Clinical Quality of Information of Primary Pregnancy Pharmacovigilance Data Sources – A contribution from the ConcePTION Project

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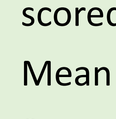
INTRODUCTION



- Clinically well-documented adverse event reports are essential for reliable safety signal assessment.
- Detailed clinical quality information for primary pregnancy pharmacovigilance (PV) data sources is lacking.
- A validated assessment tool that quantifies the suitability of information for safety assessment during pregnancy has recently been developed as part of the ConcePTION project.
- AIM: To assess clinical quality differences among various PV data sources and study the nature of information collected.

METHODS

- Data types: Spontaneous reports and reports from literature in EudraVigilance, ENTIS (UKTIS, SwissTIS, Jerusalem TIS, Zerifin TIS), Dutch Pregnancy Drug Register, enhanced PV programme (EPV, Novartis), and industry-sponsored patient support programmes (PSP, Novartis). From each data type, 50 random case reports were collected.
- For each report, twenty-one information elements within seven categories were assessed: information related to the association itself, the event, exposure to the medicinal product, maternal factors, pregnancy, labour, and the child. These information elements were assessed for both relevance and presence of meaningful information.
- The clinical quality was expressed as the number of elements present divided by the number of relevant elements, times 100. The clinical quality was scored according to the following cut off values : <45% - poor, 45-65% - intermediate, ≥65% - excellent.
- Mean quality scores were calculated per data source. Comparison of mean quality scores was done using ANOVA (analysis of variance test).
- Scores of all information elements were assessed with the purpose of identifying patterns in reporting specific information that may affect report quality.

RESULTS

Table 1: Characteristics of case reports per data source. Columns poor, intermediate and excellent show the number of case reports classified in the respective category. PV = pharmacovigilance.

DATA SOURCE	NUMBER OF CASE REPORTS	MEAN QUALITY SCORE (SD)	POOR	INTERMEDIATE	EXCELLENT
ENTIS	50	77.1 (13.3)	2 (4%)	3 (6%)	45 (90%)
ENHANCED PV PROGRAMME	28	64.7 (20.5)	6 (21.4%)	8 (28.6%)	14 (50%)
LITERATURE REPORTS	50	38.6 (18.0)	30 (60%)	17 (34%)	3 (6%)
THE DUTCH PREGNANCY DRUG REGISTER	50	89.0 (10.1)	0	1 (2%)	49 (98%)
PATIENT SUPPORT PROGRAMME	45	49.5 (16.2)	20 (44.4%)	23 (51.1%)	7 (15.6%)
SPONTANEOUS REPORTS	47	40.9 (21.6)	29 (61.7%)	12 (25.5%)	6 (12.8%)

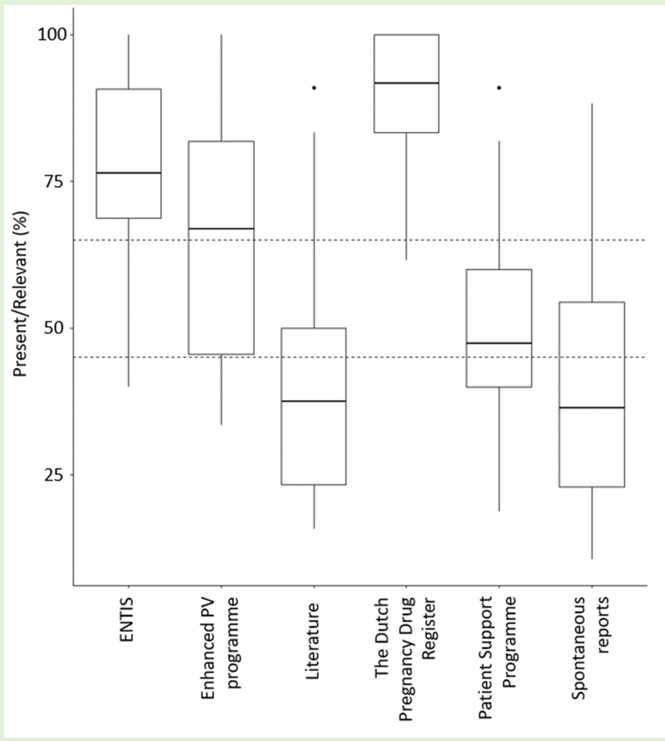


Figure 1: Boxplots of clinical quality per data source (% present over relevant information elements). Cutoff values: <45% poor, 45-65% intermediate, ≥65% excellent quality.

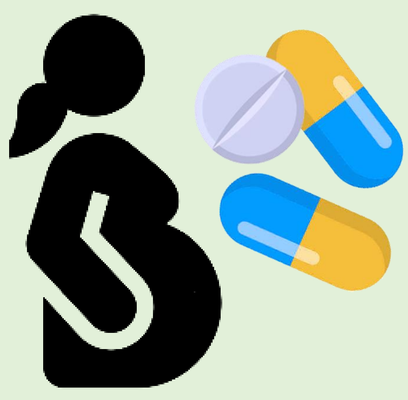
Table 2: Heatmap of Information Completeness (%); Elements with <5 relevant case reports excluded.)

	ENTIS	Enhanced PV programme	Literature reports	The Dutch Pregnancy Drug Register	Patient support programme	Spontaneous reports
Association	100.0	100.0	100.0	100.0	100.0	100.0
Validation	13.3		21.4	16.7	22.2	25.0
Timing (event)	18.8	37.5	40.0	68.2	39.1	25.0
Evolution (event)	5.9		27.3	29.2	33.3	28.1
Administration information	70.2	82.1	33.3	89.2	82.2	45.5
Timing (exposure)	79.6	78.6	35.7	77.6	53.3	34.0
Indication	64.3		66.7	96.6		50.0
Other exposures	81.6	75.0	54.8	100.0	31.1	55.3
Medical history	80.0	42.9	26.0	100.0	40.0	27.7
Maternal demographics	89.8	73.1	11.1	100.0	47.7	32.6
Life style and risk factors	87.8	32.1	15.4	100.0	11.4	9.1
Previous pregnancies	94.4	22.2	16.3	100.0	9.7	24.4
Pregnancy complications	47.8	23.8	11.4	76.1	12.5	17.6
Prenatal testing			5.3		21.4	16.7
Labour onset	12.5		0	100.0	11.8	21.4
Mode of delivery	57.1			100.0		0
Delivery complications	25.0		0	35.7	0	6.7
GA at birth	97.8	80.0	45.5	100.0	64.5	32.1
Apgar score	53.3		13.3	61.1	0	23.8
Breastfeeding	100.0		14.3	100.0		14.3
Medical information child	93.5	54.5	41.4	100.0	65.5	5.,0

CONCLUSION

Pregnancy-specific data sources (e.g., Dutch Pregnancy Drug Register and ENTIS-centers) have higher clinical information quality on average compared to general pharmacovigilance sources.

Enhanced pharmacovigilance programmes show better clinical quality scores than general spontaneous reporting for pregnancy pharmacovigilance.



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