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Buonocore Memorial Lecture

How to Bridge Research Results to Everyday Clinical Care?

Michael Buonocore

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Clinical Relevance

Partnering with health providers on studies that address everyday clinical research questions through practice-based research is a potential solution to speed up the translation of research findings.

SUMMARY

Laboratory and clinical studies are essential to the advancement of sciences. However, a significant gap exists between the research findings and clinical practice. Therefore, research findings can be of little importance if their outcome cannot be directly or indirectly applied to everyday clinical care or readily translated. This paper focuses on how we can shorten the gap between the generation of new knowledge and their implementation into everyday clinical care. A new model is discussed where clinicians are the ones generating the research idea are paired with researchers. They collaborate on studies whose results are readily applicable to everyday practice. Partnering with health providers on studies that address everyday clinical research questions is a potential solution to speed up the translation of the research findings. Generating clinically applicable results can better improve the health of the public. Quoting Dr. Lawrence W. Green: "If we want more evidence-based practice, we need more practice-based evidence." This paper presents the practice-based research model as a solution to address this knowledge gap.

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INTRODUCTION

It is an honor to be the recipient of the Buonocore Memorial Lecture and to once more celebrate his findings at the Academy of Operative Dentistry annual meeting. Dr Michael Buonocore believed in making a difference in patients' lives, challenged existing paradigms, and was a forward thinker who just over 50 years ago revolutionized how we think today about prevention and restoration.[1] With the concept of adhesive dentistry, he gave another dimension to how we restore teeth today, and as a

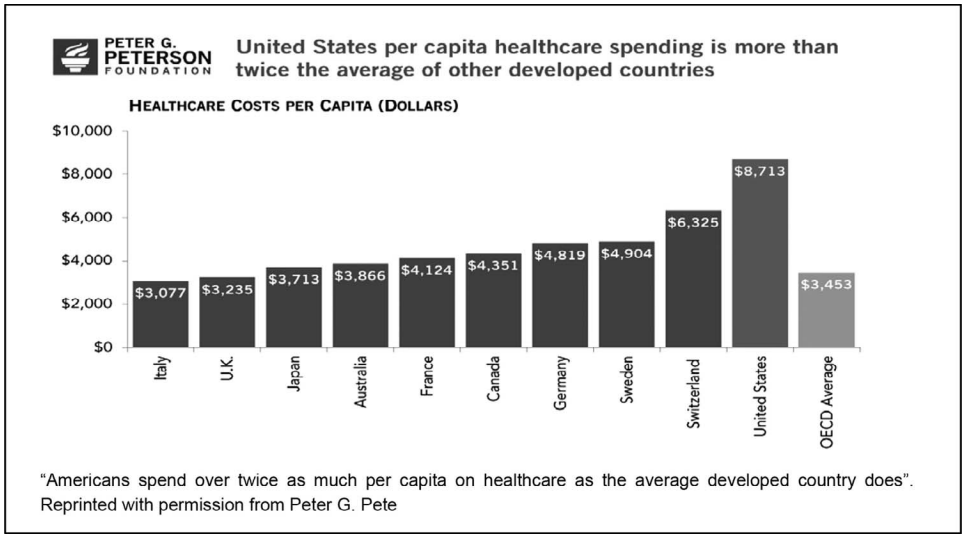

Figure 1. *Bar graph illustrating the per capita health care costs in the United States and several leading countries* for November 2015.

result, dentists can propose minimal intervention dentistry that ultimately benefits patient's health. That is where I would like to get started: on patient's health.

The cost of health care in the United States has been consistently higher than other developed countries, and it has dramatically increased in the last decade.[2] The Peter G. Peterson Foundation is an American foundation established in 2008 by Peter G. Peterson, former US Secretary of Commerce. It works to find fiscal solutions to help secure the country's economic growth. According to government projections, health care expenditures are projected to climb to 22% by 2039. Americans currently pay about twice as much per capita on health care as other leading nations. The annual cost per capita has remained high, approaching $9000 for the last four years (Figure 1). Therefore, one would expect that because the United States spends significant funds on health care that the life expectancy would be higher. Unfortunately, that is not the case, and the life expectancy in the United States is still below several leading countries.[3]

