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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Pop quiz answers

I distributed a quiz about a week ago to test your knowledge of trials.

A reply I got from Paul Leaverton:

*Not bad. But you forgot the most important question. The one that has wreaked the most havoc in the interpretation of trials by medical professionals. Should the absolute risk always accompany the relative risk found in a trial? (Gigerenzer; 2010)*

His answer (and mine and Paul's) is "of course", but the quiz was about trials. Not about reporting of trials.

Let me hear from you if you got all 16 correct or all 16 wrong.

1	<b>Belmont in the Belmont Report is the principal author of the report</b> Belmont is the conference center (Elkridge Md) where the report was written. Its official name is Belmont Report. Ethical principles and guidelines for the protection of human subjects of research	False
2	<b>A cohort study is another name for a trial</b> To be sure, trials involve cohorts of people, but in the parlance of research a "cohort study" is an observational study	False
3	<b>Interventional study and clinical trial mean the same thing in ClinicalTrials.gov</b>	True
4	<b>Consents for NIH funded research became a requirement in 1953 by order of the NIH director</b> False. It was 1966, twenty years after the Nuremberg Code was written before consents were mandated by the NIH director	False
5	<b>Trials should involve representative populations to be useful</b> False. The usefulness of trials comes from having comparable groups of people in the study groups, not in population representativeness. The reality is that all trials involve select non representative populations by virtue of the fact that you can only study people who consent to being studied	False

6	<b>The ICMJE requires trials to be registered within 30 days of the start of enrollment in order to be published in ICMJE journals</b> False. The International Committee of Medical Journal Editors requires them to be registered before the start of enrollment to qualify for publication in ICMJE journals	False
7	<b>In analysis, per protocol and per assignment mean the same thing</b> False. In per protocol analysis you counts only those treated in accordance with the study protocol. In per assignment analysis you counts people as assigned regardless of treatment received	False
8	<b>Three principles discussed in the Belmont report are beneficence, respect for persons, and justice</b>	True
9	<b>Persons who do not take the assigned study treatment should not be counted in analyses</b> False. They should be counted in the primary analysis as assigned. They can be counted other ways in secondary analyses	False
10	<b>A dropout is lost to followup</b> A dropout in the vernacular of trials is one who does not return for followup visits but they are not lost for information that can be collected other ways; for example as to alive or dead in mortality analysis	False
11	<b>Most trials are published</b> Only a small fraction are published	False
12	<b>In trials, double blind and double masked mean the same thing</b> True, but the preferred term is “double masked”	True
13	<b>A person who is assigned to receive the test treatment, but is mistakenly given the control treatment should be counted in the control treated group in the primary analysis</b> False. They should be counted to the group to which assigned even if not treated or given the wrong treatment	False
14	<b>How many people did James Lind have in his scurvy trial</b>	12
15	<b>How many treatment groups did he have</b>	6
16	<b>When was ClinicalTrials.gov launched</b>	2000