

# Biostatistics workshop series: Analytical Elements

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# What we will cover....

1 B

2 Study variables

# Conventions

The conventions I will use:

Note:.....

Things to note will occur in a green box

Pitfalls:.....

Common mistakes and things to watch out for will occur in a red box

asic elements of a study

# Target population

Should be revision for you

The **TARGET POPULATION** is the group of subjects (e.g. Patients) we want to make statements (inferences) about

The **SAMPLE** is our group of subjects that we hope (through good design) will represent the target population (an unrepresentative sample means our infernecs may not be accurate

# Study designs



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## Study design

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Randomized Controlled Trial

Quasi-experiment

Cohort(Longitudinal)

Cross-sectional

Case-Control

Ecological

Case series

Case study

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# Motivating examples

We will consider four examples (coinciding with the four main dataset you are using from the DAMUS website):

- ① The DMHT (Diabetes and Hypertension) dataset;
- ② The EMS (Emergency Medical System) dataset;
- ③ The PCTC (Prospective Cohort of Thai Children) dataset; and
- ④ TNCS: Thai Nurse Cohort Study.

To keep things simple, we will focus on cross-sectional aspects of all of the datasets (even from the PCTC and TNCS)

To keep it relevant, I will choose examples that are really close to your hearts

# The study variables

The study variables can be split into three groups:

- 1 The **Outcome(s)**: The dependant (clinical endpoints) that is of main interest in our study

The **Effects** which can subdivided into:

- 3 The **Study Effect**: The main explanatory variable (risk factor or intervention) we are interested in (research hypothesis)
- 4 The **Covariates**: Other variables that may be important to the outcome, OR the outcome-study effect relationship (more later)



## Example: TNCS study

For example:

- Our **TARGET POPULATION** is **Thai nurses**
- Our **SAMPLE**: is the **Nurses that returned the mail questionnaire in the initial sample of the baseline cohort**
- We might be interested in the **OUTCOME: Intention to leave the nursing profession (yes/no)**
- Our **STUDY EFFECT** might be **Exposure or Risk of exposure to TB (Yes/No)**
- Other **COVARIATES** we might consider are: **Age, Gender, Years experience, Type of nurse, Sector etc**

## Example: DMHT

Another example:

- The target population (in our case) are Diabetics in Thailand
- Target sample is T2DM patients (samples) at one of the 598 participating hospitals
- Our outcome might be achievement of all three (A1C, BP and LDL-C) clinical objectives (yes/no)
- Our study effect is Hypertension (yes/no)
- Covariates (we will consider) are: Age, Gender, DM Duration, Smoking

## Different types of explanatory (X) variables

We have already discussed the **Study effect**, and we have discussed before different types of covariates, but I would like to discuss them again (in detail).

A covariate can be one of three types of variables:

- 1 An **INDEPENDANT RISK FACTOR**: Something that explains the outcome in it's own right (and does NOT interfere with the study effect)
- 2 A **CONFOUNDER**: a covariate that (if we don't account for it in the model) will change (diminish or enhance) the relationship between the outcome and the study effect
- 3 An **EFFECT MODIFIER**: where the nature of the relationships between the outcome and study effect changes with the LEVEL of the effect modifying variable

# Confounders vs Effect modifiers

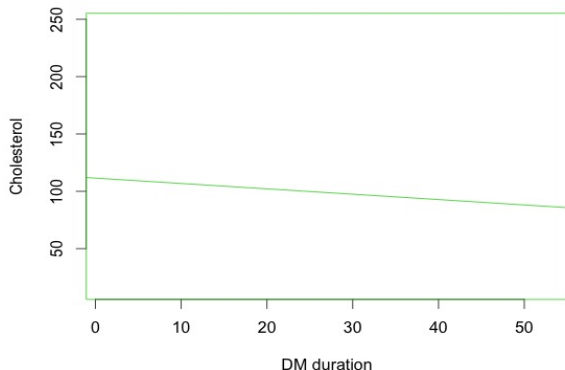
Understandable, people get confused between the difference between **CONFOUNDERS** and **EFFECT MODIFIERS** so I am going to spend the rest of this session going into detail about the difference.

**HINT:** For **CONFOUNDERS** think about **PRESENCE** and for **EFFECT MODIFIERS** think about **LEVEL**

Now let's consider some examples....

