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From bench-top to chair-side: How scientific evidence is incorporated into clinical practice

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ABSTRACT

Objectives. The objective of this manuscript is to describe the process through which bench-top research is incorporated into clinical practice from an evidence-based dentistry perspective.

Methods. Relevant literature is reviewed to describe the translation of bench-top research to clinical practice through the steps of preclinical testing; human clinical trials; systematic review development (question development, search/screen methods, evidence synthesis, and evidence appraisal); clinical recommendation development; dissemination strategies; the role of the clinician in finding and appraising relevant evidence; barriers to implementation with strategies to overcome those barriers; and finally, the fusion of evidence with clinician experience and patient needs and preferences in clinical decision-making.

Significance. Descriptions of processes, methodologies, tools, and resources are provided to help researchers and clinicians alike understand the steps that lie between bench-top research and clinical implementation. With mutual understanding of the complexity involved in translating research into practice, it is hoped that barriers to implementation can be overcome that should lead to improved patient health outcomes.

1. Introduction

The process of moving bench-top research to clinical practice is often called research "translation" [1]. Several authors [2–4] have reported that it takes 17 years for scientific knowledge ("evidence" in this context) to be translated and incorporated into clinical practice; however, Morris et al. [1] point out that the convergence on 17 years may be a coincidence, one that hides the complexities of the translation process. There is no common set of standard measurement points or even agreement of the process model itself to definitively answer how long it takes for bench-top research to be applied clinically.

It can be agreed, however, that it takes a long time to implement research in practice, and in the last decade, it may even be taking longer. In 2004, the Food and Drug Administration (FDA) published a report stating that the medical product development process was "increasingly challenging,

Abbreviations: ADA, American Dental Association; AER, ADA evidence reviewersas; CPG, clinical practice guideline; CR, clinical recommendation also known as; CSA, ADA's Council on Scientific Affairs; CS, critical summary; EBD, evidence-based dentistry; IOM, Institute of Medicine; JADA, The Journal of the American Dental Association; PICO(TS), patient-intervention-comparator-outcome-timing-setting [format of clinical questions]; SR, systematic review.

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Fig. 1 – Simplified process of translating bench-top research to clinical practice, which involves several steps. T1 is the translation of bench-top research to human clinical trials. The human clinical research is synthesized into systematic reviews. T2 is the translation of clinical knowledge into everyday practice. Research synthesis is often incorporated in clinical guidance, but need not be. Research synthesis does not imply clinical implementation. Outcomes of implementation into clinical practice ideally include improvements in patient health and, if there is widespread implementation, population health. Note that this process is bidirectional, with clinical practice also feeding in the opposite direction and informing clinical and bench-top research [7].

inefficient, and costly. During the past several years, the number of new drug and biologic applications submitted to FDA has declined significantly; the number of innovative medical device applications has also decreased. . .(and) the path to market even for successful candidates is long, costly, and inefficient" [5]. To counter this trend, the FDA has launched the Critical Path Initiative [6], which is ". . .FDA's strategy to drive innovation in the scientific processes through which medical products are developed, evaluated, and manufactured".

Fig. 1 presents the major steps in the research translation process, which is adapted from several sources [7,8–11]. There is a gap in the process of translating bench-top research to human clinical research, which is often called "T1".

As will be described in more detail later in the manuscript, research synthesis into SRs is not the end of the process [7], and it does not mean that the bench-top research has made it chair-side. At this point the research has been translated into clinical knowledge, but it has not been translated into clinical guidance nor implemented into clinical practice. A gap exists at this stage in the process, often labeled "T2".

When it is determined that a particular topic needs to be summarized, the human clinical research is synthesized into systematic reviews (SRs).

This paper describes the challenges in moving from bench-top to human clinical research, addresses the process of the generation of clinical knowledge and guidance, discusses challenges in implementation into clinical practice, and touches on shared decision making with patients.

2. Translating bench-top research to human clinical research (T1)

Sung et al. [10] defined T1 as "the transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methods for diagnosis, therapy, and prevention and their first testing in humans."

Bridging this gap is not unique to the field of dental materials. Since, to the author's knowledge, there has not been an assessment of the barriers to negotiating the T1 gap for dental materials researchers, some general advice for bridging the gap for medical research in general includes: (1) educating researchers and clinicians about the translation process; (2) standardizing translation across institutions; (3) facilitating interdisciplinary research teams, academic-industry partnerships, and researcher–clinician connections; (4) improving infrastructure including shared facilities; and (5) funding positions that provide program/project management, institutional review board (IRB) process management, intellectual property management, informatics support, and facilitation of industry-academic liaisons [12].

To facilitate dental materials researchers in bridging the T1 gap, it is useful to think about dental materials and their place in the larger system of biomaterials, medical devices, and finally medical products as illustrated in Fig. 2. This categorization helps bench-top dental materials researchers to navigate the appropriate regulatory guidance and requirements that are needed when developing a new material for clinical application. Note that this overview is not an exhaustive review of the guidance that is necessary, but is intended to provide a starting point for further investigation.

Fig. 3 illustrates the complex nature of bench-top research, the successful negotiation of which will close the T1 gap. The FDA [5] has identified three dimensions of bench-top research (also called preclinical testing) which are: medical/dental utility, safety, and industrialization.

For a material to be viable for further development in dental applications, medical/dental utility needs to be shown by, for example, material property testing to show the product performs as required in the environment of use. Standard test methods that are available from ANSI/ADA [13] and the International Standards Organization (ISO) [14] for different

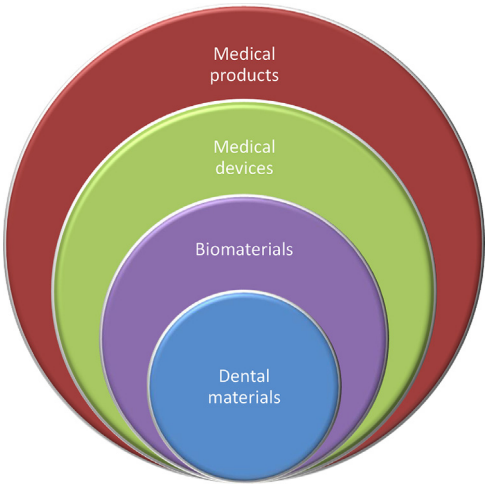

Fig. 2 – Dental materials in context as a subset of larger categories of medical products from a regulatory point of view.