Facilitating Clinical Oral Research in Canada

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Clinical research is essential in determining the appropriateness of treatment. While traditional therapies continue to be utilized based on past experience, new treatments, devices and therapies require assessment of effectiveness, side effects, durability and cost effectiveness as compared to currently available therapies or placebo.

The clinical practice of dentistry or medicine may lead to feedback to the provider suggesting that treatments are effective when, in fact, the conditions "treated" may be fluctuating or self-remitting based on their natural history. In addition, all health care treatments have placebo effects and responses influenced by the patient-provider interaction. The natural response is to attribute a change in the condition to the treatment provided, whether the patient response is due to placebo effects, a non-treatment-related fluctuation in symptoms or the treatment provided. Therefore, structured research with specific predetermined outcome measures provided in double-blind fashion and interpreted by an individual who does not know the therapy provided, is an important means of assessing treatment outcomes. There is increasing emphasis upon such clinical research in order to improve patient care.

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The imperative of good clinical data, particularly when assessing new pharmacologic approaches to the prevention or management of disease, and the need for such data for the licensing of products have resulted in increasing the need for clinical research to support new therapies and new medications. Despite this increasing emphasis and demand, funding for clinical research may be difficult to find. Appropriate funding is seldom available through federal agencies. Rather, the source of funding is often in the private sector, especially industry. Industry funding in some cases may be matched by federal or provincial agencies.

Industry-sponsored research can provide valuable information on effects, side effects, durability and risks associated with treatment. These studies must be conducted with rigorous clinical design, including control groups or placebo therapies and double-blind evaluation with predetermined endpoints and predetermined sample sizes or patient numbers.

While there is increasing demand and need for such research, the conduct of research in Canada has, in my experience, been hampered by the staffing and policies of the Therapeutic Products Directorate (TPD) of Health Canada. Many multinational studies, such as studies planned to be conducted in the United States and Canada, may not be funded by industry when different administrative procedures and delay in review of study protocols occur at the federal level in Canada. Most unfortunately, this results in reduced clinical research and academic activities in Canada, fewer jobs and lower income due to the studies not being funded in this country.

The issues appear to relate to staffing levels at the TPD and the format of application and materials required by the TPD compared to the U.S. Food and Drug Administration (FDA). In several recent potential studies, plans to establish one or more Canadian centres for such research have been terminated upon review of the regulatory time and costs entailed in the application. The application, though requiring similar information, has a different format, and the delay in response can be much greater. In these cases, industry has determined that they would proceed with FDA-approved, U.S.-based sites of study or U.S. and European study sites.

Solutions to the problems of delay at the TPD may include increased staffing, allowing more rapid approval. Other options to facilitate study opportunities in Canada might be to access FDA-formatted applications or allow study in Canada when U.S. FDA approval is in place. Study initiation would, of course, require local ethics and research board approval. This measure would not have direct application to approval of drugs for post-study marketing, but would certainly promote the ability of Canadian academics and researchers to be involved in clinical studies of new approaches to the diagnosis, prevention and management of diseases. In addition to the increased academic and research opportunities that are obvious, increased

employment in Canada and increased knowledge of new therapies would result.

This issue should be of concern to Canadian health care providers, dental providers and indeed the public so that new therapies and investigational products may be more available in controlled study environments and so that Canadian health care providers will be more knowledgeable of the new therapies through the increased opportunity for early involvement in controlled clinical trials.

Future issues of the *Journal* should discuss the nature of clinical studies and the elements of good study design. The need for evidence of safety, efficacy and understanding of risk and benefit of each new therapy should be well understood and indeed demanded by health care providers and the public.

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The views expressed are those of the author and do not necessarily reflect the opinion or official policies of the Canadian Dental Association.