliance?				
	20. Self medication with non OTC drug?				

Preventable and Non Preventable ADR

NOT FROZEN Statement

- Closely linked to **how drug is used** and **monitored**
- **D**epends on:
  - Time, space
  - Current state of knowledge on mechanism of ADR occurrence
  - Capacity of health services in developing therapeutic protocols and making tools and analysis for reducing the occurrence of ADR
- Non preventable ADR may, in future, become a preventable ADR
- Non preventable ADR in a country may be stated as a preventable ADR in another one

Thalidomide

1960’

Teratogenicity was unknown

⇩

No preventive strategy

⇩

12 000 cases of phocomelia

2009

Teratogenicity risk is known

⇩

Risk Management Plan

5. Identifying and reporting ME

5.2: Reporting ME

- Exist within places having a high level of PS culture
- Could be designed by hospital or by PSOs available in the country
- Available for healthcare practitioners, pharmaceutical and medical devices industry and patients..
- **Items to be contained in all ME reporting form:**
  - Identifiable reporter
  - Date of incident
  - Error description
  - Name of drug(s) involved

Simplified one should be used by PV centres

5. Identifying and reporting ME

5.2: Reporting ME

- Incident reports
- Chart review of patients
- Direct observations
- Interventions by pharmacist
- Adverse drug event trigger tools

6. Root Cause Analysis

- RCA is a systematic investigation technique looking beyond the affected individuals and seeing to understand the underlying causes and environmental context in which the incident related to Medical Errors happened

- It is not limited to the process of incident evaluation

- It comprises design, implementation, evaluation and the follow-up of improved safety systems

SEVERAL METHODS but with the same goal and the same concepts

Causality Assessment

Adverse Drug Reaction

Preventability Method

Preventable ADR
=
Medication Error

Non Preventable ADR

Root Cause Analysis

6. Root Cause Analysis

- **Goals**
  - What happened ?
  - Why did it happen?
  - What can be done to reduce the likelihood of a recurrence?

- **Steps**
  - What can be done to reduce the likelihood of a recurrence?
  - Describe the event
  - Identify the proximate cause(s) that led to the event
  - Identify the contributing factors (or latent errors) that led to the proximate cause(s)
  - Create an action plan

6. Root Cause Analysis

6.1: Description of the event

Using medical records and interviewing the important participants in the patient's care, describe in detail the adverse event and activities leading up to it

- When did it occur?
- Did it happen over the weekend or during off hours?
- What service areas were affected?
- Specify the injury or potential injury to the patient

6. Root Cause Analysis

6.2: Proximate cause(s)

The proximate cause explains why the event occurred

e.g.: an ADR (the event) occurred because the doctor wrote an order for a tenfold overdose of antibiotic (proximate cause) that the pharmacy dispensed (proximate cause) and a nurse administered (proximate cause)

6. Root Cause Analysis

6.3: Contributing factors (or latent errors)

Factors that led to the proximate cause(s)

e.g.: a nurse who forgot to administer a dose of medication may have been required to do a double shift. Fatigue and staff shortages were the contributing factors to this ME

6. Root Cause Analysis

6.3: Contributing factors (or latent errors)

- Patient Factors: social and cultural factors
- Individual Factors: psychological, home, work relationship…
- Team and Social Factors: communication type issues
- Education and Training Factors: availability of and quality of the training, assessment of skill acquisition, monitoring, updates
- Equipment and Resource Factors Working Conditions: uncomfortable heat, lighting; noise, overcrowding …
- Organisational and Strategic Factors: factors that are either inherent or imbedded within the organisation e.g.: procedures, rules…
- Task Factors
- Communication Factors: generally concerns any aspect of communication (verbal, written or non-verbal)

The UK National Patient Safety Agency - Vincent et al 1998 contributory factors framework. Dineen (2002)

7. Strategies to manage and minimise harms from ME

7.1: International guidance

7.2: Country strategy to develop systems for medication errors prevention strategy

7.3: basic steps to develop a national organization dedicated to medication safety

7.4: Medication Errors prevention strategies

7. Strategies to manage and minimise harms from ME

7.1: International guidance

- **WHO resolution "*Resolution WHA55-18*" of the World Health Assembly** urged Member States to pay the closest attention to PS; and to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care, **including the monitoring of drugs,** medical equipment and technology.

- **Resolution has put forward the following measures**
  - Developing of global norms, standards and guidelines for quality of care and
  - patient safety, the definition, measurement and reporting of adverse
  - events and near misses in health care, providing support in developing
  - reporting systems, taking preventive action, and implementing measures to reduce risks.
  - WHO was to support Member States' efforts to promote a culture of safety within health care organizations

7. Strategies to manage and minimise harms from ME

7.2: Country strategy to develop systems for medication errors prevention strategy

- Put in place regulation, rules and standards to develop and manage harm from ME and to promote evidence-based policies

- Development of a **national organization dedicated to medication safety**
  - Could be a patient safety organisation or part of PVC: in any case collaboration is essential
  - Could be a centralised or decentralised organization
  - Should be integrated in an international network

