Medication Safety: OPL Initiative

Review and Update

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Learning Objectives

- Define adverse drug events
- Define and classify medication errors
- Identify Medication error reporting and learning systems
- Define, Detect, recognize, classify and assess ADRs
- Review the OPL new medication safety reporting initiative
- Submit an “adverse drug reaction” report

Detentions and Terms

- Adverse Drug Event (ADE)
- Medication Error (ME)
- Adverse Drug Reaction (ADR)

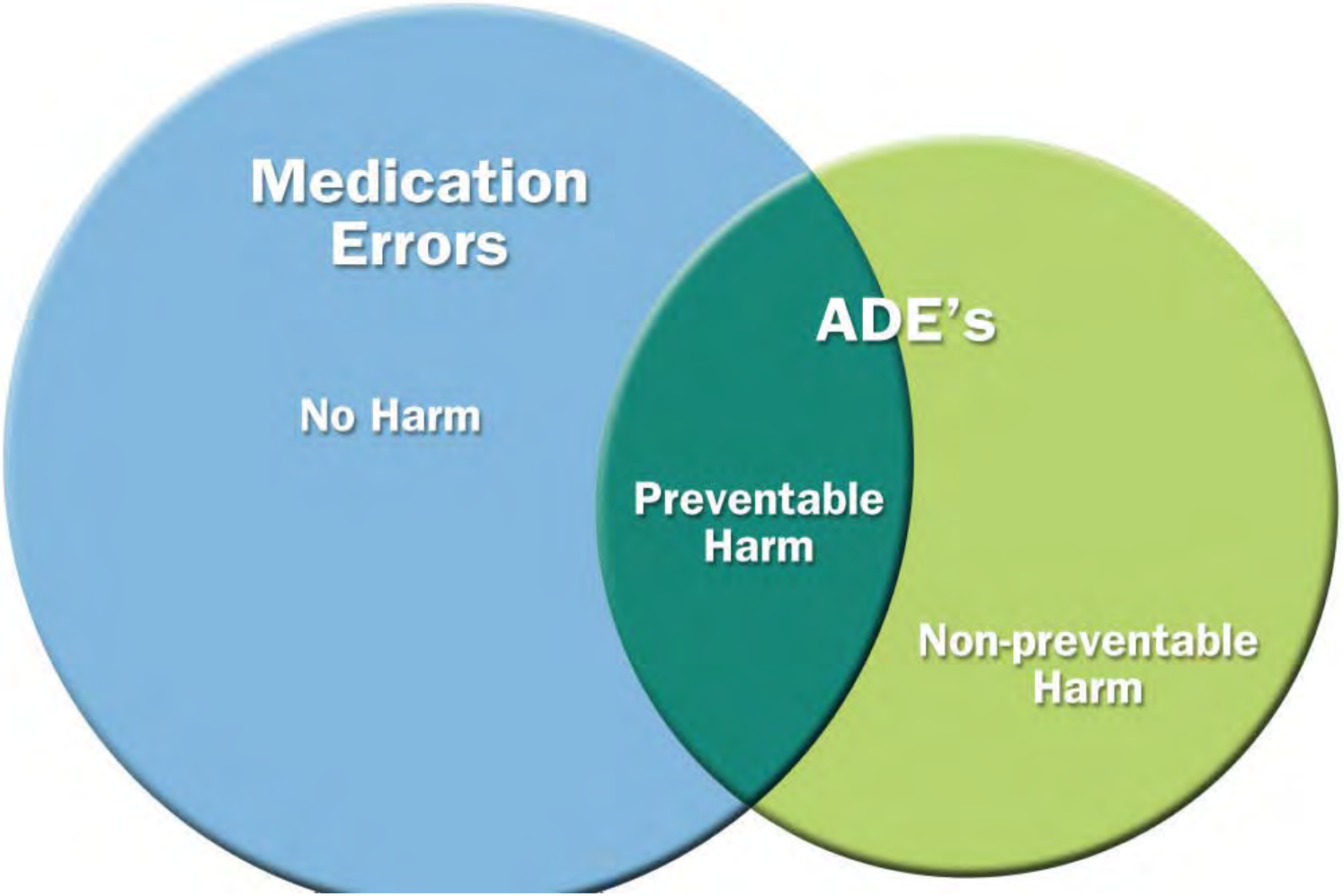
Definitions and Terms
1. Adverse Drug Events

- Any injury occurring during the patient's drug therapy and resulting either from appropriate care, or from unsuitable or suboptimal care.

- Adverse drug events include:
  - Adverse drug reactions during normal use of the medicine (non-preventable)
  - Ay harm secondary to a medication error, both errors of omission or commission (preventable)

Committee of Experts on Management of Safety and Quality in Health Care (SP-SQS) - Expert Group on Safe Medication Practices: Glossary of terms related to patient and medication safety. http://www.who.int/patientsafety/ highlights/COE_patient_and_medication_safety_gl.pdf.

I. Adverse Drug Events



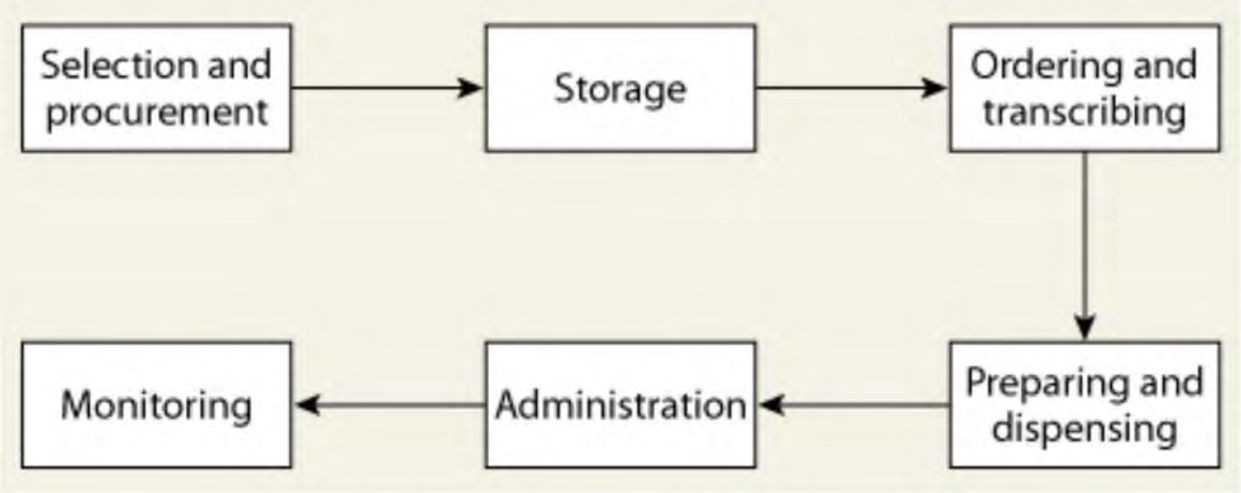
www.nccmerp.org

Definitions and Terms
II. Medication Errors

- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.

