

Data management & Statistical analysis

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Understand basic questions...







Understand basic questions...













Research question

A retrospective cohort study of kidney transplantation

(KT) patients was conducted to assess the association

between types of donors and risk of graft failure













Understand basic questions...











A retrospective cohort study of KT patients





Understand basic questions...





 Mahidol University

 Faculty of Medicine Ramathibodi Hospital

 Department of Clinical Epidemiology and Biostatistics

Factors associated with graft failure







Understand basic questions...







Factors associated with graft failure

1. Date of birth		DD/MM/YYYY)	
2. Gender	1. Male	2. Female	Study factor
3. Types of donor	1. CDKT	2. LRKT	
4. Weight	kg.		
5. Height	cm.		





Factors associated with graft failure

1. Date of visit		DD/MM/YYYY)	
2. Graft status	1. failure	2. function	
3. Date of failure			Outcome
4. Serum creatinine	mg/dL		
5. Serum albumin	g/dL		

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Understand basic questions...









How often variable will be collected...











Survey Barry

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Data management

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Case Record Form (CRF)

 a paper or electronic form designed to collect all of data , which specifies by study protocol



Typoid CRF Survey	X Typoid CRF Survey
Study NO: Patient Search	Study NO: Patient Search
A Patient Detail Consent Rel	fuse C. Bed Side Test Result Not done Admission blood glucose:
Blood for culture obtained: Ves Before After BC Bottle weight(g) Serum blood obtained: Ves N EDTA blood obtained: Ves N	No Preferred from other inpatient facility? OYes No Cough OYes NO. of days of cough NO. Breathing Difficulty OYes
P1 P2 P3 P4 P5	● P1 P2 P3 P4 P5 ●

Electronic CRF

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Poorly designed CRF

Well designed CRF

	Poorly designed	Well designed	
No boxes to	Date of visit:	Date of visit: DD/DD/DD/MM/YYYY)	
hold answers	Blood pressure: /	Blood pressure:	Provide boxes to hold answers
	Pulse:	Pulse:	
	Temperature:	Temperature:	
Unit of measurement did not display on CRF	Respiration:	Respiration:	

Units and decimal points should be displayed



Objective of CRF design...

Preserve and maintain	Quality and integrity of data
Gather	Complete and accurate data
Avoid	Duplication of data
Facilitate	Transcription of data from sources documents onto CRF



How to prepare data in Excel...









Cross-sectional data

Subject	Age	Sex	Group	Response
1	32	Female	Treatment	No
2	45	Female	Control	No
3	23	Male	Control	Yes
4	38	Female	Treatment	No
5	36	Male	Control	Yes
6	29	Male	Control	Yes
7	43	Male	Treatment	Yes
8	39	Female	Control	No
9	51	Male	Male Treatment	
10	42	Female	Treatment	No

Variable name

- Not exceed than 10 characters
- Not contain space

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Not begin with
 number



Cross-sectional data

Subject	Age	Sex Group		Response
1	32	Female	Treatment	No
2	45	Female	Control	No
3	23	Male	Control	Yes
4	38	Female	Female Treatment	
5	36	Male	Control	Yes
6	29	Male	Control	Yes
7	43	Male	Treatment	Yes
8	39	Female	Control	No
9	51	Male	Treatment	Yes
10	42	Female	Treatment	No

Types of Data

- Only numerical data
- Set special for missing data



Cross-sectional data





Cross-sectional data

Subject	DM	HT	CVD	Malignant	
1	1	2	1	2	
2	1	2	2	2	
3	2	1	2	1	
4	1	2	1	2	Use consistency code
5	2	1	2	1	1. Yes
6	2	1	2	1	2. No
7	1	1	1	1	
8	1	2	2	2	
9	2	1	1	1	
10	1	2	1	2	



Cross-sectional data

Subject	TAC	Dose_TAC	MMF	Dose_MMF
1	1	0.5	1	180
2	1	1.5	2	0
3	2	0	2	0
4	1	3.5	1	360
5	2	0	2	0
6	2	0	2	0
7	1	2.5	1	180
8	1	3	2	0
9	2	0	1	540
10	1	2.5	1	360

Dose format

• Specify unit for data entry (mg/day)

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• Enter "0" for not receive treatment

