Successes and Challenges in Accessing US Research Infrastructure for Dental Practice-Based Research by Japan

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Introduction
The National Institute of Dental and Craniofacial Research (NIDCR), one of the institutes in the US National Institutes of Health, established a dental practice-based research network (DPBRN) in 2005 with a goal of contributing to clinical decision making among community based practitioners. A stable, comprehensive, and predictable infrastructure has contributed to the success of the program, which represents a federal investment over two cycles of funding (2005-2012, 2012-2019) of about US $130 million (nominal). In the first cycle, an international collaboration was built into the budget and the international members had access to the full spectrum of the research infrastructure funded by the NIDCR. In the second cycle, a professor at a Japanese dental school self-identified as a potential collaborator and subsequently established a dental PBRN in Japan. In this paper, we explore, from a policy perspective, the necessary and sufficient conditions under which an existing research infrastructure in the US can support PBRN research in another country such that the peer reviewed science literature and the clinical decision making by practitioners is enhanced in both countries.

Structure of the collaboration
The collaboration comprises four institutions: Kyushu Dental University in Japan; University of Florida College of Dentistry in the United States (US); the University of Alabama at Birmingham School of Dentistry in the US; and the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH) in the US. The NIDCR currently funds the US National Dental Practice-Based Research network through a seven year (2012-2019) grant award to the University of Alabama at Birmingham School of Dentistry, which in turn funds by contract that part of the PBRN operated at the University of Florida College of Dentistry. There is no direct or indirect funding from the NIDCR grant to the Dental PBRN in Japan.

Description of the National Institute of Dental and Craniofacial Research (NIDCR).
NIDCR is the largest funder of oral health research in dental schools and institutions in the US; about 75% of its annual budget of US$ 400 million is distributed to researchers at universities, medical schools, and dental schools, primarily in the US but also in other countries. NIDCR, as part of the National Institutes of Health, shares the commitment to international biomedical research, training of research and providers, and improvement in global health.
The mission of the NIDCR is to improve dental, oral, and craniofacial health through research, research training, and the dissemination of health information, which is accomplished by the following:

- Performing and supporting basic, translational, and clinical research;
- Conducting and funding research training and career development programs to ensure an adequate number of talented, well-prepared, and diverse investigators;
- Coordinating and assisting relevant research and research-related activities among all sectors of the research community;
- Promoting the timely transfer of knowledge gained from research and its implications for health to the public, health professionals, researchers, and policy-makers.

**Description of the US National Dental PBRN.**

The mission and vision of the US National Dental PBRN follow.

- **Mission:** To improve oral health by conducting dental practice-based research and by serving dental professionals and their patients through education and collegiality.
- **Vision:** To lead the field of dental practice-based research and dental collegiality.

NIDCR established a dental practice-based research network (DPBRN) in 2005 with a goal of contributing to clinical decision-making among community-based practitioners. More than 6500 dental practitioners have joined the network. DPBRN members identify clinical topics (for example, how to manage a broken tooth or when to intervene to fill a small cavity), a research protocol is developed with academic and other partners, and data are collected from the practitioners, their records, and their patients. About thirty studies have been developed to date and many have been completed. Study results have been disseminated in numerous publications in peer-reviewed journals. Study designs and results have also been disseminated and discussed at numerous formal and informal meetings with university faculty and dental practitioners.

In the current funding cycle, the US-DPBRN has a national headquarters located at the University of Alabama at Birmingham School of Dentistry. There are also six regional hubs covering the US, including the one at the University of Florida College of Dentistry.

The South Atlantic Region is based at the University of Florida in Gainesville, and it encompasses the states of Florida, Georgia, South Carolina, North Carolina, and Virginia. The South Atlantic Regional Hub has approximately 1410 enrolled members, a regional director, a deputy director, and four full-time research coordinators. The regional director is also the director of Practitioner Training and Education components for the entire national network. The University of Florida has been involved with the DPBRN since its inception in 2005 and led several of the very first studies of the DPBRN.
Infrastructure funds from the NIDCR support the following activities: recruit and organize practitioners; identify and select research topics of interest to practitioners; attract and engage academic investigators to become study principal investigators; convene meetings of multiple stakeholders to develop research protocols; facilitate regulatory, monitoring, and clinical oversight; hire, train and provide access to research coordinators; recruit and train dental practitioners to conduct studies in their practices; provide data management and analysis; and prepare or assist in the publication and dissemination of study findings.

**Description of the Japan Dental PBRN (Japan-DPBRN)**

The Japan-DPBRN was established after one of the authors (NK) visited the US-DPBRN in 2010. The Japan-DPBRN is currently acknowledged by the US Agency for Healthcare Research & Quality as an international network.

