# EVALUATION OF MEDICAL TESTS AND TREATMENT

## ERRORS

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# Sampling error
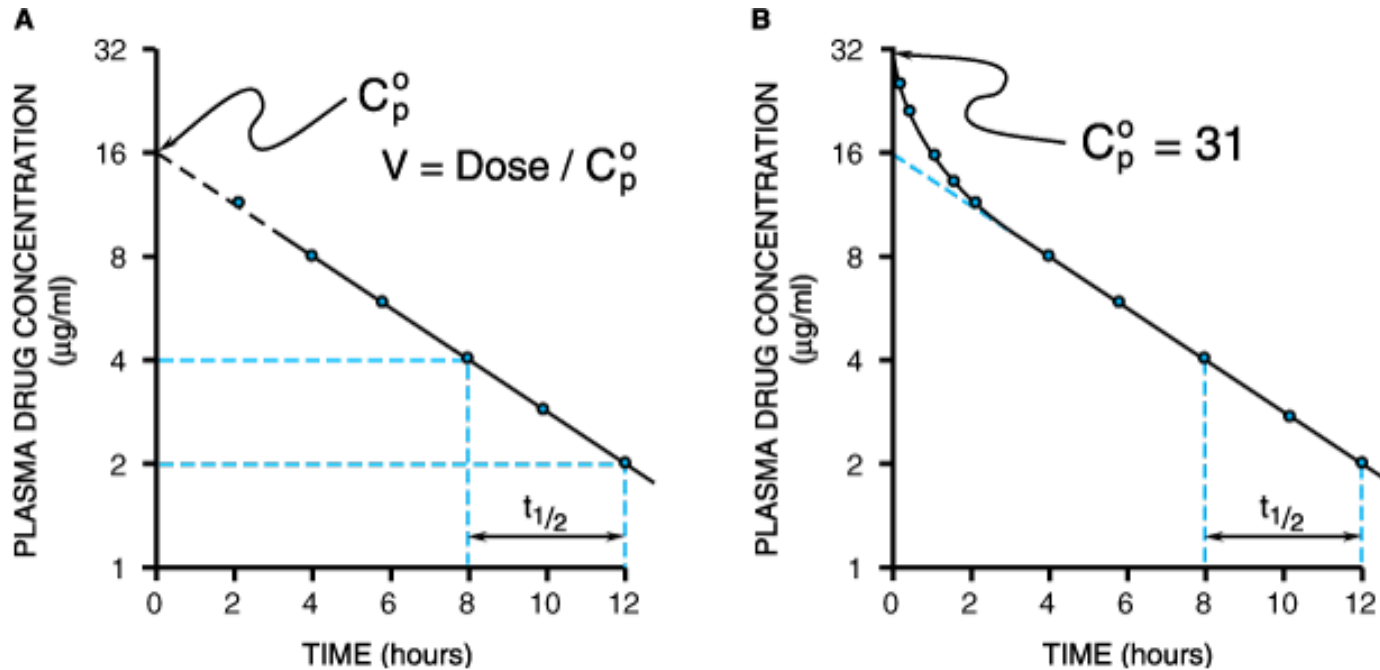
**Because of late sampling times, multicompartment distribution has been ignored.**

Fig. 1-3  Accessed 08/01/2010

# Statistical errors

- Type I error

- A Type I error is an error in the true sense. A conclusion is drawn that the null hypothesis is false when, in fact, it is true.

- Type II Error ($\beta$)

- A Type II ($\beta$) error is a potential failure to reject a false null hypothesis.

# Confidence interval

- The more an experimenter protects him or herself against Type I errors by choosing a low level, the greater the chance of a Type II error.

- Requiring very strong evidence to reject the null hypothesis makes it very unlikely that a true null hypothesis will be rejected.

- However, it increases the chance that a false null hypothesis will not be rejected, thus lowering power.

# Confidence interval

- The Type I error rate is almost always set at a p-value of 0.05 or 0.01.

-    The latter is more conservative as it requires stronger evidence to reject the null hypothesis at the 0.01 level.

- A properly structured study asks a question that requires a yes/no answer (the null hypothesis).

- The assumption is that the null hypothesis is true.

- Studies are structured to avoid errors in rejecting or accepting the null hypothesis.

# Confidence interval

- A p-value is frequently reported.

- This represents the confidence interval (mean ± standard deviation) that the result obtained is not by chance.

- A p-value of 0.05 (two standard deviations about the mean) demonstrates that a result outside the confidence interval is not due to chance is at a probability level of 5%.

- A p-value >0.05 means that the null hypothesis is statistically consistent with the observed result.

# Confidence interval

- If the investigator has set a level of significance of significance of 0.01 (three standard deviations about the mean) and reports a p-value of 0.02, the investigator has rejected the null hypothesis at that level

- The rejection is certain.

- Conversely, had a level of significance of 0.05 been set, the investigator would have accepted the null hypothesis at that level; the acceptance is certain.

- <u>The p-value is related to the level of error one is willing to tolerate.</u>

# Confidence interval

- If the 95% confidence interval for a mean difference between two variables includes 0, then there is no significant difference noted.

- If the 95% confidence interval for odds ratio or relative risk includes 1, there is a significant difference noted.

- There is no significant difference if the values overlap.

- As correlation coefficients approach 1, the greater the correlation.

# Biases

- <u>INTENT TO TREAT</u>
- Surgery is proposed for a condition.
- The endpoint is time from diagnosis to death.
- Patients who die before the surgery are included in the no surgery group.
- <u>Survival curves will favor the surgical group whether surgery is effective or not.</u>
- <u>LEAD TIME BIAS</u>
- A test detects a disease earlier than current methods.
- Earlier intervention does not change the course of the disease.
- <u>If one were to examine survival from time of diagnosis, it would appear that the test is helpful.</u>