Follow-up data: Long format

Subject	Visit	Date visit	SBP	DBP	Response	
1	1	12/08/2000	90	65	2	
1	2	05/09/2000	95	60	2	
1	3	11/12/2000	90	65	1	
2	1	16/03/2011	3/2011 120 80			
2	2	09/07/2011	7/2011 125 85		1	
3	1	06/12/2012	100 85		2	
3	2	08/06/2013	105 90		2	
3	3	10/09/2013	110 90		2	
4	1	23/04/2008	150 95		2	
4	2	19/11/2008	155	98	1	





Follow-up data: Wide format

Subject	date 1	SBP1	DBP1	resp 1	date2	SBP2	DBP2	resp2	date	SBP
1										
2										
3										
4										
5										



+ July the set

Inappropriate data format

L15	•	$\times \checkmark f_x$	0.2					
	Q	R	S	Т	U	V	W	Not appropriate
3	SARS Cov 2 IgG Spike Protein	SARS Cov 2 IgG Spike Protein	% IH Euroimmune	%inhibition (sVNT-delta)		IGRA T Cell		analysis
4		(BAU/ml)			วันที่เจาะเลือด	Interpretation	Value (mIU/mI)	
5	2.6	0.37						
6	0.1	0.01	-3.56	-13.10				Incorrect variable
7	0.2	0.03			9/22/2564	Negative	30.3	name
8	2.6	0.37						
9	56.4	8.01	-17.03					
10	15.8	2.24			26/9/2564	Negative	-1.2	



Inappropriate data format

	-						
IGRA T Cell			CODE	วันที่เจาะเลือด	ระยะเวลาเจาะ เลือดหลังฉีด จัวศับเข็บ ว	SARS Cov 2 IgG Spike Protein	
วันที่เจาะเลือด	Interpretation	Value (mIU/ml)			144211271 2	(AU/mI)	
			H3	10/2/2564	22	4.6	
			H4	8/13/2564	14	5.0	
9/22/2564	Negative	30.3	H6	10/6/2564	14	3.5	Incorrect variable name
			H8	10/1/2564	16	4.8	
			H10	10/1/2564	23	1096.8	
26/9/2564	Negative	-1.2	H11	10/16/2564	13	36.6	
			H13	10/5/2564	36	4.2	



Rest Tu Quer Part

Inappropriate data format

underlying						
	HIN	CAD	DM	hepatitis	Cancer	SLE
нт	1	0	0	0	0	0
DM,HT , CAD	1	1	1	0	0	0
DM,HT	1	0	1	0	0	0
нт	1	0	0	0	0	0
нт	1	0	0	0	0	0
нт	1	0	0	0	0	0
DM,HT , CAD	1	1	1	0	0	0

Not appropriate format for underlying disease





A STORE IN CHARACTER

Inappropriate data format




Inappropriate data format

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	ยากดภูมิที่ได้รับ Pre Vac 1					ยากดภูมิที่ได้รับ Pre Vac 2						
 Not appro follow-up 	priate for data	mat for	ograf ;/day)	Cellcept (mg/day)	Myfortic (mg/day)	Pred (mg/day)	วันที่	neoral	tacrolimus	Cellcept (mg/day)	Myfortic (mg/day)	Pred (mg/day)
 Not appro name 	priate va	riable	5	1000	0	5	8/13/2564	0	5	1000	0	5
	5/5/2564	U	4	0	1440	5	8/13/2564	0	4	0	1440	5
	5/5/2564	0	1.5	0	1080	5	7/30/2564	0	1.5	0	1080	5
	5/5/2564	0	1	1000	0	5	5/28/2564	0	1	1000	-	5



Appropriate long format for follow-up data

Subject	vaccine	neoral	prograf	cellcept	myfortic	pred
1	1	0	5	1000	0	5
1	2	0	4	1500	180	5
2	1	0	1.5	1000	360	5
2	2	100	1	0	720	5
3	1	0	0	1250	0	5
3	2	150	4	0	180	5
4	1	0	2	1000	0	5
4	2	0	0	1500	720	5
5	1	100	3.5	0	360	5
5	2	150	0	0	180	5



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Appropriate wide format for follow-up data

Subject	neoral1	prograf1	cellcept1	myfortic 1	neoral2	prograf2	cellcept2	myfortic2
1	0	5	1000	0	100	5	1000	0
2	0	4	1500	180	150	4	1500	180
3	0	1.5	1000	360	0	1.5	1000	360
4	100	1	0	720	0	1	0	720
5	0	0	1250	0	100	0	1250	0
6	150	4	0	180	0	4	0	180
7	0	2	1000	0	150	2	1000	0
8	0	0	1500	720	100	0	1500	720
9	100	3.5	0	360	0	3.5	0	360
10	150	0	0	180	150	0	0	180



