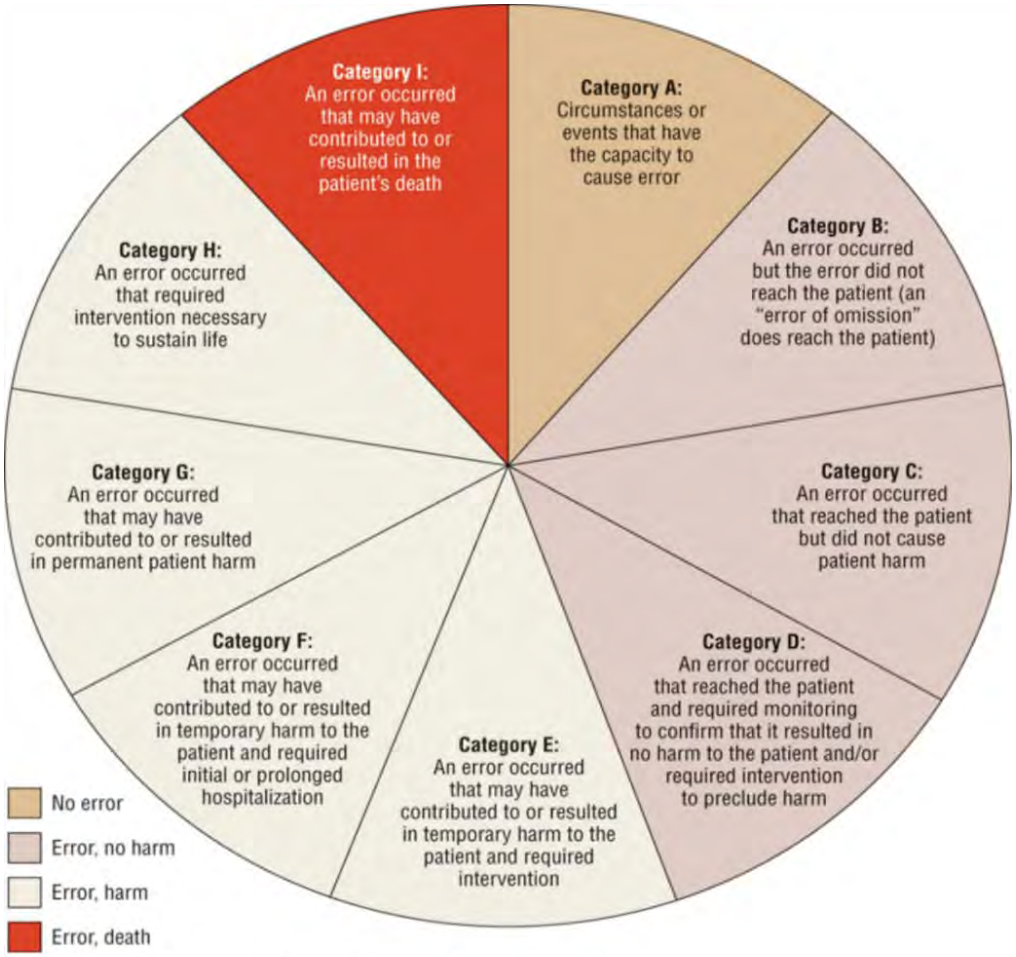
 *The National Coordinating Council for Medication Error Reporting and Prevention (**NCC MERP**), 1999*

Medication Errors
Medication Use Process



Source: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM: *Pharmacotherapy: A Pathophysiologic Approach, 8th Edition*: www.accesspharmacy.com

Medication Errors
Outcome / Severity



Source: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM: *Pharmacotherapy: A Pathophysiologic Approach, 8th Edition*: www.accesspharmacy.com

Medication Errors

Reporting and learning systems for medication errors

- Local level
  - Hospitals
  - Consumer and healthcare organizations
- National level
  - National pharmacovigilance centers (PVC)
    - (e.g. French Pharmacovigilance Database -FPVD; MedWatch -FDA)
- International level
  - World Health Organization (WHO):
    - National PVCs submitting individual case safety reports (ICSRs) to the WHO database, maintained by the Uppsala Monitoring Centre (UMC) in Sweden

Medication Errors Reporting

- Ultimate purpose of classifying, reporting, and analyzing medication errors
  - → Implementation of better systems that prevent errors

- Healthcare professionals and health systems are reluctant to report medication errors
  - "Just Culture" of Patient Safety
  - Non-punitive approach

Medication Errors
Medication Safety Form - OPL

- Medications errors are not to be reported specifically using the OPL reporting form, but they may be the cause of adverse reactions

Definitions and Terms
III. ADRs

Adverse Drug Reaction: A response to a medicinal product 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 restoration, correction or modification of physiological function

[WHO Technical Report No 498 (1972)].

ADRs Classification

- Type/Mechanism
- Onset
- Severity
- Frequency

ADRs Classification
I – Type/Mechanism

Type	Mechanism Characteristics	Example
Type A (Augmented)	• Dose-dependent • Related to Pharmacology • Common	Bradycardia with Beta-Blockers
Type B (Bizarre)	• Not predictable from pharmacology • Not dose–related • Uncommon	Anaphylaxis with Penicillin
Type C (Chemical)	• Predicted from the chemical structure • Related to cumulative dose	Paracetamol Hepatotoxicity
Type D (Delayed)	• Time-related • Seen on prolonged exposure to a drug	Teratogens or Carcinogens
Type E (End of Treatment)	• Occurs on withdrawal of a drug, especially if abrupt	Opiates or Beta-blockers withdrawal
Type F (Failure)	• Unexpected drug failure • May be caused by drug interaction	CYP 450 enzyme interactions

ADRs Classification
II- Onset

II- Classification by Onset of events:

- a. Acute
  within 60 minutes of administration
- b. Sub-acute
  1-24hours after administration
- c. Latent
  after 2 days of administration

Classification of ADRs
III- Severity

III - Classification by Severity of Action:

- a. Mild / Minor
  - Require no changes in therapy
  - No need of management therapy
- b. Moderate
  - Require change in therapy or additional treatment
- c. Severe
  - Disabling or life threatening
  - Hospitalization
  - Permanent damage
- d. Lethal (Directly or indirectly)

Classification of ADRs
IV- Frequency

IV- Classification by Frequency:

- a. Very Common (>10% of patients)
- b. Common (1-10% of patients)
- c. Uncommon (> 0.1% or 1/1000 of patients- < 1% of patients)
- d. Rare (> 1/10,000 of patients - < 0.1% of patients)
- e. Very Rare (<1/100,000 patients)

ADRs Detection

ADRs detection in clinical trials faces several limitations

- Exposure limited to few individuals
  - 3000 patients are needed to detect an ADR with incidence of 1/1000 with 95% certainty
- Exposure is often short-term
- External validity?
  - May exclude children, elderly, pregnant; and patients with severe diseases, multiple co-morbidities, or taking multiple medications

ADRs Detection

Post-marketing surveillance

- Permits the detection of less common, but sometimes very serious ADRs → may become evident only with large-scale use of the drug

ADRs Detection: How to detect?

- Subjective Report
  - Patient Complaint
- Objective Report
  - Direct observation of events
  - Abnormal findings (Physical exams; Laboratory tests; Diagnostic procedures)
- Medication Order Screening
  - Recent Medication Initiation/ Discontinuation
  - Dosage Increase/ Reduction
  - Orders for special tests or serum drug concentrations

ADRs Detection: How to detect?

Pertinent Patient/Disease Factors

- A- Demographics
- B- Medical History and Physical Exam
  - Review of systems
  - End-Organ Function
  - Social History
  - Pertinent Family History
  - Nutritional Status (special diets, malnutrition, weight loss)
- C- Medication History
  - Allergies or intolerances, and history of medication reactions
  - Cumulative medication dosages

ADRs Detection: How to detect?

