Types of Clinical Caries Studies: Discussion of Dr. Stamm's Presentation

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Dr. Stamm has presented a good historical overview of the types of clinical caries studies. In correctly identifying surveys as not being capable of establishing cause-and-effect relationships, he points out that only randomized clinical trials can establish these facts. Dental surveys are classified in the area of observational studies, while randomized clinical trials are labeled as scientific experiments.

Dr. Stamm discussed at some length the requirements of these studies, including randomness, sample size, measurement, bias, analysis, and time frame. Although well-intentioned and important, these issues should not be seen as "all or none" propositions. The difficulty with clinical research is that it deals with human populations in real-world situations. The question of how much flexibility can be tolerated has not been addressed. Procedures have been mentioned to assure success in these areas, but what degree of freedom or error is permissible and still result in an effective study? Bias, for example, must be controlled; however, it need not invalidate a study if the investigator is aware of the bias and the direction it takes. The example of dental practitioners filling teeth and causing inflated levels of DMF could be dealt with by recognizing that the sample has an overestimation of its true DMF level. Experimental treatment effects in this study, if found, would also reflect a difference lower than expected. If the bias can be assumed to be random, then both experimental and treatment groups can be expected to be treated equally.

The issue of sample size is important, but nonetheless may need to be influenced by the circumstances of the study group. When sufficiently large samples cannot be obtained, what level would be acceptable? Schoolchildren and institutionalized adults may not always be ideal, but in terms of securing sufficient size, these groups must be utilized to achieve acceptable levels.

Measurement usually seems to be a large issue that is never resolved. Calibration and training are useful and important, but these problems are still unresolved in the use of large study populations and multiple examiners. What level of measurement error is acceptable to ensure success?

The issue here is that there are many appropriate and acceptable principles for conducting clinical trials. These are issues of which we are all well aware and in which we have some expertise. In the conduct of clinical studies, however, and in dealing with people in their environment, it becomes difficult to predict and control all of these variables to the same extent. If deviations from acceptability can be identified and even measured and predicted, then the outcome will be acceptable. The level of acceptability needs to be addressed in this conference so that a consensus can be achieved.

John Snow's ability to stop the epidemic of cholera in London during the 1800's was based on sound principles of research design. He did not, however, have the benefit of our knowledge of samples, bias, measurement, etc. Controlling the water supply in London stopped the deaths from cholera. The point is that his clinical trial worked because of an acceptable level of deviation from the ideal. What we need to realize is that improvement is necessary, but that some acceptable flexibility in these parameters is necessary to be able to conduct clinical studies.

Demonstration programs, although not considered to be research as clarified by Dr. Stamm, need to be standardized and controlled to include sufficient guidelines so that valuable information can be secured from their efforts. These programs are too costly and expensive and should be defined to include evaluation. Program design needs to be reviewed and strengthened by individuals with research capabilities so that these endeavors will be able to contribute knowledge in addition to providing service.

In summary, Dr. Stamm has done a credible job of bringing together the many aspects of a diverse topic and has provided a basis for classification of clinical studies. This is an important step toward improving the quality of clinical research in dentistry.