WHO CENTRAL REGISTRY FOR THE EPIDEMIOLOGICAL SURVEILLANCE OF DRUG SAFETY IN PREGNANCY

TRAINING SLIDES - INTRODUCTION
SUMMARY

- Background - Need for evidence on drug safety in pregnancy
- Objective and features of the WHO central registry for epidemiological surveillance of drug safety in pregnancy
- Data sharing
Should the treatment guidelines recommendations be different when women are pregnant?

What should treatment guidelines recommend for women of childbearing age?

“We Don’t Know”

is not an acceptable or equitable answer to these questions.

Absence of evidence does not mean absence of risk
Possible treatment adverse effects are:
- Pregnancy loss
- Preterm birth
- Fetal growth retardation, low birth weight
- Birth defects/congenital anomalies
- Long term developmental problems
- Others
WHAT CAN BE DONE?

Needs:
- Lack of data on medicine use & impact on birth outcomes in Sub-Saharan Africa

Opportunities:
- Large scale deployment of medicines – Malaria, HIV, NTDs ....
- Increased MOH interest & ability to monitor safety & benefit in pregnancy

→ Opportunity to work together to expedite evidence & perhaps clear some drugs for use in pregnancy
Protocol for a drugs exposure pregnancy registry for implementation in resource-limited settings

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Abstract

• Systematically evaluate exposure of women at time of conception and during pregnancy and the pregnancy outcomes

• Can include easily key limited maternal outcomes and key neonatal outcomes
Follow a cohort

≠ spontaneous reporting

Include exposed and non exposed women:

Enrolment from the antenatal clinic or delivery ward irrespective of woman’s health conditions

Prospective evaluation

Exposures collected at time of delivery before outcome is known

Cover all drugs

Not specific to a single drug, collect all drugs exposures

Surface examination systematically for all newborns

Birth defect identification
• Systematic way to examine the newborn
• On live birth and stillbirths
• Detect only anomalies visible from surface examination at birth
• Birth defects arising from nutritional deficiencies or genetic factors that affect neural-development and internal organ systems are unlikely to be detected
Training and reference material:

• Video:
  
  https://www.dropbox.com/s/7bl80cyhmgx59kx/WHO-COPR_Surface_examination_newborn_30JAN2010.wmv?dl=0

• Atlas

Birth defects surveillance: atlas of selected congenital anomalies

(http://www.who.int/nutrition/publications/birthdefects_atlas/en/)
The bigger the cohort, the more representative will be the cohort, and the most likely will it allow detection of rare safety signal.

Country separately have small or bigger cohort, but pooling data together allow to increase sample size, and allow comparison between different exposure

WHO central registry for epidemiological surveillance of drug safety in pregnancy

Collaborative effort: TDR and WHO/HIV, ..
AIMS OF CENTRAL REGISTRY

- Facilitate the collection, harmonisation and pooling of data from pregnancy registries for the surveillance of drug safety in pregnancy
- Enable early detection of teratogenicity and influence on pregnancy outcome
- Inform treatment guidelines for pregnant patients
Data collected a country / project level – then share / transfer to the WHO central registry

- Individual de-identified patient data
- One record for newborn
- Data useful to the evaluation of drug safety in pregnancy
Mother:

- Demographics data
- No personal identifiers

If country decides to collect identifiers, should not be transferred to central registry
Information on potential general risk factors during pregnancy

Examples:
- Mother weight
- Blood pressure
- Hemoglobin level
Pregnancy:

- Date of conception, gestation information
  - Important for the evaluation of timing of exposure
  - In many settings not always available, or reliable
DATA COLLECTED

- Pregnancy outcome:
  - Type of delivery
  - Pregnancy outcome (baby alive, stillbirth, etc)
  - Gestation at time of pregnancy outcome

- Newborn information:
  - Weight, height, head circumference
  - Early neonatal death
  - Presence of birth defect (detected by surface examination)
DATA COLLECTED

- Exposures at time of conception and during pregnancy:
  - Maternal illnesses
  - Exposure to known toxics (alcohol, tobacco)
  - Drugs exposure

⚠️ Timing of exposure
⚠️ Ascertainment
DATA CONTRIBUTION TO CENTRAL REGISTRY

- Data collected at country or project level

- Share de-identified / anonymised data in compliance with local regulations and ethical requirements
  - No names or addresses or other identifiable information
  - Include date of birth (if possible and allowed by law in country)
  - Local registries operate according to their own national laws with regard to the need for consent
DATA CONTRIBUTION TO CENTRAL REGISTRY

- Country / Project / Site contribute data (individual cases) to central registry

- Certain criteria to fulfil (compatibility / comparability / quality of data)
  - Sites systematically collecting high quality data on exposures to drug during pregnancy and pregnancy outcomes

- Export to central registry and curation facilitated by WHO/TDR

- Central registry governance

- Contribution to be governed by standard data sharing agreement
Absence of evidence is not evidence of absence...

Very important to know drug safety profile for pregnant women so healthcare providers either:

- Do not withdraw a good treatment from them if drug is shown to be safe
- Or know to be very careful when treating women of child-bearing age if there is a safety concern

Well-designed pregnancy exposure registries can efficiently help assessment of drug safety pregnancy and provide information for optimising treatment

Pregnancy exposure registries to be coordinate as much as possible with existing pharmacovigilance system in the country (enhanced system rather than parallel system)
Size of the cohort will define the potential to detect major safety concern -> interest of pooled database

WHO central registry for epidemiological surveillance of drug safety in pregnancy aiming to facilitate data sharing and pooling of pregnancy registries / birth outcome surveillance projects

Key data defined

Engagement with current countries / project working on pregnancy registries / birth outcome surveillance

Countries / projects invite to contribute