

Growing up with SAS: It Gets Real

YEVHEN LOS, EXPERIS CLINICAL, KHARKIV, UKRAINE

DMYTRO HASAN, EXPERIS CLINICAL, KHARKIV, UKRAINE

Agenda

- What is Real World Data
- Benefits of using RWD
- Sources of RWD
- VAERS data
- Number of events vs number of vaccines
- Numbers of events for combination vaccines

What is Real World Data

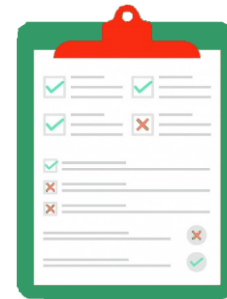
- ISPOR Task Force definition: everything that goes beyond what is normally collected in the Phase III clinical trials program in terms of efficacy
- European Forum “Relative Effectiveness” Working Group definition: a measure in understanding health care data collected under real life practice circumstances
- General definition: any healthcare data that was not obtained in an interventional study

Benefits of using RWD

- Allows to estimate the effects of a drug in a diverse study population
- Allows to collect data when it is not possible to run a Randomized Clinical Trial (RCT)
- Allows to estimate rare clinical benefits and harms
- Allows to collect broader range of results than those usually collected in RCTs
- Can be used to draw preliminary conclusions when RCT data is not available

Sources of RWD

1. Supplements to traditional RCTs
 - 😊 Can show treatment patterns for certain events
 - 😞 Same population and surrounding as for RCTs
2. Large simple trials
 - 😊 More likely to capture significant outcomes
 - 😞 Expensive
3. Health surveys and reviews
 - 😊 Data on representative target population
 - 😞 Prone to subjectivity



Sources of RWD (cont.)

4. Registries

- 😊 More diverse population than in Phase III of RCTs
- 😞 No randomization

5. Electronic health records

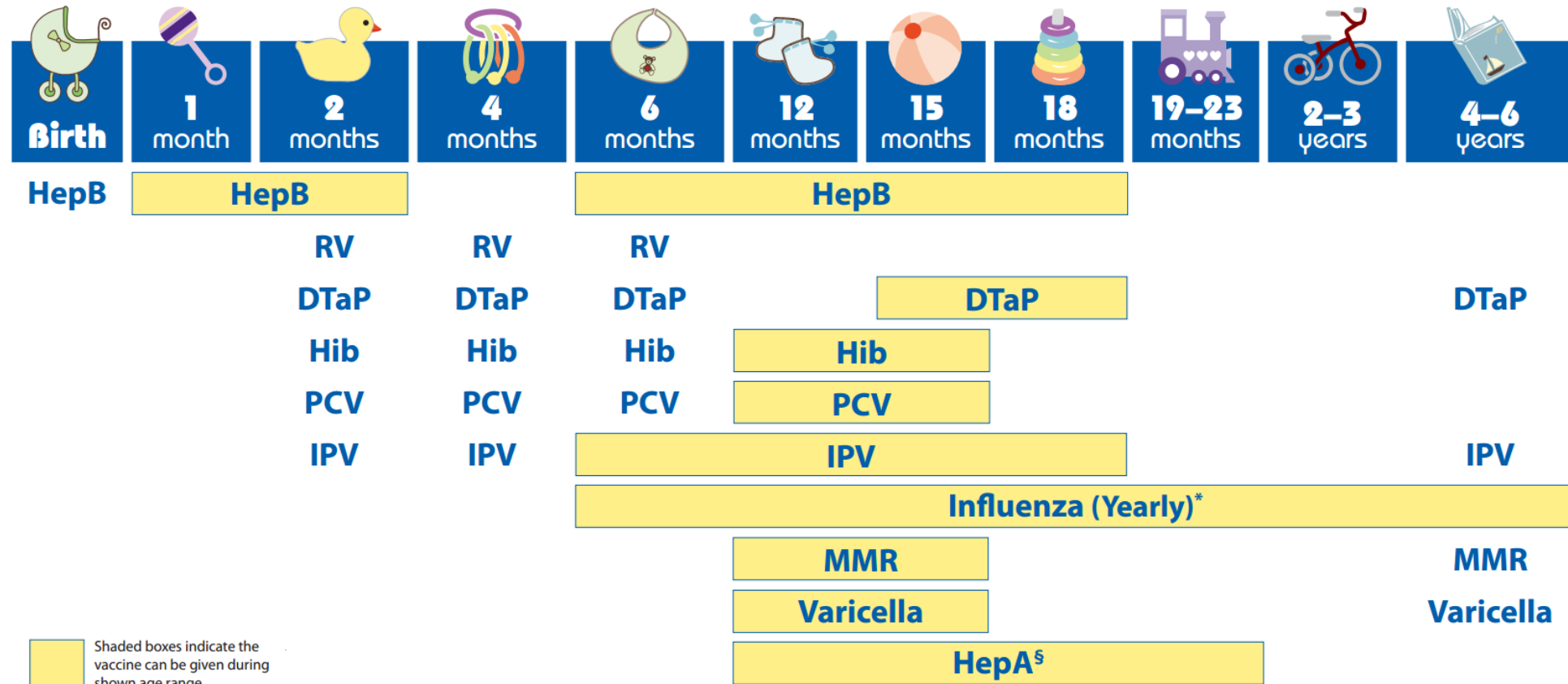
- 😊 Very detailed information
- 😞 Underreporting

