



INTEGO
GROUP

INCIDENCE RATE – INCIDENCE PROPORTION, PREVALENCE RATE AND OTHER RELATED STATISTICS



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Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Patient-Months
(Safety Population)

System Organ Class Preferred Term	Control Treatment (N=xx) n(%)	pt-month	Investigated Treatment (N=xx) n(%)	pt-month	Total (N=xx) n(%)	pt-month
Any Treatment-Emergent Adverse Event	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
SOC1	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
Term 1	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
Term 2	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
...						
SOC2	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
Term 1	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
Term 2	xx(xx.x), xx.x		xx(xx.x), xx.x		xx(xx.x), xx.x	
...						
...						

Note 1: Adverse events are coded using MedDRA version 21.1 or higher

Note 2: Treatment-emergent adverse events are defined as any adverse event that occurs after administration of the first dose of study drug and through 30 days after the last dose of study drug.

Note 3: Patients are counted once for each system organ class and once for each preferred term.

Note 4: Cell entries are number and percent of patients with at least one event of the type specified, followed by the incidence rate of the event (total number of new events per 100 patient months).

AGENDA:

- Definitions
- Mathematical Formulas
- Programming Implementation
- Example



PART I.

**DISEASE STATUS VS. DISEASE
ONSET**



TWO MAIN CLASSES:

Disease status:

- Assessment of the population at one specific moment in time
- Marker word - “prevalence”

Disease onset:

- Assessment of the frequency of disease onsets during certain time

POINT PREVALENCE

Point prevalence is the proportion of a population that has the condition **at a specific point in time.**

$$P = \frac{\text{number of subjects with event at time point}}{\text{total number of subjects in population}}$$

POINT PREVALENCE



Contents lists available at [ScienceDirect](#)

International Journal of Infectious Diseases

journal homepage: www.elsevier.com/locate/ijid



One-day point prevalence of healthcare-associated infections and antimicrobial use in four countries in Latin America



Table 2
Prevalence of at least one Healthcare-associated infections by country.

Country	Brazil	Colombia	Mexico	Venezuela	Total
Patients	761	386	1,042	551	2,740
Patients with at least one HAI	54	42	121	98	315
Prevalence of at least one HAI (%; IC 95%)	7.10 (5.27-8.92)	10.88 (7.77-13.99)	11.61 (9.67-13.56)	17.79 (14.59-20.98)	11.50 (10.37-12.77)

PERIOD PREVALENCE

Period prevalence is the proportion of a population that has the condition **at some time** during a given period.

$$P = \frac{\text{number of subjects with event at any moment of period}}{\text{total number of subjects in population}}$$

PERIOD PREVALENCE

Prevalence of the 25 Most Common CFTR Mutations in People with CF Seen in 2016					
CFTR Mutation			Mutation Class	Number of Individuals	Percent of All People with CF
Legacy Name	cDNA Name	Protein Name			
F508del	c.1521_1523delCTT	p.Phe508del	2	24,901	86.4
G542X	c.1624G>T	p.Gly542X	1	1,342	4.7
G551D	c.1652G>A	p.Gly551Asp	3	1,280	4.4
R117H	c.350G>A	p.Arg117His	4	865	3.0
N1303K	c.3909C>G	p.Asn1303Lys	2	703	2.4
W1282X	c.3846G>A	p.Trp1282X	1	658	2.3
R553X	c.1657C>T	p.Arg553X	1	527	1.8



LIFETIME PREVALENCE

Lifetime prevalence (LTP) is the proportion of a population that at some point in their life (up to the time of the assessment) has experienced the condition.

$$P = \frac{\text{number of subjects with event at any moment of their life}}{\text{total number of subjects in population}}$$

LIFETIME PREVALENCE

Rev Bras Psiquiatr. 2012;34:249-260



Revista Brasileira de Psiquiatria
RBPPsychiatry
Official Journal of the Brazilian Psychiatric Association
Volume 34 • Number 3 • October 2012