Pertinent Medication Factors

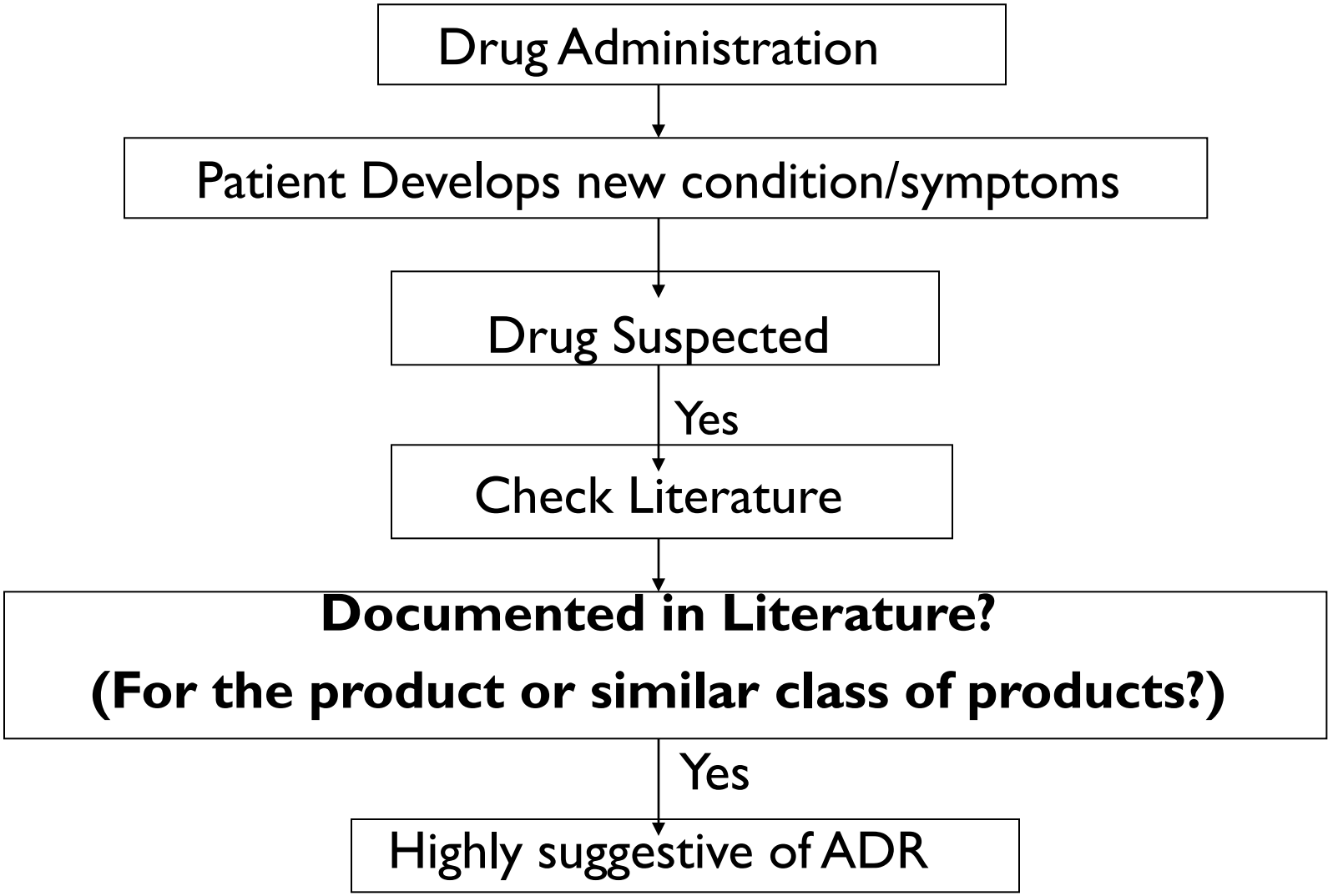
- Medication
  - Indication, Dose, Diluent, Volume
- Administration
  - Route, Schedule, Rate, Duration
- Formulation
  - Pharmaceutical Excipients
  - Ex: Colorings, Flavorings, Preservatives

ADRs Detection: How to detect?

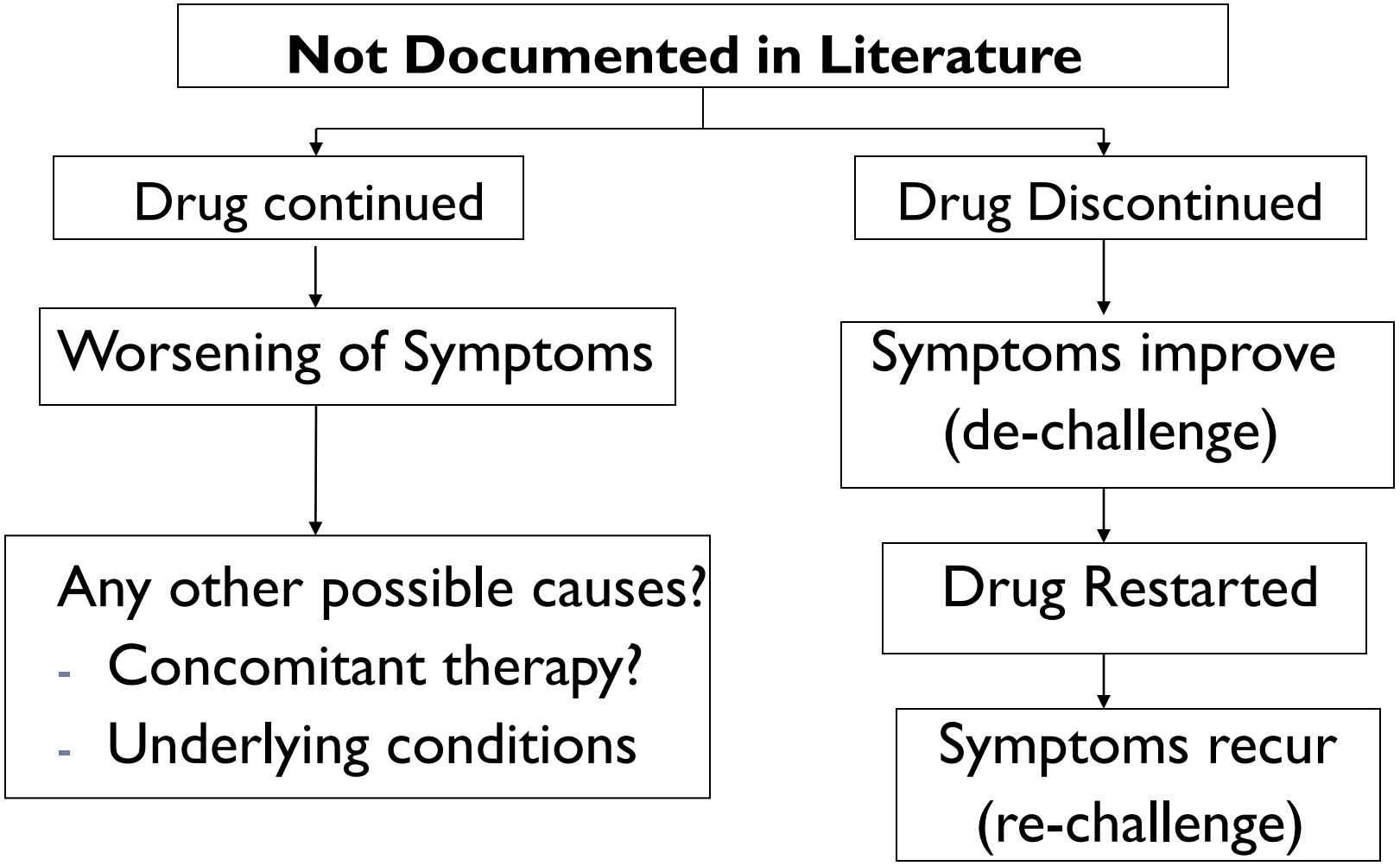
Pertinent Medication Factors

- Pharmacology
- Pharmacokinetics (ADME)
- Pharmacodynamics
- Adverse Effect profile
- Interactions
  - Drug-drug
  - Drug-nutrient
  - Drug-lab test interference
- Cross-allergenicity or cross-reactivity

ADRs Detection: How to recognize?



ADRs Detection: How to recognize?



ADRs Detection: How to recognize?