The mission of the Japan-DPBRN follows:

- To build research networks in which dental practitioners are the main actors;
- To share information on clinical research, which will have a beneficial impact on routine dental practice;
- To participate in international collaborative research and to send out evidence to the entire world;
- To enable dental professionals to participate in clinical research;
- To change dental professionals’ views of their daily dental practice and to make the practice more interesting;
- To contribute to the overall health of patients globally by improving the quality of dental practice.

In 2011, the Japan-DPBRN started the first international collaborative study with the US-DBPRN, entitled “Assessment of Caries Diagnosis and Caries Treatment in Japan,” which was a survey study of practitioners. The Japan-DPBRN was particularly interested in conducting this study because previous research revealed country-based variation in the proportion of dentists who indicated surgical intervention in proximal enamel. Participation in the collaborative study added data from Japan to the previously collected data from the US and Scandinavia. In the collaborative study, practitioners were asked about surgical intervention in enamel lesions in both low and high caries risk individuals. In the clinical scenario of low caries risk patients, the percentage of dentists by country who responded that they intervened surgically follows: Scandinavia, 0%; US, 40%; Japan, 47%. Also, most of the Japan-DPBRN survey participants responded that they would restore lesions within the enamel in high caries risk individuals. International comparisons such as these promote the assessment of each country’s dental health care system and dental education.

**Infrastructure support from US-DPBRN to Japan-DPBRN**

Above we listed the activities conducted in the US-DPBRN that define the infrastructure of the program in regard to developing, conducting, and reporting research studies conducted by practitioners. Numerous documents from completed studies were available to the Japan PBRN:
study plans, investigator's brochures, training materials, data collection forms, regulatory applications and documents, statistical analysis plans and results, presentations of findings, and manuscripts.

In addition to the research documents, the leadership of the US-DPBRN has documented lessons learned in regard to the design and operation of a DPBRN. Thus, the Japan-DPBRN was also able to receive documents about successful development and ongoing operation of a dental practice-based research network.

Consultation from US-DPBRN leaders was also provided directly, either in person when Professor Kakudate was in the US or remotely. The US National Director, Professor Gilbert, had multiple exchanges with Professor Kakudate. Professor Gilbert also addressed a Japan-DPBRN conference remotely. Considerable consultation from a regional director, Professor Gordan, was also provided to Professor Kakudate; in addition, Professor Gordan's institution provided a Visiting Professorship to Professor Kakudate, and many of their exchanges occurred in person. Professor Kakudate was also invited to attend and did attend US-DPBRN meetings and professional dental and oral health conferences. The three collaborators shared authorship on presentations and publications.

Policies that facilitated the collaboration
Policies, regulations, and practices that supported this international collaboration reside between and within countries at the federal level and between and within universities. The four institutions share the mission of creating and disseminating knowledge of dental and oral health care. There is support at each of the four institutions for national and international science collaboration. Such support includes the sponsorship of visiting and adjunct faculty and student fellowships. Each institution also shares the mission of education, training, and career development of dental practitioners.

• The National Institute of Dental and Craniofacial Research, funded by US taxpayers, is committed to making data and results from publicly funded research widely available. Grant recipients have always been encouraged to publish or otherwise share research findings, and a new law requires grantees to make some data publicly available. There is a new commitment to rigor and reproducibility in science and research in the US, and grantees are obligated to share details of research design and conduct, as well as planned and completed data analyses, broadly and transparently.

• Professor Kakudate commented on the interest of Kyushu Dental University in globalization: “We are really interested in the globalization of the DPBRN community. Global activities will enable us to assess each country’s dental practice and lead to the improvement of the quality of dental care and oral health outcomes.”

• The University of Florida is highly interested in international collaboration and has a goal of increasing globalization to enhance its effectiveness as world citizens. The University uses various metrics to assess its activities related to globalization, including percentage
of faculty, graduate students, and undergraduate students participating in study abroad experiences; percentage of faculty and graduate students participating in international conferences as participants, speakers, and leaders; number of visiting faculty positions from overseas; and number of international collaborative agreements in educational programs and research.

- During the 2005-2012 funding cycle, the DPBRN had a Scandinavian region. Administratively based at the University of Copenhagen, the region included practitioners from Denmark, Norway, and Sweden. The Scandinavian region contributed significantly to DPBRN and added to its diversity of practices and treatment philosophies. In Scandinavia, dental care for children is provided in school-based clinics, but the majority of care for adults is provided in private practice, which is very similar to adult treatment in the US, as well as some public health clinics. The approaches by Scandinavian dentists to prevention and treatment of dental caries is less surgically invasive than in the US, and thereby more in line with current scientific evidence. Additionally, the Scandinavian dentists served as change agents for US-DPBRN dentists, who also rated highly their interactions with them.

