

International Pharmaceutical Students' Federation

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#### Critical Appraisal of Journal Articles

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**IPSF** is the leading international advocacy organization for pharmaceutical students and recent graduates, promoting improved public health through provision of information, education, networking and a range of publications and professional initiatives





#### **FIPEd**

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### **Webinar Instructions**

Mute Your Microphone at all times

Introduce yourself on the chat box with Name, Country

All Questions will be taken at the end of the Speakers Presentation – Kindly type all questions in the chat box during the presentation

Fill in the evaluation form at the end of webinar: Only those who fill the post webinar evaluation form will get a Certificate at the end of the webinar

### **Introduction of Speaker**



Margaret O'Connor is a third year pharmacy student at the University of Illinois at Chicago in Chicago, Illinois, USA and is the 2019-2020 editor for the IPSF PEN and Phuture publications.

Her research interests include public health and interprofessional education.



### Background

#### What is "Critical Appraisal"?

Systematic process to determine the strengths and weaknesses of an article to assess its validity and usefulness.

#### Why do we need critical appraisal?

Needed to compile valid and useful research Not all literature is of high quality

#### What can be critically reviewed? Any article or paper





### "Critical appraisal skills enable you to assess the trustworthiness, relevance, and results of published papers so that you can decide if they are believable and useful."

- Critical Appraisal Skills, CASP (2013)

## **Hierarchy of evidence**



Level I: Evidence from a systematic review of all relevant randomized controlled trials (RCT's), or evidence-based clinical practice guidelines based on systematic reviews of RCT's

Level II: Evidence obtained from at least one well-designed Randomized Controlled Trial (RCT)

Level III: Evidence obtained from well-designed controlled trials without randomization, quasi-experimental

Level IV: Evidence from well-designed case-control and cohort studies

Level V: Evidence from systematic reviews of descriptive and qualitative studies

Level VI: Evidence from a single descriptive or qualitative study

Level VII: Evidence from the opinion of authorities and/or reports of expert committees

# Where does it fit in the research process?





## **General Guiding Questions:**

Is the question/focus of the study clear and focused? → Is it the same questions I am looking to answer?

Are the methods and analysis used valid and can they be reproduced?
→ Are the results outcomes useful or meaningful?

Ultimately, can this information be useful in Research Argument and Synthesis System or Policy change Patient Care Decisions Guideline Development



### **Bottom Line**

Can the results/information be **TRUSTED?** 

Do the outcomes **MATTER?** 





### Roadmap

Establish your needs .1 Search for bias or conflicts .2 Define who was studied .3 Find out what happened to the population .4 Determine relevance .5 Ignore potentially opinionated parts of text .6





### Set Up

### Establish a QUESTION: PICO

Patient –Intervention – Comparator – Outcomes

#### Establish your **NEEDS:** What outcomes are you looking for? What populations are you interested in?



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# **Establishing Your Needs**

**Evaluate the Title** 

Establish the Comparison

**Define the Population** 

Assess the Outcomes measured

Study Strength: Methods – Statistics

Conclusion: Best Case Scenario



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### **General Aspects to Assess**

Clinical Question(s) – Outcomes of Interest

**Population Assessed** 

**Methods Utilized** 

**Outcomes Collected** 

**Analysis Strategies** 

Conclusions





# Population

Population Size Power: generally the number of participants Greater enrollment = greater power

Population Characteristics Inclusion Criteria Exclusion Criteria Baseline Characteristics

Retention and Drop Out Consort Diagram



#### CONSORT 2010 Flow Diagram



### Methods

Randomization How are the participants assigned to groups Are these groups balanced

Blinding Single vs. Double blinded vs. No blinding Third party administration

Locations Number of sites Site location





### Validity: Internal and External

#### Internal

Study design and methodology Populations and randomization

#### **External**

Is the study applicable to others Can the methods be employed in other settings



### **Evaluating Bias**

**Randomization and Blinding** 

Were the groups truly equal?

**Conflicts of Interest** Employment or funding

**Types of Potential Bias** Selection – Performance – Detection- Attrition-Reporting



### Outcomes

Is the data collected relevant? How are outcomes organized? Primary – Secondary – Surrogate How are the outcomes analyzed? → Statistical Analysis

Are the positive outcomes of interest Due to chance alone? A result of bias?