- ADRs may act through same physiological and pathological pathways as different disease

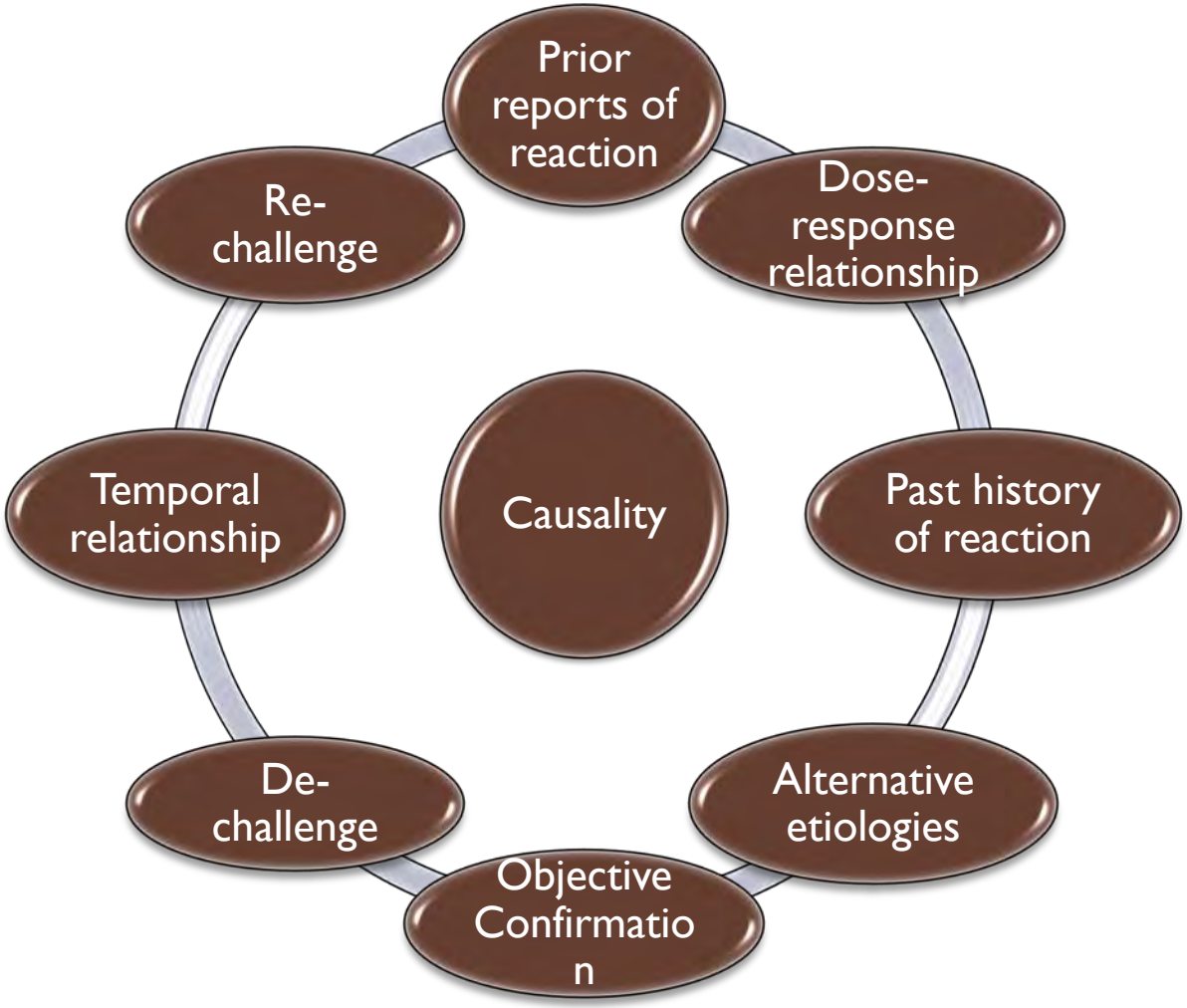
- ➔ Difficult and sometimes impossible to distinguish and recognize ADRs

ADRs Detection: Causality Assessment

- Establish the extent of relationship between a drug and a suspected reaction

- Causality assessment scales:
  - Naranjo's scale
  - WHO probability scale

ADRs Detection: Causality Assessment



ADR Detection: Naranjo Scale

The Naranjo adverse drug reaction probability scale; To assess the adverse drug reaction, please answer the following questionnaire and give the pertinent score	Yes	No	Do not know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	
2. Did the adverse event occur after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	
4. Did the adverse reaction reappear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could have on their own caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the blood detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
			Total	

ADRs
Reporting Systems

- MEDWATCH by FDA in the US
- YELLOW CARD in UK
- WHO International: Completed Case Report Form sent to
  - National or regional ADR center
  - Manufacturer of the suspected product
- P&T Committee
- Reporting “Hot Line”

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ORDER OF PHARMACISTS OF LEBANON

ADRs Reporting: OPL Initiative

ADRs Reporting:
Medication safety data: A need in every country

- Differences among countries in the occurrence of ADRs
- Data derived from within the country
  - Greater relevance and educational value
  - Encourage national regulatory decision-making

Essential Medicines and Health Products Information Portal. A World Health Organization resource
http://apps.who.int/medicinedocs/en/d/Jh2934e/2.html

ADRs Reporting
Role of health professionals

Health professionals are in the best position to detect and report on ADRs

- Encounter numerous suspected ADRs in their every day patient care

→ **All healthcare providers** should report ADRs as part of their professional responsibility, even if they are **doubtful** about the precise relationship with the given medication

Essential Medicines and Health Products Information Portal. A World Health Organization resource
http://apps.who.int/medicinedocs/en/d/Jh2934e/2.html

ADRs Reporting
OPL Medication Safety Initiative

"Adverse reaction (drug/product) reporting form"

Report adverse reactions

related to any drug or product administered to a patient in a **community or hospital setting**

ADRs Reporting
OPL Medication Safety Initiative

Evaluated data will enable OPL to classify the adverse reaction according to its severity, its probability, and the pharmaceutical category of drug/product behind its occurrence

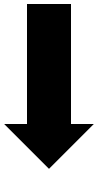
- Create a **national adverse reaction database** of health products

- Forward, at a later stage, to the Global Pharmacovigilance Database managed by WHO-UMC

ADRs Reporting
OPL Medication Safety Initiative

Our ultimate purpose

Support good decision-making regarding the benefits and risks of treatment options for patients taking medicines and



Enhancing the key role of the pharmacist in the practice of medication safety

ADRs Reporting
OPL Medication Safety Initiative

What Reports are we expecting?

- **ALL** suspected adverse reactions should be reported, especially those that are:
  - ***Unexpected***, regardless of their severity
  - ***Serious***, whether expected or not
  - Reactions to ***recently marketed health products***, regardless of their nature or severity