I. Basic concept for statistics

- Types of data
- Descriptive statistics
- Inferential statistics

II. Hypothesis testing

- Categorical outcome
- Continuous outcome





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Categorical data	Numerical data
 Nominal data Ordinal data 	Discrete dataContinuous data



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Categorical data

Nominal data	Sex: male/female>dichotomous data
	Blood group: A/B/AB/O
Ordinal data	Degree of injury: mild/moderate/severe
	Stage of cancer: I/II/III/IV







Numerical data

Discrete data	Length of hospital stay
DISCIPLE UALA	Number of heart beats per minute
Continuous data	Cholesterol level (mg/dL)
Continuous data	Fasting blood sugar (mg/dL)





Types of statistics



• Regression analysis









- Types of data
- Descriptive statistics
- Inferential statistics

II. Hypothesis testing

- Categorical outcome
- Continuous outcome





Summarizing: Categorical data

Sex	Frequency	Percentage
Male	56	80
Female	14	20
Total	70	100



Stages of	Frequency	Percentage
cancers		
1	120	15
II	320	40
111	160	20
IV	200	25
Total	800	100

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Summarizing: Numerical data









Summarizing: Numerical data

	Mean	SD
Age (year)	49.6	14.3
Weight (cm)	95.6	21.7
Height (cm)	161.5	9.2



Non-normal	distribution

	Mean	SD
CD4 count	62.4	74.4
CA score	177.7	352.9
	Median	Range
CD4 count	30.5	1,358
CA score	51.0	1,4879



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Characteristics Gender; n (%) Male Female Age; years; mean (sd) Age; n (%) <30 years <u>></u>30 years Body weight; kg; mean (sd) Diabetes; n (%) Yes No















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Inferential statistics

Parameter estimation	Hypothesis testing
Point estimateRange estimate	 Single population Two population More than two pop.





Inferential statistics

Parameter estimation

- Point estimate
- Range estimate

Hypothesis testing

- Single population
- Two population
- More than two pop.





Parameter estimation

- Estimation of mean age of patients who had breast cancer in Thailand
- Estimation prevalence of chronic kidney disease in Thai population







Continuous data

Point estimate	The mean age of 750 patients with DM was 54.42 years		
Range estimate	95% CI of <mark>mean age</mark> range from 43.65 years to 62.34 years		





Categorical data

Point estimate	42 in 350 subjects had hypertension, prevalence of hypertension was 0.12
Range estimate	95% CI of the <mark>prevalence of hypertension</mark> was from 0.09 to 0.15





Recommendation

- Point estimate should be reported with their confidence intervals to indicate their precision
- Prevalence of HT was 12% with 95% CI: 9-15%



0



Inferential statistics

Parameter estimation	Hypothesis testing
Point estimate	Single population
Range estimate	 Two population More than two pop.





Hypothesis testing

Continuous outcome

Test if the **means of BMD** between postmenopausal women who received and did not receive calcium supplements differ.

Dichotomous outcome

Assess the association between traditional medicine used and osteoporotic hip fracture.



Types of errors

Ho: $\mu_{BMD(calcium+)} = \mu_{BMD(calcium-)}$ Ha: $\mu_{BMD(calcium+)} \neq \mu_{BMD(calcium-)}$ Unknown						
Statistical D	ecision	In Population				
Based on Sa	imple	H_0 is true	H_0 is false			
Reject H ₀		a <i>(Type I error)</i>	1- b (Power of test)			
Do not rej	ect H _o	1- a <i>(Confidence)</i>	b <i>(Type II error)</i>			









Hypothesis testing







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Hypothesis testing for categorical data

Tests of association

Independent sample

Paired-sample







Hypothesis testing for categorical data

Tests of association

Independent sample

Paired-sample





Independent sample

- A case-control study was conducted to look at effect of traditional medicine and osteoporotic hip fracture.
- The outcome of interest was osteoporotic hip fracture.
- The exposure of interest was traditional medicine.





