Information On Clinical Reasoning And Heuristics, A Missing Link In Pharmacovigilance

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Conflict of Interest
Benigne Intracranial Hypertension

Well documented spontaneous report from a physician

- Female aged 27 years, with intracranial hypertension following administration of a levonorgestrel IUD.
- Latency of 10 months after start.
- Intracranial pressure was mildly increased, papillary edema and blurry vision.
- No medical history provided. The patient had no past drug therapy. Risk factor could be obesity.

Figure 2: Optic nerve with papilledema
What is the motive to report?

• Why does the reporter consider the existence of an ADR?
  - Time to onset?
  - Seen a similar case before?
  - Conclusive evidence that he/she is dealing with an ADR?
  - Which steps have been taken to reach a conclusion?

• What is the reason to report this case?
  - New ADR?
  - Concern about the unexpected severity?
  - Medical error involved?

Figure 2: Optic nerve with papilledema
The astute physician
Outline

- How the medical decision process works
- From novice to expert
- Clinical reasoning and Heuristics in PV; past, present and future
Two ways to build a house…
Clinical Reasoning

- The sum of the thinking and decision-making processes associated with clinical practice*
- Analysis of multiple variables of factors associated with the occurrence of clinical signs and symptoms, used to generate hypotheses about their cause (diagnosis)
- Aim is to prevent misdirections
- Stepwise approach determines how cases are interpreted
- Synopsis of CR in discharge letters
- Not primarily aimed at the detection of new information

* Higgs et al. Clinical reasoning in Health professionals Amsterdam: Elsevier; 2008. 4-19
Heuristics

- Any approach to problem solving, learning or discovery that employs a practical method
- Heuristics are not optimal, perfect of logical
- Sufficient to reach the goal under the given circumstances
- Make the diagnostic process more efficient
- Cognitive shortcuts
- Often based on previous experience
Performance of strategies

1. Leave responsibility to doctors

2. Use of “Heart Disease Predictive Instrument”

3. Heuristic Strategy “fast and frugal tree”

Outline

- How the medical decision process works
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- Clinical reasoning and Heuristics in PV; past, present and future
Development of experiential knowledge

Professional experience

- Novice
- Intermediate
- Experts

Method hypothesis generation

- Causal reasoning
- Illness scripts
- Heuristic reasoning
Dual process theory

- System 1:
  - intuitive, automatic, quick, effortless.
  - ‘heuristics’: aid in problem-solving learned through experience

- System 2:
  - Causal reasoning
  - analytic, reflective, slow, effortful
  - Verifying diagnosis
Reporters motives in PV

- Concise information provided on reporting forms
- We do not ask for motives or considerations to report on our reporting forms
- Follow up information about the motive may help to understand
  - Important elements for case-assessment
  - How the conclusion was reached
Outline

– How the medical decision process works

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– Clinical reasoning and Heuristics in PV; past, present and future
Past

Physician  Nat. PV centre  Internat. PV centre

Heuristic reasoning
Causal reasoning
Epidemiological reasoning

Low number of reports!
Present

Heuristic reasoning
Causal reasoning
Epidemiological reasoning

High number of reports!
Changes

- Increasing number of reports
  - In disproportionality analysis information on causal reasoning and heuristics is absent.
  - Analysis at European and global level more difficult access to additional follow up information

- Patient reporting
  - Lower threshold for retrieving information
  - In complex cases, the PV centre may have more prominent role in the clinical assessment.
  - New aspects of ADRs
Additional follow up may be needed
How to proceed?

- Understand the thought-process of the reporter
- Use of narratives in individual ICSRs
- Follow up information
  - Clinical reasoning → discharge letter or targeted information
  - Heuristic reasoning → ask for the motive to report and considerations of the reporter

- The information on our reporting forms often is too limited to really understand what was going on....
Further reading?