Let’s submit a report

Let's submit a report

- Access OPL Website at http://www.opl.org.lb/newdesign/

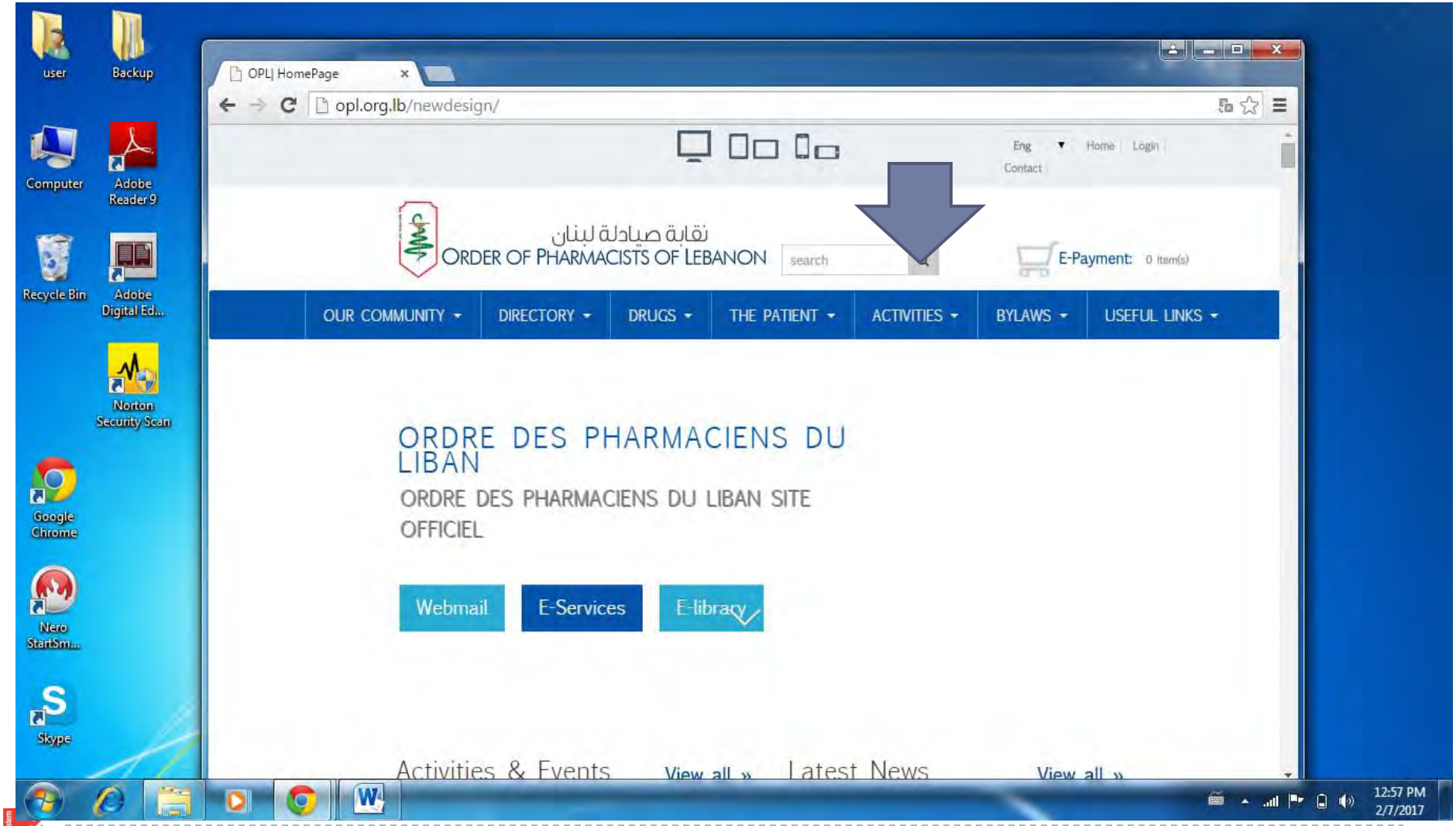
- Go to Activities

  → Professional Activities

  → Medication Safety

- Enter your username and password (PharmacistOPL#!)

Let’s submit a report



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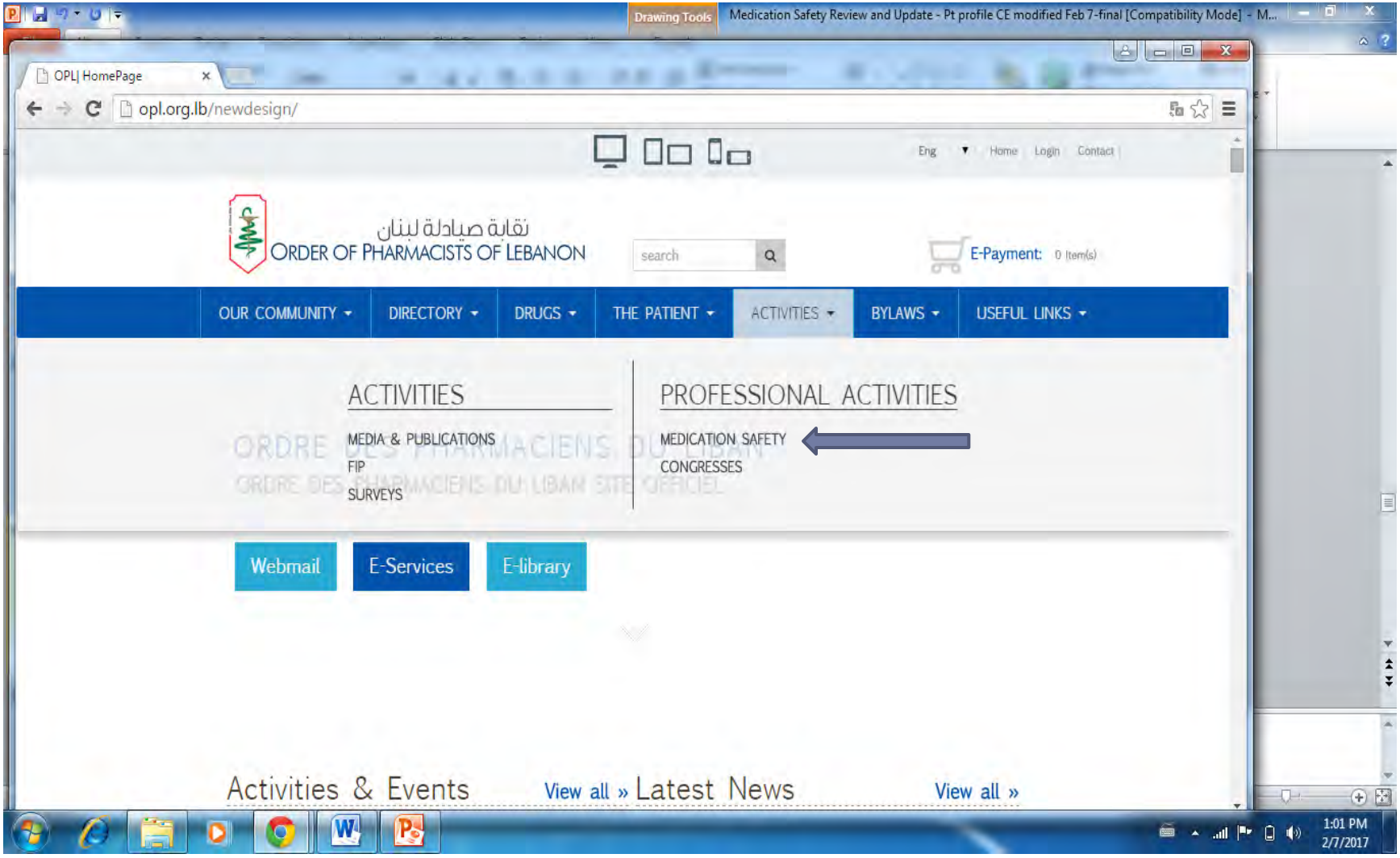

