Necessity is the Mother of Invention: The Creation and Development of the International Chiropractic Pediatric Association’s Practice-Based Research Network

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Abstract

The vision of the International Chiropractic Pediatric Association (ICPA) is to establish and advance the chiropractic family wellness lifestyle on a global basis. Guided by this vision, the research arm of the ICPA is mandated to defend and promote the chiropractic care of children, women’s health and general family wellness care. The ICPA Practice Based Research Network (PBRN) was designed to support this vision and mission. Grounded by Participatory Action Research and the principles of evidence-informed practice, the ICPA PBRN remains the most successful practice-based research network in the chiropractic profession. With its ongoing studies, the ICPA PBRN continues to address issues relevant to the chiropractic care of children, pregnant women and general family wellness care.

Key Words: Chiropractic, Practice Based Research Network, pediatrics, maternal, spinal manipulative therapy, adjustment, human subjects, information technology, compliance

Introduction

Described as a collection of practice sites with the express purpose of improving clinical outcomes in real life settings, practice-based research networks (PBRNs) were originally conceived to address clinical research findings conducted under highly controlled conditions (i.e., randomized controlled clinical trials) that were difficult to generalize or translate to other populations and clinical scenarios. Today, due to their unique and significant contributions to clinical practice and research, they have grown in size and numbers. An examination of the Agency for Healthcare Research and Policy’s registered PBRNs include not only medical PBRNs but also dental, optometry and chiropractic.

The popularity of PBRNs can be attributed to a number of factors. These include their ability to generate data with high external validity (i.e., the results are applicable to usual care settings), relatively cost effective in terms of their implementation and address practice-relevant issues germane to its participants. Although PBRNs have been implemented in chiropractic, the International Chiropractic Pediatric Association’s PBRN stands as the most productive and successful PBRN in the profession. Began in 2009 from funding generated by ICPA members and its PBRN participants, the key justification for establishing this practice-based network was demonstrated in back-to-back studies characterizing the chiropractic care of children and to address safety and effectiveness concerns in pediatric chiropractic. These two studies provided the impetus for the creation of the ICPA PBRN Program. Following the review article by Vohra

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and colleagues\(^5\) on adverse events associated with pediatric spinal manipulation, there was a consensus within the ICPA and the chiropractic profession at large that a safety study was warranted to address the Vohra study. Spanning over 100 years of literature and finding only 14 cases of direct adverse events, Vohra and her colleagues erroneously concluded that pediatric spinal manipulation was associated with adverse events. The publication of this paper in *Pediatrics*, the Official Journal of the American Pediatric Association resulted in a number of articles in the popular media raising safety concerns that “spinal manipulation may not be safe for children.” Alcantara\(^6\) critically appraised the article by Vohra and colleagues and came to the conclusion that these authors misinterpreted and misrepresented their study findings. Vohra in a Reuters Health article was quoted as saying, 

“We found more harms associated with delayed diagnosis and/or treatment than with manipulation itself.”\(^6\)

What readers may not realize was that these adverse events due to “delayed diagnosis and/or treatment” were based on Letters to the Editor and from an anti-chiropractic book – both of which have no merit for scientific scrutiny.

The first ICPA PBRN study by Alcantara and colleagues\(^4\) found a prevalence of adverse events associated with pediatric chiropractic at three adverse events per 5,438 office visits from the treatment of 577 children based on chiropractor responders and two adverse events from 1,735 office visits involving the care of 239 children based on parent responders. Admittedly, this study was retrospective in nature and suffered from the limitations of recall bias on the part of the responders. This was followed by a prospective study examining safety and the findings indicate a risk of 1000 adverse events for 1 million children under chiropractic care for a period of 1 year.\(^3\) The second ICPA PBRN study characterized the chiropractic care of children in response to a publication by Lee and colleagues\(^10\) that purported to do the same. Unfortunately, the characterization of the chiropractic care of children by Lee and colleagues was based on a survey of 90 chiropractors practicing in the Boston metropolitan area. The ICPA study was arguably more representative of the practice of chiropractic in that it involved a more nationally representative sample of US chiropractors.

These initial studies undertaken by the ICPA PBRN provided for the essential development of its infrastructure and with subsequent studies, the ICPA PBRN evolved and developed. To date, we have implemented the ICPA PBRN to characterize the chiropractic care of pregnant women\(^7\) and the use of the Webster technique in the pregnant population.\(^12\)

This list is by no means complete as we have completed studies on the attitudes, beliefs and practice activities of chiropractors in the context of evidence-based practice, the quality of life of chiropractic patients (i.e., pregnant and non-pregnant adults) under Webster Care and children using the Patient Reported Outcomes Measurement Information System.

Despite the success and productivity of the ICPA PBRN to address issues in chiropractic family practice; to date, no report in the literature exists to describe the function and structure of this successful chiropractic PBRN. The information provided herein is important not only for chiropractic practitioners but also to academics who wish to engage in practice-base research.

The ICPA PBRN Infrastructure

The vision of the ICPA is to establish and advance the chiropractic family wellness lifestyle on a global basis. Guided by this vision, the research arm of the ICPA is mandated to defend and promote the chiropractic care of children, women’s health and general family wellness care. The ICPA PBRN was designed to support this vision and mission. According to Green et al.\(^13\), there are certain elements of a PBRN infrastructure that are essential for its successful implementation. These include a research director, a coordinator, a means of communicating with membership practices, a membership roster, a provision for meetings, and an organized means of ensuring human subjects protection.

