

Evidence-Based Nursing Practice (Infection prevention & control)

Session 3: Critical appraisal Part 1: Intro, synthesis for P&P, RCTs & Systematic reviews

Feb 24, 2015

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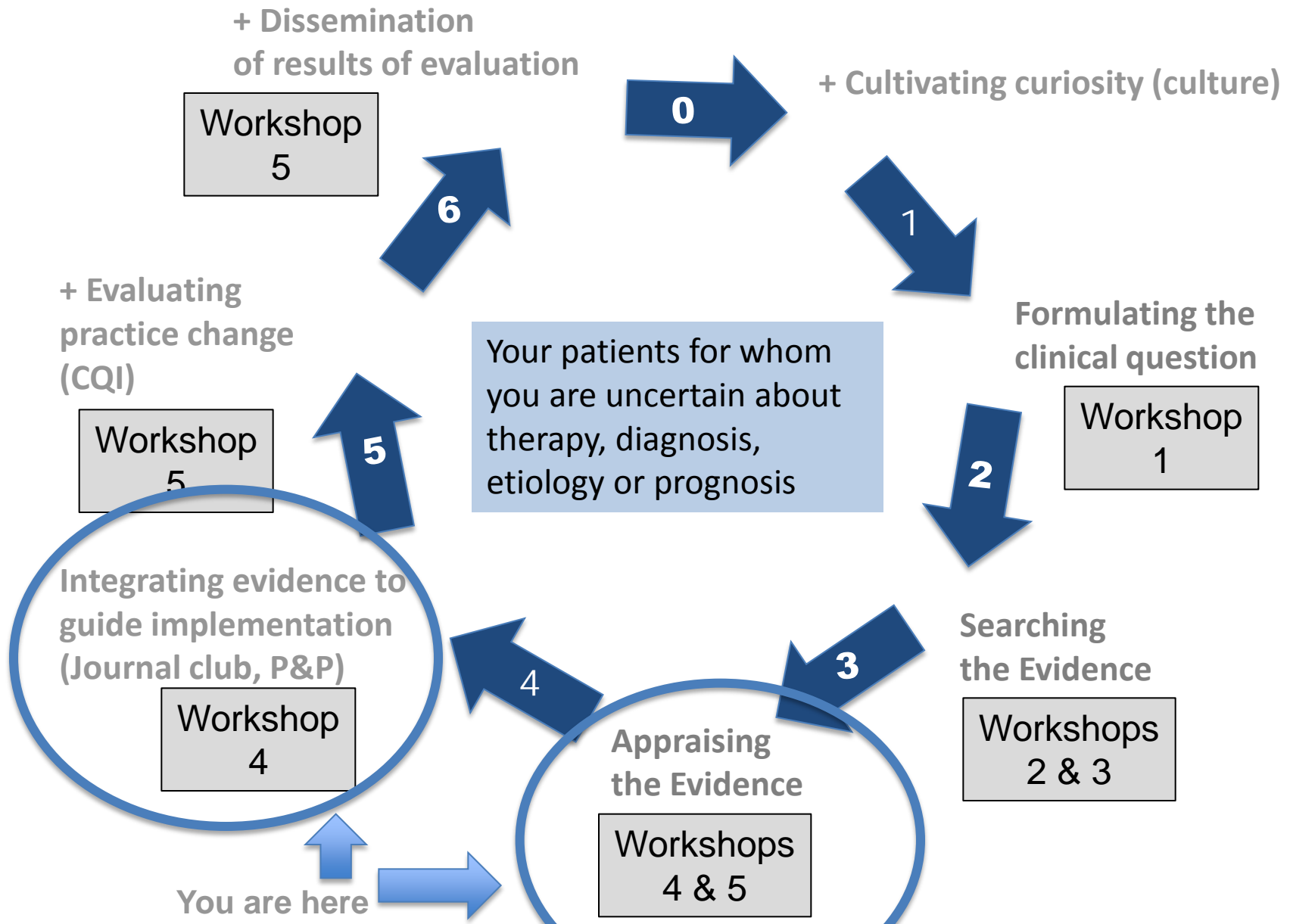
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WORKSHOPS