ORIGINAL ARTICLE

Lifetime Prevalence, Age and Gender Distribution and Age-of-Onset of Psychiatric Disorders in the São Paulo Metropolitan Area, Brazil: Results from the *São Paulo Megacity Mental Health Survey*

Table 1 Lifetime prevalence of DSM-VI WMH-CIDI disorders in the *São Paulo Megacity Survey* total sample, by age and gender

	Age group										χ^2	Gender				OR (95%CI)
	Total		18-34		35-49		50-64		65+			Male		Female		
	%	SE	%	SE	%	SE	%	SE	%	SE		%	SE	%	SE	
Major Depressive Disorder	16.9	0.9	16.2	1.2	19.0	1.3	17.2	1.2	11.8	2.2	11.1 ^a	10.0	0.67	23.0	1.31	2.7 (2.3-3.1) ^a
Dysthymia	1.6	0.3	1.6	0.3	1.7	0.4	0.8	0.3	2.9	1.2	8.0	0.9	0.34	2.2	0.44	2.5 (1.5-5.3) ^a
Bipolar Disorder (I and II)	2.1	0.2	2.4	0.4	2.6	0.4	1.3	0.5	0.8	0.5	11.3 ^a	2.2	0.40	2.1	0.28	0.96 (0.6-1.5)
Any Mood Disorder	19.1	0.8	18.6	1.4	21.7	1.1	18.5	1.2	12.8	2.3	16.4 ^{ab}	12.3	0.82	25.2	1.25	2.4 (2.0-2.9) ^a

INCIDENCE PROPORTION

Incidence proportion is the number of new cases within a specified time period divided by the size of the population initially at risk.

$$I = \frac{\text{number of new cases during period}}{\text{number of subjects in population initially at risk}}$$

INCIDENCE PROPORTION (CUMULATIVE INCIDENCE)

Five-Year Cumulative Incidence and Progression of Epiretinal Membranes

The Blue Mountains Eye Study

Samantha Fraser-Bell, MBBS, Magdalena Guzowski, MBBS, Elena Rochtchina, MAppI Stat,
Jie Jin Wang, MMed, PhD, Paul Mitchell, MD, PhD

Table 2. Incidence of Idiopathic and Secondary Epiretinal Membranes in Participants with No Preexisting Lesion at Baseline

Type of Epiretinal Membrane	Cases	Incidence % (95% Confidence Interval)
Idiopathic epiretinal membranes (n = 1851)		
PMF	29	1.6 (1.1–2.3)
CMR	69	3.7 (2.9–4.7)
Any	97*	5.2 (4.2–6.3)
Secondary epiretinal membranes (n = 179)		
PMF	2	1.1 (0.1–4.0)
CMR	8	4.5 (2.0–8.7)
Any	10	5.6 (2.7–10.1)

*One participant developed CMR in one eye and PMF in the other eye.
CMR = cellophane macular reflex; PMF = preretinal macular fibrosis.

INCIDENCE RATE

Incidence rate is a measure of frequency with which a disease or other incident occurs over a specified time period.

$$I = \frac{\text{number of new cases during period}}{\text{total time subjects in population at risk}}$$

INCIDENCE RATE

Journal of Neurology, Neurosurgery, and Psychiatry
BMJ

Incidence and prevalence of multiple sclerosis in the UK 1990–2010: a descriptive study in the General Practice Research Database

	Patient years (thousands)	GPRD only where HES available		GPRD plus HES	
		New cases	Incidence (/10 ⁵ /year)	New cases	Incidence (/10 ⁵ /year)
Male					
Under 10	841.0	0	0.00	1	0.11
10–19	1146.2	6	0.52	7	0.61
20–29	974.8	40	4.10	42	4.30
30–39	1294.1	100	7.72	107	8.26
40–49	1429.6	129	9.02	143	10.00
50–59	1301.4	97	7.45	123	9.45
60–69	1013.5	53	5.22	75	7.39
70–79	675.6	16	2.36	50	7.40
80–89	296.2	4	1.35	14	4.72
90	40.1	0	0	4	9.98
Plus					
Total	9012.6	445	4.93	566	6.28

RAPORTING RATE

Reporting rate consists of the numerator derived from spontaneous adverse event report, and the denominator representing the population at risk for the adverse events.

$$R = \frac{\textit{number of spontaneous reported events}}{\textit{estimates of subjects exposure}}$$

REPORTING RATE

Numbers of reported cases and reporting rates for 12 drugs marketed in France between 1988 and 1993. RRR is the ratio of the reporting rates for the two drugs of the same pair. The bold figures correspond to the drug marketed by the company which originally developed the compound.