Research Director: Dr Joel Alcantara, BSc, DC

Dr Alcantara is the Research Director of the ICPA. In this capacity, he is also the Director of the ICPA PBRN. He is ultimately responsible and accountable for the successful (or failure) operation of the PBRN. He is responsible for ensuring that projects undertaken are congruent with the network’s research focus and mission, resources, and other research endeavors undertaken by the ICPA. For example, at the time of writing this article, two new PBRN studies received Institutional Review Board approval for implementation while at the same time a study characterizing the force-time measurements of spinal manipulation applied to infants, children and adults was completed. The research director must ensure the timely execution and completion of these various projects in light of limited resources/funding and time constraints.

PBRN Coordinator: Dr Jeanne Ohm, DC

As Chief Executive Officer of the ICPA, Dr Ohm is responsible for the day-to-day operation of the ICPA. In this capacity, she naturally fit the position of PBRN coordinator and is also responsible for the day-to-day operations of the PBRN. In both capacities as CEO and PBRN coordinator, Dr Ohm assumes the overlapping roles as research manager, an infrastructure administrator, and an assistant to the PBRN director.

One-Way Communication with ICPA Members.

The ICPA PedEx Newsletter serves to inform the ICPA membership and the chiropractic profession in general on recent news of interest, including the ICPA PBRN. This is augmented by a Research link on the ICPA website to inform and educate interested individuals on the research efforts of the ICPA and the means by which to participate in various ICPA PBRN Projects.

Two-Way Communication with ICPA Members.

The 2-way communication function of the ICPA PBRN is supported by the ability of member practices to email questions to the PBRN Director and participate in a Clinical Forum where ICPA members are required to actively sign-in
with password and username. In addition to questions regarding their PBRN participation, active members can make inquiries pertinent to daily practice and receive responses from participating members as well as from the instructors of the ICPA post-graduate program.

**Membership Roster**

As part of the ICPA membership benefits and services, all practitioners are listed in a referral network and also form the roster database for PBRN studies.

**ICPA Board**

The ICPA is a free-standing non-profit 501C(3) corporation and have a Board structure dictated by its legal status. The ICPA Board of Directors also functions to run the ICPA PBRN from a top-down approach. The Board of Directors developed the vision, missions and goals of the organization and mandated its Research Director to develop an action plan from a research perspective to meet the strategic goals and objectives of the ICPA.

**Human Subjects Protection Management**

The ICPA PBRN members must fulfill a number of requirements for participation. For participation, PBRN members are required to have training and certification in human subjects protection. The required training program is the Protection of Human Subjects offered as an online course by National Institutes of Health. The PBRN infrastructure provides a means of determining certification and provide support for assisting access to the online course through the ICPA website.

Thus far, all ICPA PBRN projects have received Institutional Review Boards (IRB) approval from Life University (Marietta, GA) and/or Life Chiropractic College West (Hayward, CA).

**Mission-Dependent Infrastructure Elements**

**Research Assistants**

The ICPA PBRN program is wholly funded by the ICPA and its practitioner-members. The ICPA employs a number of individuals that function as research assistants based on their qualifications for the specific research undertaken.

**Information Technology Infrastructure**

Each project undertaken by the ICPA PBRN has a dedicated database designed and created specifically to meet the needs of collecting and processing data obtained for the study. Multiuser databases containing potentially sensitive information are restricted to the appropriate personnel with careful attention to username and password protection requirements for access.

**Regulatory Compliance**

All PBRN participants must comply with the Health Insurance Portability and Accountability Act (HIPAA). HIPAA compliance requirements are also formalized in an agreement between the ICPA and its member practitioners, wherein the ICPA PBRN is privileged to patient data for purposes of the study or to perform a quality audit.

**Research Consulting Expertise**

When required, the ICPA PBRN will recruit statistical consultation and research methodology expertise through formal consulting arrangements.

**Lesson Learned: Value and Sustainability of the ICPA PBRN**

- With over 4,500 members worldwide, the ICPA is the largest and most successful pediatric chiropractic organization in the profession. This is attributable in large part to the success of its post-graduate seminars (i.e., 150 scheduled seminars yearly), its advocacy for the chiropractic care of children, pregnancy care and general family wellness care through patient education, service and research. Towards these efforts, the ICPA Board of Directors have mandated the vision, missions and goals of the ICPA are of sufficient value for its practice members, thus ensuring that the organization not only survives but thrives. It is this critical mandate from the ICPA Board that the ICPA PBRN research efforts are of value to its members and the rest of the chiropractic profession.

- Key informants attending the ICPA post-graduate seminars or from clinicians involved in a variety of functions for the ICPA have been an integral part in the decision-making regarding what and how to study a clinical issue, and how to analyze and frame the data. This collective, self-reflective inquiry among the ICPA members to understand and improve practice of chiropractic is grounded in Participatory Action Research. The ICPA PBRN reflects Participatory Action Research in that the focus of our research is to enable action. In the process of patient care, PBRN Chiropractors participate to collect and analyze data and based on iterative self-reflection, determine what action to follow within their individual practices. The patients as study subjects become partners in the research process. As such, both the practitioner and their patients are actively involved in the process of research.

- Research in a natural setting such as that in chiropractic practices is arguably more relevant and generalizable. As participants of research, clinicians are more likely to use or implement the results of research. In the world of classical research design, this may be attributed to the Hawthorne effect (i.e., observer expectancy effect), and viewed as contamination. However, new paradigms of research such as practice-based research embraces this phenomenon and viewed as a benefit.
The ICPA PBRN receives financial support from the ICPA general operating funds to maintain its infrastructure. Therefore, the research undertaken reflects the values and interests of the ICPA membership.

Summary

Grounded by Participatory Action Research and the principles of evidence-informed practice, the ICPA PBRN remains the most successful practice-based research network in the chiropractic profession. With its ongoing studies, the ICPA PBRN continues to address issues relevant to the chiropractic care of children, pregnant women and general family wellness care.

References