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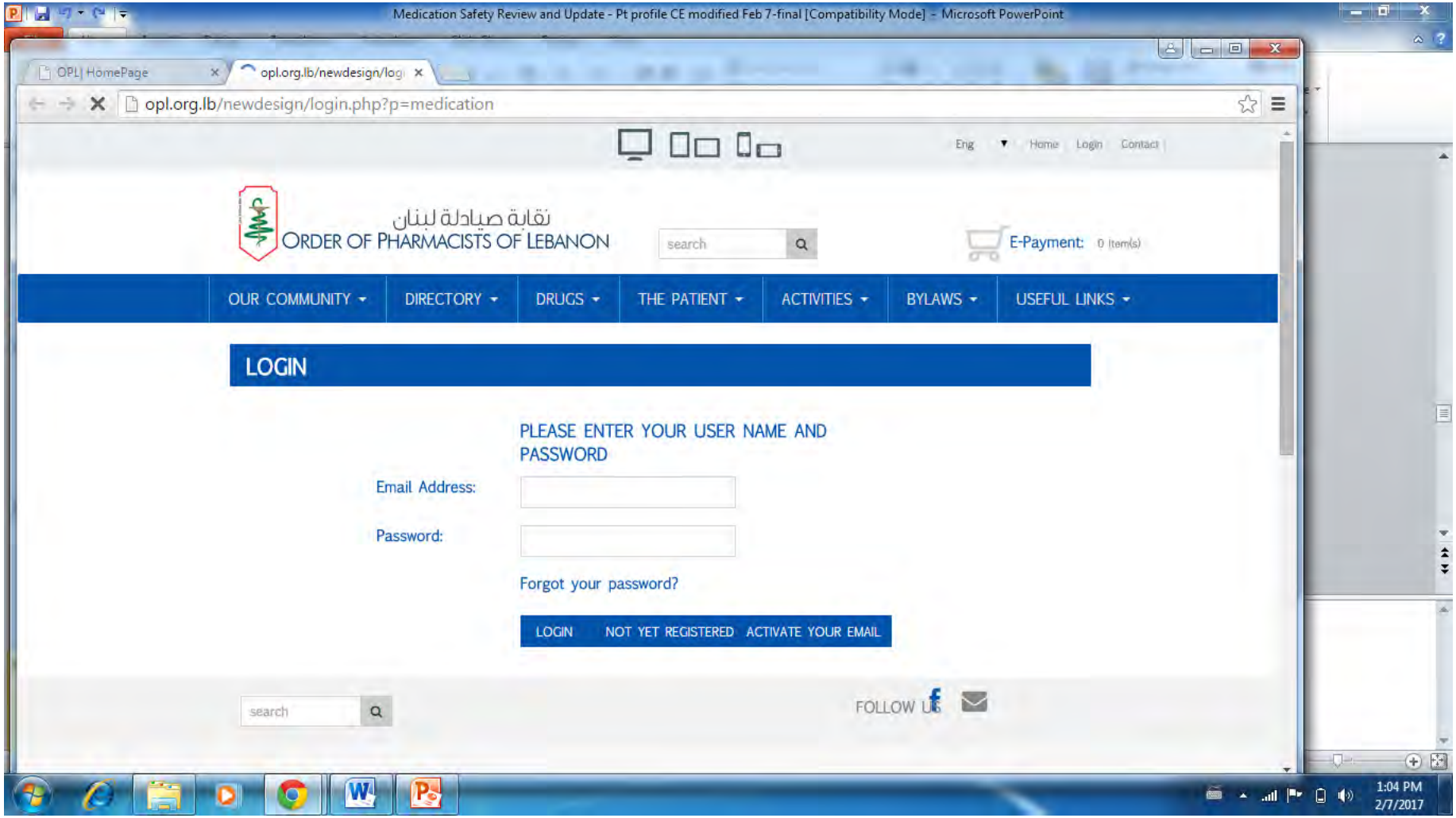

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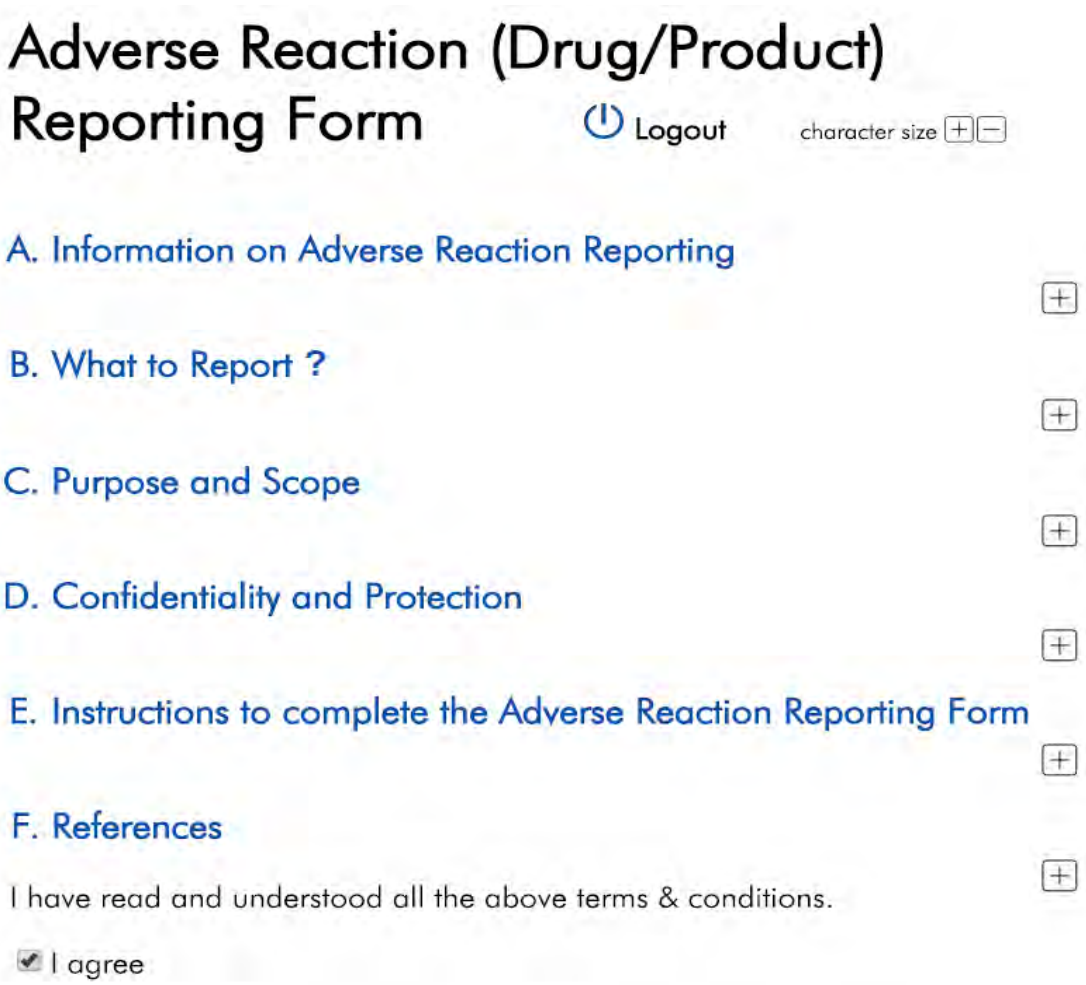