# DMHT: Cholesterol vs Duration of DM

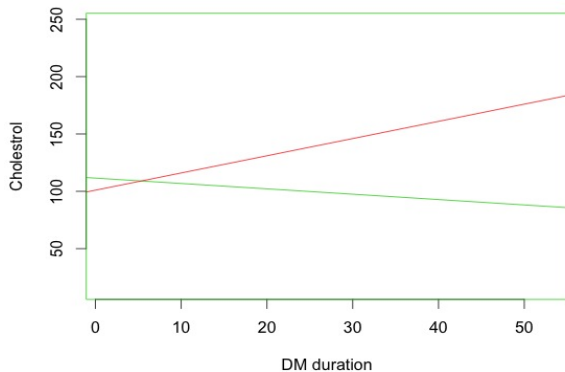
Let's consider the relationship between Cholesterol level (Y) against the duration of diabetes.



Crude model: DuraDM significant effect [ $p < 0.01$ ]:

$$LDL - C = 111.5 + -0.5DuraDM$$

# DMHT: Now let's adjust for age



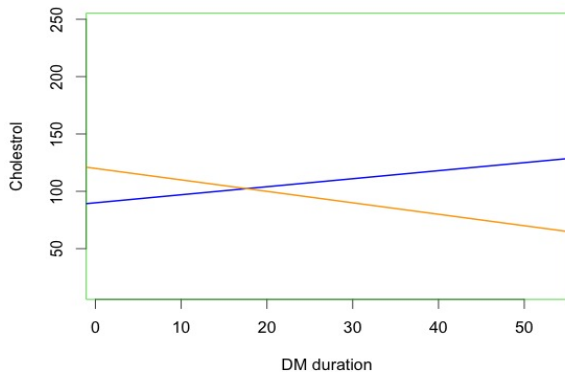
Model1 (green):  $LDL - C = 111.5 + -0.5DuraDM$

Model2 (red):  $LDL - C = 111.5 + -0.5DuraDM + \beta_{Age}Age$

**Is Age a confounder or and effect modifier????**

Think: **LEVEL** or **PRESENCE**

# LDLC vs Dura: Males Vs Females



**Females:**  $LDLC = 120 + -1DuraDM$

**Males:**  $LDLC = 90 + 0.7DuraDM$

**Is Gender a confounder or an effect modifier???:**

Think: **LEVEL** or **PRESENCE**

# Your turn: PCTC

- Outcome: Cognitive ability (CogAb: low / not low)
- Study effect: Reared by grand parents (Grand parents: no/yes)
- Covariate: Rurality (Rural: urban/rural)

As it is a binary outcome we use binary logistic regression and our measure of association will be ORs

| Effect        | $OR_{Crude}$ | $OR_{adjusted}$ | $OR_{Rural}$ | $OR_{Urban}$ |
|---------------|--------------|-----------------|--------------|--------------|
| Grand parents | 1.5          | 2.5*            | 1.95         | 2.05         |
| Rurality      | 2*           | 2.3*            | -            | -            |

\* means significant at 0.05 level

Is RURALITY: (a) an Independent risk factor; (b) a confounder; or (c) an effect modifier??



# Your turn: TNCS

- Outcome: Intention to Leave (IoL: yes / no)
- Study effect: Exposed to TB (TB: no/ yes)
- Covariate: Age (young/old)

As it is a binary outcome we will (again) use binary logistic regression and our measure of association will be ORs

| Effect | $OR_{Crude}$ | $OR_{adjusted}$ | $OR_{Young}$ | $OR_{Old}$ |
|--------|--------------|-----------------|--------------|------------|
| TB     | 10*          | 9.5*            | 25           | 1.5        |
| Age    | 5*           | 4*              | -            | -          |

\* means significant at 0.05 level

Is Age: (a) an Independent risk factor; (b) a confounder; or (c) an effect modifier??

# Your turn: EMS

- Outcome: Dead on arrival for cardiac arrest patients (DoA: yes / no)
- Study effect: CPR administered (CPR: yes / no)
- Covariate: Response time (RT: < 8 mins / >8 mins)

Again binary outcome, so ORs

HINT: A tricky one.

| Effect | $OR_{Crude}$ | $OR_{adjusted}$ | $OR_{<8mins}$ | $OR_{>8mins}$ |
|--------|--------------|-----------------|---------------|---------------|
| CPR    | 10*          | 2               | 1.2           | 20            |
| RT     | 10*          | 8*              | -             | -             |

\* means significant at 0.05 level

Is RT: (a) an Independent risk factor; (b) a confounder; or (c) an effect modifier??

THANK-YOU!!

Questions??

YOUR TURN