ADR Reporting – Medical Content Needed for Analysis

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the UPPSALA MONITORING CENTRE

Outline

- Regulatory requirements
- Medical diagnosis
- The PV reviewer's wildest dream
- Reality
- The importance of a common format
- Conclusions

Regulatory requirements

- Minimal reporting criteria
  - A patient
  - A reporter
  - An ADR
  - A drug

-> valid case

Example

- A pharmacist reported that a male patient complained about hair loss. He was taking co-trimoxazole.

An ADR is...

- … a drug induced disease that does not differ significantly from its natural form and therefore should be investigated as such

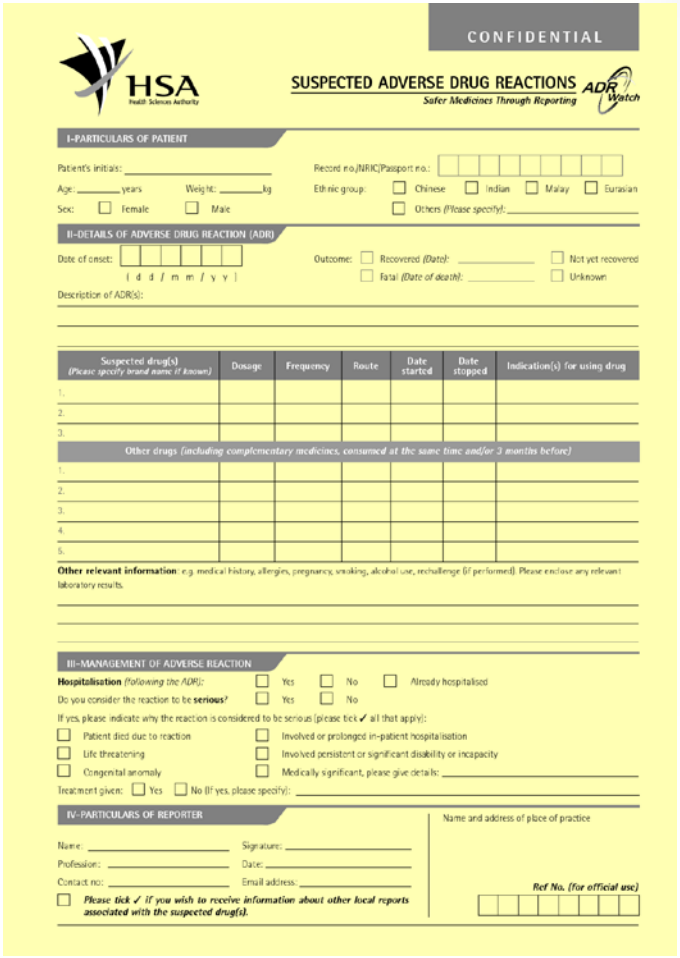
Clinical diagnosis

- Information about the patient
  - Demographics
  - Family/personal medical history
- Information about the current problem
  - Description
  - Measures taken by patient

- Physical examination
- Additional investigations
  - Lab tests
  - X ray etc

- -> most likely cause for disease

Clinical Assessment of reported ADRs



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HSA Health Sciences Authority

SUSPECTED ADVERSE DRUG REACTIONS ADR Watch

Safer Medicines Through Reporting

I-PARTICULARS OF PATIENT

Patient's initials: _____ Record no./NRIC/Passport no.: _____

Age: _____ years Weight: _____ kg Ethnic group: ☐ Chinese ☐ Indian ☐ Malay ☐ Eurasian

Sex: ☐ Female ☐ Male ☐ Others (Please specify): _____

II-DETAILS OF ADVERSE DRUG REACTION (ADR)

Date of onset: ☐☐☐☐☐☐ (d d / m m / y y) Outcome: ☐ Recovered (Date): _____ ☐ Not yet recovered

☐ Fatal (Date of death): _____ ☐ Unknown

Description of ADR(s):

Suspected drug(s) (Please specify brand name if known)	Dosage	Frequency	Route	Date started	Date stopped	Indication(s) for using drug
1.						
2.						
3.						
Other drugs (including complementary medicines, consumed at the same time and/or 3 months before)						
1.						
2.						
3.						
4.						
5.						

