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One Dental Hygienist's Role in Clinical Research

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After graduation from a dental hygiene program, dental hygienists are faced with a multitude of professional pathways to pursue beyond the private practice scenario. The dental hygiene education and licensure uniquely qualifies them for a professional career in clinical research.

Clinical research is growing quickly in medicine and dentistry today. Moving research findings from the bench top of a scientific laboratory to the private practitioner's clinical setting is what translational research is all about. The National Institutes of Health (NIH) Roadmap 2002 for biomedical research has highlighted translational research within medicine, and that includes oral health, as part of reengineering the clinical research enterprise in the United States. The National Institute of Dental and Craniofacial Research support this mission, along with their mission, which is "to improve oral, dental and craniofacial health through research, research training, and the dissemination of health information."

I began my dental hygiene career in private practice and about 10 years ago transitioned to working in clinical research settings. I was working full time as a clinical dental hygienist for the University of Michigan (U-M) Faculty Practice when I was recruited as a clinical examiner and coordinator for a clinical research project that was studying a local delivery antimicrobial for the treatment of periodontal disease. It was a large, multi-centered study utilizing 5 private practices in 10 geographically different areas (multi-centered) throughout the United States.

The clinical research study was a hands-on learning experience for me, beginning with the site initiation and investigator meeting. There were drug sponsor meetings, study monitor visits, subject advertising, recruitment and enrollment, case report form development, source documentation guidelines, and adverse event reporting, just to name a few of the responsibilities. Once enrollment of the research subjects was complete, I provided initial scaling and root planing and then followed up with periodontal assessments every 3 months for a year. The site investigator and the drug sponsor company's study monitor were very helpful in mentoring me about my role as a clinician/examiner. Networking with the other coordinators and examiners helped achieve a high quality study with 100% subject compliance.

When my career evolved as a clinical examiner for research clinical trials, the skills I had acquired as a dental hygienist came in to use. I conducted a thorough oral examination, periodontal assessments that included probing pocket depth, measuring attachment levels, grading mobility, and furcations. Studies also may include utilizing various periodontal indices for plaque, gingivitis, and bleeding. The protocols for each individual study direct the type of indices to be used. Measurements for all studies must be standardized to assure validity of the data collected. In order to achieve this standard, examiners must be calibrated for each study. I have participated in numerous calibration exercises all over the United States and with other examiners from as far away as Japan and Italy.

My role in clinical research has since expanded to administration, management, performing quality audits, and coordination of the projects. I saw opportunities for career expansion through my involvement in clinical research organizational groups such as the Society of Clinical Research Associates (SoCRA) and the Association of Clinical Research Professionals. The goal of these organizations, which include almost 30 000 members, is to provide opportunities and certifications that address the distinct educational and networking needs of those working in clinical investigations. I became a Certified

Clinical Research Professional (CCRP) through SoCRA in 2003 by studying, taking coursework, and then passing a certification examination. In order to remain certified, every 3 years she must complete 45 continuing education hours and pass a recertification examination that includes updates to the laws of the FDA and standards that guide quality clinical research. I stay abreast of clinical research education by being part of the U-M's Center for the Advancement of Clinical Research that includes clinical research physicians, nurses, and administrative personnel, and by attending the International SoCRA Annual Conference. Currently, I am co-coordinating efforts to maintain the SoCRA Chapter in the Great Lakes Region.

Wendy Kerschbaum, Director of the U-M Dental Hygiene Program, collaborates with me to provide clinical research experiences for the dental hygiene students within the Graduate Periodontics program and at the Michigan Center for Oral Health Research (MCOHR) facility where I work. The dental hygiene students can be found as work-study students participating on study teams at MCOHR or on required rotations their second and third years within the projects occurring in the U-M Graduate Periodontics Program. This rotational exposure and work experience is a benefit for our dental hygiene students to see how the dental hygienist can play an active role in clinical research. It provides them with another professional avenue they may someday want to pursue.

There are an increasing number of universities and colleges in the United States that provide courses for certifications in clinical research, as well as, bachelor's and master's degree programs in clinical research. The dental hygiene degree qualifies a person for the pursuit of these various certifications or degrees.

Below is a weblink for a list of clinical research training programs in the United States:

<http://www.aamc.org/research/clinicalresearch/training/start.htm>

Additional schools with certification, long distance; and/or degree programs are:

Campbell University

Cornell University

Eastern Michigan University

Ohio State University

University of Arizona Health Science Center

University of North Carolina

University of Texas SW Medical Center

University of Washington

Wake Forest University

There are many online resources for clinical research education, publications and training.

These may be governmental websites:

<http://hhs.gov/ohrp/>

<http://www.fda.gov>

Or professional, educational, or publication websites:

<http://socra.org>

<http://www.acrpnet.org/>

<http://www.barnettinternational.com>

<http://www.diahome.org>

<http://www.centerwatch.com>

<http://www.actmagazine.com/appliedclinicaltrials/>

Currently, I work at U-M as a Research Laboratory Specialist Senior, both in the Graduate Periodontics Clinic, directed by Hom-Lay Wang, DDS, MSD, and the Michigan Center for Oral Health Research, directed by William V. Giannobile, DDS, DMSc. Here, studies are sponsored through NIH, the University of Michigan, industry, and /or pharmaceutical companies. I have been part of clinical research studies that last from 6 months to 3 years and have included local delivery of various antimicrobials, periodontal drug development, various dental implants and implant techniques, different types of tissue grafts, multiple methods to repair bone defects, identification of biomarkers in saliva, and power toothbrushes. For more information about the work that I do, please contact me at maryl@umich.edu.