Quickly gathering and evaluating evidence presented in reports of randomized controlled trials

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TOPIC SELECTION

Topic/Goal of Instruction:

When published guidelines and point-of-care information resources such as UpToDate or DynaMed Plus do not have the answer to clinical questions, healthcare professionals turn to the journal literature. Randomized controlled trials (RCT) are considered the ideal type of study to determine, without bias, the benefit or harm of an intervention and are often sought as evidence-based, authoritative sources of information to answer questions about complicated clinical scenarios. However, healthcare professionals do not have time to read lengthy and complex documents.

The goal of this module is to prepare third-year medical students in their clinical clerkships for the situation laid out above. By the end of the unit, students will be able to look at an RCT, quickly locate key pieces of information about the study design, and use a tool called a critical appraisal worksheet to evaluate the evidence. Twenty minutes is a perfectly reasonable amount of time for this module, considering the goals are more to equip the audience with the tools to perform the task rather than to actually appraise evidence together (since I am not a medical subject expert, but a librarian). This is still an intellectual skill, though, because the information they locate will need to be interpreted and synthesized.

Rationale:

As a medical librarian and liaison to the medical school who already teaches in the curriculum, I am knowledgeable about both the subject and the need for this type of module. One of the primary responsibilities of my job is to help people locate and assess high quality information, and this case is no different. This unit would be immensely useful because, at this point in time, critical appraisal of the literature is not part of the medical school's curriculum, despite being part of a forthcoming Core Entrustable Professional Activity for Entering Residency laid out by the accrediting body the Association of American Medical Colleges. Since medical students do not receive instruction in this area and the prospect of reading a lengthy and complex document is daunting for them, they end up basing clinical care decisions on less timely, less applicable, and less evidence-based information. The module aims to modify that behavior.

TASK ANALYSIS

Goal of Instruction: Quickly locate and extract the information from a report of an RCT necessary to evaluate the evidence it presents.

Context: The audience for this module will already know how to search the biomedical literature to find a promising RCT, thus the task analysis starts with the reading.

Tasks:

1. Conduct high-level screening evaluation of the relevance of the paper

    a. Determine if the study content matches the clinical question at hand (thinking about population/problem, interventions, comparative interventions, outcomes measured)

    b. Determine if the study design is appropriate to answer the type of question being asked (RCT for therapy questions, blind comparison to the gold standard for diagnostic questions, etc.)

2. Collect information from the report to assess the validity of the study design and execution

a. Find out if/how patient follow-up was conducted, record on critical appraisal form

b. Find out if/how patient randomization was achieved, record

c. Conduct intention-to-treat analysis, record

d. Locate the baseline characteristics of the patients, record

e. Find out if/how blinding took place, record

f. Determine if study groups were treated equally, record

g. Locate the conflict of interest section, record

3. Determine the treatment effect and precision of the treatment effect

a. Complete the matrix of treated/exposed, control, outcome present, and outcome absent to calculate experimental event rate and control event rate

    a. Calculate experimental event rate by dividing the number of treated patients with the outcome present by the total number of treated patients

    b. Calculate control event rate by dividing the number of control patients with the outcome present by the total number of control patients

b. Calculate relative risk reduction/increase, absolute risk reduction/increase, and numbers needed to treat/harm

    a. Calculate the relative risk by dividing the difference between the control and experimental event rates by the control event rate

    b. Calculate the absolute risk reduction by finding the difference between the control and experimental event rates

    c. Calculate the number needed to treat by doing one divided by the absolute risk reduction

Questions related to the tasks for the SME:

1. What kind of numbers in the treatment effect and precision of the treatment effect are meaningful?

2. How do you weigh the various factors in the validity section against each other to make a determination in the strength of the evidence?

3. How close does the population of the study need to resemble the patient at hand in the scenario for it to be relevant?

PERFORMANCE OBJECTIVES AND MEASUREMENTS

Further context: the School of Medicine curriculum heavily emphasizes self-directed learning; there are no grades or ranking and few required, formal assessments. The likelihood of this module ever being required is slim, the likelihood of getting a required assessment included is even slimmer. Therefore, the measurements/evaluation section is largely activities that demonstrate evidence of understanding and then what would ultimately be an optional exercise.

Objectives

By the end of this module, students will be able to:

1. Identify the key elements needed to evaluate evidence presented by a report of a randomized controlled trial (RCT).

2. Quickly locate the key elements in published final reports.

3. Utilize a critical appraisal worksheet to evaluate the evidence presented by a report of a randomized controlled trial (RCT).

Measurements/Evaluation

1. Pre/post survey where students list out the key elements of an RCT. The pre-module survey would be a reflective exercise, the post-module survey would indicate short-term retention of the information presented.

2. There will be an interactive exercise where students can drag and drop the key elements of the paper onto the section of the report where that information is generally located.

3. Students will be given access to three RCT papers and accompanying critical appraisal worksheets. If they choose to complete the form, feedback will be given by the librarian.