

### **Online Resources 1-3**

**Title:**

Spontaneous reporting on adverse events by consumers in the United States: an analysis of the Food and Drug Administration Adverse Event Reporting System database

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**Online Resource 1. Reporting rates (report completeness) for each item in spontaneous reports by the type of reporters**

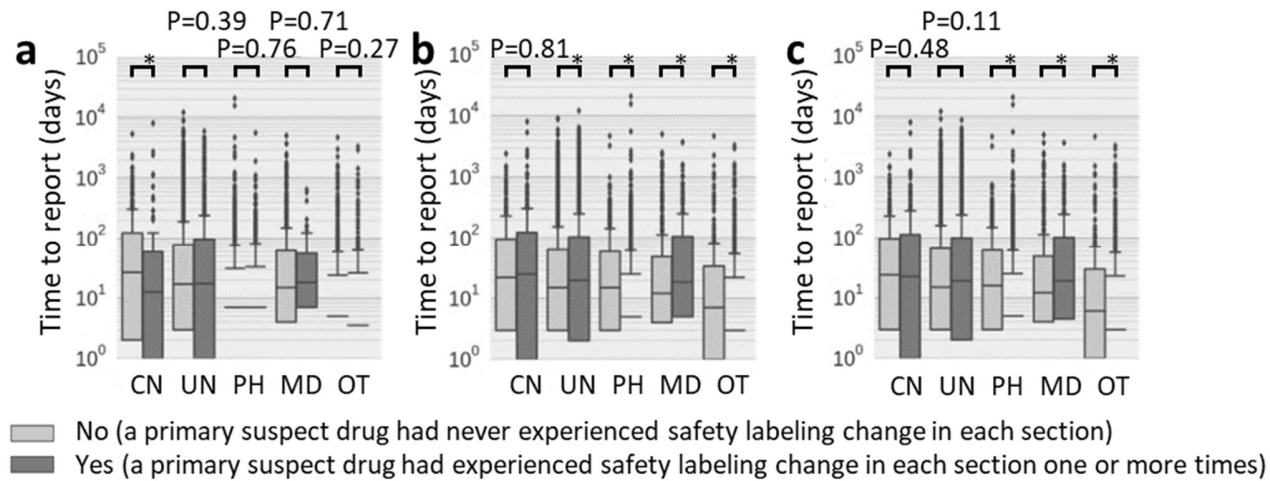
		Filled reports / All reports (Reporting rate%)				
		CN	UN	PH	MD	OT
Patient sex		1038/1068 (97%)	9068/9461 (96%)	10935/11309 (97%)	1155/1165 (99%)	2758/2811 (98%)
	p-value (vs CN)	-	0.034	0.381	<0.001	0.076
	p-value (vs UN)	-	-	0.001	<0.001	<0.001
Patient age		948/1068 (89%)	7455/9461 (79%)	9894/11309 (87%)	1045/1165 (90%)	2358/2811 (84%)
	p-value (vs CN)	-	<0.001	0.226	0.476	<0.001
	p-value (vs UN)	-	-	<0.001	<0.001	<0.001
Patient weight		593/1068 (56%)	5903/9461 (62%)	2889/11309 (26%)	956/1165 (82%)	902/2811 (32%)
	p-value (vs CN)	-	<0.001	<0.001	<0.001	<0.001
	p-value (vs UN)	-	-	<0.001	<0.001	<0.001
Indication		839/1068 (79%)	5804/9461 (61%)	9104/11309 (81%)	612/1165 (53%)	2029/2811 (72%)
	p-value (vs CN)	-	0.000	0.127	<0.001	<0.001
	p-value (vs UN)	-	-	<0.001	<0.001	<0.001
Event date		694/1068 (65%)	6372/9461 (67%)	8215/11309 (73%)	946/1165 (81%)	2052/2811 (73%)
	p-value (vs CN)	-	0.118	<0.001	<0.001	<0.001
	p-value (vs UN)	-	-	<0.001	<0.001	<0.001
Route of primary suspect drug		587/1068 (55%)	5115/9461 (54%)	8860/11309 (78%)	571/1165 (49%)	1933/2811 (69%)
	p-value (vs CN)	-	0.576	<0.001	0.005	<0.001
	p-value (vs UN)	-	-	<0.001	0.001	<0.001
Secondary suspect drug		142/1068 (13%)	1362/9461 (14%)	1230/11309 (11%)	277/1165 (24%)	304/2811 (11%)
	p-value (vs CN)	-	0.330	0.016	<0.001	0.030
	p-value (vs UN)	-	-	<0.001	<0.001	<0.001
Concomitant drug		569/1068 (53%)	4629/9461 (49%)	2630/11309 (23%)	320/1165 (27%)	448/2811 (16%)
	p-value (vs CN)	-	0.007	<0.001	<0.001	<0.001
	p-value (vs UN)	-	-	<0.001	<0.001	<0.001

CN for consumer, UN for “unknown occupation” reporter, PH for pharmacist, MD for physician, and OT for other healthcare professional. P values were calculated from Chi-square test.

**Online Resource 2. Proportions of reports (a) which have any known adverse drug reactions, (b) for which primary suspect drug experienced safety labeling change (SLC) in the boxed warning, (c) for which primary suspect drug experienced SLC in the warning section, and (d) for which primary suspect drug experienced SLC in the precaution section, by the type of reporters**

	"Yes" reports / All reports (Proportion%)				
	CN	UN	PH	MD	OT
(a) Primary suspect drug known	294/553 (53%)	3182/5616 (57%)	3703/6057 (61%)	384/658 (58%)	900/1522 (59%)
p-value (vs CN)	-	0.114	<0.001	0.070	0.015
p-value (vs UN)	-	-	<0.001	0.405	0.084
(b) SLC in boxed warning	517/1068 (48%)	3822/9461 (40%)	5712/11309 (51%)	345/1165 (30%)	1586/2811 (56%)
p-value (vs CN)	-	<0.001	0.189	<0.001	<0.001
p-value (vs UN)	-	-	<0.001	<0.001	<0.001
(c) SLC in warning	176/1068 (16%)	1324/9461 (14%)	1872/11309 (17%)	80/1165 (7%)	635/2811 (23%)
p-value (vs CN)	-	0.028	0.951	<0.001	<0.001
p-value (vs UN)	-	-	<0.001	<0.001	<0.001
(d) SLC in precaution	524/1068 (49%)	3834/9458 (41%)	5911/11305 (52%)	369/1165 (32%)	1615/2810 (57%)
p-value (vs CN)	-	<0.001	0.044	<0.001	<0.001
p-value (vs UN)	-	-	<0.001	<0.001	<0.001

CN for consumer, UN for "unknown occupation" reporter, PH for pharmacist, MD for physician, and OT for other healthcare professional. P-values were calculated from Chi-square test. This table was attached as supplement data for Fig. 4 and Online Resource 3.



**Online Resource 3. Distributions of time to report grouped by whether a primary suspect drug in a report experienced safety labeling changes in black box warning (a), warning (b), or precaution (c) sections.**

Boxplot with whiskers with maximum 1.5 interquartile range. Any data not included between whiskers are plotted as an outlier with a dot. When the value for the first quartile is zero, the box is not shown. CN for consumer, UN for “unknown occupation” reporter, PH for pharmacist, MD for physician, and OT for other healthcare professional. P-values were calculated from Wilcoxon rank-sum test. \* indicates  $p < 0.05$ .