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Tele-Care (TC) For Comparative Individual Patient Effectiveness Research (CIPER) In Dentistry

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Abstract

In the context of translational healthcare, the construct of Evidence-Based Dentistry (EBD) consists of two fundamental and intertwined domains. From the viewpoint of research, EBD is driven by the paradigm of comparative effectiveness research, which seeks to uncover the consensus of the best available evidence. From the perspective of dental practice, EBD strives to provide patient-centered, effectiveness-focused and evidence-based treatment intervention. Patient-centered care implies that the best evidence base that serves as the basis of effectiveness-focused intervention must be derived from a process of comparative individual patient effectiveness research (CIPER). Patient-centered care also implies that novel tele-health communication technologies (Tele-Care, TC) must be developed and standardized across dental specialties to distribute the best evidence base to clinicians, patients, caregivers and other stakeholders in real-time. In brief, the next decade will witness significant progress in perfecting EBD by improving TC modalities of distribution of the consensus of the best evidence base obtained through stringent CIPER protocols.

Keywords: Evidence-Based Dentistry (EBD); Patient-Centered Dental Care; Effectiveness-Focused Dental Care; Evidence-Based Dental Care; Comparative Individual Patient Effectiveness Research (CIPER), Tele-Care (TC); Tele-Health Communication Technologies; Stakeholders

Introduction

We have discussed in depth elsewhere [1] translational research, defined by the National Institutes of Health as the characterization of the patient's pathology based on biological research of the biopsies obtained from the patient and processed in the laboratory, and the integration of this new knowledge in the clinical decision-making process for treatment. We also discussed the concept of translational effectiveness, defined by the Agency for Healthcare Research and Quality as the performance of comparative effectiveness research designed to elucidate the quantitative and the qualitative consensus of the best evidence base for delivering patient-centered, effectiveness-focused and evidence-based treatment [1]. It is self-evident that translational research and translational effectiveness are two sides of the same coin, that is translational healthcare, which will be, beyond doubt, the choice model of care in the next decade and beyond, across the various division of health care, from dentistry, medicine, epidemiology, clinical psychology, nursing, pharmacy and related allied fields.

The domain of translational effectiveness is in and of itself a complex domain, a meta-construct that requires attentive and stringent validation. At its center lays the systematic process by which the consensus of the best evidence base is obtained. That step corresponds to the process of comparative effectiveness research, which we examined in depth elsewhere [2-4], and that proceeds from the research synthesis design, the assessment of the level and the quality of the evidence, the analysis of acceptable sampling, and qualitative and quantitative (i.e., meta-analysis) consensus of the best evidence [1-5].

Other important steps in translational effectiveness involve the process of dissemination of the best evidence base to clinicians, patients, caregivers and other stakeholders, with the purpose and intent of raising health literacy. To be clear, the process of optimization of information dissemination is one critical component of translational effectiveness. The receptivity and engagement of all the stakeholders that must be involved in an informed clinical decision-making process [6] is another critical aspect of translational effectiveness. Last but not least, it is self-evident that the purpose of disseminating the best evidence base to the interested parties must be with the intent of raising the level of awareness and knowledge of the stakeholders – that is to say, raising their health literacy specifically as it pertains to the novel evidence-based consensus: health literacy is a third critical *sine qua non* area of scientific endeavor to ensure translational effectiveness [1,4].

Evidence-Based Dentistry

The American Dental Association defined evidence-based dentistry in 1999 as "…an approach to oral healthcare that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment needs and preferences...". That is to say, evidence-based dentistry (EBD) is a patient-centered approach to dental treatment decisions, which provides dental care that is focused on effectiveness (i.e., increase patient benefits, decrease costs and risks), and that is based on the best (i.e., acceptable sampling derived from systematic assessment of the level and the quality of the evidence) available (i.e., most current) scientific knowledge. The best evidence based thusly generated is reported in systematic reviews, which are the primary dissemination tool of comparative effectiveness research.

Another increasingly useful and popular means of disseminating the consensus of the best evidence base is subsumed under the general term of "tele health", or tele-care (TC). In brief, tele health, or TC, is a component of the health care system that connects patients and healthcare providers through the use of communication technologies [1,4]. Starting in 2005, specialty infectious disease tele-consultations have been provided through Army Knowledge Online. According to the Association of Military Surgeons, from 2005 through 2008, infectious disease TC consults ranked second in the total number of online consults.

Today, TC technologies for that specific purpose vary in their nature and application, including but not limited, to video consultations, online health records, sensors that monitor movement, medical devices and dental implants, and computer based information systems to enhance the access. TC falls into one of five general types [1,7]:

a. Care provided long-distance (TC)

b. Electronic health records,

c. Decision support systems,

d. Web-Based packages, or

e. Assistive information technologies.

The health care provider (i.e., dentist, physician, nurse) can perform TC in the form of tele-consultation and tele-diagnosis through the use of these electronic applications [1,8]. That is to say, TC enables patients who live in rural areas or far away from health care services to receive the best available treatment and care in a cost-effective modality. It ensures that dentists and other healthcare providers connect and treat patients in need with the proper communication technology in place.