6. Administrative databases

- 😊 Huge volumes of data
- 😞 Quality of the data may not be great

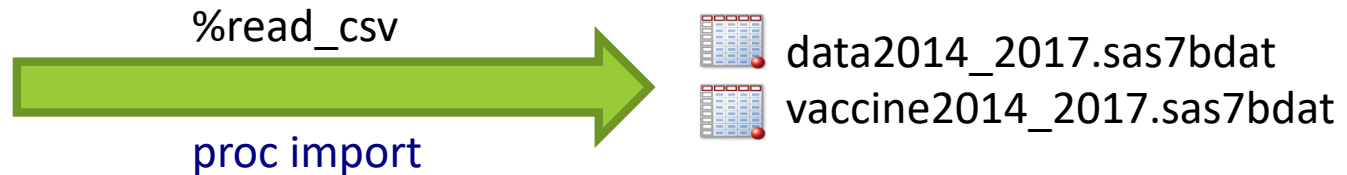


Recommended Immunisation Schedule for infants and children



Data Manipulation

 201XVAERSDATA.csv
 201XVAERSSYMPTOMS.csv
 201XVAERSVAX.csv



Vaccine Code	Vaccine Type
LYME	LYME DISEASE VACCINE
MEA	MEASLES
MEN	MENINGOCOCCAL POLYSACCHARIDE VACCINE
MENB	MENINGOCOCCAL GROUP B VACCINE, rDNA ABSORBED
MENHIB	MENINGOCOCCAL CONJUGATE + HIB
MER	MEASLES AND RUBELLA VIRUS VACCINE, LIVE
MM	MEASLES AND MUMPS VIRUS VACCINE, LIVE
MMR	MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE
MMRV	MEASLES, MUMPS, ROUBELLA AND VARICELLA VACCINE LIVE
MNC	MENINGOCOCCAL CONJUGATE VACCINE
MNQ	MENINGOCOCCAL CONJUGATE VACCINE

+

Disease	Vaccine
Influenza (Flu)	Flu vaccine protects against influenza.
Measles	MMR** vaccine protects against measles.
Mumps	MMR** vaccine protects against mumps.

=

```

if find(upcase(VACCINE), "MEA") or
   find(upcase(VACCINE), "MER") or
   index(upcase(VACCINE), "MM") then
  Disease = &Conc_Desease||"Measles";
  
```

Serious VAEs

- Death
- Life-threatening
- Emergency Room or doctor visit
- Hospitalisation

The reports of serious events are of greatest concern and receive the most careful scrutiny by VAERS staff

VAES and number of vaccinations

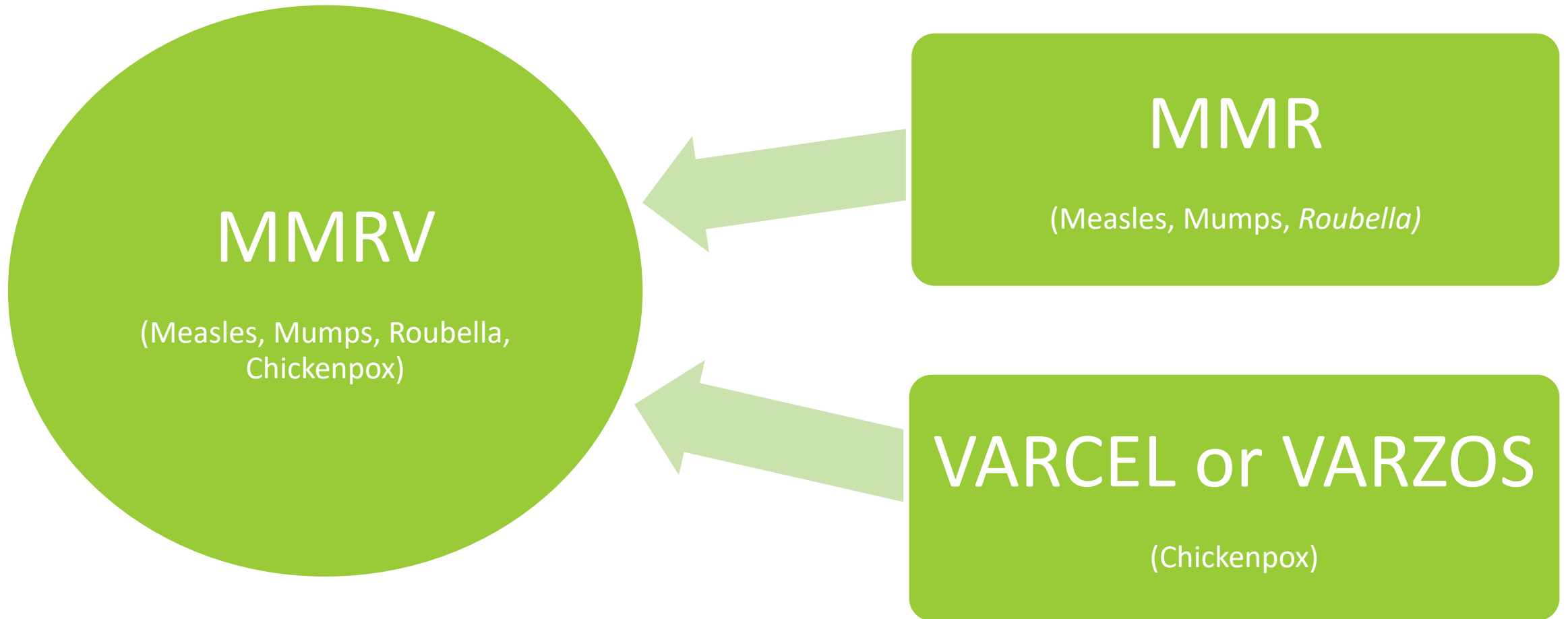
```
proc freq data = SAMPLE noprint;  
  by DISEASE;  
  tables N_TAKEN*SEVAE_N / chisq relrisk;  
  output out = TESTS chisq relrisk  
run;
```

