The importance of Pharmacovigilance

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Outline

Definition of PV

Why is PV important

Examples of when PV would have been helpful
Definition of PV

"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems." (1)
Why is PV important

• To minimize harm (not eliminate)
• To understand harm (and then prevent)
• To maintain confidence (of all players)
Are vaccines not always safe?
Yellow fever vaccination of US military troops

2.5 Million vaccinated
-> 26 thousand cases of hepatitis
-> 62 deaths \(^{(2)}\)

Shown to be HepB related
Poliomyelitis cases in school clinics, April-May 1955

- **Cutter**: 25 reported, 0 expected
- **Lilly**: 10 reported, 5 expected
- **Parke Davis**: 3 reported, 2 expected
- **Wyeth**: 1 reported, 1 expected
References

• (1): The importance of pharmacovigilance. WHO 2002

• (2): Lancet 1942; 73: 1110