

Moving ACCP Beyond “ $P < .05$ ”

Charles D. Sands III PharmD

Former:

Dean and Professor, McWhorter School of Pharmacy, College
of Health Sciences, Samford University, Birmingham,
Alabama, USA

Professor, Yanbian University Medical College, Yanji, China

Director, Dept of Pharmaceutical Services and Research,
Wallace Memorial Baptist Hospital, Pusan, Korea

“The primary product of a research inquiry is one or more measures of effect size, not p values.”

2

$p < 0.05$

Statistical Analysis of Research Results

- ACCP has encouraged excellent research with excellent statistical analysis.
- The quality of research and statistical analysis have improved tremendously.
- To keep pace with changes in requirements for statistical analysis in publications, ACCP needs to “move beyond $P < 0.05$ ”
- ACCP needs to continue to be a leader in Asia in the statistical revolution.




P VALUES

Journal editors: in addition to P Values, report EFFECT SIZES.


“Avoid relying solely on statistical hypothesis testing, such as P values, which fail to convey important information about effect size and precision of estimates.”

New England Journal of Medicine: “significance tests should be accompanied by effect estimates with standard errors or confidence intervals.”

An illustration on a light blue background. A magnifying glass with a black handle and silver frame is positioned over a small square graph. The graph shows a bell-shaped curve. Two question marks are floating around the graph, one above and one to the right. The background has a faint grid pattern.

P-Value
[ˈpē ˈvæl-(,)yü]

A statistical measure used to determine the likelihood that an observed outcome is the result of chance.

 Investopedia

No longer is it acceptable to infer meaning of research results solely on the basis of P values.

Need to Interpret Effect Sizes

- There is a need to:
 - Interpret Effect Sizes
 - Distinguish Practical (clinical) from Statistical significance
 - Gauge the POWER of published research
 - Design studies with sufficient POWER to detect sought-after results

American Statistical Association Statement on P Values

Do not
base

Do not base conclusions solely on
statistical significance ($P < 0.05$)

Do not
believe

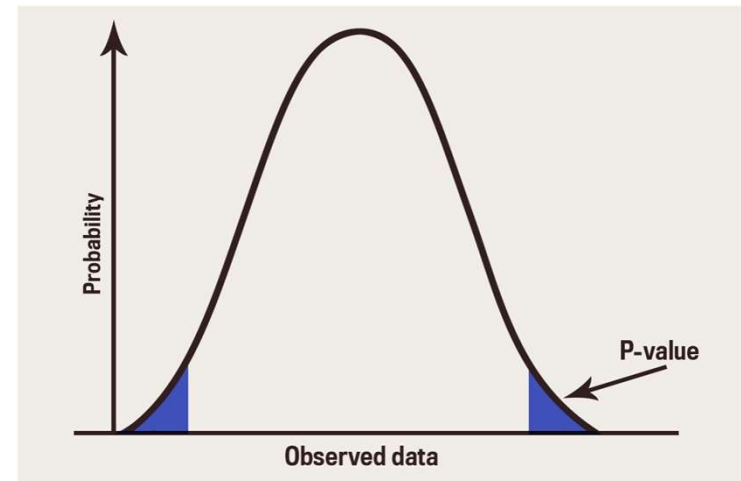
Do not believe an effect exists just
because $p < 0.05$

Do not
believe

Do not believe there is no effect just
because $p > 0.05$

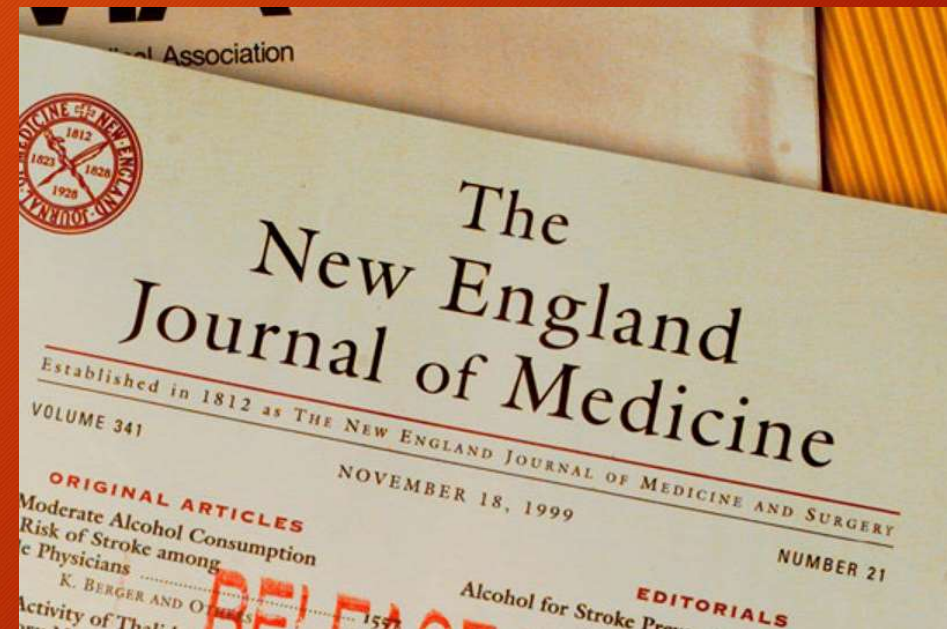
Reconsider the Role of the P Value

- In a study comparing a new hypertension drug against placebo ---
- Not enough to just attain a statistically significant difference.
- There must also be compelling evidence of **CLINICAL SIGNIFICANCE**
- We need to reconsider the role of the P value.