Is reporting rate a good predictor of risks associated with drugs?

<i>Pairs</i>	<i>Number of case reports</i>	<i>Reporting rate per 10⁶ patient-months</i>	<i>RRR</i>	<i>RRR 95% CI</i>
1	134	3.37	1.28	[1.01; 1.60]
	164	2.64		
2	151	1.69	0.84	[0.68; 1.02]
	260	2.02		
3	409	2.75	1.33	[1.06; 1.74]
	74	2.06		
4	47	1.45	0.76	[0.49; 1.19]
	36	1.90		
5	91	2.37	1.33	[0.97; 1.85]
	63	1.78		
6	24	2.45	1.32	[0.71; 2.66]
	16	1.85		



PART II.

**PROGRAMMING
IMPLEMENTATION**



REAL WORLD DATA



The primary objectives of VAERS are to:

- Detect new, unusual, or rare vaccine adverse events;
- Monitor increases in known adverse events;
- Identify potential patient risk factors for particular types of adverse events;
- Assess the safety of newly licensed vaccines;
- Determine and address possible reporting clusters (*e.g., suspected localized [temporally or geographically] or product-/batch-/lot-specific adverse event reporting*);
- Recognize persistent safe-use problems and administration errors;
- Provide a national safety monitoring system that extends to the entire general population for response to public health emergencies, such as a large-scale pandemic influenza vaccination program.

PERIOD PREVALENCE PROPORTION INCIDENCE RATE

```
proc sql;
/* period prevalence proportion */
  create table prev_prop as
    select distinct TRT, AETERM,
/* number of subjects with event */
      count(distinct USUBJID) as S_COUNT,
/* number of subj with event/total number of subjects */
      100*count(distinct USUBJID)/TRTTOT as P_PROP
  from anl
  group by TRT, AETERM
  order by PERCENT desc;
quit;
```

```
proc sql;
/* incidence rate per 100 patient-years */
  create table inc_rate as
    select distinct TRT, AETERM,
/* number of events */
      count(USUBJID) as E_COUNT,
/* number of events/total treatment duration */
      100*count(USUBJID)/DURTOT as I_RATE
  from anl
  group by TRT, AETERM
  order by PERCENT desc;
quit;
```

ANY SYMPTOM

```
proc sql;  
    /* period prevalence proportion for any event */  
    create table prev_prop_any as  
        select distinct TRT,  
            /* number of subjects with any event */  
            count(distinct USUBJID) as S_COUNT,  
            /* number of subjects with any event/number of subjects in population */  
            100*count(distinct USUBJID)/TRTTOT as P_PROP  
        from anl  
        group by TRT, AETERM  
        order by PERCENT desc;  
quit;
```

OUTPUT TABLE

Summary of Adverse Events with Incidence Proportion at least 10% by Term and Treatment

Event Name	Alfurix (N= 917)	Fluarix (N= 997)
Any Adverse Event	3916 (427.04)	4168 (418.05)
Injection site pain	139 (15.16)	174 (17.45)
Pain	153 (16.68)	127 (12.74)
Pain in extremity	109 (11.89)	130 (13.04)
Pyrexia	113 (12.32)	108 (10.83)
Injection site erythema	0	123 (12.34)
Headache	96 (10.47)	0

PRESENTATION TAKEAWAYS:

- Statistician and programming team should speak the same language
- Use correct terminology
- Understand methodology
- Expect the same results

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THANK YOU

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