Another policy that supports the collaboration is the autonomy of the partners. Because of the senior faculty status of each of the university professors, they have autonomy over developing national and international research collaborations. They also manage their own schedules for allocating professional time and effort to such collaborations. Similarly, NIDCR grant recipients and subcontractors have autonomy to develop national and international collaborations, within award or contract constraints.

Both countries support the access of researchers to multiple sources of funds (private, university, government).
International laws supporting global trade and marketing support the development of technology that advances remote communication across and within countries.

Finally, the ability to travel between countries is obviously important to international science collaboration. Professor Kakudate was able to visit the US multiple times, including, earlier in his career, a year-long fellowship in the US.

**Successes of the collaboration**

Shared benefits include benefits to dental science, dental education, dental practice, and collaborating institutions. In regard to dental science, the collaboration allows for comparisons by geography, population groups and subgroups, dental education, dental systems, and dental practices. Conducting the same studies in two countries also advances science by identifying cultural differences in DPBRN study results. Differences in results between the two countries will also inform efforts to strengthen rigor and reproducibility in biomedical research. The collaboration facilitates the development of a community of scholars dedicated to dental practice-based research. The training of scientists and practitioners in multiple locations will increase the number of studies and the samples sizes overall, thus increasing the generation of knowledge, the reliability of findings, the generalizability of findings, and the dissemination of research findings. The research findings that improve the knowledge base for dental practice should lead to changes in dental school curricula.

In regard to dental practices, the primary shared benefit is access to an evidence base that informs clinical decision making, treatment planning, and patient education. Practitioners in both countries also benefit from professional development and continuing education and new interactions with other practitioners and university faculty. The comparison of dental treatment patterns in countries with different practice systems will facilitate the discussion of global standards for dental care. At the individual practitioner level, research findings from multiple countries and many practitioners lead to objective evaluation and change in one’s own practice. Practitioners in both countries enjoy participation in the DPBRNs, finding intellectual and personal satisfaction in contributing to the knowledge base for dental treatment.

At the institutional level, the collaboration has facilitated the leveraging of resources by all four collaborators. For example, NIDCR contributed no funds to the collaboration but will experience benefits because of the expansion of DPBRN knowledge and the enlarged community of scholars dedicated to oral health research.

**Costs of the collaboration**

As stated above, no funding was available from the NIDCR to support the Japan-DPBRN; however, the US-DPBRN was able to provide some resources at no cost and the University of Florida College of Dentistry, which is specifically invested in expanding its global outreach, also provided a modest amount of resources. Small amounts of public and private funds in Japan were available to the Japanese professor to support the Japan-DPBRN.
One way that costs were minimized for the Japan-DPBRN was that the Japan-DPBRN adapted already completed or implemented studies from the US DPBRN. Resources were devoted in the US but not in Japan to designing a study, creating and pre-testing initial data collection forms, and writing the investigator’s brochure and other documents; however, the documents served only as templates and had to be substantially modified for differences in language, culture, and dental practices.

**Challenges in the collaboration**

The roles of the National Coordinator and the Regional Coordinator are vital in the US-DPBRN. The Regional Coordinators have numerous interactions with Practitioners, including engagement in specific studies, training of Practitioners and staff, study monitoring, and study data management. The Regional Coordinators have numerous interactions with the National Coordinator. The Coordinators consult with study Principal Investigators to ensure that studies are appropriate for dental practices, and they also consult with the Coordinating Center staff on research design and data collection instruments. Finally, the Coordinators lead or assist in the planning and management of regional and national meetings. US-DPBRN was unable to support a National or Regional Coordinator role in Japan-DPBRN, thus limiting, for example, the complexity of studies, such as longitudinal clinical studies, available to the Japan-DPBRN.

There are also linguistic, cultural, and dental care system differences between the two countries that inhibited the collaboration. For example, the continuing education requirements for practicing dentists are different. In Japan, a dentist is licensed initially and does not have to renew the license. In the US, dental practitioners must regularly renew their licenses, thus making it necessary for them to complete continuing education. The US-DPBRN offered continuing education at a minimal or no cost to members, which facilitated the enrollment of members. Similarly, in the US, clinical research is a significant component of the dental school curriculum, but it is not in Japan. Thus, there are more dental school faculty in the US than in Japan who are accustomed to designing and conducting research, as well as securing research funds, and publishing research findings.

**Conclusions: What are the necessary and sufficient policies for a successful Dental PBRN collaboration between the US and Japan?**

Having reviewed the structure of the collaboration, the missions of the collaborators, the research infrastructure supported provided to the Japan-DPBRN by the US-DPBRN, the successes, costs, and challenges to the collaboration, we now identify the polices that were most beneficial to the collaboration. These reside in three domains:

- **Domain 1:** Shared mission, autonomy of researchers
- **Domain 2:** Federal and institutional support, few travel restrictions
- **Domain 3:** Access to multiple sources of funds
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