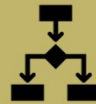
New England Journal of Medicine Editorial

“We have become increasingly concerned about the overuse and misinterpretation of significance testing and P values in the medical literature.”



Harrington D, D'Agnostino RB, Gatsonis C. et al. New Guidelines for statistical reporting in the journal. N Engl J Med 2019;382(3):285-286

Core Set of Best Statistical Practices



Abandon the use of the conclusion “statistically significant.”



Report value as continuous measures to the number of digits computed (Ex., $P = .002$ or $P = .15$) [Not $P < .05$]



State observed effect sizes and interpret their clinical or scientific relevance in context.

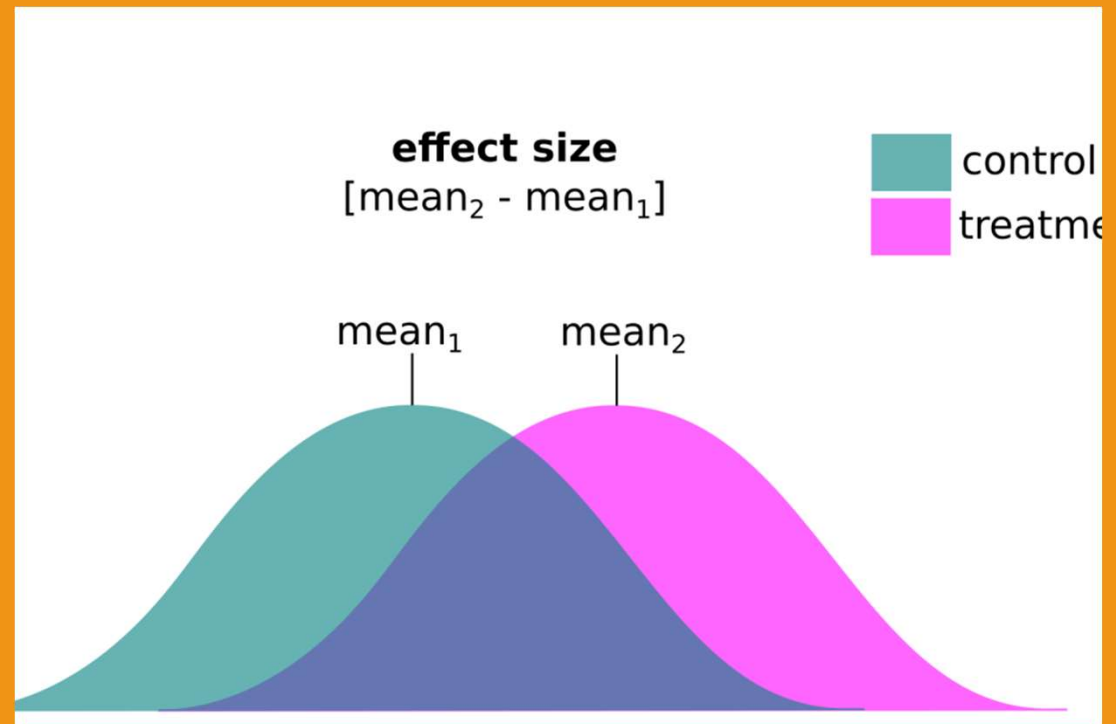


Report confidence intervals but refrain from using them to test a hypothesis.

EFFECT SIZE

EFFECT SIZE

- Primary purpose of research:
- to estimate the magnitude and direction of effects
- Example: To measure the size of the effect of a drug on blood pressure.
- A difference between drug A and drug B on SBP of 2.4 mmHg may be statistically significant --- but is it clinically significant?



Estimating the Size of Effects is What Researchers Do

- The effect that is measured in most ACCP research is the result of a treatment of intervention.
- It is essential that researchers interpret not only the statistical significance of results but also their practical (clinical) significance as well.
- STATISTICAL SIGNIFICANCE
- PRACTICAL (CLINICAL) SIGNIFICANCE

There is a Need for ACCP Researchers to:

Interpret
EFFECT SIZES

Distinguish
practical
(clinical) from
statistical
significance

Guage the
POWER of
published
research

Design studies
with sufficient
POWER to
detect sought-
after effects.

The Researcher Needs to Ask Two Questions

How do I interpret the practical or everyday significance of my research results?

Does my study have sufficient POWER to find what I am seeking?

**IT IS NO LONGER
ACCEPTABLE TO INFER
MEANING SOLELY ON
THE BASIS OF P VALUES**

Does my study have enough POWER?

Should be asked and calculated before any study begins.

Power: the probability that the study will detect the effect.

Many studies do not have the POWER to detect the effect the researchers is looking for.

Insufficient power means: increased risk of missing any real effects (a Type II error)

Many journal editors ask the researcher to submit the results of a prospective power analysis.

WHAT IS POWER?

Power = the probability of correctly rejecting a false null hypothesis (when the alternative hypothesis is true)

$$\text{Power} = 1 - \beta$$

More powerful experiment = better chance of rejecting a false null hypothesis

Thus, reducing the likelihood of Type II error

EFFECT SIZE



Relates to the magnitude of the result of a research investigation.



It is essential to the interpretation of a study's results.



There are many kinds of EFFECT SIZES.



Examples: Relative Risk, Odds Ratio, Correlation Coefficient (measures of association), Cohn's' d, Glass's delta (d), etc.

CONCLUSION

It is strongly suggested that the Asian Conference on Clinical Pharmacy (ACCP) seize this opportunity to become the leader in appropriately reporting, interpreting, and publishing the results of important clinical pharmacy research in Asia.

Join the movement in statistics to MOVE BEYOND “P < 0.05”