7. Strategies to manage and minimise harms from ME

7.2: Country strategy for ME prevention strategy

7.2.1: basic steps to develop a national organization dedicated to medication safety

- Make contact with health authorities and with PVCs, PCCs, Patient organisations etc… to outline importance of project and close collaboration
- Implement patient incident reporting form and improved ADR reporting form
- Need for trained staff to detect and analyze ME
- Produce material to promote PS culture
- Build a database shared with PVCs

7. Strategies to manage and minimise harms from ME

7.2: Country strategy for ME prevention strategy

7.2.2: Practical methods to minimise harm from ME

- At all level of drug delivery
- Actions concern all medicine products, medical devices, industry, regulators, HCP and patients with 3 actions
  - **Preventing ADEs**: posters, legible handwriting, decrease workload
  - **Making them visible**: double-check by pharmacists and nurses…
  - **Mitigating their effects**: antidotes, guidelines…, Sensitization, education, training and improved work competencies
- Prevention strategies in pre and post- marketing process

  Using Failure Mode and Effects Analysis (FMEA)

7. Strategies to manage and minimise harms from ME

7.2: Country strategy for ME prevention strategy

7.2.3: Prevention strategies in pre and post- marketing process

- **Prevention strategies for medicine regulators and industry**

  The design of labelling and packaging of medicine products, medicine names, medicine product technical information, formulation and presentation of medicine products

- **Prevention strategies for medical devices regulators and Industry, for individual practitioners, for healthcare provider organisations, for patients and carer**

7. Strategies to manage and minimise harms from ME

Examples of medication errors prevention strategies

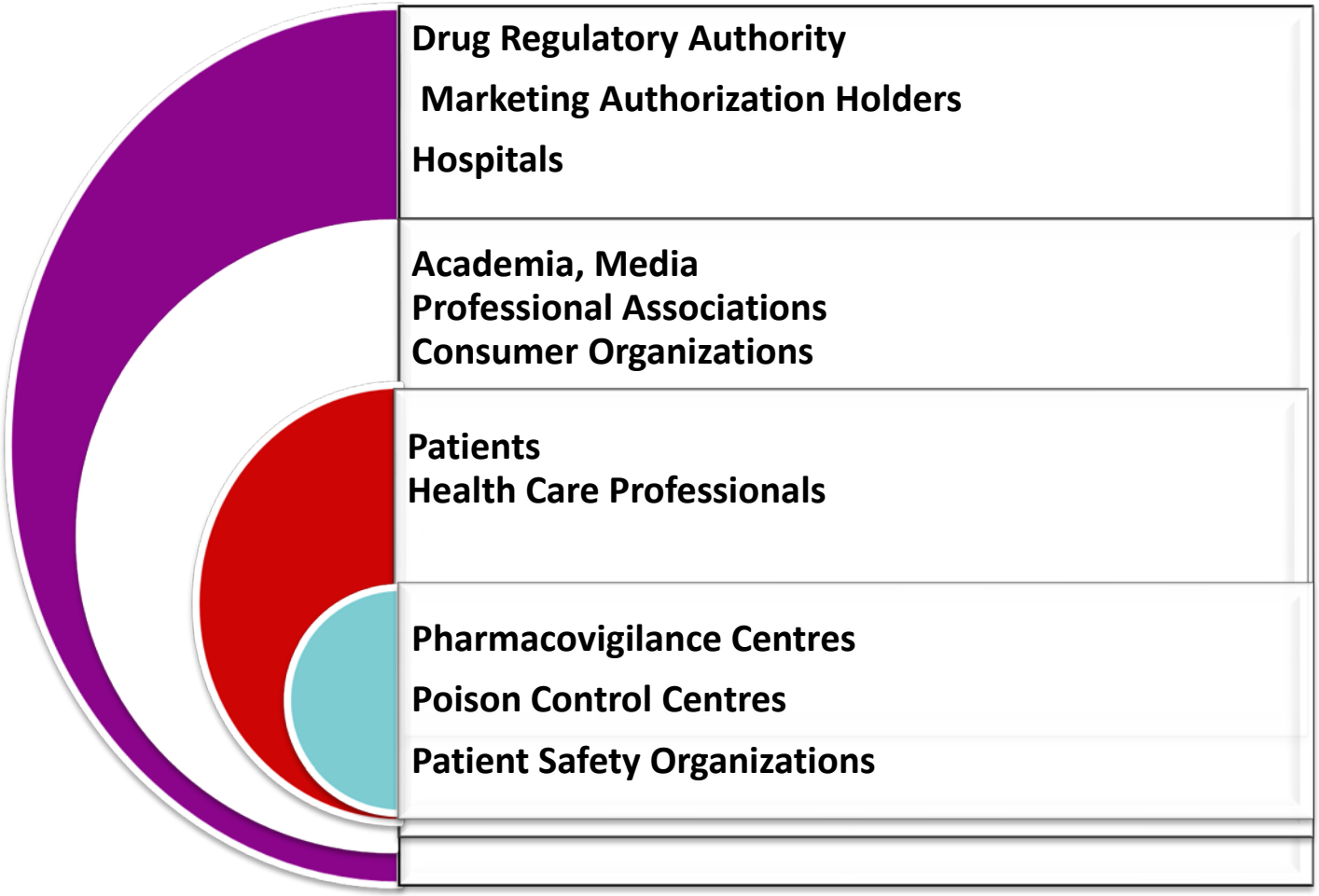
- Design of labelling and packaging of medicine products strategy
- Medicine name error prevention strategy
- Medicine product technical information error prevention strategy
- Medicine product formulation and presentation error prevention strategy
- Medical devices ME prevention Strategies
- ME prevention strategies involving actions for healthcare practitioners
- ME prevention strategies for healthcare provider organisations
- ME prevention strategies for patients and carers

