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International Standards for Clinical Trial Conduct and Reporting

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International, explicit, rules-based methods are extant for all aspects of clinical trial implementation and reporting. These standards include hypothesis formulation, literature searching, literature review, trial planning, ethical review, trial conduct, trial reporting, systematic reviews, and meta-analysis (Table). However, these standards have not yet come into common use in the oral health community. Recent Cochrane Collaboration Oral Health Group reviews highlight this lack of standardization (see below).

On January 11, 2003, at the Forsyth Conference on Evidence-Based Dentistry, The Cochrane Collaboration's Oral Health Group (<http://www.cochrane-oral.man.ac.uk>), one of 49 international non-profit Cochrane Collaboration research groups with centers in 13 countries, presented results of a new systematic review on electric toothbrushes (Heanue *et al.*, 2003). This review was noteworthy for three reasons: First, it systematically examined over 30 years of published studies. Second, an international team used international standards to identify, evaluate, compile, analyze, and report the data. Third, and surprisingly, the work indicated that only one type of electric toothbrush, rotating oscillating, provides a statistically significant, though modest, clinical benefit over manual toothbrushes in reducing plaque and gingivitis—7% plaque reduction and 17% gingivitis reduction. [Trials lasting less than one month and trials published after 2001 were not included in the Cochrane findings.]

During the week following the Oral Health Group's presentation, reports on the electric toothbrush findings appeared in over 100 media outlets in the US, the UK, Australia, and Asia. The media venues included *The Washington Post*, *Wall St. Journal*, Reuters, *Newsweek*, CNN, NPR, ABC, and the BBC.

KEY WORDS: clinical trials, diagnosis, practice guidelines, literature review.

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This media interest may not be surprising, given that 42% of US adults and 34% of US teens view toothbrushes as an invention they cannot live without (Lemelson-MIT Invention Index Survey, 2003). Further, in the Lemelson-MIT Survey, toothbrushes were listed as more important than automobiles, PCs, cell phones, and microwave ovens!

As valuable as systematic reviews can be, their usefulness depends on the quality of previously published studies. For example, in the Cochrane toothbrush review, 29 studies met review standards, but 118 did not. If the purpose of a clinical trial is to determine clinical effectiveness, then the 118 trials not included because of poor trial design or poor reporting represent a significant loss of effort and resources. The observation of poor trial quality or reporting in the toothbrush review was not unique. Twenty-seven of the first 29 completed Cochrane Oral Health Group's reviews on diverse topics—including orthodontic treatment, treatment of decay in primary teeth, fluoride varnish, dental implants, dentin hypersensitivity, treatment of TMD problems, treatment of pre-cancerous lesions, and the oral care of children receiving cancer treatment—found that the evidence provided in the available trials was weak and unreliable.

Thus, despite the fact that oral health in the US is a multibillion-dollar industry, even recent trials do not adhere to CONSORT (Consolidated Standards of Reporting Trials), a set of guidelines developed in the mid-1990s by a group of leading international scientists and editors concerned with the quality of medical evidence (<http://www.consort-statement.org>). These standards for trial conduct and reporting are now being implemented by multiple medical journals, and they result in improved clinical trial conduct and reporting (Moher *et al.*, 2001b). As indicated at the outset, international standards are now in place for all aspects of clinical trial design, implementation, and reporting.

If oral health care is to be improved, meeting these standards of excellence is the joint responsibility of all oral health stakeholders. These stakeholders include journals in their editorial review criteria, funding agencies in their planning and grant review, associations in their position statements, researchers in their trial design and reporting, product manufacturers in their research and claims, and third-party payers in compensating health care delivery. Systematic

Table. International Standards for Clinical Trials

Focus	URL	Reference
1. Hypothesis articulation		Richardson <i>et al.</i> , 1995
2. Literature searching for diagnosis, etiology, prognosis, and therapy	http://www.shef.ac.uk/~scharr/ir/adept/	
3. Levels of clinical evidence	http://www.eboncall.co.uk/content/levels.html	
4. Ethical review of clinical trial proposals and monitoring	http://www.assert-statement.org/	
5. Randomized controlled trial conduct and reporting	http://www.consort-statement.org	Moher <i>et al.</i> , 2001a
6. Diagnostic trials conduct and reporting	http://www.consort-statement.org/stardstatement.htm	
7. Critical appraisal of clinical trials	http://www.phru.org.uk/~casp/appraisa.htm	
8. Meta analysis of randomized controlled trials conduct and reporting	http://www.consort-statement.org/QUOROM.pdf	Moher <i>et al.</i> , 1999
9. Meta analysis of observational trials conduct and reporting	http://www.consort-statement.org/MOOSE.pdf	Stroup <i>et al.</i> , 2000
10. Systematic reviews of randomized controlled clinical trials	The Cochrane Collaboration http://www.cochrane.org http://www.cochrane.org/cochrane/hbook.htm	
11. Systematic reviews of controlled clinical trials	Center for Reviews and Dissemination http://www.york.ac.uk/inst/crd/report4.htm	
12. Systematic reviews of social, psychological, and educational policies and practices	Campbell Collaboration http://www.campbellcollaboration.org http://www.campbellcollaboration.org/guidelines.html	
13. Clinical guideline development	Scottish Intercollegiate Guideline Network http://www.sign.ac.uk/ http://www.sign.ac.uk/methodology/index.html	
14. Technology appraisal of clinical guidelines	National Institute for Clinical Excellence http://www.nice.org.uk http://www.nice.org.uk/cat.asp?c=154 http://www.nice.org.uk/cat.asp?c=29	
15. Clinical practice guidelines assessment	http://www.agreecollaboration.org/	

implementation of these standards by all stakeholders is essential if the oral health community seeks to improve health care as well as health.

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REFERENCES

- Heanue M, Deacon SA, Deery C, Robinson PG, Walmsley AD, Worthington HV, *et al.* (2003). Manual versus powered toothbrushing for oral health (Cochrane Review). In: The Cochrane Review, Issue 1, 2003. Oxford: Update Software.
- Lemelson-MIT Invention Index Survey (2003). <http://mit.edu/invent/n-pressreleases/n-press-03index.html>
- Moher D, Schulz KF, Altman D (2001a). The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *J Am Med Assoc* 285:1987-1991.
- Moher D, Jones A, Lepage L (2001b). Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. *J Am Med Assoc* 285:1992-1995.
- Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF (1999). Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of Reporting of Meta-analyses. *Lancet* 354:1896-1900.
- Richardson WS, Wilson MC, Nishikawa J, Hayward RS (1995). The well-built clinical question: a key to evidence-based decisions. *ACP J Club* 123:A12-A13.
- Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, *et al.* (2000). Meta-analysis of observational studies in epidemiology. A proposal for reporting. *J Am Med Assoc* 283:2008-2012.