THE UNDER-REPORTING RATE AS A PHARMACOVIGILANCE PROCESS INDICATOR IN A COMPREHENSIVE CANCER

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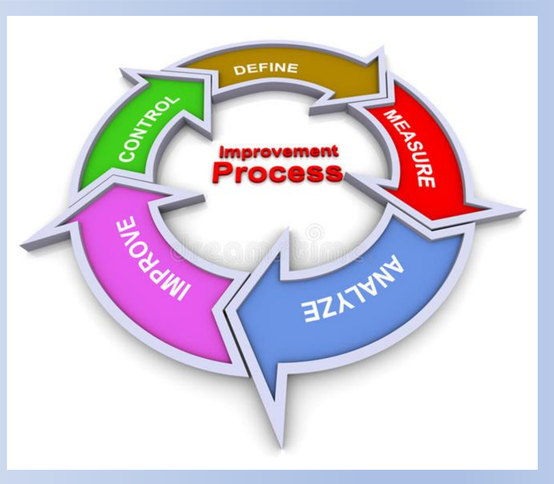
Background

- Under-reporting in oncology practice is a known phenomenon linked to the predictable toxicity of these drugs.
- Reporting indicators are often calculated on very large catchment area and limits the capacity for self-assessment of the performances in each hospital.
- Pharmacovigilance data analysis and signal detection are conducted on central big databases, but the information are collected locally in single institution…

We need to improve the number and the quality of ADR reports in oncology.

- To focus objectives, measure performances and to address interventions to the most critical areas we need indicators.
- Quality indicators in pharmacovigilance are easy to implement (presence of essential information, % od Serious ADR/total ADR…)
- Underreporting is a «quantity» issue
- Quantity indicators and targets are usually measured on large populations (n°ADR/inhabitants) and are intended to be used in larger setting than a single hospital centre.



Aim of the work

The purpose of this work is to evaluate the feasibility of an underreporting rate index in a single cancer centre as a quantitative process indicator.

Material and methods

The ADRs reports from 1 January 2018 to 31 January 2019 in our Institute were collected in a database. The reporting rates of the most 9 active ingredients were calculated using the following formulas:

$$\frac{number\ of\ drug\ reports\ X}{number\ of\ patients\ treated\ with\ the\ drug\ X} \text{ x } 100 \qquad \frac{number\ of\ drug\ reports\ x}{number\ of\ drug\ administrations\ x} \text{ x } 100$$

The expected value was evaluated using the formula:

$$\frac{expected\ frequency\ * number\ of\ patients\ treated\ with\ the\ drug\ X}{100}$$

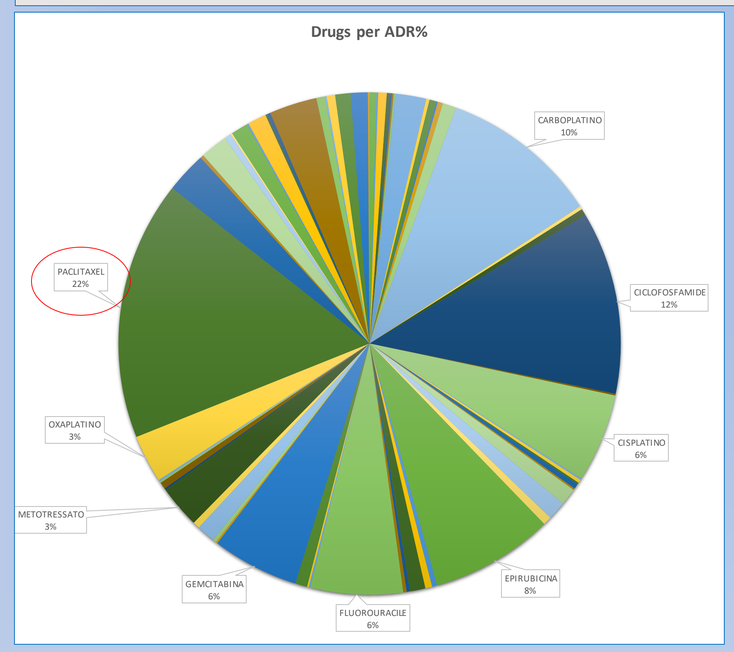
The expected frequency has been calculated by Summary of Product Characteristics and literature reports.
The rate of under-reporting was calculated as a ratio:

$$\frac{missing\ episodes}{expected\ episodes} \text{ x } 100$$

Only results of paclitaxel are reported in the present work.

Results

In the period January 2018/January 2019, total ADRs reported were 230. Mean under-reporting rate for single expected toxicity among the 9 most signalled drugs: 64,4 %.
Paclitaxel (most signalled drug) related ADRs were 51 in 412 patients treated (3293 total administrations).
The reporting rate for the number of patients treated is 12.4% while the reporting rate by number of administrations is 1.5%.



Events=51; Pts=412		*%*	
ADR (Paclitaxel)	*Reporting rate*	*min UR rate*	*max UR rate*
neutropenia	6,41	74,86	82,17
febrile neutropenia	0,49	51,46	97,22
transaminite	2,43	75,73	94,49
thrombocytopenia	0,73	93,38	98,46
diarrhoea	2,69	86,65	91,02

PACLITAXEL. Severe neutropenia represents the main toxicity with an expected incidence from 28% to 39%, while the reported incidence was 6.41%.
The max underreporting rate of ADR related to paclitaxel were: neutropenia (82.17%), febrile neutropenia (97.22%), transaminite (94.49%), thrombocytopenia (98.46%), diarrhoea (91.02%).
Some gastrointestinal and musculoskeletal system reactions are very common (≥ 1/10), but there was no report at all.

Conclusions

The indicator allows us to better identify area of under reporting over time in a more precise way than the absolute number of reports, it is feasible, but when the expected frequency of the event drops below 10%, the indicator loses reliability for samples less than 1000 patients. It is therefore mainly a quantitative indicator on frequent events.