Other relevant information: e.g. medical history, allergies, pregnancy, smoking, alcohol use, rechallenge (if performed). Please enclose any relevant laboratory results.

III-MANAGEMENT OF ADVERSE REACTION

Hospitalisation (Following the ADR): ☐ Yes ☐ No ☐ Already hospitalised

Do you consider the reaction to be **serious**? ☐ Yes ☐ No

If yes, please indicate why the reaction is considered to be serious (please tick ✓ all that apply):

☐ Patient died due to reaction ☐ Involved or prolonged in-patient hospitalisation

☐ Life threatening ☐ Involved persistent or significant disability or incapacity

☐ Congenital anomaly ☐ Medically significant, please give details: _____

Treatment given: ☐ Yes ☐ No (If yes, please specify): _____

IV-PARTICULARS OF REPORTER

Name: _____ Signature: _____

Profession: _____ Date: _____

Contact no.: _____ Email address: _____

☐ ***Please tick ✓ if you wish to receive information about other local reports associated with the suspected drug(s).***

Name and address of place of practice

Ref No. (for official use) ☐☐☐☐☐☐☐☐

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Ideally…

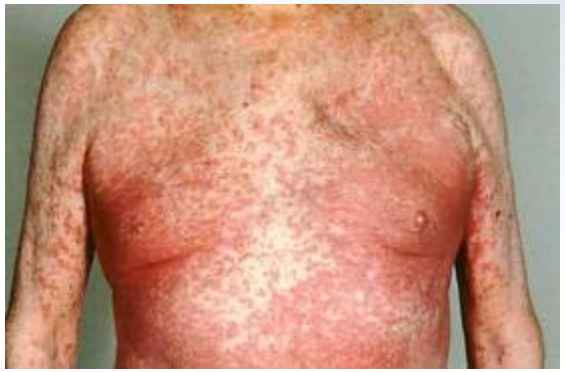
- The reporting form should provide the same information as a clinicial would seek when interviewing/examining/treating a patient

The PV reviewer's wildest dream

- Patient
  - Age
  - Gender
  - Ethnicity
  - Height/weight
  - Family/personal history
  - Recreational habits

ADR

- Exact chronology
- Severity
- Seriousness
- Development
- Measures taken
- Outcome



Drugs

- Active ingredient
- Product
- Galenic form/batch
- Dose
- Regimen
- Route of administration
- Duration
- De/rechallenge

Findings

- Physical examination
- Lab test as appropriate
- Other investigations


to Dream

Reality

- Reports often lack the essential information
- Following up incomplete reports is onerous and often yields poor results
- The first contact with the primary reporter is crucial

Essential data

- Patient
  - Gender
  - Age or age group
- History
  - Allergies
  - Renal/hepatic problems
  - Chronic disease
  - Recreational habits

- ADR
  - Description
  - Date of onset
  - Development
  - Outcome
- Drug
  - Substance/Product
  - Therapy dates
  - Dose/regimen
  - De/rechallenge

- Reporter
  - Contact details
- Other
  - Free field for any information reporter wants to add
- Special requirements
  - Ex. Hepatic ADRs

Common Format

- Exchange and pooling of information is essential -> PV is a global activity
- An efficient exchange of information requires a common format
- An automated electronic exchange is only possible with a common format

ICH E2B

GUIDELINE ON CLINICAL SAFETY DATA MANAGEMENT: DATA ELEMENTS FOR TRANSMISSION OF INDIVIDUAL CASE SAFETY REPORTS

-> defines what kind of information should be captured in specific fields in a database

-> allows transmission of data from one database in another in the correct fields

E2B – Key Elements

- Title and content of each data field
- Technical specification of data fields (length, value etc.)
- Abbreviations for units
- Units for time intervals
- Routes of administration

Conclusions

Reporting tools must be user friendly and should not be a burden

however

they should provide the information needed for a sound assessment to allow risk minimizing action to be taken if appropriate

Harmonization of format is a prerogative for an automated data exchange

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