Significant time and money has been spent in biomedical research in the United States[4] and worldwide. We have accumulated a significant number of clinical and *in vitro* study results. Despite the immense amount of new knowledge, health in the United States is still below our expectation and below several industrialized countries. Several reasons need to be considered; however, we can focus on the following three. 1) A significant delay exists between the generation of new knowledge and its application into the medical/dental practicing community where it is delivered to patients. It takes an average of between 17 and 24 years to translate study findings to routine clinical practice.[5] 2) Too often, the study results are not immediately applied to everyday clinical care (ie, the results cannot be applied to benefit the patient's health).[5-7] 3) There is insufficient research that is evidence based on clinical practice for clinicians to make the correct choice during their decision-making process.[8] It is estimated that as little as 8% of clinical practice is based on peer-reviewed and critically appraised evidence.[9,10]

One example that has been my research interest is the treatment of defective restorations. It is one of the most frequent problems encountered by general practitioners today and accounts for more than 50% of all the treatment performed in general dental practice.[11-13] Several *in vitro* and clinical studies have shown that removal of the existing restoration will significantly reduce sound tooth structure, resulting in subsequently larger dental restorations.[14-17] Additionally, the removal of existing restorations may cause further trauma on the tooth with possible dentinal/pulpal response to thermal, chemical, or mechanical stimuli, depending on the size and depth of the existing restored site.[18-20] The consequence of replacing existing restorations could alter the outcome of the tooth and result in additional cost and time of treatment. All of these issues have a negative effect on patients. Two separate groups of investigators[21-26] through clinical studies have concluded that the repair of defective restorations is a viable treatment option that increased the longevity of the original restoration. Despite the results of the clinical studies involving the repair of restorations and several schools

including the teaching of repair of restorations in their curriculum,[27-30] most clinicians still do not routinely consider the repair or sealing of defective restorations as a viable treatment option,[31-34] and patients who may be eligible for repair of restorations are not offered this alternative treatment. One study published by the Dental Practice-Based Research Network (PBRN) in the United States involving close to 10,000 restorations (9875 restorations in 7502 patients) concluded that 75% of clinicians chose replacement over repair of defective restorations.[35-37] We also learned that dentists' decisions and bias will actually affect the restoration longevity.[35] A survival analysis of posterior restorations using an insurance claims database concludes that patients who change dentists are far more likely to have restorations replaced than if they do not.[38] An interesting finding is that most patients accept the repair of defective restorations. In another practice-based study involving close to 10,000 restorations and 200 clinicians, we assessed the behavioral aspect of patient satisfaction and found out that overall patient satisfaction was higher when the defective restoration was repaired compared with replaced.[39,40] Another study by the Network assessed the outcome of almost 6000 restorations that had been repaired vs replaced after 12 months by 195 dentists. The results showed that repaired restorations were less likely to need an aggressive treatment than restorations that had been replaced. Overall, the failure rate was low (n=378 [–6%]). When the restoration required additional treatment after the one-year follow-up, it was less likely to need a replacement, a root canal treatment, or an extraction if the restoration had been repaired (74%) rather than if it had been replaced (85%). In other words, although some repaired restorations failed, the failure was not catastrophic, it was a "friendly failure": a failure that could be repaired.[37]

PARADIGM SHIFT

Despite all the efforts to study the treatment of defective restorations and ways to improve the longevity of the tooth and existing restoration through clinical studies, clinicians still do not routinely consider the repair of defective restorations as a viable treatment option. Therefore, a knowledge gap exists between the generation of new knowledge and its application to routine clinical care. How do we bridge the gap between research and clinical practice? How do we make sure that the topics being researched are of interest or will benefit the majority of the public at large? How do we make sure that once research findings become available that they will actually be implemented in dental and medical practices? These questions must be addressed if we hope to improve health while reducing costs.

Taxpayers and the public are very interested in immediate benefits from research investment.[41] Search engines have been created an easy way for the public to access the results generated from federally funded research (eg, http://www.ncbi.nlm.nih.gov/pubmed; http://www.nidcr.nih.gov/oralhealth/; http://www.webmd.com/; http://www.healthline.com/; and http://www.nidcr.nih.gov/research/ResearchResults/NewsReleases/). The committee for economic development concluded that "increased public access accelerates progress in science by speeding up and broadening diffusion of knowledge" and "increased public-access policies should be judged by their impact on the society and the development of high-quality scientific research." This opportunity for patients to access new results may lead patients to choose providers who rapidly implement research findings. A way to speed up the implementation of the research findings into clinical practice is to involve practitioners in the research process. That opportunity now exists with the creation of practice-based research (PBR). The commitment from the National Institute of Health (NIH) to fund PBR consolidates and attests where research efforts are headed (http://www.nidcr.nih.gov/research/ResearchResults/NewsReleases/CurrentNewsReleases/NDPBRN.htm and https://www.dentistry.ucla.edu/events/research-symposium-0).[42-44]