Date	Topic	Time	Location
December 16 January 13	Introduction to EBNP	1.5 hours	Conference room 2
January 20 February 17	Basics of searching 1- clinical tools	1.5 hours	Conference room 2
January 27 February 17	Basics of searching 2- biomedical databases	1.5 hours	A-805
February 3, 10 February 24	Critical appraisal 1- Intro/P&P, RCT, systematic review	1.5 hours	Conference room 2
February 10, 24 TBD	Critical appraisal 2 – implementing/evaluating, Case control, cohort	1.5 hours	Conference room 2



EBNP PROCESS: A METHODOLOGY + A FRAMEWORK



Workshop 4 - Objectives

By the end of the workshop, you will be able to:

1. Understand the basics of critical appraisal
2. Understand the basics of how critical appraisal is used to synthesize evidence for P&P development
3. Understand the basics of how to apply criteria to appraise a randomized controlled trial
4. Understand the basics of how to apply criteria to appraise a systematic review



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INTRODUCTION TO CRITICAL APPRAISAL

What is critical appraisal?

WHAT IS CRITICAL APPRAISAL?

- A systematic way of assessing the quality and relevance to practice of a given research article.
- Instead of looking at the abstract and conclusions we look at the methods section of the study
- Each study design (type of evidence) has a methodology that needs to be followed in order to achieve its objectives
- Some evidence has been pre-appraised and assigned a “level of evidence”
 - You may wish to do this yourself when synthesizing the evidence for a P&P- see next section



WHAT ARE LEVELS OF EVIDENCE?

- Used to grade evidence quality by type of study.
- Sometimes classified by question type (Therapy, Diagnosis etc).
- Not the same as the ~~evidence hierarchy pyramid~~.
- Over 100 different grading scales in use¹!
- A few commonly used examples:
 - Centre for Evidence-Based Medicine, Oxford: 1a-5
 - GRADE: A-D combined with 1 or 2 (UpToDate uses this system)
 - SORT (Patient centered, used in family medicine since 2004): A-C

¹ Ebell, et al

OXFORD CENTRE FOR EVIDENCE-BASED MEDICINE

www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/

Level	Therapy / Prevention, Aetiology / Harm	Prognosis	Diagnosis	Differential diagnosis / symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR* validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR* with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval†)	Individual inception cohort study with > 80% follow-up; CDR* validated in a single population	Validating** cohort study with good*** reference standards; or CDR* tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts* **	All or none case-series	Absolute better-value or worse-value analyses *****
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR* or validated on split-sample§§§§ only	Exploratory** cohort study with good*** reference standards; CDR* after derivation, or validated only on split-sample§§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

GRADE EXAMPLE FROM UPTODATE

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 Print

Grade 2C recommendation

A Grade 2C recommendation is a very weak recommendation; other alternatives may be equally reasonable.

Explanation:

A Grade 2 recommendation is a weak recommendation. It means "this is our suggestion, but you may want to think about it." It is unlikely that you should follow the suggested approach in all your patients, and you might reasonably choose an alternative approach. For Grade 2 recommendations, benefits and risks may be finely balanced, or the benefits and risks may be uncertain. In deciding whether to follow a Grade 2 recommendation in an individual patient, you may want to think about your patient's values and preferences or about your patient's risk aversion.

Grade C means the evidence comes from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.

Recommendation grades

1. Strong recommendation: Benefits clearly outweigh the risks and burdens (or vice versa) for most, if not all, patients
2. Weak recommendation: Benefits and risks closely balanced and/or uncertain

Evidence grades

- A. High-quality evidence: Consistent evidence from randomized trials, or overwhelming evidence of some other form
- B. Moderate-quality evidence: Evidence from randomized trials with important limitations, or very strong evidence of some other form
- C. Low-quality evidence: Evidence from observational studies, unsystematic clinical observations, or from randomized trials with serious flaws

For a complete description of our grading system, please see the UpToDate editorial policy.