- N_TAKEN is a binary variable which shows whether VAE occurred after administration of one vaccine or several
- SEVAE_N is a binary variable which shows whether VAE is serious

Association between serious VAEs and number of taken vaccinations. Population: Infants aged 12-21 months.

Obs	Vaccines	Chi-Square	Cramer's V	Odds Ratio (95% CI)	p-value
1	Chickenpox	61.70	0.24	4.260 (2.905 , 6.248)	<.0001
2	Chickenpox,Measles,Mumps,Rubella	0.88	0.06	1.324 (0.735 , 2.385)	0.3500
3	Diphtheria,Haemophilus b,Pertussis,Polio,Tetanus	0.44	0.09	1.530 (0.434 , 5.401)	0.5100
4	Diphtheria,Hepatitis B,Pertussis,Polio,Tetanus	2.43	0.16	2.799 (0.737 , 10.626)	0.1200
5	Diphtheria,Pertussis,Polio,Tetanus	12.39	0.26	4.370 (1.835 , 10.407)	<.0001
6	Diphtheria,Pertussis,Tetanus	10.94	0.12	1.909 (1.296 , 2.812)	<.0001
7	Haemophilus b	57.97	0.27	13.428 (5.793 , 31.124)	<.0001
8	Hepatitis A	6.45	0.09	1.693 (1.124 , 2.550)	0.0100
9	Hepatitis B	4.44	0.24	4.833 (1.001 , 23.344)	0.0400
10	Influenza	22.61	0.21	2.871 (1.840 , 4.482)	<.0001
11	Measles,Mumps,Rubella	15.53	0.12	1.873 (1.367 , 2.567)	<.0001
12	Pneumococcal	11.41	0.12	2.511 (1.449 , 4.350)	<.0001

Combination vaccines



VAES and combination vaccines

Table of Dise1 by TAKEN			
Dise1	TAKEN		
	Multiple	One	Total
Chickenpox,Measles,Mumps,Rubella	161	69	230
Diphtheria,Haemophilus b,Pertussis,Polio,Tetanus	6	13	19
Diphtheria,Haemophilus b,Pertussis,Tetanus	71	7	78
Diphtheria,Pertussis,Polio,Tetanus	9	49	58
Total	247	138	385

Statistics for Table of Dise1 by TAKEN

Statistic	DF	Value	Prob
Chi-Square	3	96.3404	<.0001
Likelihood Ratio Chi-Square	3	100.5748	<.0001
Mantel-Haenszel Chi-Square	1	19.3297	<.0001
Phi Coefficient		0.5002	
Contingency Coefficient		0.4474	
Cramer's V		0.5002	

Sample Size = 385

Conclusions

- RWD can play an essential role in evaluating the benefits of a drug or therapy
- There are many types of RWD, useful in different situations
- However, there are also many issues with using RWD
- You are encouraged to check, build on or contribute to our analysis:
<https://github.com/dimagmehanic/Growing-up-with-SAS-it-gets-real>
- Check out the BONUS folder!

Thank you for your time!

Name: Yevhen Los

Organisation: Experis Clinical

Address: Haharina Ave 43/2

61000, Kharkiv, Ukraine

Phone: +1 407 512 1006 ext. 2417

E-mail: yevhen.los@intego-group.com

Name: Dmytro Hasan

Organisation: Experis Clinical

Address: Haharina Ave 43/2

61000, Kharkiv, Ukraine

Phone: +1 407 512 1006 ext. 2432

E-mail: dmytro.hasan@intego-group.com,
dimagmehanic@gmail.com

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