Let's submit a report

Adverse Reaction (Drug/Product) Reporting Form

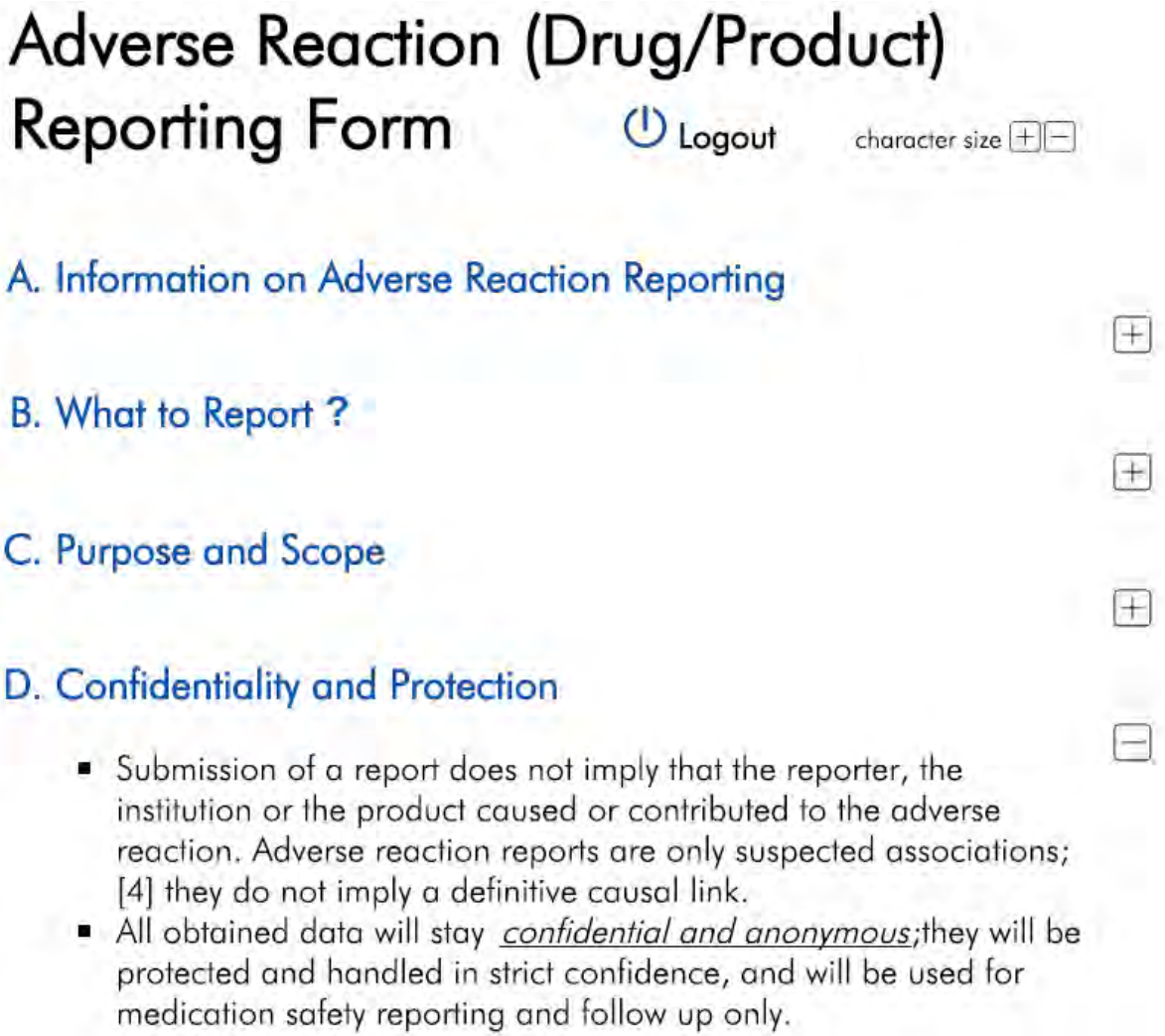
Logout character size

A. Information on Adverse Reaction Reporting

B. What to Report ?

- All suspected adverse reactions should be reported, especially those that are:
  - *Unexpected*, regardless of their severity
  - *Serious*, whether expected or not
  - Reactions to *recently marketed health products* , regardless of their nature or severity.
- A serious adverse reaction is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability, is life-threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

Let's submit a report



Adverse Reaction (Drug/Product) Reporting Form

Logout character size

A. Information on Adverse Reaction Reporting

B. What to Report ?

C. Purpose and Scope

D. Confidentiality and Protection

- Submission of a report does not imply that the reporter, the institution or the product caused or contributed to the adverse reaction. Adverse reaction reports are only suspected associations; [4] they do not imply a definitive causal link.
- All obtained data will stay *confidential and anonymous*;they will be protected and handled in strict confidence, and will be used for medication safety reporting and follow up only.

Let's submit a report

E. Instructions to complete the Adverse Reaction Reporting Form

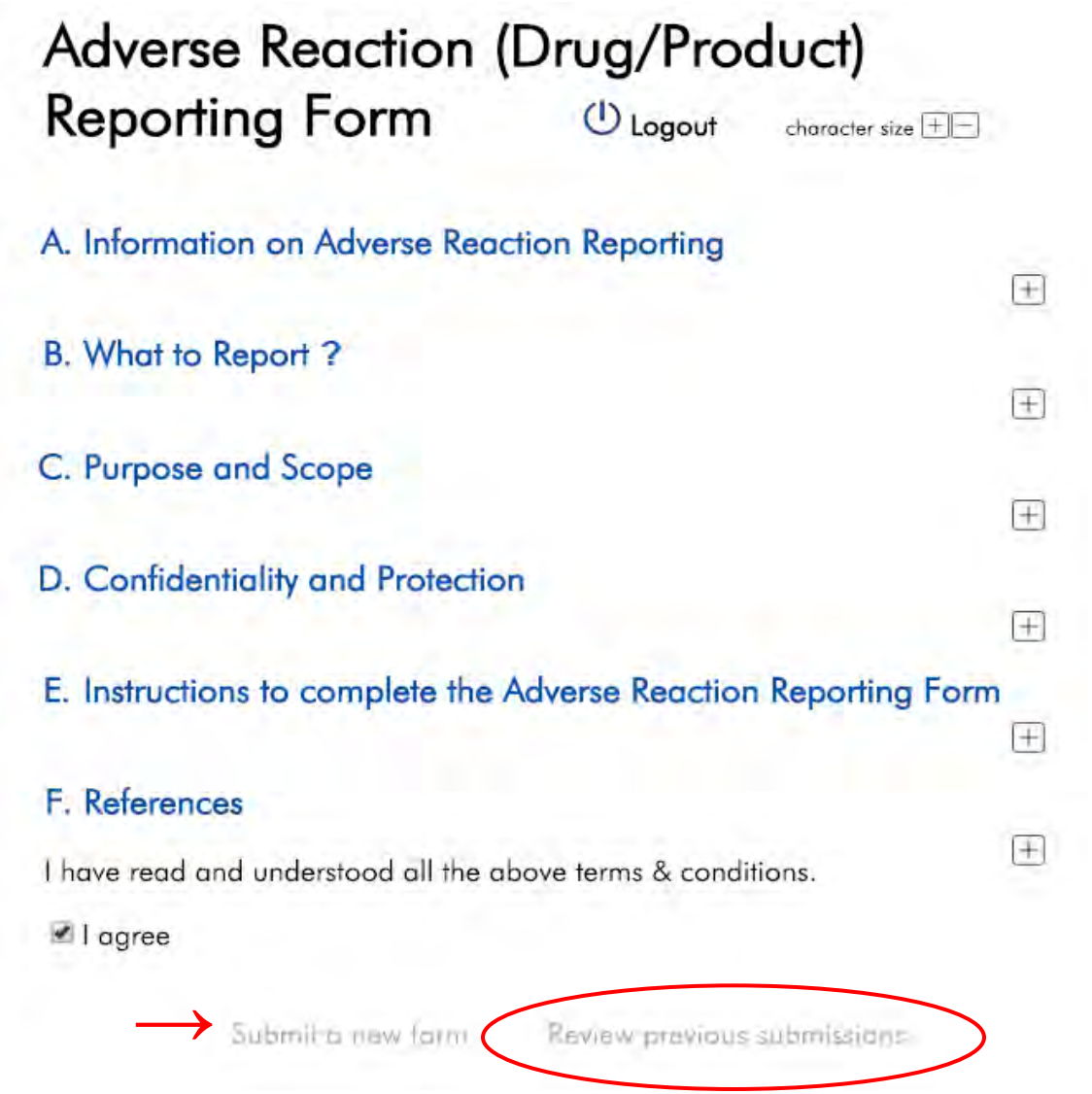
F. References

1. U.S. Food and Drug Administration, Medication Errors Related to Drugs [updated 07/08/2016]. Available from: http://www.fda.gov/drugs/drugsafety/medicationerrors/
2. The use of the WHO-UMC system for standardised case causality assessment. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcau
3. Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981;30(2):239-45.
4. http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_indus_form-eng.php

I have read and understood all the above terms & conditions.