Hopefully we can prove that they are due to the intervention





# Help us to determine if OUTCOMES are due to chance or are due to the intervention

Means of evaluating validity and strength of outcomes



Absolute Numbers: how many subjects in each group experienced an event

Group A Events:  $80/1000 \rightarrow 8\%$ Group B Events:  $60/1000 \rightarrow 6\%$ 2% absolute difference: Absolute Risk Reduction (ARR)

Relative Numbers: likelihood of event without knowing your baseline 6% vs. 8% → 25% difference between groups Relative Risk Reduction (RRR) – 0.75

**Hazard Ratio**: often describe relative differences Total number of adverse events AND their timing Hazard: slope of the survival curve for each group Hazard Ratio: ratio of both of the slopes At any given time:

HR: 0.5 – half as many patients in the treatment group are experiencing events

- HR: 1 rates of events are identical in both groups
- HR: 2 twice as many patients in the treatment group are experiencing events

**Confidence Interval**: allowable margin of error Provides a plausible range of values for the actual effect NOT a probability of magnitude If the CI INCLUDES 1 – difference is NOT statistically significant

**P Values**: shows how often a result would occur by chance alone if there was NO DIFFERENCE between our two groups

P= 0.04  $\rightarrow$  4% of the time you would have similar outcome by chance

Generally, P values < 0.05 are deemed to statistically significant

May be less useful than CI as it does not highlight the possible range of results

#### **Intention-to-Treat Analysis:**

All subjects that were randomized in the beginning are included in the final analysis Used to avoid the effects of crossovers/drop-outs which detriment initial randomization

#### **Per-Protocol Analysis:**

Only subjects who completed the entire study and follow-up are included in final analysis. Reduces the chance of false concluding non-inferiority

### **Statistical Error Types**

Decision you made			
	· ·	Do <u>not reject</u> the null hypothesis	<u>Reject</u> the null hypothesis
True condition in the population	The null hypothesis should <u>not</u> be <u>rejected</u>	You are correct in not rejecting the null. (True negative) Probability of correctly not rejecting the null hypothesis = $1-\alpha$ (equivalent to confidence level)	You made a mistake! Type I error: Rejected the null hypothesis, when you should not. (False positive) The risk of making Type I error = of (equivalent to significance level)
	The null hypothesis should be <u>rejected</u>	You made a mistake! Type II error: Research hypothesis is true but you decide to stick with the null hypothesis.	You are correct in rejecting the nul hypothesis and accepting the research hypothesis.
		(False negative) The risk of making Type II error = $\beta$	(True positive) $\bigcirc$ $\bigcirc$ $\bigcirc$ $\bigcirc$ Probability of getting correct = 1- $\beta$
		The risk of making Type II error = $\beta$	Probability of getting correct = 1 (This is also called statistical por

Type I Error - alpha Reject the null when the null is true False Positive

Type II Error – beta Accept the null when the null is true False Negative b= power (population size) Type II error decreased with higher power

# **Summarizing and Presenting Results**

Systematic Review

Journal Club\*

**Guideline Development** 

**Patient Care Decisions** 





# **Components of a Journal Club**

**Title/Citation** Objective Background **Methods Trial Design** Study Population/Inclusion Criteria **Exclusion** Criteria **Treatment Arms Outcome Measures Statistical Analysis** 

Results Enrollment Baseline Characteristics Treatment Efficacy Adverse Effects

Authors Conclusion Discussion Strengths Limitations Discussion



### **Potential Pitfalls**

Avoid echoing the authors conclusions that are presented in the results/discussion

If results seem too good to be true, they probably are

Be sure to compare outcomes to previous studies

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### **Useful resources**

CEBM: <u>https://www.cebm.net/2014/06/critical-appraisal/</u> Worksheets in several different languages

CASP UK Checklists: <u>https://casp-uk.net/casp-tools-checklists/</u> Critical appraisal tools for different paper types BMJ: <u>https://www.bmj.com/about-bmj/resources-readers/publications/how-read-paper</u> How to read papers and other helpful resources

ACP Journal Clubs: <u>https://annals.org/aim/journal-club</u>

Temple University Libraries: <u>https://guides.temple.edu/systematicreviews/criticalappraisal</u> Tools for Critical Appraisal

University of South Australia: <u>https://guides.library.unisa.edu.au/SystematicReviews/CriticalAppraisal</u> Tools for Critical Appraisal





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# Any Questions?

### **Phuture 2020: Call for Research Articles**

#### **Examples of Potential Topics:**

Pharmacogenomics Novel Drug Delivery Systems and Pharmaceutical Technology Medication Access – Cost and Availability Complicated Disease State Management Pain Management – Oncology – Psychology - etc. Digital Health and Telemedicine

#### Call:

https://drive.google.com/file/d/1d7EyypB0E69j1bbtJ9ON1z8yxBHVyKrR/view?u sp=sharing

Google Form: https://forms.gle/TmXPA76hw5FgLZyr7











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