

# ICBDMS

(International Clearinghouse for Birth  
Defects Monitoring System)

国際先天異常監視機構(WHO)

<先天異常モニタリング・サーベイランス>

WHO関連国際共同監視機構

先進25カ国(米、英、仏、独、北欧、豪、南ア、  
ハンガリー、南米、メキシコ、中国、日本等

- ・モニタリング
- ・サーベイランス
- ・予防

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(International Clearinghouse for Birth Defects  
Monitoring Systems)

国際先天異常監視機構(本部ローマ)WHO

<先天異常モニタリング・サーベイランス>

<国際共同委員会>

環境・職業委員会

分類用語委員会

薬剤影響委員会

多発奇形委員会

出生前先天異常委員会

<協同研究プロジェクト>

# 薬剂影响委员会

Table 1. Number of malformed fetuses exposed to drugs during the 1st trimester by registry and year

Program / Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	Total
Australia: National	28	20	20										68
France: Central East	132	146	113	178	183	135	186	218	220	278	223	172	2,184
France: Paris			219	170	183	154	136	126	113	121			1,222
Israel: IBDMS	15	15	27	16	6	12	15	14	16	16	13	16	181
Italy: IMER	73	71	114	132	75	76	74	57	51	46	38	43	850
Italy: IPIMC	189	261	437	394	359								1,640
Italy: ISMAC		27	21	21	7	7	11						94
Japan: JAOG	48	41	52	51	35	43	32	57	73	44	51	114	641
Northern Netherlands	47	80	70	45	86	70	128	195	175	185	54		1,135
South America: ECLAMC	61	255	458	714	674	624	596						3,382
Total	593	916	1,531	1,721	1,608	1,121	1,178	667	648	690	379	345	11,397

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Table 2. Number of malformed fetuses exposed to drugs during the 1st trimester by registry and year

Association	Malformation	Drug	cases	OR-MH	95% LL MH	95% UL MH	MH test	p	BD test	p	No of PRGs
745	A10	Anomalies of Cardiac Septal Closure	104	2,72	2,14	3,47	98,10	0,00	8,04	0,53	10
741	N03	Spina Bifida	51	3,94	2,90	5,34	78,64	0,00	10,70	0,22	9
747	A10	Other congenital anomalies of the circulatory system	44	2,79	2,02	3,86	57,73	0,00	8,91	0,45	10
752	C04	Congenital Anomalies of Genital Organs	153	1,38	1,12	1,70	53,34	0,00	9,40	0,15	7
753	H03	Congenital Anomalies of Urinary System	83	1,79	1,39	2,32	39,06	0,00	8,65	0,37	9
752	G03	Congenital Anomalies of Genital Organs	222	1,25	1,06	1,48	37,87	0,00	5,41	0,80	10

OR-MH = Mantel-Haenszel Odds Ratio; 95% LL MH = 95% confidence interval, lower level, Mantel-Haenszel; 95% UL MH = 95% confidence interval, upper level, Mantel-Haenszel; MH test = Mantel-Haenszel test; BD test = Breslow-Day test; No of PRGs = Number of number of Programmes from which cases involved in the test (cases or controls, exposed or not exposed) come.

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Antivirals: VSD

	Cases	Controls	Total
Exposed	5	30	35
Not exposed	780	10991	11771
Total	785	11021	11806

OR(CI 95%) = 2.35 (0.93, 5.90) MHOR = 1.55  
(0.60, 4.01) Breslow-Day Test: Chi-square = 2.86  
DF=6 p=0.83