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SORT EXAMPLE FROM AMERICAN FAMILY PHYSICIAN

Identification and Management of Latent Tuberculosis

Infection

SORT: KEY RECOMMENDATIONS FOR PRACTICE		
CLINICAL RECOMMENDATION	EVIDENCE RATING	REFERENCES
High-risk populations should be screened and treated for tuberculosis.	C	14
Tuberculin skin tests should be performed in persons at high risk of latent tuberculosis infection or progression to active tuberculosis, even if they have received previous bacille Calmette-Guérin vaccination.	C	14
The QuantiFeron-TB Gold test can be used to screen for tuberculosis wherever tuberculin skin testing is currently used.	C	19
The treatment of choice for latent tuberculosis infection is daily isoniazid for nine months.	A	14, 21, 22
Short-course rifampin (Rifadin) plus isoniazid (three months) is equivalent to standard isoniazid therapy and may increase compliance in persons with latent tuberculosis infection.	B	25

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to <http://www.aafp.org/aafpsort.xml>.

NURSING REFERENCE CENTRE CODING MATRIX

Question: is this a critical appraisal matrix?

Answer: Placing studies in a hierarchy is not the same as critically appraising each study since the *quality* of each study is not evaluated

Coding Matrix

References are rated using the following codes, listed in order of strength:

Code Description

- M** Published meta-analysis
- SR** Published systematic or integrative literature review
- RCT** Published research (randomized controlled trial)
- R** Published research (not randomized controlled trial)
- C** Case histories, case studies
- G** Published guidelines
- RV** Published review of the literature
- RU** Published research utilization report
- QI** Published quality improvement report
- L** Legislation
- PGR** Published government report
- PFR** Published funded report
- PP** Policies, procedures, protocols
- X** Practice exemplars, stories, opinions
- GI** General or background information/texts/reports
- U** Unpublished research, reviews, poster presentations or other such materials
- CP** Conference proceedings, abstracts, presentation



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HOW DO WE APPRAISE AN ARTICLE?

- Critical appraisal looks at whether a given study has met the standards for its chosen design.
- Each type of evidence has its own set of criteria-you can use worksheets to help you.
- Some general criteria:
 - Is the methodology appropriate and clearly reported?
 - Is the study well designed?
 - Are the findings well reported?
 - Are the findings relevant to your institution/patient(s)?
 - Should you change your practice based on these findings?

WHY IS CRITICAL APPRAISAL IMPORTANT?

- Not all studies are of equally good quality
 - Many systematic reviews are poorly done
 - e.g. librarians as co-authors increase the quality of the search and reporting- the opposite often results in poorly conducted searches
 - Sometimes the authors' conclusions are not supported by the data
- Not all patients are the same
- This is where your clinical judgment and patients' preferences come in!



APPRAISAL AND SYNTHESIS

Putting it into context

WHAT DOES THIS MEAN FOR NURSES INVOLVED IN P&P AND CQI?

- Evidence is not only used to inform patient care by individual nurses.
- Nurses need to use evidence to support P&P development and CQI.
- P&P should be based on the best evidence.



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WHAT DOES THIS MEAN FOR NURSES INVOLVED IN P&P AND CQI?

- Developing a P&P requires synthesizing the evidence i.e. putting it all together into a summary and recommendations
- To know what is the best evidence you need to appraise what is out there and select the best studies to support your P&P.
 - Use the Step-by-Step series of articles published in AJN to guide you in this process- see next slides for template and examples



EBNP STEP-BY-STEP ARTICLE SERIES

- Developed by a group of nurses at the Arizona State University College of Nursing and Health Innovation's Center for the Advancement of Evidence-Based Practice.
- 12 articles published every few months in AJN 2009-2011.
- “The purpose of this series is to give nurses the knowledge and skills they need to implement EBP consistently, one step at a time”.
- At the time of publication “Chat with the Authors” phonecalls were scheduled to provide additional support.
- The articles are written in a narrative format following the 7 steps of EBNP ending in the implementation and evaluation of a Rapid Response Team initiative in a hospital.
- See bibliography at www.jgh.ca/en/hslebnp



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SAMPLE CRITICAL APPRAISAL TABLE



Online-only content for "Critical Appraisal of the Evidence: Part I," by Fineout-Overholt and colleagues in the *American Journal of Nursing*, July 2010, p. 47-52.