PBR is done by a teamwork approach: an effort in which clinicians and investigators work together to address clinical research questions that will ultimately benefit patient's health.[45] Dental practice-based research is conducted by dentists who are affiliated to investigate research questions and to share experiences and expertise. The dentists provide dental care to the public and are affiliated with an academic center that serves as the administrative base. The research is done by practitioners in and about the "real world" of dental practice, where the majority of the population receives its dental care. Practice-based research is not a new concept. It was introduced by the medical field back in 1970s. In 2012, AHRQ (Agency for Healthcare Research and Quality), US Department of Health & Human Services, identified more than 150 primary care PBRNs operating across the United States with more than 55,000 clinicians in more than 17,000

locations, serving approximately 46 million patients. Today, there are more than 170 networks registered at the AHRQ website.[43]

A handicap in most *in vitro* and some clinical studies is the translation of the research findings to everyday clinical practice. One limiting factor of traditional institutional-based clinical study is the lack of generalizability and external validity.[46] The result findings may not be readily applicable to everyday patients. Even if the findings are applicable to the everyday patient care, it takes time to translate the research results to everyday clinical practice. PBR addresses these obstacles in two ways: 1) it generates evidence-based knowledge with good external validity (the results apply to populations involved in the study (ie, the evidence comes directly from the end user, "the everyday patient"); and 2) PBR speeds up the adoption of the research findings by dentists who participated in the study. Passive absorption of knowledge usually does not work or works slowly.[5] In PBR, clinicians are involved in the entire research process from its inception: asking the clinical questions, gathering the research findings, and being involved in its dissemination. As the practitioner is involved in the research process, it is more likely that he or she will implement the research findings into their routine delivery of clinical care.

Although a well-conducted randomized clinical trial (RCT) is typically the most scientifically rigorous design for clinical studies, it is not always the best design to help move scientific evidence promptly into routine clinical practice. A key advantage of most PBRN studies is that they intentionally do not use highly selected samples, but instead enroll consecutive patients for whom certain treatment options would be appropriate. In that manner, they maximize the generalizability of conclusions made about treatment effectiveness. They also allow for an analysis of the process of care, such as determining which patients are offered treatment by clinicians and which patients choose to accept it, a possibility precluded in a RCT design.

The benefit of PBR supersedes the notion of access to large number of patients. Besides the diversity of patient population, it is in PBR where "effectiveness can be measured, where new clinical questions arise, and where readiness to change and adopt new treatments can be studied and addressed."[45] It is also "where the interface between patients and their physicians can be explored and medical care improved."[45] Two main points are critical for the success of PBR: 1) it needs to address questions that practicing clinicians judge to be important with the potential the results could improve clinical practice; and 2) the research must be feasible in most busy clinical practices.

What drives clinicians to participate in PBR? According to multiple testimonies over the 11 years of the existence of the Dental PBRN in the United States, participants reported that they 1) desire interaction with other colleagues in the dental field; 2) want to belong to a community or entity, 3) have a desire to give back to the profession, and 4) want to know the answers to everyday clinical questions.[47] Participants seek evidence-based answers to clinical questions and do not want to rely on biased opinions. Most information that is directed to clinicians is manufacturer driven, and bias is a major concern. The desire to be a part of a community that values answers informed by high-quality research drives most clinicians to join PBR.

Because networking with colleagues is important to practitioners, it is important that PBR allow an environment that fosters these interactions. One strategy is annual or semiannual meetings in which interaction with fellow practitioners is promoted. In those meetings, time is set aside for discussion among colleagues about the research results, including how to best implement the results into practice.

We discovered at the end of one of our interactive meetings that a significant number of practitioners actually changed how they practice as a result of the interactive discussion with their fellow clinicians. The improvement was toward using more prevention to treat dental caries and delaying the surgical treatment process in certain instances, according to the latest evidence-based research results.[48,49] We learned that a highly interactive meeting with fellow practitioner-investigators could be an effective mean to apply scientific findings into clinical practice, as clinicians reported that they would change how they treat patients as a result of being engaged in the scientific process. This "change in intention" is consistent with the health change theory, which suggests that this step is a prelude to the subsequent next step, which is the actual implementation of change in the practice.[50,51]