With improving technology, TC has much potential as a healthcare service, particularly in situations such as complex dental interventions (e.g., one-day crowns, immediate loading or delayed loading dental implants, mini-implants, inlays and onlays, etc.) By substantially reducing the cost of healthcare delivery and increasing instant access to providers without the need to travel, TC technologies improve the quality of dental care, and healthcare in general given to the patients in inaccessible communities, and raise patient and healthcare provider's satisfaction [7,8].

Implementation of TC communication technologies for mentally handicapped patients, elderly and disabled patients, and other special populations is particularly important, because TC can be optimized through the use of an electronic application across the five domains listed above. The same benefits of TC scan also be obtained with other difficult patient groups, such as patients with high levels of dental anxiety and dental phobia, homeless and destitute patients who live in poverty-stricken environments and have access – at best – to dilapidated healthcare structure with intrinsic limits of patient access to clinical services. In these extreme situations, TC can vastly improve the wellbeing of dental patients in need of simple restorative dentistry or more complex and involved endodontic, periodontal or prosthodontic treatment intervention.

Patients who are afflicted with serious infectious diseases, such as HIV/AIDS, Ebola, Zika, and other communicable diseases, are oftentimes quarantined due to the infectious nature of the disease. These patients can be diagnosed and treated for dental problems and oral pathologies by means of TC, even if dentists, physicians and nurses are ordered to stay a safe distance away from those infected to prevent transmission of the virus from other vectors while providing diagnoses and treatment assistance via electronic devices. That is in part the reason why tele-consultation, a low-cost and low-bandwidth exchange of information between health specialists and patients when specialists are not available, is among the most common type of tele-health service in developing countries [1,7,8].

Tele-health has shown great promise across a variety of health problems, and TC is increasingly benefiting dental patients as well [9]. But, this will be obtained only if concerted research is sustained in this field, which must include the development of faster and more user-friendly technologies [1,7-9]. Improved TC technologies require, particularly in the field of dentistry, seamless interconnectedness among clinical professionals and direct access to patients in critical needs.

In dentistry, and in other domains of healthcare, the need for cutting-edge, reliable, fast and hack-free TC is unquestionable. When implemented effectively, TC will greatly increase the treatment and care for dental patients.

One aspect of TC that is fast emerging with increasing relevance to situations of complex dental interventions, or to some of the more difficult patient populations briefly outlined above, is that it must ensure individualized, patient-centered care. Consequently, one important development in translational effectiveness that must go forth hand in hand with new developments in TC, require the validation of new research tools and protocols to analyze and interpret individual patient data [1-5].

The term individual patient data refers to the availability of raw data for each study participant in each included trial, as opposed to aggregate data (summary data for the comparison groups in each study). Reviews using individual patient data require collaboration of the investigators who conducted the original trials, who must provide the necessary data. From a methodological standpoint, the domain of individual patient data gathering, analysis and inference needs to specify the specifics of the individual patient data outcomes under study – *viz*, individual patient data outcomes research. This requires a cogent characterization of the variables to measure, the analyses to plan and the type of data (i.e., qualitative vs. quantitative; categorical vs. continuous) to gather. Thence will derive the type of analyses – usually longitudinal repeated-measures type analyses [1,2,10] – that will be most appropriate and informative.

That is, altogether, relatively simple for a research methodologist and biostatistician involved in the type of study outlined here. What become several orders of magnitude more complex is the performance of a research synthesis design, described above, for the purpose of a PICOTS-driven systematic review and meta-analysis with individual patient data. In that case, the comparative effectiveness research paradigm is integrated within the construct of individual patient data analysis and inference, thus generating a novel, and fast emerging sub-domain of the field of translational effectiveness, which has been termed Comparative Individual Patient Effectiveness Research (CIPER).

CIPER is designed to compare effectiveness outcomes research obtained from independent patient data analyses and inferences. The protocol follows that outlined above for CER. But, the problem arises at the level of analysis of the quantitative consensus. Indeed, and as discussed in greater depth elsewhere [1,4], whereas many standard statistical packages exist to perform the necessary analyses of individual patient data from individual studies, meta-analyses of such data sets are unwieldy and time-consuming because commercially available software are not currently available that supports the direct analysis, pooling and plotting of independent patient data in meta-analytical. These are large data sets, often as complex as what is today referred to as "big data", the analysis of which in translational science is still at its infancy [1,5].

Conclusion

Practically speaking, individual patient data can rarely be analyzed directly in RevMan, the Review Manager (RevMan) software used for preparing and maintaining meta-analyses in Cochrane Reviews (current version: 5.2.5; http://ims.cochrane.org/revman/download). The data need to be first analyzed outside of this software, and summary statistics for each study may be entered into RevMan. The SAS package, 'SCHARP', or the MedCalc statistical softwares for biomedical research can perform analysis each study – not yet fixed or random model meta-analyses – by pooling results and tabulating time-to-event individual patient data.

As CIPER continues to evolve, driven by the need of clinical situations such as TC in dentistry novel, biostatistics protocols adequate and pertinent to the urgent needs of this domain of translational effectiveness will also surely evolve in parallel.

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