☐ I agree

Let's submit a report



Let's submit a report

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Adverse Reactions Reporting Form

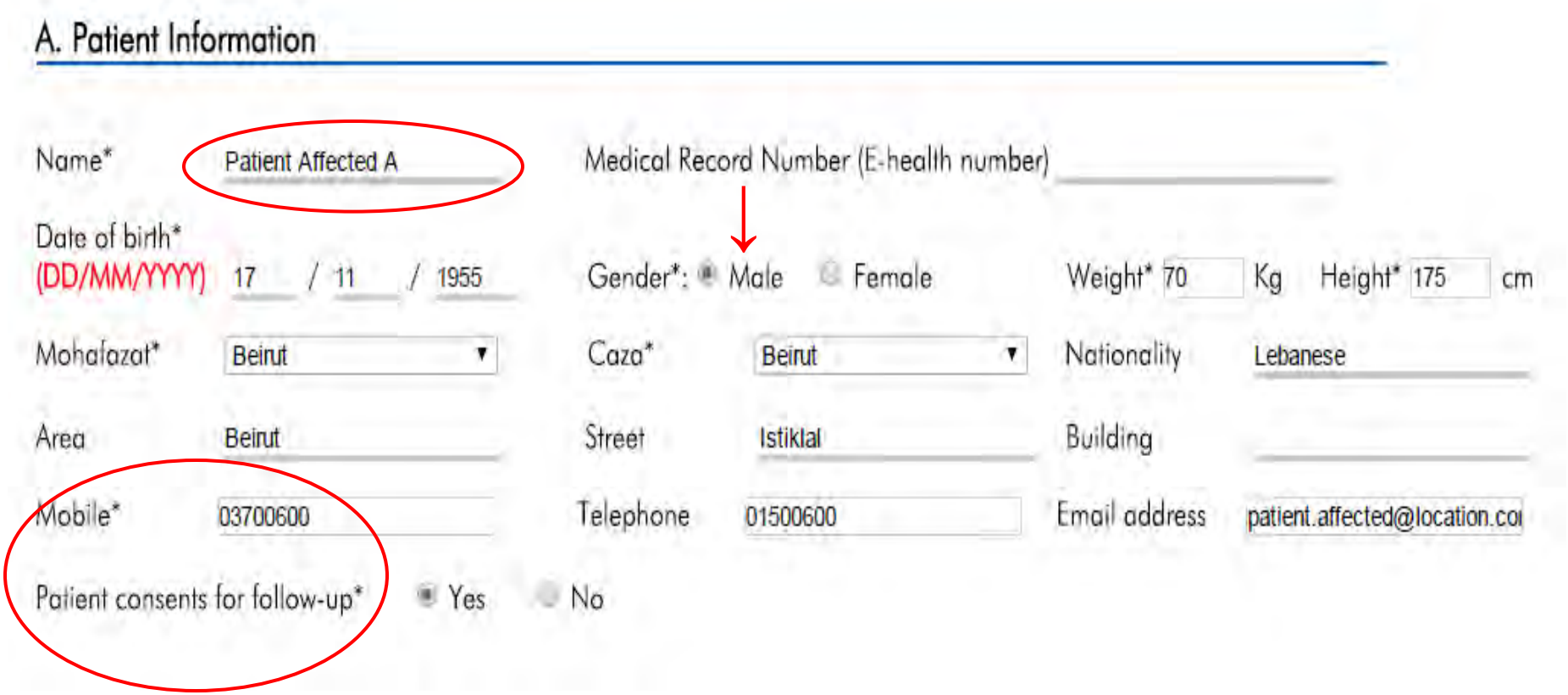
*Fields marked with an * are required*

Health care institution*: Pharmacie Patient Oriented

Institution type

- [x] Community Pharmacy
- [ ] Public Hospital
- [ ] Private Hospital
- [ ] University Medical Center/University-Affiliated Hospital
- [ ] Other: _____

Let's submit a report



A. Patient Information

Name* Patient Affected A

Medical Record Number (E-health number)

Date of birth* (DD/MM/YYYY) 17 / 11 / 1955

Gender*: Male Female

Weight* 70 Kg Height* 175 cm

Mohafazat* Beirut

Caza* Beirut

Nationality Lebanese

Area Beirut

Street Istiklal

Building

Mobile* 03700600

Telephone 01500600

Email address patient.affected@location.co

Patient consents for follow-up* Yes No

Let's submit a report

B. Suspected Product

1. Product type*

- ○ Non-prescription drug
- ● Prescription drug
- ○ Vaccine
- ○ Herbal
- ○ Cosmetic
- ○ Diagnostics
- ○ Supplements (vitamins and derivatives)
- ○ Enteral & Parenteral nutrition
- ○ Milk products & formulas
- ○ Serum & electrolytes
- ○ Other _____

2. List medications and supplements that the patient is currently taking*

	Brand Name	Active Ingredient	Manufacturer	Strength or Concentration	Dosage Form	Indication	Dose	Frequency	Route	Start Date	Stop Date	Lot Number	Expiry Date	Reference Code Number
Suspected Drug		Active drug A			Tablet	Blood Pressur10		bid	Per oral	01/11/2016	08/11/2016	5647	02/12/2016	C3425
Non Suspected Drugs														

Add Suspected Add others

Let's submit a report

4. Who prescribed the drug/product?*

- (•) Physician
- ( ) Dentist
- ( ) Midwife
- ( ) Pharmacist suggestion
- ( ) Self-medication
- ( ) Other _____

5. Is the adverse reaction related to a medication error*? Yes ( ) No (•)

5. Is the adverse reaction related to a medication error*? Yes (•) No ( )

If yes, in which phase the error that caused the reaction was made?

- ( ) Selection & Procurement
- ( ) Ordering/Prescribing & Transcribing
- ( ) Dosing
- ( ) Administering
- ( ) Monitoring

Let's submit a report

C. Adverse Reaction or Product Problem

1. Date reaction started*: Date: 07/11/2016 Time: --:-- --

Date Reaction stopped*: (•) Yes Date: 11/09/2016 Time: --:-- --
( ) No, is still on-going

2. Describe the reaction

Patient had itching, and redness that started on his head/neck and spread to his lower body.

Please upload any photo, document(tests,etc...) that you think are appropriate to the reporting form

Add file (please note that the combined file size should be less than 2 megabytes)

3. Reaction appeared after initiating the drug/product*? (•) Yes ( ) No ( ) Don't know

4. Reaction stopped after discontinuing the drug/product*? (•) Yes ( ) No ( ) Don't know

5. Reaction reappeared after restarting/reintroducing the drug/product*? ( ) Yes ( ) No ( ) Don't know
(•) Did not retake/reintroduce the drug/product

Let's submit a report

6. What was the outcome of the reaction?

- [ ] Requiring no interventions
- [x] Discontinuing the drug/product
- [x] Changing the therapy
- [ ] Administration of an antidote
- [ ] Requiring supportive treatment
- [ ] Hospitalization (Emergency Room or less than 24 hours)
- [ ] Hospitalization (for more than 24 hours)
- [ ] Prolonged hospitalization in case of in-patients

- [ ] Interventions to prevent permanent impairment or damage
- [ ] Transfer to an intensive care unit
- [ ] Disability
- [ ] Life-threatening
- [ ] Death
- [ ] Unknown
- [ ] Congenital anomaly
- [ ] Other: _____

Let's submit a report

7. Relevant laboratory data including dates

None were taken

Other relevant history including preexisting medical conditions: (ex: allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction,drug-drug interactions, drug-food interactions, drug-disease interactions, drug-laboratory interactions, substance abuse, etc...)

the patient is a smoker, hypertensive. otherwise healthy.

Let's submit a report

8. Further action taken

- [ ] No further action taken
- [x] Prescriber was notified
- [ ] Medical record documentation was written
- [x] Patient was counseled

9. How is the patient doing now?*

- (•) Recovering
- ( ) Recovered
- ( ) No improvement
- ( ) Unknown
- ( ) Fatal

Let's submit a report

D. Reporter details

Physician ◉ Pharmacist Nurse Public-Patient Other _____

Name*: elsy ramia Speciality: _____ OPL Registration Number: 6067

Address: _____ Email: elsy .ramia@opl.org.lb Phone Number: _____

Submit

Date of report: Monday 14/11/16

Automatically Filled by logging in to OPL with your user name and password

Let's submit a report

- Remember…
  - The form is available in three different languages
    - Arabic
    - English
    - French

- All you need to do is to **SUBMIT**!!

Improve Patient Outcomes

THANK YOU