Another benefit to the clinician's career of participating in a PBR network is that it provides clinicians an opportunity to present the research findings at national and international meetings. This is a benefit not only to the clinicians, but also for the research community in which the paper is being presented, as researchers and academicians

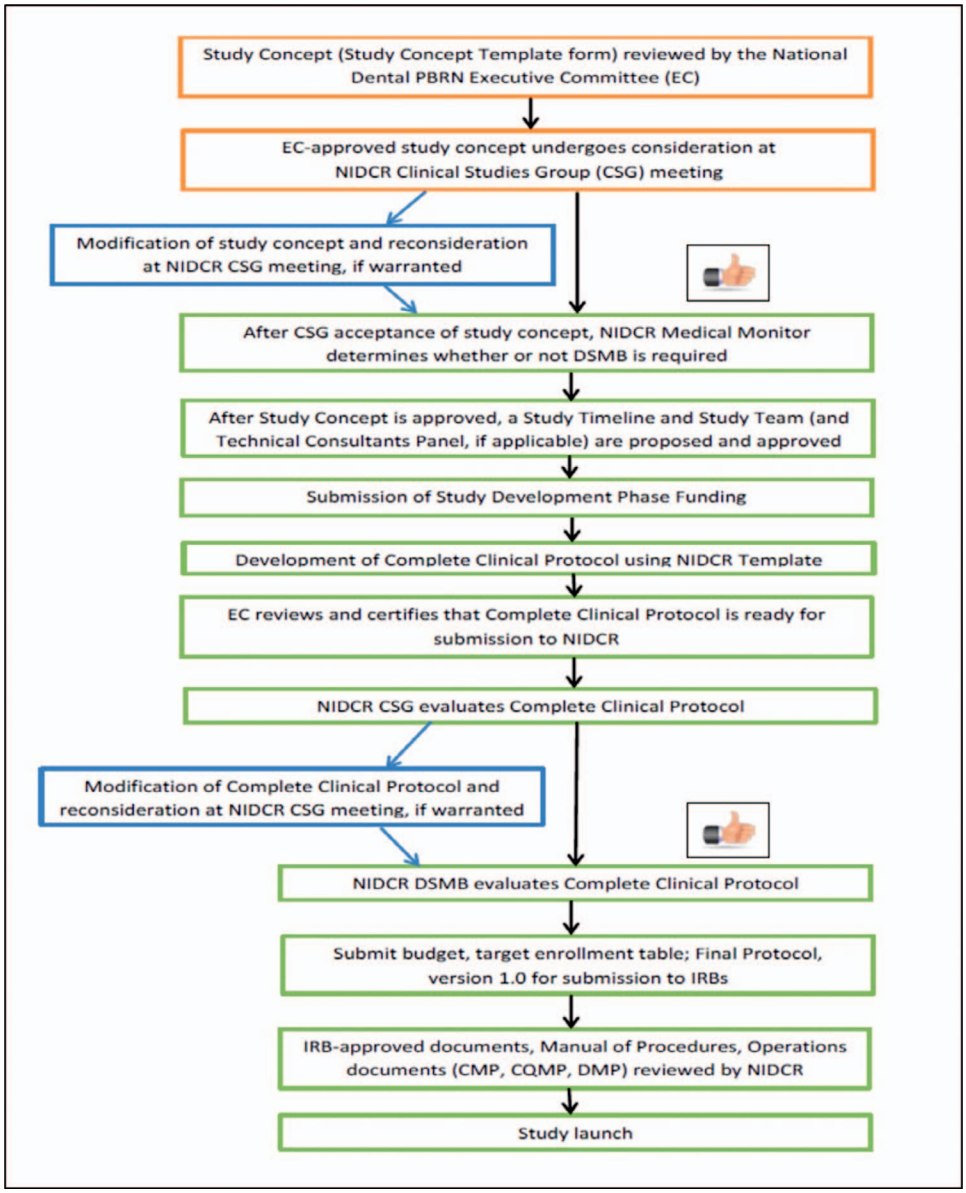

Figure 2. *Example of a diagram illustrating the steps from study concept to study launch by the National Dental PBRN funded by the NIH-NIDCR (http://www.nationaldentalpbrn.org/study%20development.php).*

get to hear from a clinician working in everyday practice about their experiences. PBR promotes interaction of researchers and academicians with their fellow practitioners and another opportunity to be a part of the research and educational processes.