2x2 contingency table for independent sample

Lip fracture	Traditi			
прпасше	Yes	No	n	Data layout
Yes	20	208	228	
No	8	216	224	

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Statistical analysis

- The Chi-square test is used to examine association between two categorical variables
- H₀: The proportions of the interested event between two independent groups are not different
- ➡ H₀: Two categorical variables are independent




H₀: No association between traditional medicine and hip fracture

Conclusion

- Reject null hypothesis
- There was association between traditional medicine and hip fracture

. tab tredmed hip, col exp chi2

┗ –		-
	Key	
- 1		
I	frequency	
I	expected frequency	
	column percentage	
┝-		-

traditiona	hip fo	racture	
l medicine	l yes	no	Total
	+		+
yes	20	8	28
	14.1	13.9	28.0
	<mark>8.77</mark>	<mark>3.57</mark>	6.19
	+		+
no	208	216	424
	213.9	210.1	424.0
	91.23	96.43	93.81
	+		+
Total	228	224	452
	228.0	224.0	452.0
	100.00	100.00	100.00

Pearson chi2(1) = 5.2588 Pr = 0.022

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Statistical analysis

- The Chi-square test is not appropriate if small sample.
- Expected frequency is less than 5 for more than 20% of the total cells
- The Fisher's exact test is an alternative method





Independent with small sample

- A case-control study was conducted to look at effect of receiving HRT on risk of hip fracture.
- The outcome of interest was hip fracture.
- Solution ⇒ The exposure of interest was HRT.





2x2 contingency table for independent sample







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H₀: No association between HRT and hip fracture

. tab hrt hip, col exp exact

┸-		. 上
т 	Кеу	1
-		·I
I	frequency	I
Ι	expected frequency	I
Ι	column percentage	I

	I	hij		
	hrt +-	yes	no	Total
Conclusion	yes 	1 1.5 <mark>0.47</mark>	2 1.5 <mark>0.93</mark>	3 3.0 0.70
Fail to reject null hypothesis There was no association between HRT	no 	213 212.5 99.53	214 214.5 99.07	427 427.0 99.30
and hip fracture	Total 	214 214.0 100.00	216 216.0 100.00	430 430.0 100.00

	Fisher's	exact	=	1.000
1-sided	Fisher's	exact	=	0.503

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	Characteristics	Hip fracture	Non-hip fracture	P value
	-	n (%)	n (%)	
	Age, year			
Dummy table for two	< 60			
	≥ 60			
groups comparison	Gender			
	Male			
	Femal			
	Hypertension			
	Yes			
	No			





Hypothesis testing for categorical data

Tests of association

Independent sample

Paired-sample







Paired sample

- Comparison of pain relief (yes/no) by two different analgesics in the same subjects.
- In a matched case-control study, matched case to control patients with BMI, aim to assess the association between HRT and the hip fracture.





2x2 contingency table for paired sample







H₀: No association between HRT and hip fracture

Conclusion

- Reject null hypothesis
- There was association between HRT and hip fracture

. mcc case control



McNemar's chi2(1) = 16.67 Prob > chi2 = 0.0000 Exact McNemar significance probability = 0.0001

Proportion with fac	tor			
Cases	.4086022			
Controls	.5430108	[95% Conf.	Interval]	
difference	1344086	2001631	0686541	
ratio	.7524752	.656141	.8629532	
rel. diff.	2941176	4547495	1334858	
odde ratio	5	3487202	7089431	(evact)
odds ratio	. 5	.340/202	./009431	(exact

Note: if number of discordant pairs is less than 20, the Exact McNemar's test is more appropriate











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Hypothesis testing for continuous data



Single group

Two groups

- Independent sample
- Paired sample

Three groups or more







Hypothesis testing for continuous data



Single group

Two groups

- Independent sample
- Paired sample

Three groups or more







Independent sample

- Comparison of systolic blood pressure between men and women.
- Comparison of cholesterol level between patients with and without chronic kidney disease.





Statistical test for two independent groups

Distribution	Parameter	Statistical test
Normal	Mean	- Student t-test with equal variance
		- Student t-test with unequal variance
Non-normal	Median	- Mann-Whitney test,
		- Quantile regression







Researchers wanted to test if means/median of <u>weights</u> of HIV patients who received NVP, and HIV patients who received EFV, are different.







Variance ratio test

. sdtest Variance	bw,by(group) ratio test					
Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
NVP EFV	70 70	54.82286 54.36429	1.034775 1.266647	8.657545 10.59753	52.75854 51.83739	56.88718 56.89118
combined	140	54.59357	.8150796	9.644152	52.98201	56.20513
ratio Ho: ratio Ha: r) = sd(NVP) /) = 1 ratio < 1	sd(EFV)	Ha: ratio !=	degrees 1	f of freedom Ha: r	= 0.6674 = 69,69 atio > 1
$\Pr(F <$	f) = 0.0477	2*1	$\Pr(F < f) = 0.$	0954	Pr(F > f) = 0.9523

Conclusion



Variances between two groups are not different.





