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Dr. Hertzel C. Gerstein is an Endocrinologist and Professor at McMaster University and Hamilton Health Sciences, where he holds the Population Health Institute Chair in Diabetes Research. He is also Director of the Division of Endocrinology & Metabolism, Director of the Diabetes Care and Research Program and Deputy Director of the Population Health Research Institute. He has received several honors including the Canadian Diabetes Association's Young Scientist Award (1999), Frederick G. Banting award (1999), Charles H. Best award (2007) and Lifetime Achievement Award (2012). Dr. Gerstein has led the application of large simple outcome trials to people with diabetes globally, and developed the concept of dysglycemia as an important risk factor for many of the serious health outcomes that afflict people with an elevated glucose level regardless of diabetes status. His research spans over 50 countries, and has been funded by the Canadian Institutes of Health Research, the National Institutes of Health, the Heart and Stroke Foundation, the Canadian Diabetes Association and Industry. Dr. Gerstein has published more than 300 papers, editorials and commentaries, mainly on diabetes-related issues.

Why do we need large pragmatic outcomes RCT's of nutritional interventions?

Changes in nutrition throughout history have had remarkable effects on clinically important outcomes. Such clinically important outcomes include death, strokes, disability, cognitive decline and other things that are important to both patients as well as healthcare providers. Nutritional interventions that can be proven to have clinically important effects on these health outcomes are likely to be rapidly adopted by people. Conversely interventions that simply affect biochemical or clinical parameters such as serum analytes or blood pressure or glucose level will be subject to controversy. Large clinical outcomes trials that are focused on outcomes that are important to society, patients and providers are clearly the best way to demonstrate the value of new nutritional interventions in the general population and in subgroups such as those with diabetes. Such trials can do this convincingly and effectively because of the very powerful tool of randomization. Epidemiological approaches that analyze databases or even prospectively recruit and follow participants are unable to clearly establish the effect of any intervention. At best they can identify risk factors and stratify people into lower versus higher risk groups. They may also suggest hypotheses regarding the effects of interventions however they are unable to determine whether: (a) any particular therapy is effective at reducing outcomes; (b) any benefits of such therapies outweigh the risks; and (c) whether the measured effect is due to the therapy or to patient characteristics associated with the propensity to get the therapy and the outcome. Conversely the randomized controlled trial is able to make this determination because randomization ensures that: (a) both measured and unmeasured confounders are randomly distributed within the 2 groups; and (if the groups are large enough) the groups are equal on average except for the therapy provider that will not provide it. Once the trial is finished researchers can assume with great confidence that any difference in outcomes between the 2 groups is due to the therapy that was assessed. Such clinical trials are arduous and costly however they are indispensable and have definitively and unequivocally proven the benefits of a wide variety of therapies throughout medicine. This evidence is used by governments and other third party payers to justify adoption of these therapies and have dramatically reduced outcomes in various populations.

Learning objectives:

1. Clarify what is meant when discussing clinical outcomes and outcomes trials
2. Identify the methodologic weaknesses inherent in all non-randomized comparisons and highlight the strengths of randomization
3. Illustrate the limitations of "big data" using examples from the diabetes literature