One of the biggest challenges of practice-based research is to coordinate all the parts involved in the research process. We have learned that a lot can be accomplished when we have an organized teamwork approach. The academic institution provides a framework for the development of practice-based research, creating opportunities and resources for all those involved to be a part of the research process, but this would be meaningless if it did not have the involvement of the teams in the offices as the gathering of the research data takes place by the clinician and the dental team.

There are various steps involved in the PBR research process, from idea generation by the clinician (through the development of the study concept) all the way to the study launching (Figure 2). After a study concept is approved by both the executive committee and National Institute of Dental and Craniofacial Research (NIDCR) Clinical Studies Group, a study team is formed composed of statistician, one or more research investigators, private practitioner(s), research coordinator, a data manager staff, and a principal investigator. The study team will then develop and submit a complete clinical protocol using the NIDCR clinical study

protocol template.[52] After the approval of the complete protocol, the Coordinating Center will support the study team in the development of all required study startup documents, such as the Operations documents, Statistical Analysis Plan, Manual of Procedures, and Case Report Forms, using the NIDCR Toolkit templates.[53] Once all the forms are completed and approved, the study is implemented in the offices that agreed to participate and that had completed the training requirement for participation in in-office research.

Throughout the 11 years of existence of the dental PBR in the United States, we learned that patients' attitudes toward participation in dental research and experience with the delivery of care were valuable. We generated valuable results in the studies that had patient participation, ie, not only the attrition rate on survey studies was low, but also the overall response was positive. One behavioral science study involving 8000 patients asked patients about their dental office experience and their satisfaction with the dental procedure received.[39,40] Because we wanted to make sure that the anesthesia had worn off when patients responded the questionnaire (so that the report would be most unbiased), patients had to respond no sooner than 24 hours, which meant that they would have left the office when they responded. The research group had some concern if patients would remember to respond to the questionnaire and mail it accordingly 24 hours later. We were pleasantly surprised with a 78% patient response rate. According to dentists' reports, patients enjoyed being a part of the research process and appreciated the fact that the dental office was involved in research. Although there was some compensation for patients to participate (a $10 gift card), some patients returned the card back to the research as they felt it was "their responsibility to contribute to science."

We also learned that it is fundamental for clinicians to be a part of the dissemination of the research findings. In fact, we learned that clinicians may respond more positively to findings presented by other clinicians rather than by academic researchers. Therefore, close to 70% of publications and presentations from the National Dental Network include at least one full-time practicing clinician as a coauthor.[54,55] The roles of the clinicians have ranged from presenters, to coauthors, to lead authors. It is our impression that when a clinician working in the field presents the data, there seems to have a more positive interaction between the presenter and the audience. There is a higher sense of ownership and experience that is shared as opposed to a researcher who may understand the clinician's experiences, but is not participating in the daily routine of the dental office.

Another approach to communicate with clinicians about research findings, particularly those who participate in studies is to summarize their individual study results and to compare them with other practitioners working in their region and network-wide (ie, nationally). The careful analysis of their individual study results creates opportunities for them to reflect on their decision-making process and quality of care and if applicable consider a change in their practice pattern. Therefore, the Network will provide a summary of the research findings to those participating in the research process. The findings have bar graphs and/or tables illustrating the research results and a sentence summarizing it.

PBR is an excellent venue to foster international collaboration. Besides the exchange of information among clinicians and researchers, it explores the unique aspect that diversity of patient population and culture brings to the scientific process and discovery. The National Dental Network in the Unites States (http://www.nationaldentalpbrn.org/) favors global collaboration. At the request of the NIDCR Director, Dr Martha Somerman, the International Association of Dental Research Network workshop in Boston in 2015 included global/international collaboration as a discussion topic. The symposium had 20 guests from various countries with representation from most continents on the globe. Some discussion has already been initiated among some countries and ongoing work anticipates a fruitful collaboration.[56-60]

FUTURE PLANS AND CONCLUSIONS

In conclusion, what does the future hold for clinicians and researchers? Three important key points to consider before formulating new research ideas: 1) research approaches and methods must be timely, relevant, nontraditional, and practical[61]; 2) traditional federally funded or corporate-funded research in academic institutions has significant value that can complement the studies that are conducted in PBRNs, but they must be innovative and readily applicable to survive in today's research climate; and 3) engaging clinicians in the research process will increase the potential for research that is relevant to daily practice and it will speed up the translation and dissemination of research findings that is fundamental to advancing population health. PBRNs can be an effective avenue for translation of

research findings as participants serve as change agents.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the University of Florida IRB 01. The approval code for this study is 161-2005.

Conflict of Interest

The author of this manuscript certifies that she has no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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