Evaluation Table Template

A. The column headings for the evaluation table. Copy and paste this header into a text document.

Author (Year)	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables Studied (and Their Definitions)	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice

B. A description of each column's content. Put the data extracted from the studies in the correct column.

(Put citation here.)	(Theoretical basis for study goes here.)	(Describe design and how study was carried out.)	(This column contains number and characteristics of patients; attrition rate and why.)	(List and define independent and dependent variables.)	(Here go scales used to measure outcome variables, including name and author of scale and data on validity and reliability.)	(Put statistics used to answer clinical question here; but don't need to include all.)	(These are statistical or qualitative findings—there should be a finding for every statistical test in previous column.)	(Describe strengths and limitations of study; risk or harm if study intervention or findings are implemented; feasibility of use in your practice. Remember: level of evidence + quality of evidence = strength of evidence and confidence to act.)
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© 2007 Fineout-Overholt.

Critical Appraisal of the Evidence: Part I

EXAMPLE SYNTHESIS TABLE

Table 2: The 15 Studies: Levels and Types of Evidence

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Level I: Systematic review or meta-analysis	X	X	X												
Level II: Randomized controlled trial				X											
Level III: Controlled trial without randomization															
Level IV: Case-control or cohort study					X	X									
Level V: Systematic review of qualitative or descriptive studies															
Level VI: Qualitative or descriptive study (includes evidence implementation projects)							X	X	X	X	X	X	X	X	X
Level VII: Expert opinion or consensus															

Adapted with permission from Melnyk BM, Fineout-Overholt E, editors. Evidence-based practice in nursing and healthcare: a guide to best practice. 2nd ed. Philadelphia: Wolters Kluwer Health / Lippincott Williams and Wilkins; 2010.

1 = Chan PS, et al. (2010); 2 = McGaughey J, et al.; 3 = Winters BD, et al.; 4 = Hillman K, et al.; 5 = Sharek PJ, et al.; 6 = Chan PS, et al. (2009); 7 = DeVita MA, et al.; 8 = Mailey J, et al.; 9 = Dacey MJ, et al.; 10 = McFarlan SJ, Hensley S.; 11 = Offner PJ, et al.; 12 = Bertaut Y, et al.; 13 = Benson L, et al.; 14 = Hatler C, et al.; 15 = Bader MK, et al.



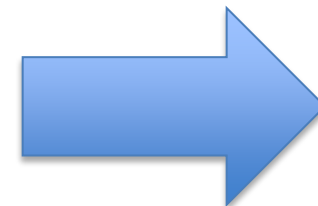
EXAMPLE CRITERIA SYNTHESIS

Table 4. Defined Criteria for Initiating an RRT Consult

	4	8	9	13	15
Respiratory distress (breaths/min)	Airway threatened Respiratory arrest RR < 5 or > 36	RR < 10 or > 30	RR < 8 or > 30 Unexplained dyspnea	RR < 8 or > 28 New-onset difficulty breathing	RR < 10 or > 30 Shortness of breath
Change in mental status	Change in LOC Decrease in Glasgow Coma Scale of > 2 points	ND	Unexplained change	Sudden decrease in LOC with normal blood glucose	Decreased LOC
Tachycardia (beats/min)	> 140	> 130	Unexplained > 130 for 15 min	> 120	> 130
Bradycardia (beats/min)	< 40	< 60	Unexplained < 50 for 15 min	< 40	< 40
Blood pressure (mmHg)	SBP < 90	SBP < 90 or > 180	Hypotension (unexplained)	SBP > 200 or < 90	SBP < 90
Chest pain	Cardiac arrest	ND	ND	Complaint of nontraumatic chest pain	Complaint of nontraumatic chest pain
Seizures	Sudden or extended	ND	ND	Repeated or prolonged	ND
Concern/worry about patient	Serious concern about a patient who doesn't fit the above criteria	NE	Nurse concern about overall deterioration in patients' condition without any of the above criteria (p. 2077)	Nurse concern	<ul style="list-style-type: none"> • Uncontrolled pain • Failure to respond to treatment • Unable to obtain prompt assistance for unstable patient
Pulse oximetry (SpO₂)	NE	NE	NE	< 92%	< 92%
Other				<ul style="list-style-type: none"> • Color change of patient • Unexplained agitation for > 10 min • CIWA > 15 points 	<ul style="list-style-type: none"> • UOP < 50 cc/4 hr • Color change of patient (pale, dusky, gray, or blue) • New-onset limb weakness or smile droop • Sepsis: ≥ 2 SIRS criteria