Student t-test with equal variance

Two-sample t test with equal variances

Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
NVP EFV	70 70	54.82286 54.36429	1.034775 1.266647	8.657545 10.59753	52.75854 51.83739	56.88718 56.89118
combined	140	54.59357	.8150796	9.644152	52.98201	56.20513
diff		.4585714	1.635589		-2.775485	3.692628
diff = Ho: diff =	= mean(NVP) = 0	- mean(EFV)		degrees	t = of freedom =	= 0.2804 = 138
Ha: d: Pr(T < t)	iff < 0) = 0.6102	Pr(1	Ha: diff != ! > t) =	0 0.7796	Ha: d: Pr(T > t)	iff > 0) = 0.3898

Conclusion



Mean weights between two groups are not different.

[.] ttest bw,by(group)





Researchers wanted to test if CD4 count of HIV patients who received NVP, and HIV patients who received EFV, are different.





Quantile regression

. xi:qreg cd4c	c i.group					
i.group	_Igroup_	1-2	(naturall	y coded	: _Igroup_1 om	itted)
Iteration 1:	WLS sum of	weighted devi	lations =	7527.2	2521	
Iteration 1.	sum of abs	weighted devi	iations =		7546	
Itoration 2:	sum of abs.	weighted devi	iations -	. ,	7178	
Iteration 2.	sum of abs.	weighted devi	lations =	-	7 I 7 0 2 7 0 <i>1</i>	
iteration 5:	Sum of abs.	weighted devi	Lations =	-	0/04	
Median regress	sion			Ni	umber of obs =	140
Raw sum of c	leviations	6802 (about	z 29)			
Min sum of c	leviations	6784		Ps	seudo R2 =	0.0026
cd4c	Coef.	 Std. Err.	 t	 P> t	[95% Conf.	Intervall
+						
Igroup 2	-7	11.96985	-0.58	0.560	-30.66803	16.66803
cons	36	8.463962	4.25	0.000	19.26418	52.73582
Conclusion >	Median of	CD4 count	betwee	n two c	roups are no	t different.

Median of CD4 count between two groups are not different.

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Dummy table for two groups comparison

Characteristics	NVP	EFV	P value
	Mean (SD)	Mean (SD)	
Age (year)			
Weight (kg)			
Height (cm)			
BMI (kg/m³)			
CD4 count; median (range)			







- Comparison of systolic blood pressure before and after used of OC in pre-menopausal women.
- In matched case-control study, matched by age and sex, which aim to compare oral hygiene index between periodontitis and non-periodontitis patients.







Statistical test for paired sample

Distribution	Parameter	Statistical test
Normal	Mean	Paired t-test
Non-normal	Median	Wilcoxon matched signed-rank test







Researchers wanted to test if mean weights of HIV
patients before and after receiving an antiretroviral
therapy regimen are different.





Paired t-test

. ttest bw0 Paired t te	= bw12 st 					
Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
bw0 bw12	121 121	54.56694 57.31322	.8926941 .9380435	9.819635 10.31848	52.79947 55.45596	56.33441 59.17048
diff	121	-2.746281	.3710625	4.081688	-3.480959	-2.011603
mean(d Ho: mean(d Ha: mean(d Pr(T < t)	iff) = me iff) = 0 iff) < 0 = 0.0000	ean(bw0 - bw1 Ha Pr(12) a: mean(diff) T > t) =	degrees != 0 0.0000	t s of freedom Ha: mean Pr(T > t	= -7.4011 = 120 (diff) > 0) = 1.0000

Mean weights before and after receiving regimen are different.

Conclusion

 \bigcirc









Researchers wanted to test if median of CD4 count of HIV patients before and after receiving an antiretroviral therapy regimen are different.



Wilcoxon matched signed-rank test

 \cdot signrank cd4c0= cd4c12

	Wilcoxon signe sign	d-rank test obs	sum ranks	expected
	+ positive negative zero	 7 112 0	256.5 6883.5 0	3570 3570 3570 0
esis : before and men are	all unadjusted var adjustment for adjustment for	7140		
	adjusted varia Ho: cd4c0 = cd z Prob > z	nce 142 4c12 = -8.787 = 0.000(2199.63	

Conclusion

- Reject null hypothe \square
- Median CD4 count after receiving regi different













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