8. Collaborations

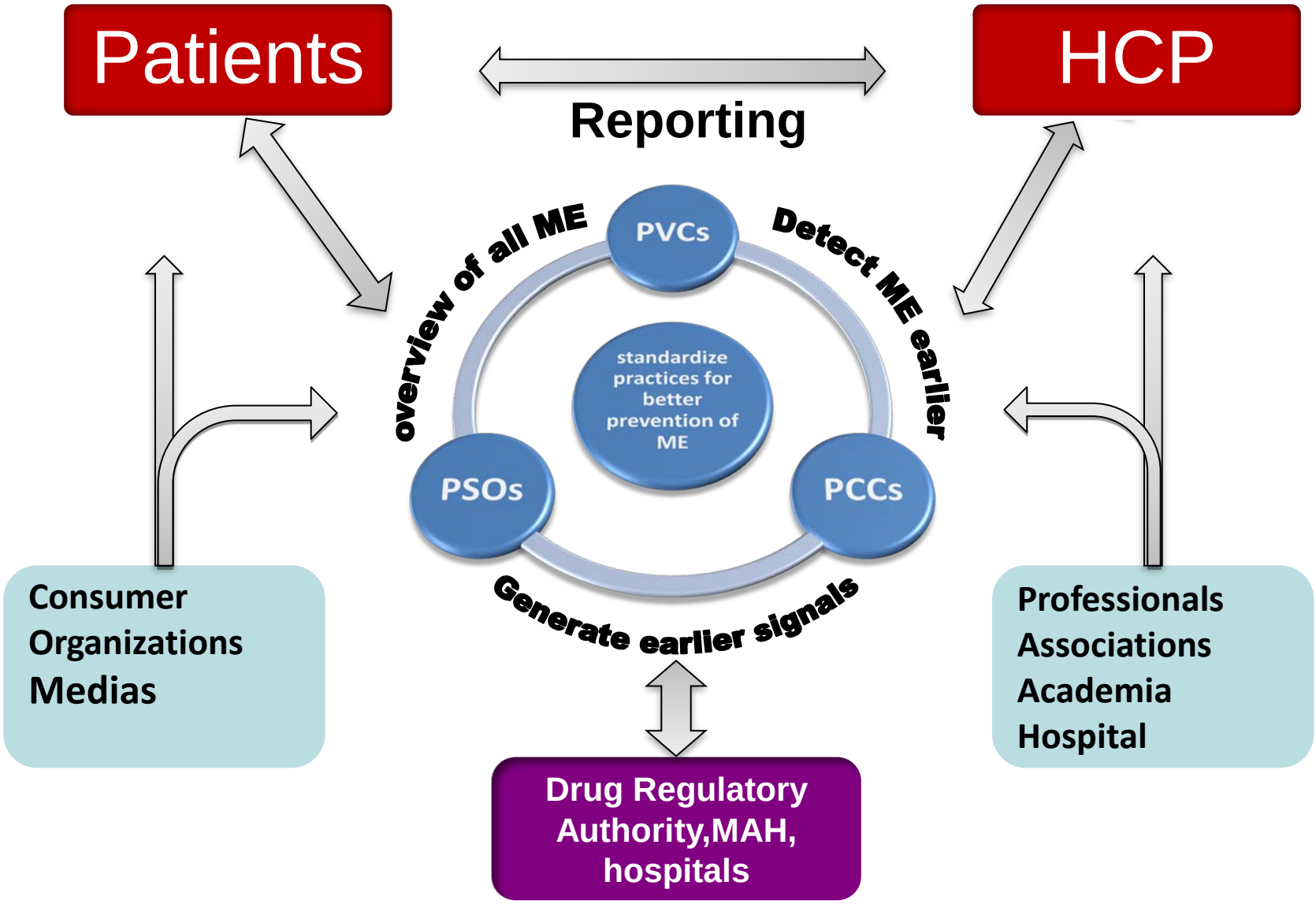
- **Actors of patient safety promotion**
  - **First level**
  - **Second level**
  - **Third level**
  - **Fourth level**

- **Collaboration between the four levels of partnership**

Levels of Partnerships



1st, 2nd, 3rd and 4th level of Partnerships



MONITORING MEDICINES

Optimizing drug safety monitoring to enhance patient safety and achieve better health outcome

COOPERATION

the UPPSALA MONITORING CENTRE

World Health Organization

European Research Area

Moroccan Team

Loubna - Raja – Rita

Thank you for your attention