4 – Hillman K, et al.; 8 – Mailey J, et al.; 9 – Dacey MJ, et al.; 13 – Benson L, et al.; 15 – Bader MK, et al.

cc – cubic centimeters; CIWA – Clinical Institute Withdrawal Assessment; hr – hour; LOC – level of consciousness; min – minute; mmHg – millimeters of mercury; ND – not defined; NE – not evaluated; RR – respiratory rate; SBP – systolic blood pressure; SIRS – systemic inflammatory response syndrome; SpO₂ – arterial oxygen saturation; UOP – urine output



EXAMPLE CRITERIA FOR P&P

Table 5. Defined Criteria for Initiating an RRT Consult at Our Hospital

Pulmonary	
Ventilation	Color change of patient (pale, dusky, gray, or blue)
Respiratory distress	RR < 10 or > 30 breaths/min or unexplained dyspnea or new-onset difficulty breathing or shortness of breath
Cardiovascular	
Tachycardia	Unexplained > 130 beats/min for 15 min
Bradycardia	Unexplained < 50 beats/min for 15 min
Blood pressure	Unexplained SBP < 90 or > 200 mmHg
Chest pain	Complaint of nontraumatic chest pain
Pulse oximetry	< 92% SpO ₂
Perfusion	UOP < 50 cc/4 hr
Neurologic	
Seizures	Initial, repeated, or prolonged
Change in mental status	<ul style="list-style-type: none"> • Sudden decrease in LOC with normal blood glucose • Unexplained agitation for > 10 min • New-onset limb weakness or smile droop
Concern/worry about patient	Nurse concern about overall deterioration in patients' condition without any of the above criteria
Sepsis	
	<ul style="list-style-type: none"> • Temp, > 38°C • HR, > 90 beats/min • RR, > 20 breaths/min • WBC, > 12,000, < 4,000, or > 10% bands

cc – cubic centimeters; hr – hours; HR – heart rate; LOC – level of consciousness; min – minute; mmHg – millimeters of mercury; RR – respiratory rate; SBP – systolic blood pressure; SpO₂ – arterial oxygen saturation; Temp – temperature; UOP – urine output; WBC – white blood count



STATISTICS AS PART OF CRITICAL APPRAISAL

- Understanding statistics is an important part of critical appraisal
- They can tell you a lot about the quality of the study
- They can also tell you a lot about the significance of the findings (see statistical significance versus clinical significance on next slide)
- Using statistics in your synthesis will allow you to compare across studies



STATISTICS CONT...

- A few definitions:
 - **CI (confidence interval):** “Quantifies the uncertainty in measurement. It is usually reported as a “(95% CI 5-15) which is the range of values within which we can be 95% sure that the true value for the whole population lies. For example, for an NNT of 10 with a 95% CI of 5 to 15, we would have 95% confidence that the true NNT value lies between 5 and 15.”
 - **NNT (number needed to treat):** how many patients need to be treated in order for one patient to benefit from the treatment (fewer is better)
 - **Statistical significance:** do the numbers show that the difference between the control and the intervention was not due to chance?
 - **Clinical significance:** is the difference between control and intervention significant enough to change your practice?



