THERAPY MODULE
Relative Efficacy of High-Dose Influenza Vaccine
over Standard-Dose Influenza Vaccine in Older Adults

Objectives:

In this session, the learner will:
1. Assess the validity (risk of bias) of a therapy paper.
2. Determine the clinical importance of the results of a valid therapy paper.
3. Address how valid and important results from a therapy paper can be applied to our patient.

Assignment:

Review the enclosed paper and discuss:

1. Are the results of this therapy article valid (low risk of bias)?
2. Are the results of this study important?
3. Can we apply this valid, important evidence in caring for our patient?

Clinical Scenario:

One fine October afternoon, Ms. Thomas, an 81 year old African-American female comes in for a chronic condition follow-up visit with you, her primary care provider. She has a past medical history of diabetes mellitus type 2, hypertension, coronary artery disease, mild asthma and obstructive sleep apnea. Today, she is accompanied by her daughter Tanya, who assists with the health maintenance discussion. After the issues of colonoscopy and mammography have been discussed, you broach the topic of preventive immunizations and recommend that she get the high-dose flu shot today. The daughter asks you, "Last week, my father went to the local pharmacy and got himself a high-dose flu shot. He said it hurt quite a bit for a few days. Is it really important for my mother to get the high dose shot instead of the regular one?"

Your clinic stocks the high dose as well as the regular influenza vaccines, but you are not sure if the high dose is better than the regular vaccine. Because you want to counsel the patient and the daughter with the correct information, you try to look into the evidence on this topic. You start your search with PubMed Clinical Queries with the phrase "high dose influenza vaccine elderly" and find 61 individual studies under the "therapy" category with a "narrow" scope of search, and no recent meta-analysis. Upon closer review of the titles of the articles, you locate a 2014 NEJM article by DiazGranados CA, et al.

Enclosed Materials:

1. In Guyatt GH, Rennie D, Made MO, Cook DJ, Editors. JAMAevidence User's Guides to the Medical Literature: A Manual for Evidence Based Clinical Practice, 3rd Edition, New York, NY: The McGraw-Hill Companies, Inc. 2015.

2. Worksheet for the evaluation of a therapy article.

3. DiazGranados CA, et al. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. N Engl J Med. 2014 Aug 14; 371(7):635-45. doi: 10.1056/NEJMoa1315727.

FORMULAS

2x2 table	Event	No Event	N
Experimental	a	b	N for Experimental Group
Control	c	d	N for Control Group

EER = Experimental event rate. $EER = a / a + b$
CER = Control event rate. $CER = c / c + d$

ARR*: (Absolute Risk Reduction; difference in the event rates between control and experimental group, expressed over time)*
$ARR = |CER – EER |$
$ARR = |c/c+d - a/a+b|$

RRR*: (Relative risk reduction (RRR) is the proportion of baseline risk reduced by the therapy, calculated by dividing the ARR by the absolute risk in the control group (CER), expressed over time. It is larger and more impressive. It is independent of baseline risk)*
$RRR = 1 - | EER/CER |$
$RRR = 1 - [c/c+d – a/a+b]$

NNT (*Number needed to treat is the number of patients who need to be treated over a specific period of time to prevent one outcome*)
$NNT = 1 / ARR$ (if using fraction) or $100 / ARR$ (if using %)