



Farmacovigilância : Rumo a uma Abordagem Integrada

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A INTEROPERABILIDADE DE SISTEMAS DE INFORMAÇÃO EM PORTUGAL

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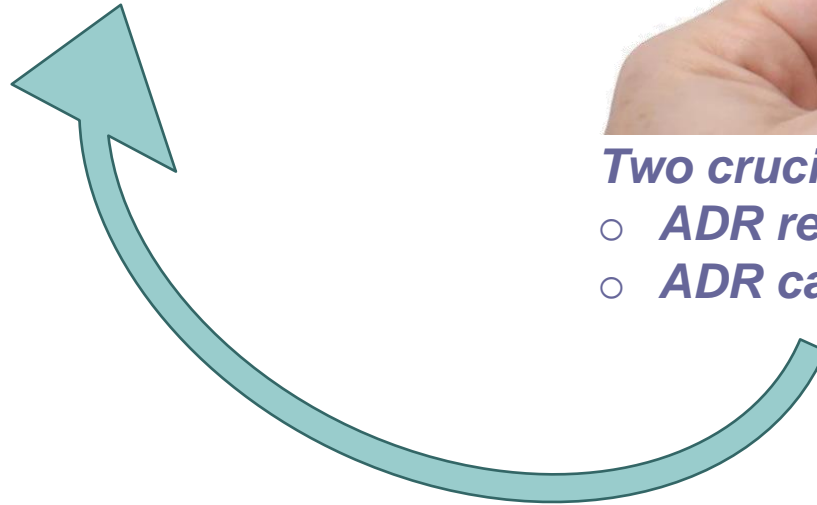
System output: Signal?

- * ADR not previously described?
- * Increasing frequency?
- * Unexpected seriousness?
- * Other unexpected feature?



Two crucial steps:

- *ADR reporting*
- *ADR causality assessment*





Limitations... ADR reporting

Knowledge and attitudes of health professionals continue to be the main determinants of ADR underreporting, namely:

- **lack of knowledge** (*only serious ADRs need to be reported*)
 - **lethargy** (*procrastination, lack of interest and other justifications*)
 - **complacency** (*the belief that only well-tolerated medications are allowed on the market*)
 - **shyness** (*fear of appearing ridiculous when reporting only suspected ADRs*)
 - **unreliability** (*it is almost impossible to determine whether or not a medication is responsible for a specific ADR*)
- • **lack of feedback** **immediate and delayed** ← **systems integration**
- **non-obligation to report**
 - **confidentiality concerns**

García-Abeijon P et al, 2023



Limitations... causality assessment



→ Accessibility of data and quality of raw data.

More than one third of the reports coming from manufacturers did not include information that is considered a limiting factor to evaluate any causal relationship, and can be an issue for the detection of safety signals. *Plessis L et al, 2017*

→ Quality of narratives.



Standard Narrative Template

CIOMS Working Group V.

Current Challenges in Pharmacovigilance: Pragmatic Approaches.

CIOMS, 2001. pp. 297-8

→ Need for high quality assessment tools *Khan LM et al, 2016*

→ Clinical advisory support for causality assessment



Limitations...

**A clinical exemple:
symptom associations/constellations and key symptoms/signs**

Aches all over: myalgia and/or arthralgia?...

Vagal episodes ← fainting, vomiting, blurred vision, breathlessness...

Hypersensitivity reactions

Blindness: Ophth? Neuro? Psych? Vagal?

Abdominal pain, colic, diarrhoea, weakness

Tremor + sweating → fever?

Nausea, vomiting, jaundice, raised LFTs → hepatitis



Limitations

- **Acessibility of data and quality of raw data**
- **Quality of narratives**
- **Need for high quality assessment tools**
- **Clinical advisory support for causality assessment**