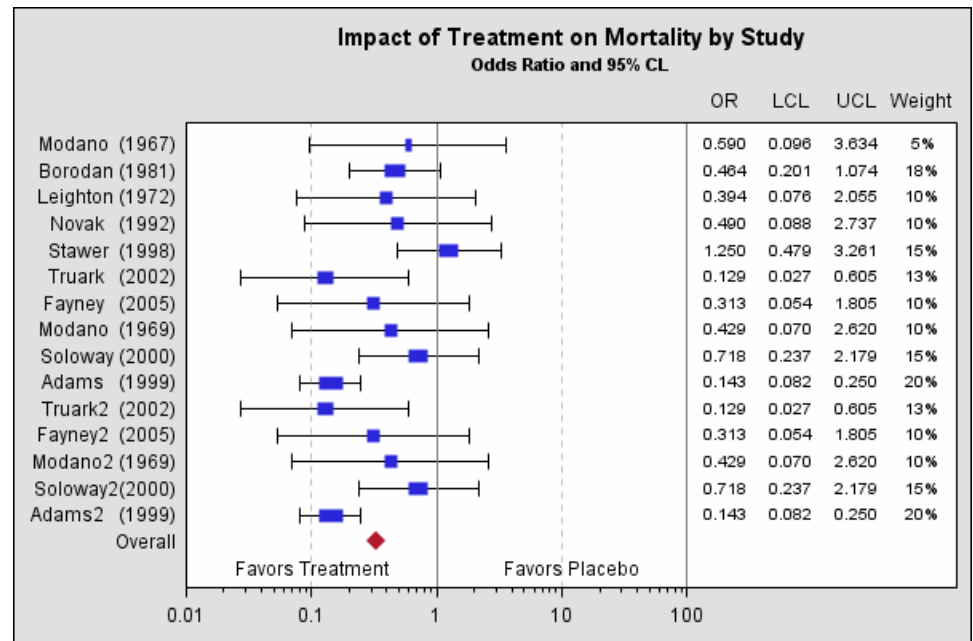
STATISTICS CONT...

- **P-value:** “The probability that the difference(s) observed between two or more groups in a study would occurred if there were no differences between the groups other than those created by random selection. Many researchers use a probability (**p-value**) of less than **0.05 as the cut-off for "statistical significance"**, i.e. when the sort of result seen in a study would occur by chance less than once in 20 studies.”*
- **Odds ratio:** “the odds in favor of being exposed in subjects with the target disorder divided by the odds in favor of being exposed in control subjects (without the target disorder).”*
- AR (**Absolute Risk**) versus RR (**Relative Risk**): risk of developing a disease in the population at large versus comparative risk in two different groups of people (i.e smokers vs non-smokers)
- **Intention to treat:** “A method of analysis for randomized trials in which all patients randomly assigned to one of the treatment groups is analyzed with that assigned group, regardless of whether or not they completed or received the treatment.”



STATISTICS CONT...

- **Forest Plot Chart:** Graphically represents whether the control or the intervention/treatment groups are favoured.
 - How to interpret a Forest Plot Chart (watch on youtube):
<https://www.youtube.com/watch?v=py-L8DvJmDc>



STATISTICS CONT...

- As you fill out the appraisal sheet for a study look up the terms you don't understand on Google- you'll find many tutorials that explain what they mean and how they are calculated.
- See definitions handout at jgh.ca/en/hslworkshops



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APPRAISING AN RCT

Let's appraise together

APPRAISING AN RCT

FRISBE

- F= Follow-up- is everyone accounted for?
- R= Randomization- was assignment of patients to treatment or control random? Was allocation concealed?
- I= intention to treat analysis- were all patients analysed in the group to which they were assigned?
- S= Similar baseline characteristics of patients- were groups similar at start of study?
- B= Blinding- were patients, health workers and study personnel “blinded” to who had treatment and who placebo/comparison?
- E= Equal treatment- aside from the intervention was everyone treated equally?

[Critical Appraisal tools](#) - Dartmouth College



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APPRAISING A SYSTEMATIC REVIEW

1. What question was addressed? Was it focused and clearly stated and?
2. Were all relevant studies identified? (published and unpublished). Was the search well reported/conducted? Can it be repeated with same results?
3. Were inclusion criteria predetermined, clearly stated and appropriate?
4. Were the included studies valid? Were the studies appraised?
5. Did 2 or more individuals select studies and extract data?
6. Were results similar from study to study? Ideally there would be homogeneity in the results. See forest plot.
7. Was conflict of interest reported?
8. What is the clinical importance of the results? Are the results precise? Does the authors' interpretation of results match the results themselves?

IN CONCLUSION

SUPPORT FOR YOU

- A JGH Librarian is available to provide one-on-one instruction or to conduct literature searches
 - Francesca Frati, local 2438, ffrati@jgh.mcgill.ca
 - Jacynthe Touchette, local 2453, jtouchette@jgh.mcgill.ca
- Tutorials are available 24/7
 - JGH.ca/HSL > Subject Guides
or
 - www.jgh.ca/en/hslworkshops



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THANK YOU!



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