

## **"Clinical Research in Oral Health"**

**William V. Giannobile, Brian A. Burt, and Robert J. Genco, editors, 2009, 372 pages, Wiley-Blackwell, \$89.99**

**Review by Norman M. Goldfarb**

"Clinical Research in Oral Health" is an introductory survey of clinical research topics tailored for oral health professionals.

The question about what to measure in oral health studies is keeping pace with other therapeutic areas, as illustrated by the following passage:

Clinical outcomes are most widely reported in dental clinical trials. These outcomes can be classified into survival outcomes (longevity of restoration or loss of tooth or restoration); mechanical outcomes (smoothness of margins, conformation of contours, mobility of teeth); diagnostic outcomes (presence of pathology, caries, periodontal disease, open bites, crossbites, malocclusion); and functional outcomes (chewing of foods, speaking, swallowing after cancer treatment).

A significant interest has emerged during the last decade in evaluating psychosocial outcomes. Oral health and dental care influence the quality of life, and assessment of this outcome is necessary to understand the full impact of dental interventions on patients' well-being. Hence, it is now customary in clinical trials to assess quality of life and answer the question of whether the intervention improves the quality of oral health-related quality of life. Psychosocial outcomes include satisfaction with treatment, providers or outcomes of interventions. Perception outcomes are related to how people feel about esthetics and their oral health status. Preference for outcome states is another important, but not yet fully developed, research area. Preference refers to the choices that individuals make between two or more outcomes under conditions of uncertainty (probability of success is known but it varies). There are different methods to assess preferences, including health time equivalents, willingness to pay (WTP), and quality-adjusted life (tooth) years, among others (Birch and Ismail, 2002; Birch et al., 2004; Ismail et al., 2004). Utility assessment measures the expected effect of undertaking an intervention on an individual's assessment of his or her well-being. The trade-offs between two interventions depends on whether the well-being associated with a treatment more than offset the reduction in well-being associated with the additional cost and discomfort, and inconvenience associated with an alternative treatment. This is an important dimension of assessing outcomes in clinical research because, while a new treatment may be more effective than the standard of care, the associated loss of well-being may be higher, and hence, patients will continue to prefer the standard of care, even though it is less effective. Hence, by focusing only on physical outcomes, the full impact of newly discovered interventions on oral health will not be known.

Assessment and measurement in oral health studies is often challenging, as illustrated by the following passage:

Since its first description in newer times (Elaci 1913) and despite significant limitations, the periodontal probe has remained the main instrument for the clinical evaluation of periodontal tissues in health as well as in disease. Originally, periodontal probes were uncalibrated, but later, various incremental marks were

added to the probes to accurately determine distances, gingivo-apically either for penetration (pocket, probing) depth or for measuring to what extent fibers of the periodontal ligament have been detached (loss of attachment). Incremental markings on the probe include a variety of systems. Millimeter markings (PCP-UNC: U of North Carolina 15) are usually difficult to read for the examiner, and hence, other increments have been applied (e.g., 2 mm: U of California). Also, variable incremental units characterize some periodontal probes, such as 3-6-8-11 mm (U of Michigan M1) or 3-6-9-12 mm markings. Some probes employ color coatings for easier readability.

The shape (round vs. flat) and the dimensions of probes may also vary. Today, slightly tapered metal cylinders with a point diameter of 0.4-0.5 mm are preferred in clinical research and dental practice. Regarding the markings, it has to be realized that increased readability may be at the expense of measurement accuracy.

It is evident that one type of measurement instrument has to be selected for a clinical study and applied by all examiners. As manufacturers work with some tolerance in accuracy, it cannot be expected that all instruments of the same type present accurate and identical markings and/or dimensions, even when from the same brand (Ramfjord, 1974). Hence, it is imperative to select study instruments and to verify the accuracy of dimensions and markings on the instruments prior to examiner training. Depending on the manufacturer, it can be anticipated that only approximately 70% of instruments yield identical markings and dimensions.

Manual probing generally allows the distinction of 1 mm increments for a single reading. The standard deviation for a single measurement has been reported to be in the range of 0.4-1.0 mm. (Glavind and Lae,1967; Abbas et al.,1982; Haffajee et al.,1983; Badersten et al.,1984; Osborn et al.,1990;1992). Novel probe tip designs (flat and rounded) may have greater validity, good reproducibility, and may produce less patient discomfort (Vartoukian et al., 2004) than conventional probes hitherto used. Electronic probes, on the other hand, may improve the resolution up to 0.2-0.3 mm (Clark et al.,1992) and, hence, may be more suitable to detect smaller changes of probing depth (PD) or clinical attachment level over time (Jeffcoat and Reddy,1991; Marks et al.,1991; Clark et al.,1992; Mombelli et al.,1997).

The book includes 18 essays by 53 contributors:

- Clinical and translational research: implications in the promotion of oral health
- Ethics in oral health research
- Responsibilities of institutions and individuals in clinical research in the oral health sciences
- Regulatory process for the evaluation of dental drugs, devices and biologics
- Clinical and translational research grantsmanship: funding opportunities and obtaining research support
- Data management in oral health research
- Hypothesis testing and avoiding false-positive conclusions
- Outcomes in oral health research
- Examiner training: standardization and calibration in periodontal studies
- Observational studies in oral health research
- Initial clinical trials allow assessment of safety, dosing and preliminary efficacy prior to large randomized controlled pivotal studies
- Phase III pivotal clinical trials: clinical decision making
- Postmarketing surveillance

- Dental practice-based research networks
- The technology transfer process for life science innovations in academic institutions
- Adoption of new technologies for clinical practice
- Publication of research findings
- The evidence base for oral health

The book is available in bookstores.

### **Reviewer**

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