



Memorandum

To: Trialists

Fr: Curtis Meinert, trialist, CERist, PCORist, and translational researcher

Re: Fancy terms for old concepts

We have a propensity for renaming things. Industry does it all the time with new names for the same old thing and then calling it new and improved. We went through a name change here a few years back. The School of Hygiene and Public Health became the Bloomberg School of Public Health with lots of hype. I remember walking into the school the day people were changing the name on the entry. I wondered if my office would be suddenly neat but I discovered it was the same mess as before the name change.

In the field of clinical research terms are introduced for old concepts and then used as if they embody something new and innovative. Four of my "favorites" are:

- comparative effectiveness research
- patient-centered outcomes research
- technology transfer
- translational research

Comparative effectiveness research (CER)

Defined by the Institute of Medicine as *the generation and synthesis of evidence that compares the benefits and harm of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.*

Comment: So broadly defined so as to include everything but the kitchen sink when it comes to comparison. Without knowing, I have devoted my entire professional life to comparative effectiveness research. That being so, I am inclined to stop referring to myself as a trialist and start calling myself a comparative effectiveness researcher, a CERist, if you will. My company is broad. It includes synthesizers engaged in meta-analyses and systematic overviews of trials, case-control study investigators involved in comparisons of treatments, diagnostic regimens, and of "clinical conditions to improve delivery of care" and observationists using literature controls.

Patient-centered outcomes research (PCOR)

Broadly, patient-centered outcomes research is any research where the focus of study is on persons with the aim of trying to improve the health and well-being of the persons, especially such research where the measures of primary interest are those related to quality of life and on outcomes of obvious meaning and relevance to persons studied. The activities include treatment and prevention trials and also observational studies where the focus is on person and measures of well-being.

Comment: The term arises in the Patient Protection and Affordable Care Act health reform bill, signed into law by President Obama in the spring of 2010. The Act authorizes creation of a nonprofit, nongovernmental, agency to be known as the Patient-Centered Outcomes Research Institute (PCORI). The purpose of the Institute is "*to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of medical treatments, services, and items.*"

(<https://www.aamc.org/download/131994/data/pcorsummary04022010.pdf>)

Reading the definition makes me think I should refer to myself as a patient-centered outcomes researcher – a PCORist. For sure, all the trials I have done have been patient-centered and have been concerned with quality of life.

Technology transfer

1. The movement of information from originators to others for the purpose of promoting development of new information and uses. 2. *The process of skill transferring, knowledge, technologies, methods of manufacturing, samples of manufacturing and facilities among governments or universities and other institutions to ensure that scientific and technological developments are accessible to a wider range of users who can then further develop and exploit the technology into new products, processes, applications, materials or services* (Wikipedia; 1 Aug 2012).

Comment: Broadly, technology transfer is knowledge transfer. The most basic form of transfer is via publications in scientific journals by originators of the information. The term took on new currency with passage of the Federal Technology Transfer Act of 1986 (by amendment of the Stevenson-Wydler Technology Innovation Act of 1980). The act, among its various elements, authorized the NIH to enter into CRDAs (cooperative research and development agreements) and grant funding via cooperative agreements (U01 and U10).

Most major academic institutions have offices for technology transfer. The mission of the Johns Hopkins Technology Transfer Office is to serve as the "University's intellectual property administration center, serving Johns Hopkins researchers and inventors as a licensing, patent, and technology commercialization office and acting as an active liaison to parties interested in leveraging JHU research or materials for academic or corporate endeavors". The mission is neutral on the primary mode of technology transfer – publication.

Translational research

1. Research undertaken for the purpose of or having the effect of translating or extending findings of basic research to everyday circumstance or use. 2. A trial involving a drug, biologic, or device undertaken primarily to provide information as to dose, method, or mode of administration for the purpose of aiding investigators in deciding whether it is safe and appropriate to proceed to more definitive trials of that drug, biologic, or device.

Comment: *Translational research is a way of thinking about and conducting scientific research to make the results of research applicable to the population under study and is*

practiced in the natural and biological, behavioral, and social sciences. In the field of medicine, for example, it is used to translate the findings in basic research more quickly and efficiently into medical practice and, thus, meaningful health outcomes, whether those are physical, mental, or social outcomes. In medicine in particular, governmental funders of research and pharmaceutical companies have spent vast amounts internationally on basic research and have seen that the return on investment is significantly less than anticipated. Translational research has come to be seen as the key, missing component. (Wikipedia; 1 Aug 2012)

It seems to me I also qualify as a translational researcher. That makes me wonder if I would be better off calling myself a translational researcher than a trialist. Certainly, it has a sexier ring than "trialist", to say nothing about the possibility of "trialist" being confused with a courtroom lawyer.